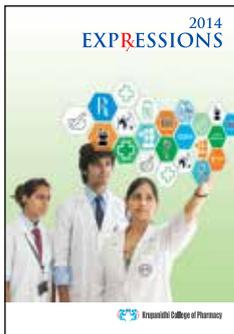






“We carve stones, we just don’t polish them.  
We make monuments out of them.”

Prof. Dr. Suresh Nagpal  
Founder Chairman - Krupanidhi Educational Trust



### Perfect Pharmacist

Perfection is a state of being complete, impeccable and being at pinnacle of our chosen profession. We at KCP are passionate about creating Perfect Pharmacists to serve humanity.

It takes a lot to be perfect - unceasing practise, mastery, elan, zeitgeist and ethics. KCP is committed to carve and to deliver the Gen Z pharmacists who will embody all these virtues and retain their relentless pursuit for perfection across the pharmaceutical spectrum.



# 2014 EXPRESSIONS

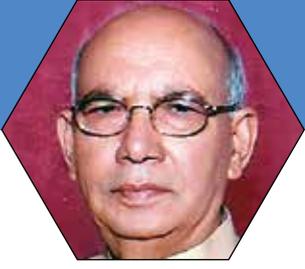
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# Commendations

2014  
EXPRESSIONS



## Message

**Shri H. R. Bhardwaj**

*His Excellency Governor of Karnataka*

22. 05. 2014

I am happy to learn that 'KRUPANIDHI COLLEGE OF PHARMACY' Bengaluru, a constituent of "KRUPANIDHI GROUP OF INSTITUTIONS", established in 1985 has been imparting quality Education in Pharmacy and providing opportunity to the students to groom to excel, is bringing out its College Magazine 'EXPRESSIONS-2014' in June 2014 showcasing the academic and cultural talents of the Students, Faculty and Staff.

I send my felicitations & best wishes to the Management, Teaching and Non-Teaching Staff, Editorial Team and also the Students of the College on this happy Occasion.

**SHRI H. R. BHARDWAJ**

*Governor of Karnataka*



## Message

**Shri U. T. Khader**

*Minister of Health and Family Welfare, Government of Karnataka*

27. 05. 2014

I am happy to know that, the Krupanidhi College of Pharmacy is coming up with a magazine - Expressions 2014. I wish them all the success in all their activities. I also pray that Almighty God gives them more strength to carry on their good work.

I wish the celebrations a "Great Success".

A handwritten signature in black ink, appearing to read 'U. T. Khader', written over a horizontal line.

**SHRI U. T. KHADER**

*Minister of Health and Family Welfare, Government of Karnataka*



## Message



**Dr. B. Suresh**

*President - Pharmacy Council of India (PCI)*

17. 05. 2014

It is indeed a matter of pleasure that Krupanidhi College of Pharmacy, Bangalore, is bringing out a college magazine 'EXPRESSIONS 2014'.

I am happy to understand that the college is contributing to the needs of Healthcare System, Pharmaceutical Industries, Research and Development and Pharma Education of the country, through its students who come out successfully. I am also sure that this college magazine will represent the spirit, technical and literary talent hidden of the students and staff of the college to share their views.

As the President of Pharmacy Council of India, I would like to convey my heartiest wishes on the occasion of the release of the said magazine.

With best wishes,

**Dr. B. SURESH**

*President - PCI*



## Message

**Dr. Sriprakash** MD (Ophth)

*Vice Chancellor, Rajiv Gandhi University of Health Sciences, Karnataka*

17. 05. 2014

I am very happy to note that Krupanidhi College of Pharmacy, Bangalore is bringing out the Annual College Magazine "EXPRESSIONS 2014".

I hope that the Magazine being brought out will be interesting and will stimulate and encourage the hidden talents of the students.

My best wishes to the faculty members and student of the college.

Dr. SRIPRAKASH K. S.

*Vice Chancellor, Rajiv Gandhi University of Health Sciences*



## Message

**Dr. D. Prem Kumar**

*Registrar, Rajiv Gandhi University of Health Sciences, Karnataka*

08. 05. 2014

Its is a pleasure to learn that the Krupanidhi College of Pharmacy, Bangalore is releasing the college magazine - Expressions - 2014.

College Magazines are sources of inspiration for students and faculty to express their creativity. These act as springs for nurturing of talents and future growth. Krupanidhi College of Pharmacy has a long and commendable tradition of nurturing talents and supporting creativity.

I hope that the college magazine Expressions - 2014 will live upto its meaning of letting the students and faculty expressing their inherent capacity to excel.

I wish the best for your endeavours.

**Dr. D. PREMKUMAR**

*Registrar, Rajiv Gandhi University of Health Sciences*



## Message

**Dr. S. Sacchidanand**

*Registrar (Evaluation), Rajiv Gandhi University of Health Sciences, Karnataka*

08. 05. 2014

I am happy to know that your Institution is bringing out a magazine "Expressions-2014" during a glittering function in June 2014. This is the occasion for your staff/students to showcase their talent and contribute their might to make your college magazine more meaningful. A coordinated effort by your esteemed institution and your staff/students will enhance the image of your Institution to grow to newer height.

I take this opportunity to wish you all success in your endeavor, and wish to see your college as a center of Excellence in the near future.

Regards

**Dr. S. SACCHIDANAND**

*Registrar (Evaluation), Rajiv Gandhi University of Health Sciences*



## Message

**Dr. G. V. Niranjana**

*Director - CDC, Rajiv Gandhi University of Health Sciences, Karnataka*

It is indeed a pleasure to note that Krupanidhi College of Pharmacy, Bangalore is bringing out the annual college Souvenir, "Expressions".

The magazine provides an excellent opportunity through various genres of writing.

I appreciate the efforts and hard work and enthused endeavours of the staff and students in bringing out this magazine.

I wish the magazine "Expressions" is widely read and cherished and hope it will continue to inspire all the students, staff of Krupanidhi College of Pharmacy and other Pharmacy faculty.

**Dr. G. V. NIRANJANA**

*Director - CDC, Rajiv Gandhi University of Health Sciences, Karnataka*



## Message

**Prof. Dr. Nazim SEKEROGLU**

*President of AMAPMED*

*Manager of Vocational School of Kilis 7 Aralik University*

May 20, 2014

Kilis, Turkey

It is great pleasure for me to write this message for congratulation both distinguished scientific person Prof. Dr. Raman DANG and his new position at the Krupanidhi College of Pharmacy. In changing and developing research and education systems throughout the World, farsighted persons with scientific vision are crucial important for their societies and foundations. In this concept, I believe with my entire heart that Prof. Dr. Raman DANG will take the college to the top in educational and scientific level in pharmaceutical sectors.

I wish you continued success in your career and good expressions in your life.

Yours sincerely.

**Prof. Dr. Nazim SEKEROGLU**

*President of AMAPMED*



## Message



### Shri S. V. Veerramani

*President - Indian Drug Manufacturers' Association (IDMA)*

Educational institutions are “temples of Learning” in parlance of great thinkers. It is institutions which create Individual Values as contributing citizens of India.

Profession of Pharmacy though is old as human life is yet to be synchronized globally thereby giving deserved respectability to the pharmacist. It is in this direction much work needs to be done through continuous productive interactions between institutions, manufacturing associations and global regulatory bodies.

It is heartening to learn about your institutions and the service it has rendered in shaping lives of youngsters who arrive as raw individuals at the portals of your institution.

Deep rooted conviction of management combined with dedicated faculty has made KCP stand out as an institution of reckoning for the past 25 years. My best wishes to every member of KCP staff and team of Expressions for making Expressions become the much awaited house magazine of Indian Pharmaceutical fraternity.

**SHRI S. V. VEERRAMANI**

*President - IDMA*



## Message

### Shri Jatish Sheth

*President - Karnataka Drugs & Pharmaceuticals Manufacturers' Association (KDPMA)*

05.04.2014

The last two decades has seen tremendous changes and these changes have been fuelled by a few individuals which has had a lot of impact on lives of human beings across the globe.

Changes in the communication technology impacted our social life, the way we think, the way we interact and the way we behave in a major way.

Changes in expression have lead to changes in governments and rulers across the globe. President Obama leading a nation of predominantly white immigrants was unthinkable till a decade ago.

Pharmaceutical plants which were virtually a few rooms operation has changed into sprawling areas with attention to the smallest detail. Emphasis is on Safety & Efficacy of the Drug Products. The products should meet the specifications of Impurity Profile as well as In Vitro Bioequivalence. Dissolution test has become the norm instead of Disintegration time. Similarly on the analysis front, testing by way sophisticated instruments like HPLC, GC, FTIR is the norm instead of Titrimetry or UV of earlier days. Validation for any and all operation, proof of concept, standard operating procedures, change control, the change from quality control to quality assurance has brought about tremendous changes in the way we pharmacists make medicines for the mankind with a singular purpose in mind to alleviate their sufferings.

Dosage forms are no longer confined to tablets, capsules, liquids. Change has been necessary in Pharmaceuticals because of need - the need for every human to have a healthy life. Insulin dependent patients need an injection daily and the need to change the dosage from injections to auto-injectable occurred to someone.

Institutes like Krupanidhi College of Pharmacy are no longer confined to only teaching. They are focussing on helping students realize their potential and play a major role in changing the mind-sets. The students are at the doorstep of a world they can change because it's truly said that what is within you is more powerful than what is outside.

The potential is tremendous. Make dreams come to reality. A dream coming to reality is the pursuit of every single human in earth and that is the pursuit of happiness.

Change is the only permanence in life. A look into the world of pharmacy gives an insight the unlimited possibilities of change and the potential to make a giant stride.

On behalf of Karnataka Drugs and Pharmaceuticals Manufacturer's Association, I wish all the students a happy journey of discovery...discovery of yourself and realize your great potential, talent, and the effect it can have on your world.

**SHRI JATISH SHETH**

*President, KDPMA*



## Message

### Shri D. A. Gundu Rao

*President - Karnataka State Pharmacy Council (KSPC)  
Bangalore*

With the change in disease pattern and the increase in number of patients with Diabetes and Hypertension and other diseases requiring long term therapy, there is growing need for medicines and newer molecules. In this back drop the needs and adopting new technologies in the Pharmaceutical Industry is ever changing. Both the Society and Industry are looking for a technically qualified Pharmacist from a reputed college.

I have been closely watching the progress of Krupanidhi College of Pharmacy, Bangalore from its inception and am happy to note that the college has made a steady progress without compromising to provide quality education.

I am happy to note that the College has well qualified and student friendly Teachers who have made all the difference.

I am sure your College magazine "Expressions", will provide a platform for both Teachers and Students to ventilate their novel ideas in their ultimate desire to serve the ailing community at large which is the essence of KARMA YOGA in Bhagavad-Gita.

Good wishes to all.

**SHRI D. A. GUNDU RAO**

*President, KSPC*



## Message

**Dr. M. J. Mohan**

*Chairman - MVJ Medical College & Research Hospital, Bangalore*

It gives me immense pleasure to know that Krupanidhi College of Pharmacy is bringing out the college magazine "Expressions"

I appreciate the students community for taking the yeoman responsibility in bringing up this magazine, while expressing their talents and skill, not only in students but also in extracurricular activities. It speaks rich in culture and highest standard of education imbibed by these students of this institution.

I appreciate the efforts contributed and hard work of all the faculties and students concerned in bringing out the magazine.

Wishing "Expressions 2014" in wide circulation not only among professionals but also among student community.

**Dr. M J MOHAN**

*Chairman, MVJ Medical College & Research Hospital*



## Pharmacognosy: Past & Present

**Prof. Dr. Ilkay ERDOGAN ORHAN**

*Department of Pharmacognosy, Faculty of Pharmacy, Gazi University, 06330 Ankara, Turkey*

*Dean – Faculty of Pharmacy, Eastern Mediterranean University, Gazimagusa (Famagusta), The Northern Cyprus.*

Dear scientists and students of Krupanidhi College of Pharmacy,

I congratulate you on initiative of such a good magazine “Expressions-2014”. I think, this is very important to start this kind of activity during your college life, which will contribute a lot to your future life after you graduate.

Pharmacognosy, as well-known, the science of drugs of natural origins including plants, animals, marine organisms as well as microorganisms. Its history dates back thousands of years since the records revealed that many antique civilizations used medicines of herbal and animal origins for the treatment of diseases. Diseases are born with man and drugs came into existence since a very early period to remove the pain of diseases and to cure them. Plants as food and medicine since the early history. For example; Archeological findings from 30.000 years ago in Shanidar (Iraq) show polen and plants that are still in use. The records of King Hammurabi of Babylon (c. 1800 B.C.) include instructions for using medicinal plants. The entire Middle East has a rich history of herbal healing. There are texts surviving from the ancient cultures of Mesopotamia, Egypt, and India that describe and illustrate the use of many medicinal plant products, including castor oil, linseed oil, and white poppies. Fundamentals of Ayurvedic medicine rooted in ancient Indian Civilization. Traditional Chinese Medicine has been existing at least since last 3000 years. Thus, the story of drugs is as old as mankind. Many drugs commonly used today are of herbal origin.

Indeed, about 25% of the prescription drugs dispensed in the United States contain at least one active ingredient derived from plant material. Some are made from plant extracts; others are synthesized to mimic a natural plant compound. Many drugs listed as conventional medications were originally derived from plants. Pharmacognosy is still a popular field in the pharmaceutical sciences, and due to development in chemistry and medicine, it has become more sophisticated and changed a face turning to “omics” such as metabolomics. The Pharmacognosic research is moving in more molecular level. However, we should still keep the classical approach to Pharmacognosy for our research in which the modern scientific techniques should be embedded and enriched.

I wish you a successful and fruitful publication life with your newly launched magazine.



## Setting up of Modern Gurukulam

**Prof. Dr. Suresh Nagpal**

*Founder Chairman, Krupanidhi Educational Trust, Bangalore*

A Gurukulam is the family or lineage of a Guru. The family of a Sannyasin (renunciate monastic) is made up of the lineage of the Guru and Shishyas (students). Gurukulam also means abode of the guru. A Gurukulam is also an Ashram. An Ashram is a place where religious-minded people live together and practise the tenets set out in the Sastras (scriptures).

**In the tradition, there are three kinds of graduates (snatakas) ;**

Vidya-snataka : those who have graduated with honours in an area of knowledge;

Vrata-snataka : those who may not be brilliant in intellect but may have excelled in disciplines;

Vidya-vrata-snataka : those who have excelled both in learning and in disciplines.

**The main goal of the Guru-kulam is to prepare,**

- (a) citizens who hold a personal spiritual philosophy of life based on meditative experience and traditions, and will translate it into all areas of life in the world,
- (b) teachers and guides (whether swamis or householders) who will give their lives to creating the next generation of such citizens,
- (c) a select few of whom may establish or manage and advance the work of pre-established centres for the next several generations, and
- (d) who in turn, will train again the teachers and guides for the generations that follow them.

### Areas of Learning

1. Meditation, its philosophy, practice and application for daily life in contemporary context, as taught by the Himalayan Tradition and interpreted by Swami Rama of the Himalayas.
2. An understanding of the vast expanse of the meditation methods, their interconnectivity and sequential procedures. This can by no means be completed in one life time, but a general understanding, including the personal experience imparted to the student to the extent of his/her capacity (adhikara) can be given.
3. The ancient texts, such as the Vedas and the Upanishads, that were revealed in the meditative states of the rishis, serve also as guides to meditation. (a) How they depict the meditation methods and the meditative states will be taught in an experiential context. (b) The keys to the interpretation of these texts will be imparted to those with a sufficient background in the language.
4. Sanskrit and related languages such as Pali, at different levels according to demand, for example Sanskrit (a) for international yoga teachers and (b) for advanced students who wish to learn the ways of interpreting the texts.
5. An introduction to a limited number of sciences and arts that have developed out of the meditative traditions, for example ayurveda, phonetic astrology, vastu, Vedic recitation, fundamentals of Indian

music and dance, and so forth. Those who desire to specialize in any area of their choice will be given the necessary advice and any available opportunity--after the fundamental courses have been completed.

6. Brief history of the meditative and spiritual traditions of different cultures in all parts of the world, together with selective readings from their texts.
7. How meditation, its practices, philosophy and psychology may be applied to such contemporary concerns as (a) personal and interpersonal emotional problems, (b) psychosomatic illness (c) questions of war and peace (d) social justice (e) spirituality in business, management and administration, and so forth.
- (a) Contemporary scientific investigations into meditation and related disciplines (b) the areas of scientific and medical concern where further research may be undertaken.
8. How to teach in different cultures and for that purpose acquiring skills in intercultural communication, establish centres, train teachers, and so forth,
9. Training the minds to bear that in an ever changing world the methods, languages and terminologies of the teaching will need to be resilient enough to alter these according to the needs of the times, but never changing the underlying principles and the purity of the spiritual experience.

The age-old gurukulam concepts that created a holistic student seem to be back with the modern schools realising the importance of those practices and implementing it in their new-age curriculum.

Giving importance to co-curricular activities, attention on physical exercises through specified time for games and sports and a hostel far away from the hustle and bustle of the city life is the in-thing now and bait for parents who can afford such education. After all, education is not just books and classrooms, and it involves a lot more activities that strengthen the relationship between the school, teacher and the students.

Parents who were completely in the awe of convent education giving a go-by to the holistic development of the wards are changing now going by the response such schools are getting. "Perhaps realised by what they missed in school most of the young parents now want holistic development of kids," says Yarlagadda Rajasekhara Babu, Managing Director, Oakridge International School that has adopted the old-age gurukulam concept with a modern approach. While stress is laid on extra-curricular activities and sports, children get to indulge in the modern gadgets that help in making learning attractive and easy. A few years back parents used to laugh if a school sold the concept of teaching other activities like pottery, dance, music or drawing. But now things have changed and parents want kids to dabble with these as they promote creativity at different levels and in different forms. In fact, majority of the new-age schools are now vying with each other to attract parents with these academic qualities. Some academics say our State was pioneer in promoting gurukulam concept.

In modern age, gurukulam professionalise the management of development efforts in general and the efforts for enhancing the livelihoods of the poor in particular, by various individuals and agencies.

### Specifically it aims to:

1. Provide fresh professionals for the development efforts in general and for enhancing livelihoods of the poor in particular.
2. Build the competencies in terms of knowledge, skills and motivation of the existing human resources including the poor themselves, the professionals and support functionaries in governmental and civil society development organisations engaged in the development efforts; and
3. Offer a variety of platforms and opportunities for improving their professional competencies and fostering requisite value orientation.

In particular, Gurukulam aims at sourcing, creating, nurturing and developing the development management professionals with clear bias towards the poor to improve their livelihoods and livelihoods options. Their specific foci of intervention in the economic field include the processes that lead to increased income, decreased expenditure, increased employment and opportunities and decreased/ diversified risk.

The 21st Century Gurukulam ( 21CG) is a new educational program designed to provide enhanced opportunities for gifted rural youth of Andhra Pradesh. A 21CG is envisioned as a self-sustaining, self-governing, and self-supporting community, modeled after the ancient Gurukulam and the modern-day kibbutz. Its primary purpose is to provide remedial education and IT training leading to a postgraduate degree in IT for the current top 1% of the rural youth. The gifted rural graduates defined as the top 1% based on merit and another 1% based on social criteria are expected to be selected from each mandal. The entrance test is state wide but the selection is based among the best in each mandal. The rural mandal residency will be determined based on the location of the high school graduation of the candidate.

It is our hypothesis that, intelligence is not concentrated in the cities but is, in all probability, uniformly distributed throughout the entire population. If this hypothesis is correct, even partially, then we are leaving behind 80% of the gifted youth just because they happen to be born in rural environments to semi-literate parents. Given this serious and genuinely unfair disparity, the State of Andhra Pradesh is considering various alternatives to enable the gifted rural youth to achieve their full potential. 21CG is the first initiative.

Of course, most of the time, the preceptors would be respected Sages who had renounced worldly pleasures to dedicate themselves to imparting knowledge of every kind to the seekers. Cut to today's environment, the word Gurukul to one of today's ultra-smart kids would only mean a Guru who is "Cool" - today's slang for something that is good! How in Heaven's name are we going to get Gurukula in the current scheme of things? In the first place, where is space for a sprawling Ashram? Where are the erudite scholars who have the capability of handling today's super brats, leave aside teaching them? Where are the patrons who are needed to support such worthy schemes? Most importantly, where are the dedicated students who would have to undergo the rigors of roughing it out at the Gurukula, forgetting their social standing? All that one can now think of is how to apply standards and principles of the Gurukula system in today's environment. If any one may be pardoned for saying so, we rarely find an Ustad, Pandit or Vidwan who would dedicate his life to teaching without expecting too much in return. And, neither can one blame him for this. He has to fend for himself, look to the welfare of his family, manage to obtain adequate accommodation in highly congested cities and to top it all, be able to churn out good students - who again, are fickle-minded in their pursuit of real "Vidya". Today, the teachers have to depend on monthly fees from students. If they go on vacations or during examination times no classes - so, no fees! What is the Guru expected to do? Unfortunately, commercialization is the order of the day and the narrow-minded attitude of students or their parents leads to avarice on the part of the Guru. In such a none-too-happy scenario, how does one go about inculcating the best of the Gurukula system? As per the title of this discussion, let us devote our attention to Music in general and percussions in particular.

1. Musical Institutions should be established with extensive Government support and the backing of munificent donors who have, today, taken the place of kings. These Institutions should have residential or hostel facilities for aspiring students to stay during the course of their instructions, for a minimum period of five years.
2. The students have to be in constant touch with their Gurus / Ustads, not only imbibing knowledge, but, try to witness their "Riyaz" or practice sessions and live recordings. These being performing arts, the student should also learn how to react to situation arising on the stage.
3. Total dedication of students and of course, the co-operation of their parents is absolutely necessary.

4. Handsome salaries should be paid to the teaching staff, to ensure their unswerving attention to the job they are expected to do, and that is to produce top-notch performers. They have to be provided with the best of facilities so that they cannot be lured by others. Care should be taken to research their backgrounds to find their sincerity.
5. A minimum standard of proficiency should be made a criterion for admissions to such Institutions as also age, whereby a student also gets the time to obtain a basic qualification such as B.A. / B.Com. / B.Sc. etc., and also attain the required level of proficiency in his chosen field.
6. Every family must try to impart some sort of musical training to every child.
7. Each student must be allowed to reside with the Guru and his family, on a rotational basis, for a period of a week or fortnight, so as to enable him to establish a personal rapport with the Guru and get to know him better.
8. Each student must, in addition to his own field, be made to undergo basic training in other branches. In these days of specialization one often finds percussionists who know very little about vocal music and vice-versa.
9. There should be close interaction between all the faculties, especially between Hindustani and Carnatic music students.
10. Instructions should be so designed that the student imbibes the lessons in spirit rather than by rote. This will be the basis on which he will learn to improvise.
11. Periodical performances of all students should be held and attendance of all students, junior and senior must be made mandatory. It may surprise many of the seniors how much they can learn by listening to their juniors
12. For percussion students in particular, every student should be made to recite each and every composition before he masters it on his instrument. This will enable him to play the composition in the same spirit as the composer intended it to be.
13. Every day should begin and end with soulful prayers to the Almighty. Every musical activity must be treated as an offering to God. Without sounding over-critical of today's standards and means of spreading cultural awareness, this has been an attempt to highlight the virtues of the Gurukula system.

Create Gurukula is based on altruistic principles. Make your contribution and get involved now. When create is running full steam and educating our brightest children, knowing your contribution made all this possible is guaranteed to be fulfilling. It is an ambitious project that aims to bring unprecedented levels of learning and opportunity to qualified students from around the world. The success of this unique and noble project requires steadfast commitment from people like you, who care enough to get involved. Your energy and enthusiasm drives our action, and with your continued support our schools can achieve ever greater success. Please donate and get involved - together we will create a better tomorrow. Your monetary support will go to construct buildings to house classrooms, laboratories, dormitories, a library, a computer facility, an auditorium, a kitchen and dining hall, as well as build a playground and athletic facility. Furthermore your contribution will aid in bringing the associated research wing of the school intended to carryout world class research thereby provide a model creative atmosphere for the students of all ages to participate in research projects, as part of their curricula. The entire construction and operation is strictly monitored by the directors and independent auditors, and are open to scrutiny by large donors. Rest assured that all your contributions will go to support the schools and research facilities; our administrative costs are negligible, since all our staff and directors are volunteers. Let us come together and create a proud tomorrow for us all to cherish.



## Mrs. Geetha Nagpal

*Vice Chairperson, Krupanidhi Educational Trust, Bangalore*

Education in the largest sense is any act or experience that has a formative effect on the mind, character or physical ability of an individual. In its technical sense, education is the process by which society deliberately transmits its accumulated knowledge, skills and values from one generation to another. Hence an education is the means for bringing socio- economic transformation in a society, various measures are being taken to enhance the access of education to the marginalized sections of the society. The word education is derived from Latin term i.e. educare means “bring up”, which is related to educere “bring out”, “bring forth what is within”, “bring out potential” and ducere, “to lead”. It is the history of teaching and learning. Hence Education is the process by which people learn: Instruction refers to the facilitating of learning, usually by a teacher, Teaching refers to the actions of a real live instructor to impart learning to the student and finally Learning refers to learning with a view toward preparing learners with specific knowledge, skills, or abilities that can be applied immediately upon completion.

Each generation, since the beginning of human existence, has sought to pass on cultural and social values, traditions, morality, religion and skills to the next generation. The passing on of culture is also known as enculturation and the learning of social values and behaviours is socialization. In pre-literate societies, education was achieved orally and through observation and imitation. The young learned informally from their parents, family members and grand parents. At later stages of their lives, they received instruction of a more structured and formal nature, imparted by people not necessarily related, in the context of initiation, religion or ritual. The history of the curricula of such education reflects the history of knowledge, beliefs, skills and cultures of humanity. Settlement, agriculture and metalwork brought new knowledge and skills to be learned and taught by each generation.

Today the system of education is very broad based. The student needs to be treated like a friend and teacher should be more of a counselor. The world changes and the trends are different but the relation of a teacher and the student remains the same. Teachers are role models and need to do their best for grooming the future of a student.

*“A child cannot be taught by anyone who despises him, and a child cannot afford to be fooled”.*

- James Baldwin



## India as Educational Hub by 2020

**Prof. Sunil Dhamanigi**

*Secretary, Krupanidhi Educational Trust, Bangalore*

The intellect in India is immense. Many talents go untapped. India needs a true modern gurukulam to nurture and groom these bright minds. There is a need to ignite the spirit of education. If we see the past statistics it is very evident and clear that there is decline in result percentage from 10th to 12th standard. The results are plenty it may be many attention diverters, distraction from studies, addiction to social networking and most important hormonal changes. A child needs to be studied not made to study. The interest of education should naturally inculcate in him/her. Counseling plays a very essential role in understanding the perceptions and ideas a child has. Value based education is the need for the day. We hear about enormous number of suicides the day the results are announced, why? Parents play a very important role in child's future. There is need to create an atmosphere of cheer, happiness and efforts rather than pressurizing them with undue competition and comparison. Parent is a comfort zone. Let us not forget the first step a child takes in life is by holding the finger of his parent. When there is need to extend a hand we get busy with our professional routine. Tuitions and outside guidance is sort. Can you believe it that more than defense money there is money spent on tuitions which only makes the child more lost and confused. The personal touch is lacking among a teacher and a student. There is need for centre of excellence. Please remember a strong foundation is needed for any building to stand tall. 12th is the base for shaping the career of a child. Modern technology should be used for temperamental analysis of a child. Soft wares should be developed to tap the true talent in an individual. The child needs focus. Today's children are very smart, aware and confident. Their energy needs to be channelized. Not all may excel in studies alone. There are number of options available. The child's interest is very important. No ideas should be imposed on them. However their own ideas should be refined and made to work.

Integrated programmes should be part of our education system. Cultural activities and holistic approach to things is what we require today. There is no rationale and standards maintained in colleges/Universities today. Corruption is playing the central part in education. Uniform education policy is required.

We can create 1000 Oxford Universities in India itself provided we work with our conscious. We need to polish ourselves and not create anything new. It is the awakening of the awareness that is required and not any new creation.

Krupanidhi Educational Trust is committed to complete overall development of a child.



### Dr. M D Karvekar

*Director - Academics, Krupanidhi College of Pharmacy (KCP)*

The profession of pharmacy is undergoing a rapid change. Pharma industry has shown a spectacular progress and ranks 4th in the volume worldwide. Today pharmacist is no longer a mere dispenser of drugs but has assumed a more crucial role in medicine management and as an overall healthcare programmer. To meet the growing requirements of their practice side and to overcome the problems faced by pharmacy graduates in practicing the pharmacy profession in other countries, Pharmacy Council of India has introduced Pharm D and Pharm.D (Post Baccalaureate) courses which has greater emphasis on clinical pharmacy. Overall development of the individual is the goal of education and Krupanidhi College of Pharmacy is one of the colleges which is working hard for the challenges of life and has not left any stone unturned. We not only carve the stones into statues but we polish them so that they attract the public. I wish to congratulate the entire faculty and other staff for encouraging and guiding the students in all facets for their well rounded development.



## A Brave New World of Pharma emergence Be future ready

**Prof. Prakash V Mallya**

*Director, Center for Pharmaceutical Professional Advancement, KCP*

In the years following 2014, the pharmaceutical industry will continue to witness major changes and challenges. New technologies that help researchers better understand the biology of disease could be the catalyst for an R&D overhaul in the pharma world, which could see companies using virtual R&D to increase innovation. The in-depth knowledge about the human body and the pathophysiology of disease will be generated through a collaborative research network of pharmaceutical companies, CROs, IT verticals, industry regulators and academia.

The evolution of 'Virtual man' will enable researchers to predict the effects of new drug candidates before they enter human beings. Models of the heart, organ, cells systems and musculoskeletal architecture are already being developed by academics around the world. Such technologies can be used to simulate the physiological effects of interacting with specific drugs and identify which drugs have a bearing on the course of a disease. Some companies using virtual technology have reduced clinical trial times by 40 percent and reduced the number of patients required by two thirds. Thus the 'Virtual man' could ultimately evolve from the deployment of existing technologies that are connected in a new ways.

Considering global economic uncertainties, emergence of new-disease patterns, shrinking of newer pipeline products, huge fundings for new drug discoveries - upward of \$ One Billion or six thousand Crores and on an average a ten years wait for marketing approvals - increasing healthcare costs and expiring patents, the pharmaceutical industry appears to be in a state of turmoil. At the same time, markets are diversifying and new fields of growth are opening up. Rapid development of the emerging markets, progress in drug research, the rise in generics production, the availability of high-potency drugs and innovations in manufacturing processes will sustainably modify the global pharmaceutical landscape.

As population growth and rising incomes contribute to the dramatically higher use of medicines. The industry is re-inventing its Strategic Business models Due to increasing cost pressure and increased local demand, the production is being relocated and outsourced to the emerging markets. In many cases, this also applies to the production of generics. While the share of the industrialized nations in global pharmaceutical expenditure will continue to decline, spending on generics will increase due to expiring patents accompanied by higher generic use for off-patent molecules. Advantage China and India.

Pharmaceutical manufacturers are outsourcing more critical functions to contract manufacturing organizations. Biologics will also contribute to higher spending, as research brings clinical advances for the treatment of patients all over the world. Cutting-edge developments in personalized medicine have led to sophisticated solutions tailored to stratified groups. We observe a global trend towards combining pharmaceuticals with medical technology applications. The development of new drug delivery devices increasingly focuses on patients' individual needs. Some of the devices such as inhalers are necessary applications to transport the active substance to where it is needed. Tools such as insulin pens have been optimized, in particular with respect to convenience and ease of use, while the equipment generally tends to be smaller and much safer to handle. In this sense, medical technology applications improve the quality of patients' lives. At the same time, drug delivery devices are used as a targeted measure for product differentiation. The availability of high-potency treatments has also exploded in the past decade. High-

potency active pharmaceutical ingredients (HPAPIs), for example, is a fast growing segment, and is projected to grow at a compound annual growth rate (CAGR) of 9.9% through 2018 .

To keep pace with these advances, engineering expertise is required to design equipment that can handle, package and secure such substances. Pharmaceuticals, biopharmaceuticals, vaccines and anti-virals must be manufactured and packaged with the utmost caution and attention to detail. It is with these requirements in mind that we see five particular trends emerging in the field of pharmaceutical processing and packaging equipment, namely: a rising demand for pharmaceutical quality and safety through inspection technology; the ability to handle potent substances; adapting lines for small batch sizes and research purposes; an increasing use of single-use components; and the need to improve productivity by optimizing manufacturing processes with respect to Overall Equipment Effectiveness (OEE).

Strict pharmaceutical quality and safety standards such as Process Analytical Technology (PAT), Quality by Design ( QbD) as well as Current Good Manufacturing Practice (GMP) set the framework for pharmaceutical manufacturing processes. They aim at reducing the risk of product recalls and, most importantly, are designed to safeguard consumers' health.

Quality control is essential for liquid and solid pharmaceuticals such as syringes, ampoules, vials, as well as tablets and capsules. One of the most common and reliable methods for particle inspection is the "static division" (SD) technology. It derives its name from the ability to differentiate static from moving objects, using light transmission to detect moving particles by measuring dynamic light fluctuation. The SD technology is also suited for inspecting filling levels. In turn, sophisticated high-speed cameras allow for the reliable detection of particles and cosmetic container defects. The combination of these two inspection methods provide for best inspection results.

Machines based on x-ray technology provide the means for comprehensive quality and weight control of capsules. These technologies are advancing rapidly due to software development and new imaging capabilities. More recently developed inspection platforms are able to check simultaneously all quality features like weight, foreign particles, deformation of capsule top and bottom, as well as length in real-time and at high throughput rates. The exact process control adopts several functions of visual systems for error identification and provides significant benefits such as reduced reject rates and the prevention of packaging errors.

With pharma's futuristic and exponential changes outlined above in all areas of its operations. Our Pharmacy academic programs should be strategically positioned and gear up full throttle to keep pace in the dynamic and revolutionary era in student education to prepare our graduates for successful careers in the next few decades in this Brave new world. The literature on graduate education in the biomedical sciences has long been advocating educating students to hone soft skills like communication and teamwork, in addition to maintaining excellent basic skills in research. Our graduate programs should bring to education the innovation and collaboration that our industry also requires to be successful and relevant in this century. The Pharmacy faculty should be developed and supported to lead and contribute significantly to fields such as cell and systems biology, genomics, proteomics and nanotechnology besides other emerging sciences.

A Brave new World of Pharma emergence awaits us - Are we ready?



## Annual Report

**Dr. Raman Dang**

*Principal, Krupanidhi College of Pharmacy (KCP)*

The session commenced from 1st August, 2014. It was thought wise to have an orientation programme for the new comers. The students were apprised about the norms and principles of Krupanidhi. Each teacher spoke to students for a period extending upto 10 days. The entire process of grooming and embedding the students into the culture of krupanidhi helped them to be more presentable, smart. They approach teachers with their problems without any hesitation. The personal bond established made the teaching learning process more interesting.

September 5th saw the celebration of teachers day. Our beloved chairman graced the function with his esteemed presence. The teacher of teachers was honoured and applauded for nurturing the institute with utmost care for 29 years. The institute has grown from a two room wonder to a massive 11 acres college campus. The basic principles of modern gurukula remain the same. Students are still taught with immense dedication and care.

Prof. Uday Arur of Biz Mantra Management, Mumbai held a workshop on 'Leader in Me' on 28th September. To commemorate the Gandhi Jayanti the Ethnic day was celebrated on 1st Oct. The Staff and students came dressed up in their ethnic wear. The atmosphere had lot of warmth and prizes were given for the best dressed lot.

Prof. Anila, Director CLHRD, Mangalore held an interactive session for the teachers on 8th November. Her well conducted workshop on "Understanding Effectiveness for Teachers" made teachers learn a lot. She had a seminar on "Building Competence" for students on the subsequent day.

The students were fortunate to have a talk from Mr. Krishna Kumar, Head QA- Biocon on 16th November. The Pharmacy week saw galaxy of Industry personnel conducting many interactive sessions for the teachers and the students.

A massive rally was held during the world AIDS day. The villagers were told how to protect themselves and play safe.

14th December saw the students at their best during the Freshers Day Celebration. It is a tradition at Krupanidhi to welcome the freshers into the family with love and affection.

Christmas Day and New Year Celebrations saw the students enacting the scene of Christ's Birth and singing Carols, distributing sweets. There was spirit of festivity all around.

Saraswati Puja too was celebrated in a grand way and so was the valentine's day. Talents and sports week saw all the students taking part in various events and winning prizes. Our Vice-Chairperson was present all through, encouraging students and being part of all the events. Her presence and active participation showed the care the management always shower on the students.

Dr. G. Jagadeesh of US FDA and many other luminaries visit to the Pharmacy Block kept the atmosphere at Krupanidhi all charged up. Prof. Mallya's Finishing school session made students

learn a lot in a very friendly atmosphere. He also took lot of interest in taking the staff and students for various industrial visits.

The Placement was tremendous this year. Many Students got placed in jobs of their preference. Companies like Indegene, Religare and many more came for the campus drive.

The institute saw the reconstruction of the Ladies and the Boys Common Room. The medicinal garden and the animal house were revamped in an ultra modern way. The drug information centre at MVJ Hospital Research Centre got a new look near to the out patient department.

Students got many acclaims by participating and winning prizes at the events held on National Level. The Teaching staff was very active all through the year. Apart from the regular academic and research wonders they took part in many national and international seminars and workshops. There were many invited talks delivered by our staff.

We also signed a MoU with the Teleradiology and Green Chem for advancement of Research and Collaborative work. The staff was given the much awaited sixth pay consession salary scale with revision.

*Synergia* our Pharm D News letter is being praised from all corners. Dr. Syed Rabbani is actively involved as an editorial board member of Indian Journal of Pharmacy Practice. Dr. R.S. Thakur the pearl of Krupanidhi was made the Chief Editor of University Journal of Pharmaceutical Sciences. Dr. Sonal Dubey to joined the team as Associate Editor. *The Journal of Pharmaceuticals Research* published by KCP has increased readership.

The Students excelled in academics with many University and College Ranks.

To conclude we can say that there was active participation by all. The National events like Indian Pharmaceutical Conference, National Level Pharm D meet at Sheraton Bangalore and other important programmes were well attended. The NAAC work is in full swing. All the Staff members are working day and night to bring national quality certification to the institute.

Graduation Day, Alumni meet too will have great fanfare and participation.



## Pharmaceutical research: concepts and complexities

Dr. R. S. Thakur

Professor and Head of Department of Pharmaceutics, Krupanidhi College of Pharmacy, Bangalore

*"The challenge of finding a new drug is an incredible thing. You are trying to solve a complex disease with a single molecule. We employ technologies that are just unbelievable in their depth and complexity. At the end of the day, we do this to bring some comfort to people who are suffering and dealing with the anguish and despair of a chronic disease. It's to bring some hope to them"*

- Thomas E. Hughens, Novartis

### Preamble

Concepts in Pharmaceutical Research, develops clinical solutions for the therapeutic areas.

The need to discover new drugs for the treatment of existing or emerging diseases will never cease. Diseases keep on evolving treatments available do fail to give desired results. Moreover, resistance/tolerance to the existing drugs do develop in case of anti bacterial therapy, anti viral and anti parasitic therapy. The changing life style, expanded life span also increase burden of disease. Progress in molecular biology has created new avenues for precisely understanding mechanism of drug action and hence changed direction of pharmaceutical research. Recombinant technologies enable production of proteins and monoclonal antibodies as important therapeutic agents. Combinatorial chemistry and high throughput screening facilitate more rapid drug discovery.

### Historical

History of pharmaceutical research reveal that this field was ladden with mysteries and superstitions of alchemy. When Paracelsus declared "Chemistry is not designed to make gold but medicines" the concept changed. This was foundation for a renaissance in pharmacy and medicine. Paracelsus's assertion that man is a chemical compound; his ailments are due to some alteration in his composition and can only be cured by the influence of other compounds, tranformed the prevailing knowledge of diseases and medicines. This led to establishment of iatrochemical school and eventually overthrew the older galenical school of thought. Iatrochemists introduced use of mercury, lead, iron, antimony, arsenic and other salts. This was overtaken after emergence of Boyle in the experimental chemistry scene in the middle of 17th century. Now chemistry became a science and iatrochemistry a division of chemistry.

The emergence of pharmaceutical chemistry may be attributed to Serturmer, who while working in his apothecary shop isolated morphine in 1817. Till then organic bases were not known. Serturmer's discovery was important for several reasons.

- It was isolation of first pure alkaloid from crude drug. Hence marked the way for isolation of other alkaloids and other chemical constituents of crude drugs.
- The isolation replaced use of crude drug and promoted use of pure chemical as medicine.
- When use of pure chemicals became popular, dose related response could be measured and dose accuracy could be ensured.
- The pure chemicals could be administered hypodermically, hence taste related problems associated with oral administration of crude drug products, extracts etc. could be overcome.
- The exponential increase in knowledge of chemistry led to development of analytical techniques by Lavoisier and Liebig.
- Understanding of the chemical structure, synthesis of ammonia by Wohler, concept of the structure of organic molecules led to understanding the natural compounds/phytochemicals.
- Isolation, purification, characterization and attempts for synthesis completely changed the scene and use of pharmaceuticals became order of the day.

- This helped progress of synthetic organic chemistry.
- By the beginning of 20th century it became common that if structure of an organic compound is known its synthesis could be possible.

## The Renaissance

On the other front in medical research, between 1880 and 1890 the works of Pasteur, Koch and other scientists discovered causal relationship of infectious diseases and developed science of bacteriology. This paved way for development of science of immunology during 1890 and 1900. The new era of multidisciplinary developments related to disease and medicines prospered due to dedicated works of scientists from various fields and thus developed endocrinology, pathology, X-rays, virology and so on. The developments in allied sciences boosted pharmaceutical research and it took full advantage of all the progress in the contemporary scientific arena. The trend in pharmacy changed from use of crude drugs and their preparations to preferred use of pure synthetic compounds as also the use of serums, vaccines, antitoxins, antiseptics and diagnostic agents.

This change of trend expanded research base in pharmacy and superspeciality disciplines could be established and expanded for fullest utilization of knowledge in scientific domain and give mankind safe and effective medicines of modern times.

Research no more remained a subordinate activity. It occupied prime place both in academic and industries. Devastations of the first world war not only ruined economy but health also. Demand for antibacterials, stress-relievers, increased by many folds, for physical and economic recovery of war ravaged nations. The governments gave free hand to let pharmaceutical companies flourish unfettered. On this policy break was applied only when sulphanilamide and thalidomide disaster demanded stringent regulations to ensure safety and efficacy of medicines in the market place.

In the chemistry centric Pharmaceutical era the important concept in pharmaceutical research was translational chemistry. How to convert a small molecule into a marketable drug product for medical benefits became the theme. The task was formidable but could not discourage researchers and emergence of new drug continued.

## Drug discovery starting point

Approaches to drug discovery

- Historical; cinchona (quinine) & willow barks (aspirin); chinese medicine currently.
- Study disease process; breast cancer (tamoxifen); Parkinson's disease (L-dopa)
- Study biochem/physiological pathway; renin/angiotensin
- Develop SAR to natural compound; beta-adrenoceptors (propranolol), H<sub>2</sub>-receptors (cimetidine)
- Design to fit known structurally identified biological site; angiotensin-converting enzyme inhibitors
- By chance (serendipity); random screening (HTS); penicillin; dimenhydrinate; pethidine
- Genomics; identification of receptors; gene therapy; recombinant materials;

## Concepts

### Translational chemistry

The history of natural products, chemical related observations that a particular substance exhibited specific biological activities that can be therapeutically exploited, served a great stride in drug discovery. The drug d-tubocurarine was the first example of translational chemistry. The observation that a natural product from the hot water extract of a south American plant was used by native Americans for hunting by way of paralysing the prey by the arrow dipped in the extract, was translated into muscle relaxant effect that could be utilized to paralyse diaphragm during open chest surgery. Thus emerged the cholinergic neuromuscular blocker. This was no mean research finding. It served great needs of medical sciences.

### **Translational research**

Similarly, another concept in pharmaceutical research emerged from the hypothesis of James Whyte Black a Scottish doctor and pharmacologist, while working at ICI Pharmaceuticals from 1958 to 1964. He observed that activation of the  $\beta$ -adrenergic system increases sympathetic drive and oxygen consumption within cardiac muscle. Therefore, he postulated that it might be possible to protect ischemic heart and alleviate angina pectoris by administering  $\beta$ -adrenergic blockers. Investigations of the compounds for  $\beta$ -adrenergic blocking effect led to the introduction of propranolol for treatment of hypertension. This orally active drug is the best example of translational research. However propranolol having half life of 4-5 hrs proved useful during chronic dosing. For emergency treatment it had limitations. Because of the long half life it was not suitable during critical care situations. Thus Black pioneered a new concept in pharmaceutical research where drug molecules were purposefully built instead of being synthesised first and then investigated for their potential medical uses. The discovery of propranolol is the greatest breakthrough in the treatment of heart disease since the discovery of digitalis.

Subsequently, Black continued his research with same concept for treatment of stomach ulcers, but ICI did not show interest, hence he resigned in 1964 and joined Smith, Kline and French where he worked for nine years until 1973 and during this period developed his second major drug, cimetidine, which was launched under the brand name Tagamet in 1975 and soon outsold propranolol to become the world's largest-selling prescription drug. He was awarded the Nobel Prize for Medicine in 1988 for work leading to the development of propranolol and cimetidine.

### **Translational medicine**

To overcome the limitations of propranolol the third concept in drug discovery was explored. This is translational medicine. The background was that propranolol having long half life of 4-5 hrs was not desirable during critical care. Hence, the search for compounds having  $\beta$ -adrenergic blocking effect but ultra-short duration of action for i.v. use during emergency led to introduction of esmolol as an antiarrhythmic drug having half life of 9 minutes.

### **Combination of all three concepts**

The most significant revolutionary concept in pharmaceutical research can be exemplified by sildenafil, which combines all the three concepts illustrated above. Sildenafil discovery was a combination of collaborative chemical and pharmacological findings. The drug proved effective inhibitor of the enzyme phosphodiesterase V (PDE V) which is known to catabolize cyclic guanosine monophosphate (cGMP), an intracellular second messenger associated with calcium homeostasis causing relaxation of vascular beds. The result of inhibition of PDE V is higher level of intracellular cGMP, useful in treatment of hypertension or angina pectoris. The clinical trial records reveal that sildenafil was subjected to clinical trials twice. The first trial to examine its antihypertensive effect and when it failed it was tried for therapy of angina pectoris. Unfortunately the second trial also failed. However during these clinical trials it was observed that another vascular bed was significantly dilated. As a translational medicine sildenafil emerged as a good candidate for erectile dysfunction. A multimillion market was born. This was possible because of the beauty of clinical research. Thus accuracy of observations in the research are very important. The original target may be missed but one should never overlook the unexpected effects. The chemically driven or biologically driven fundamentals must be extended and extrapolated to clinical situation and if minutely understood and logically interpreted, huge benefits may be harnessed from research. If this principle was not utilized the mankind must have missed sildenafil once for all.

### **The Synthetic era**

This is best explained as "Adam goes into the test tube and Eve comes out." - Dr. George Rosenkranz

Numerous analogues were synthesized in laboratories and attrition factor was very high. The concept of receptor and ligand promoted research in a great way. QSAR studies served as useful tool in visualizing possible biological activities.

### **The lead likeness concept**

What makes a good lead recognised the concept of lead likeness. There may be hundreds of thousands of molecules who are suitable ligand for receptor. However, no matter how good they fit the receptor, if they are not

absorbed adequately or they are excreted too slowly from the body its likeliness as a successful drug candidate is highly doubtful. In light of this renewed knowledge, in 1997 Christopher A Lipinski, re-focused drug discovery back to the principles of medicinal chemistry in the high-throughput era as key to reducing attrition. After data analyses of 2,245 molecules a set of rules called Lipinski rule of five as cut-off values in the physico-chemical profile of chemical libraries were arrived. It is a rule of thumb to determine if a chemical compound with a certain biological activity has properties that would make it a likely orally active drug in humans. A candidate molecule is more likely to have poor absorption or permeability if

- The Molecular weight is more than 500
- Partition coefficient (Octanol/Water) is more than 5
- There are more than 5 H-bond donors expressed as the sum of -OH and NH groups
- There are more than 10 H-bond acceptors expressed as the sum of N and O atoms

### **Changed concept**

- synthetic chemistry offered the promise that if a drug could be envisioned, it could be made.
- the ability to prepare analogs (with the natural  $\beta$ -lactam core but carrying a non-natural side chain) proved to have activity against resistant strains.

### **Pregenomic era**

During pregenomic era many highly successful drugs were launched. Such discoveries may be classified as

- Receptor agonists
- Receptor antagonists
- Enzyme inhibitors
- Signal transduction inhibitors
- Inhibitors of protein-protein interactions

The examples of the above class include:

- COX inhibitors – celecoxib, rofecoxib
- ACE inhibitors – captopril, lisinopril
- Histamine H1receptor antagonist – fexofenadine
- Histamine H2receptor antagonists – cimetidine, ranitidine
- Proton pump inhibitors –omeprazole, esomeprazole
- PPAR- $\gamma$  activators – pioglitazone, troglitazone
- Lipid lowering agents – atorvastatin, cerivastatin
- Acetylcholinesterase inhibitor – donepezil
- Anti influenza – zanamivir
- Antiobesity – orlistat
- Antipsychotic – quetiapine, olanzapine

## **Impact of Pharmacogenomics**

It is well established that different patients with the same disease symptoms respond differently to same drug both in terms of efficacy and toxicity because of varied genetic make up. This demands tailor-made therapy for specific genetic population. Pharmacogenomics attempts to address the issues of efficacy and toxicity in individuals.

## **Conclusion**

Glimpses of research trend as depicted above demonstrate that drug discovery has been a continuously changing and evolving field. Attempts have continued to discover more and more safer and effective drugs over the existing one. This is a gigantic task which attracts multidisciplinary approach and team spirit to proceed.

Company was started in the year 1992. We would like to take this opportunity of briefly introducing M/s THORNS & ROSES OUTDOORS which is a well established advertising agency for the past 22 years, with business being carried out in all over Karnataka as well as in India. The company deals with a varied range of medias, namely - such as Hoarding, Bus shelters, Poll kiosks, Road medians & Mobile displays.

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### **Thorns & Roses Outdoors**

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# 2014 EXPRESSIONS

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## Expressing my Expressions!

**Shri. Ajit Kaikini**

*Director, Growth & Corporate Training, Buoyancee*

Life after college!!! How many times would you not have discussed this with your friends, what you will be doing after your college, what kind of job will you land in, what would your friends be doing at the same time, what will happen to your cricket / dance practice.

I had similar thoughts too. As a student at Manipal from 1974 to 1978, I always wondered if I would ever learn the secret to success. However, certain events around me prompted me to look at things differently.

As I noticed more and more people around me, (as you will too), the questions that had begun to intrigue me were:

- How come my uncle with lesser education & lesser marks is more successful as a professional than another uncle who has a professional degree?
- A prize winner in school/ college, yet struggling as a professional...
- A gold medallist at academics yet is not able to control the labour effectively - whereas the so called mediocre found on the playground & participating in various activities, is at the helm of affairs of a company...

And many such 'real life' situations which seemed to be against the 'norms' and 'rules'

The realisation came to me just like it does to a talentless hero in the middle of the movie, who then spurts talent in the rest of the movie and claims his title of being the 'hero'.

Being just a book worm, or being the encyclopaedia wasn't enough. Knowledge put together with personality was the success mantra in an ever evolving world of progress. Being an all-rounder is important, communication, attitude, persona, everything matters in success.

After over three decades of working experience in different jobs, I learnt that to be a success, one needs to be grounded, to be strong like the tall building. And like every building stands on its pillars, the 4 pillars of

success to be a great professional are the right mix of:

**Capability + Capacity + Compatibility + Credibility**

What are these you ask me???

**Capability:** The ability to do the TASK.

T – Do I have the right tools to work with?

A – Do I have the right attitude and approach to work?

S – Do I have the right skills as needed for my work?

K – Do I have the right knowledge as required for the job at hand?

Post my graduation, not being very good at studies; I decided to go in for a job. When I joined as a medical representative, I realised that most did not have the right tools & skills needed to be a professional. To develop them, I realised that attitude was of utmost importance and very few institutes help to acquire the same.

Luckily for me, while balancing my studies to acquire knowledge in Manipal, I saw some illiterate mess helpers and cleaners talking quite good English and it motivated me to develop further the English tool and the Communication skill.

Not all the experiences were the best ones. I had to struggle through many. But all these experiences truly taught me how failure could be used as a stepping stone to go up the ladder. These attributes helped me to face any client and reach my targets in sales with ease, and I could still see my friends who were brilliant in academics but unwilling to pay attention to these skill sets were still struggling to make the cut in the market.

**Capacity:** The stamina needed to go on with one's Capabilities.

If you notice in every sport, the coach would first train you on your stamina rather than your technique. While watching & playing football, I realised that the crux of winning this game was stamina. The best of dribbling without stamina had no value.

I made a list of stamina required to shift from being a good professional to a great professional. I realised that resilience, patience, tolerance and many such attributes give an impetus to one's capability.

Managing change was very vital, which people with only great capability found it to be of importance! Treks, participating in social functions and doing things out of routine helped me befriend risks. It helped me improve my emotional quotient and help take pressure as pleasure towards gain!

People with capacity face situations with confidence and get promoted faster, and those who rise only with capability may land up with stress.

**Compatibility:** The chemistry to blend with people & situations.

Friends, companions, company are the key to our lives. There is a huge difference in doing things alone and while in a team.

While playing football, I realised that I had to manage not only the ball but people also. We all in the team had to find a common objective to work together amicably and that was the goal post.

If I had resisted all the changes which happened on the field during the game, I would have been found complaining forever, and consecutively become an average player. However, I decided to invest my Time, Energy, Attention & Resources contemplating, how to manage them amicably. I learnt the importance of doing things with help. "Mile sur mera tumhara..." became my slogan. I realised the importance of working towards making things complete rather than compete!

The missing letter L is the love for the self, the work and people involved. I realised one's formidable significance in teams rather than working alone. Conflicts, I realised, was the way to bring out the best in one and understand people better. Not just being independent but being interdependent is the way to go was the learning I got. Rising up the ladder became easy as I got pushed up. Respecting people for what they have and motivating them to be inspired & contribute more, helped improve profitability too.

**Credibility:** One's ability to anchor to the values.

Once a team player, people start trusting your judgements. An ability to retain this trust is the most important factor to retain people in your life. I realised how people caught cheating were dropped like hot

potatoes. Recently, even the best like Tiger Woods and Lance Armstrong were not spared.

"Able VALUE able": I realised that to prefix able before value was more important than to suffix it. I also realised that values cannot be taught and that it has to be caught for peace & happiness in one's life. The single gift of credibility is authority! I started anchoring to the vital things in life like truth, trust, help, service and many more. Valuables just followed!

Using these on myself and seeing the impact, I started experiments on people who wanted to be successful in life. When at Buoyancee an illiterate became a consultant to Times of India and a security guard became a sales manager in Qatar, we started uplifting professionals in companies. Just developing these soft skills in the professionals within the company, we could help Sutures India & Ghataprabha Fertilisers almost double their turnover to nearly 100 crores. In collaboration with UNIDO, we could help KAPL & KTC bring down rejection rates to zero parts per million and even support Bank of India to improve profitability.

The importance of life skills starts from a nascent stage of your life but go on until the very end. The emphasis is not just about what you do but how you do it as well. If you want to be recognized as a leader in whatever venture, then these four qualities are what you need to achieve. Your each step up the ladder of success is a resultant of successfully accomplishing these qualities. Having said that, these aren't exactly difficult to attain. You just have to have the interest and the openness to the experiences which you have through your life, and with the right effort, you can easily possess them.

Now I realise, that success is not a wonder, it is something that is waiting for us all along. It depends on us how we find it and what we do to get to it. After due consideration, even after three decades of working experience, I still see my future bright and strong as I am venturing into new things. Now it's your turn. Do you see it too???

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## How intelligent are you?

**Prof. Anila**

*Principal, College for Leadership and HRD*

Someone said in a discussion, “Wonderful things in the world cannot be seen or even touched. They can only be felt with the heart”

Anybody would agree with the statement.

But do feelings really stem from the heart?

Acute anger, love, jealousy, grief or such other feelings do result in the harder pounding of the heart which probably would have led to the general belief that feelings stem from the heart. But, do they really?

Daniel Goleman, a psychologist, decided to venture out on this issue of feelings especially in view of some people with high IQ floundering in life while those with modest IQ doing surprisingly well.

He says in his book, ‘Emotional Intelligence’, that it is the EQ (Emotional quotient) of an individual that works out to be the decisive factor in the success and effectiveness of an individual rather than the IQ (Intelligence quotient). The argument given by him is that emotional intelligence hinges on the link between sentiment, character and moral moorings. There is growing evidence that fundamental ethical stances in life stem from underlying emotional capacities. Impulse is the medium of emotion: the seed of all impulses is a feeling bursting to express itself in action. Those who are at the mercy of impulse suffer a moral deficiency. The competence to regulate impulse is the base for character and its will power, they say.

In ‘The Nicomachean Ethics’, Aristotle’s philosophical enquiry into virtue, character and the good life, his challenge is on issues connected with management of human’s emotional life with intelligence. Passions when exercised well have wisdom: they guide human thinking, values and thus, the survival. But they can easily go awry.

He said, “Anyone can become angry – that is easy. But to be angry with the right person, to the right degree, at the right time, for the right purpose, and in the right way – this is not easy.”

In his work where there were far reaching implications for understanding mental life, Dr. Antonio Damasio, a neurologist, made careful studies of just what impaired patients whose decision making was terribly flawed. He saw that there was no deterioration at all in their IQ or any cognitive ability. Despite their intact intelligence, they had made disastrous choices in business and their personal lives. Dr. Damasio’s argument was that they had lost access to their emotional equilibrium that ought to have offered the much needed support.

This led Dr. Damasio to believe that feelings are typically indispensable for rational decisions. He argued that emotional brain is as involved in reasoning as is the thinking brain.

This way, we have two brains, two minds and two different kinds of intelligence; rational and emotional. How we do in life is determined by both. Indeed intellect cannot work at its best without emotional intelligence. It is necessary to harmonise both head and heart in their own equations in different functions.

There is also much more to the complexities of intelligence itself.

The ‘Theory of multiple intelligences’ was propagated by Howard Gardner in an article which he exemplified further in his 1983 book *Frames of Mind: The Theory of Multiple Intelligences* as a model of intelligence that differentiates it into specific (primarily sensory) “modalities”, rather than seeing it as dominated by a single general ability. Gardner articulated seven criteria for a behaviour to be considered intelligent. These were that the intelligences showed: potential for brain isolation by brain damage, place in evolutionary history, presence of core operations, susceptibility to encoding (symbolic expression), a distinct developmental progression, the existence of savants, prodigies and other exceptional people, and support from experimental psychology and psychometric findings.

Gardner chose eight abilities that he held to meet these criteria: musical – rhythmic; visual – spatial;

verbal – linguistic; logical – mathematical; bodily – kinesthetic; interpersonal; intrapersonal; and naturalistic. He later suggested that existential and moral intelligence may also be worthy of inclusion.

He refuted the IQ view. Intelligence, according to him, was not just one monolithic kind but rather had a wider spectrum. Gardner acknowledges that seven or eight or nine are arbitrary numbers for the variety of intelligences; there is no magic number to the multiplicity of human intelligences. In fact, at one point, Gardner as well as his colleagues in research had stretched the number of intelligences to a list of twenty different varieties. His thinking about multiplicity of intelligence continues to evolve.

Asforemotional intelligence not having been included in his list, Gardner says, in intrapersonal intelligence, the key to self knowledge, there is access to one's own feelings and the ability to discriminate among them and draw upon them to guide a personal behaviour. And the core of interpersonal intelligence includes the capacities to discern and respond appropriately to the moods, temperaments, motivation and desires of other people.

Gardner agrees to the fact that he has focused more on feelings as part of cognition rather than the role of feelings in these intelligences.

Albert Camus in his book 'The Outsider' brings in poignantly the tragedy of the protagonist where he is sent to the gallows not for killing while defending himself but for having not shown any emotion at the time of his mother's death. The jury holds him incapable of having emotions which would have driven him to the murder.

There's a point to ponder here. Whose and which are the views to be considered here? Aristotle's, Gardner's, Goleman's, or even Dr Antonio Damasio's? Or is there still more to be considered that are yet to be born?

The degree of intelligence, as understood commonly, varies from individual to individual. Aristotle and Gardner and Goleman and Dr. Antonio are but a few who tried to give an explanation to the term by looking at it from different dimensions, in the process, making it a subject much more to be studied and researched into.

One thing that can be surmised from all the studies that have been made so far about intelligence is that the best of it is yet to be learnt. This is apart from the fact that enhancement of intelligence can happen provided intellectual revolutions keep happening.

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# Concepts on Quality Compliance and Quality Assurance

**Shri. A. R. Hegde**

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No sane management would like to remain complacent & thereby becoming obsolete by simply standing still. The famous Chinese philosopher, Lao Tse said a few hundred years ago that a "journey of a thousand miles begins with the first step".

For a reputed Pharmaceutical manufacturing Plant, one needs to plan for minimal resources that provide a strong base for a Quality Enterprise. Experts on Pharmaceutical operations have been guiding us on the journey of Quality Excellence. Technical experts with hands on experience of several years of exposure & relevance can & will take us through critical milestones.

Healthy discussions on guidelines & concepts are imparted for improvements. Scientific training needs are identified & focused during the training provided. There are several milestones to be gone through for achieving Quality Excellence.

## Milestone 1- Quality Unit

One can have one's own QC laboratories with Chemical, Instrumentation & Microbiological testing facilities. With these facilities, a unit qualifies for basic operations.

For Quality Excellence, we need well qualified & well trained personnel, properly calibrated & maintained instruments & equipment, safety system, reference standards, good laboratory practices (GLP) standard operating procedures (SOPs) validated methods of analysis, cleaning & disposal of rejected/redundant materials & documentation of all activities.

## Mile stone 2- Documents & Records.

By maintaining relevant documents & records at the required stages, a good Pharmaceutical unit would qualify for basic operations. For Excellence, one needs to have documents for stages/activities, legible correct records maintained concurrently, reviewed & approved by designated personnel (authorized) securely stored with easy retrievability.

## Mile stone 3- Good House Keeping

If the Plant is clean, it qualifies for basic operations.

For Excellence, you need safe, well maintained, clean & aesthetic, free from pests, well lit & ventilated Plant; personnel wearing correct & clean working garments-different in different Class areas.

## Mile stone 4- In Process Quality Control (IPQC)

Adequate control on in Process Quality ensures compliance norms. However, for excellence, you need suitable specifications, trained & assertive personnel & adequate equipment.

## Mile stone 5- Stability

If Stability studies support shelf life for one's products, compliance norms are met. For Excellence, need ongoing real time stability studies, determination "extrusions" beyond prescribed storage conditions.

## Quality for Excellence:

Increased self confidence & morale would improve sales through better medical acceptance, reduced manpower turnover, greater visibility & increased productivity.

Points for adherence In QA Labs /QC Cells

### 1 Respect seniors

- Follow hierarchical discipline
- Tone, tenor & language
- Communication: simple, true, straight to the point; no double meaning
- Movement of hands
- Discuss, debate but follow the final decision without dilution.
- Self & timely feed back.

### 2 Personal disciplines

- Avoid discussing people- openly or in private
- Focus on issues & solutions to problems
- Discuss on continuous improvements

- Honesty is the best policy
- Accept mistakes if any, rather than offer excuses
- Get rid of mental clutter
- Observe manners & etiquettes

### 3 Functional

- First check is the best check. All subsequent checks are no substitutes for the first check
- Be alert, observant & sensitive as you are the Guardian of Quality
- Ensure that SOPs are followed across the organization
- Ensure on -line status of Operations & Documentation
- Observe your own operational & general areas clean & orderly:
  - Table & chairs & filing rack
  - Stacking of files
  - Storage of files
  - Security of information
  - Ease of retrieval of documents
- Avoid assumptions as accidents; mishaps do not take place everyday
- Verify & re-verify security & adequacy of safety aspects of quality
- Innovate for continuous improvement

- Involve people concerned to make decisions effective, precise & sustainable
- Develop presentation skills
- Know that you have the ONUS of Quality with You

### 4 Do your own Job:

- There is a lot you could still achieve in your own work
- You will enjoy if you are sincere, innovative & work by heart.
- Avoid sharp criticism; instead, support others.
- Positive criticism if any, should be direct with the concerned person

### 5 GLP Commitment

- Online Documentation
- No manipulation of any kind
- Approach/ consult superiors in case of doubts

In conclusion, by thorough understanding of all aspects on Quality Compliance & Assurance & strict adherence to discipline in QA & QC laboratories & personal commitment to cooperation & integrity, an organization of Quality Excellence can be established & improved upon by continuous application of mind & updating with on going developments across the Globe.

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# Regulation of Indian pharmaceutical market: A historical perspective



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## Abstract

## Context

The Indian pharmaceutical industry has come a long way, being almost non-existing before independence to a vital supplier of healthcare products worldwide, serving almost 70% of the country's pharmaceuticals needs. The pharmaceutical industry in India is regulated by a number of laws and regulations.

## Objective

This paper presents an overview of the main regulations governing Indian pharmaceutical market along with its historical perspective.

## Methods

A prior art search was conducted to find literature on rules and regulation governing Indian pharmaceutical market and its historical perspective. The literature was searched using the following key words: Indian pharmaceutical industry, market, history, Act, legislation and regulation. Apart from this, text books and Bare Acts on the subject were also referred.

## Findings

The search results were filtered to find out the literature describing rules and regulation governing Indian pharmaceutical market and its historical perspective. After the screening, total 19 applicable literature remained.

## Results and Conclusion

Indian pharmaceutical market has developed mainly after its independence. A large number of regulations govern the Indian pharmaceutical market today. Although these regulations are continuously evolving, still they have to be further strengthened so that the Indian pharmaceutical industry can face the growing

demand and competition at international level in a better way.

## Introduction

The current pharmaceutical industry in India is well organized and regulatory compliant sector. There are approximately 250 large and about 8000 small scale pharmaceutical units in India. The Pharmaceutical industry in India meets around 70% of the country's demand for medicines including human and veterinary chemical/ biological drugs, medical devices, herbal products and cosmetics. The Indian pharmaceutical industry grew at a CAGR of 12.5% during the last five years and it is expected to grow at a CAGR of 15.1% during 2012-17.

India has the highest number of USFDA approved plants outside USA. Indian Pharma companies are filing highest Abbreviated New Drugs Approval (ANDA) applications in USA. The Indian pharmaceutical industry is 3rd largest in the world by volume. It is ranked very high amongst all the third world countries, in terms of technology, quality and the vast range of medicines manufactured here.

Almost all the activities pertaining to pharmaceutical industry like import, manufacture, distribution and sale of drug substances and drug products are controlled under various regulations of the country. This paper presents an overview of the main laws and regulations governing Indian pharmaceutical market along with its historical perspective.

The information presented in this paper was collected via online searching on internet, text books and Bare Acts. For internet searching the search terms used were Indian pharmaceutical industry, market, history, Act, legislation and regulation. The downloaded literature was screened and the most relevant articles i.e., those describing the historical aspects of regulations governing the Indian pharmaceutical market were selected for the study.

## Historical Perspective

India's tradition in health science goes back to the days of Susruta, Vagudatta and Charka. The Ayurvedic system of medicine of India is the most ancient system of medicine in the world. Ayurveda is considered to be of vedic origin and is a part of Hindu culture. This system suffered a great blow by the Arabic or Unani Tibb system brought into India by the muslim rulers. Allopathic system of medicine was introduced into India by the British rulers. Under the British Rule in India majority of the drugs were imported from abroad. There was no control on the quality of drugs imported in the country and the Indian market was flooded with adulterated and spurious drugs. In response to widespread "Great Quinine Fraud", the Government, then, formed the Drug Enquiry Committee (Chopra Committee) under the chairmanship of Col. Ram Nath Chopra in 1927. The report of Chopra Committee was published in 1931 and presented a picture of the state of affairs then prevalent. Unfortunately, no immediate action on this report was taken by the government. However, five years after the publication of this report the Biochemical Standardization Laboratory was established in Calcutta to implement one of the recommendations made by the Chopra Committee. In 1940, the Drugs Bill was introduced by the Government of India to regulate the import, manufacture, distribution and sale of drugs in India. On 10th April, 1940 the bill was passed and it became the Drugs Act, 1940. Later on, in 1962 the Act was amended as Drugs and Cosmetics Act, 1940. This Act established the Central Drugs Standard Control Organization (CDSCO), and the office of its controller, the Drugs Controller General (India) [DCG (I)].

The British Government appointed another committee, the Health Survey and Development Committee in 1943 to make a survey of the existing position in respect of health organization in the country and to make recommendations for future development. As a result of the recommendations made by this committee, the Pharmacy bill was introduced in 1945 to regulate the profession and practice of pharmacy in India. This bill was passed in the shape of Pharmacy Act, 1948.

## Pharmaceutical Regulations in India

The current India pharmaceutical market is fully regulated with the help of a number of legislations

and regulations. A brief overview of some of the major legislations and regulations is provided here.

- **Drugs and Cosmetics Act, 1940 and Rules, 1945:** This is the central legislation which regulates import, manufacture, distribution and sale of drugs in India. The Act consists of 38 sections under 5 chapters and 2 schedules. The Rules consists of 168 rules under more than 19 parts, 18 schedules and 11 appendices. All medicines including ayurvedic, siddha, and unani, for internal or external use of human being or animals and cosmetics are covered under the Act. The Act and rules have been amended several times. Schedule M of the Drugs and Cosmetics Rules specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs. Schedule T of the rules prescribes Good Manufacturing Practices (GMP) specifications for manufacture of Ayurvedic, Siddha and Unani medicines. Schedule H of the rules provides the list of the prescription drugs. Schedule Y of the rules prescribes the requirements and guidelines for permission to import and/ or manufacture of new drugs for sale or to undertake clinical trials. The Drugs and Cosmetics Rules have been amended recently in 2013 to introduce Rule 122 DAB, Rule 122 DAC, Rule 122 DD and Appendix XII of Schedule Y. These amendments are aimed to strengthen the clinical trial regulations in India. These amendments will remove the loopholes during clinical trials like trials being conducted in an unethical manner; the free medical treatment and inadequate compensation given to subjects; and trial related deaths and injuries being ignored by the sponsor and its representatives.
- **Pharmacy Act, 1948:** The Act was passed with the broad objective to regulate the profession and practice of pharmacy in India. To achieve this objective Pharmacy Council of India (PCI) and various State Pharmacy Councils have been constituted. The Pharmacy Council of India makes regulations called as Education Regulations with the approval of Central Government and prescribes the minimum qualification required for registration as a pharmacist. Education Regulations-1991 are currently into force which makes a two years Diploma in Pharmacy as the minimum qualification for registration as a pharmacist in India.

- **Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955:** This Act controls the advertisement of drugs and prohibits the advertising of remedies alleged to possess magical qualities. In particular the Act prohibits - advertisement of certain drugs for treatment of certain diseases and disorders; misleading advertisements relating to drugs; advertisement of magic remedies for treatment of certain diseases and disorders; and import into, and export from, India of certain advertisements.
- **National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012):** The policy puts in place a regulatory framework for pricing of drugs so as to ensure availability of required essential medicines at reasonable prices. The key principles for regulation of prices in the NPPP-2012 are: essentiality of drugs, control of formulations prices only and market based pricing.
- **Drugs (Prices Control) Order (DPCO), 2013:** Recently in May, 2013, DPCO-2013 has been implemented replacing the existing DPCO-1995. The new DPCO authorizes the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of drugs on India's National List of Essential Medicines (NLEM) 2011 using new market-based rules. DPCO-1995 regulated prices of only 74 bulk drugs whereas the current DPCO will regulate prices of 384 essential drugs covering over 600 formulations. The DPCO, 2013 aims to provide incentives to the companies that develop new drug/ new formulation/ new process through indigenous Research & Development and get it patented in India. Such patented drugs or formulations shall be exempted from price control over a period of 5 years. As per the new DPCO, price of a formulation would be calculated based on the moving annual turnover of the existing selling brands of the same drug. This shifts the ceiling price calculation from a cost based to a market based method.
- **Narcotic Drugs and Psychotropic Substances Act and Rules, 1985:** This is an Act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances. As per this Act - a) The cultivation, production, manufacture, possession, sale, purchase, transportation, warehousing, consumption, inter-State movement, transshipment and import and export of narcotic drugs and psychotropic substances is prohibited, except for medical or scientific purposes and in accordance with the terms and conditions of any license, permit or authorization given by the Government. b) The Central Government is empowered to regulate the cultivation production, manufacture, import, export, sale, consumption, use etc of narcotic drugs and psychotropic substances. c) State Governments are empowered to permit and regulate possession and inter-State movement of opium, poppy straw, the manufacture of medicinal opium and the cultivation of cannabis excluding hashish.
- **Poisons Act, 1919:** This Act regulates possession of substance or sale of substances specified as poison. It also specifies the safe custody of the poisons, labeling and packaging of poisons, maximum quantity to be sold and inspection as well as examination of the poison sold by vendor during the year.
- **The Medicinal and Toilet Preparations (Excise Duties) Act, 1955 and Rules, 1956:** This Act provides for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drug or narcotic substance.

## Indian Business Laws

All of the above laws and regulations specifically relates to the pharmaceutical industry in one way or other. Apart from these, there are many business laws and regulations which also affect the pharmaceutical industry and market in significant way. Following is a brief overview of some of these major business laws in India.

- **Indian Contract Act, 1872:** The Act was passed by British India and is based on the principles of English Common Law. This legislation governs contracts. It lays down the general principles relating to formation, performance and enforceability of contracts and the rules relating to certain special types of contracts like Indemnity and Guarantee; Bailment and Pledge; and Agency.
- **Patents Act, 1970 and Rules 2003:** The Patents Act, 1970 came into force in the year 1972 which allowed only process patenting and no product patenting. After the implementation of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), India amended its Patent Act in

a major way through Patents (Amendment) Act, 1999, 2002 and 2005. The current Patent Act allows product as well as process patenting in all fields of technology with 20 years term. Pre- and post-grant opposition, compulsory licensing and section 3 (d) are some salient features of the Act.

- **Trade Marks Act, 1999 and Rules 2002:** This Act allows registration of a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others. A trade mark includes words, logos, colours, slogans, three-dimensional shapes and sometimes sounds and gestures.
- **Consumer Protection Act, 1986:** It is implemented to protect consumer rights and provides a simple quasi-judicial dispute resolution system for resolving complaints with respect to unfair trade practices. The Act was amended in 1993 and 2002.
- **Company Act, 1956:** To regulate setting up and operation of companies in India. It regulates the formation, financing, functioning and winding up of companies.

- **Factories Act, 1948:** Umbrella legislation to regulate the working conditions in factories.
- **Foreign Exchange Management Act (FEMA), 1999:** It is implemented to facilitate external trade and payments and to promote the orderly development and maintenance of the foreign exchange market.

## Conclusion

Today, India has acquired a distinct place in the world's pharmaceutical market due to producing and exporting low cost, high quality medicines. Further, India is poised to be one of the fastest growing pharmaceutical markets in the world. Due to expected high growth rate in the pharmaceutical market, government needs to strengthen further the existing legislative framework and to provide measures for speedy dispute resolution, so that the industry can face in a better way the growing demand and competition on international level.

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## Indian pharmaceutical research – New vistas

**Dr. Dinesh Shenoy**

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It all started with the Indian Patent Act of 1970 – which set the milestone for the growth trajectory of Indian pharmaceutical industry. It was the enactment of this act that was a crucial initiative to facilitate a domestically-owned pharmaceutical industry as an alternative to the very expensive pharmaceuticals imported from Britain and European countries. Coming into force in 1972, this act was designed to offer process patents for only five years, and no product patents, on pharmaceuticals. There has been no looking back since then.

First, the Indian pharmaceutical industry observed an explosive growth in active pharmaceutical ingredients (API) business. This was followed by the finished drug product (or the formulations) business – which was a logical forward integration and progression of the field of pharmaceutical research. The supporting fields like analytical, bio-analytical, pre-clinical and clinical research had no choice but to grow simultaneously to keep-up with the pace of overall growth of the industry. With the Pharma Y2K closing-in and aftermath the implementation of GATT in January 2005, the understanding of the global pharma market demands and the natural state of desire to expand beyond geographical boundaries further forced enhancements in the fields of regulatory, quality, compliance and intellectual property. Several of the Indian companies like Sun Pharma, Zydus-Cadila, Ranbaxy, Dr. Reddy's, Lupin etc. emerged as global players by expanding the foot-print into USA and European Union. Conversely, the global pharmaceutical giants also acknowledged the strength of the Indian pharma companies – which eventually led to several acquisitions namely, Daiichi-Ranbaxy later acquired by Sun Pharmaceuticals, Abbott-Piramal, Mylan-Matrix/Agila, Sanofi-Shanta Biotech etc..

One must understand the continuing trend of technological complexity. First it was simple APIs, through process modification, this was followed by APIs requiring multi-step processes requiring more complex non-infringing routes of synthesis; next came the formulations – in terms of simple non-infringing

process changes and routes of administration. Soon, the reverse engineering of complex formulation technologies followed. Today, the Indian pharma companies or the R&D shops that are set-up in India by global companies are involved in the development of extremely complex APIs like proteins, peptides, hormones, polysaccharides etc. as well as complex formulation technologies. Indian pharma companies challenging the Discovery, Innovators and Brand MNC's via Paragraph IV filing has become a routine.

### What's next?

Considering the past trend and accomplishments, the strength of Indian scientific community and the future need from global perspective, Indian pharma industry would fuel the process of continuous incremental improvement rather than sudden large jumps in technology through breakthrough discoveries. This would be particularly true for formulation technologies – for varied routes of administration viz; oral, injectable, nasal, ophthalmic, transdermal etc. In-line with the global trends, as demonstrated by leading generic players like Teva, Sandoz, Sun Pharma, Mylan, Actavis etc., there would be focus of bridging the gap between branded formulations and the generic formulations through generic-plus or branded generic drug products – which are created through incremental innovations – mostly in order to meet the unmet medical needs. While the last decade could be dedicated to novel drug delivery systems (NDDS), the next decade can be dedicated to nanotechnology-derived products – both in pharma and biopharma sectors.

While the global biotech bubble has been burst, the Indian biopharma industry is poised to take a leap into unlocking the value of multi-billion dollar biogenerics market. Over last decade, the technological and knowledge-based in this field has expanded exponentially. With the rise of Indian biotech firms like Biocon, Bharat Biotech, Serum Institute, Shantha Biotech etc., there is much hype and hope to witness the biotech boom in Indian subcontinent. Again – this

would be restricted to creation of biogeneric drug product rather than innovative biotechnology-derived drugs or even biobetter versions.

The key challenge in this path of brilliant growth has been related to quality and compliance. The Indian pharma industry has been under scrutiny of global regulatory agencies for deficiencies in quality and

ethics-related aspects and multiple cases are being discovered off-late – resulting in warning letters and import bans. All the accomplishments of the past and the future growth prospects will be shunted unless the Indian pharma industry, the Regulatory and Compliance systems wake-up to the current quality requirements.

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## Role of Indian Pharmacopoeia commission (IPC) in ensuring quality & safety of medicine



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*Drugs Controller General of India*

**Dr. V. Kalaiselvan**

*Senior Scientific Officer, Indian Pharmacopoeia Commission*

**Ms. Archana Saurabh**

*Pharmacovigilance Technical Associate at Indian Pharmacopoeia Commission*

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. The Commission has become fully operational from 1st January, 2009. IPC is created to set standards of drugs in the country. It's basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India.

### Mission:

To protect and promote public health by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients, dosage forms and medical devices for use by health professionals, patients and consumers.

### Vision:

To promote the highest standards for drugs for use in humans and animals within practical limits of the technologies available for manufacture and analysis.

### Objectives:

To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, excipients and dosage forms as well as medical devices, and to keep them updated by reviews and revisions on a regular basis.

### IPC Play vital roles in ensuring the quality and safety of medicines:

IP prescribes standards for identity, purity and

strength of drugs essentially required from health care perspective of human beings and animals.

IPC provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP. IP is an official document meant for overall Quality Control and Assurance of Pharmaceutical products marketed in India by way of contributing on their safety, efficacy and affordability.

The work of the IPC is performed in collaboration with members of the Scientific Body, subject experts as well as with representatives from Central Drugs Standard Control Organization (CDSCO), State Regulatory authorities, specialist from Industries, Associations, Councils and from other Scientific and Academic Institutions.

IPC also acts as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), thereby coordinating all the activities related to pharmacovigilance in India.

The Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India has initiated a nation-wide Pharmacovigilance programme in July, 2010, with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre (NCC) for monitoring Adverse Drug Reactions (ADR) in the country to safe-guard Public Health. The PvPI started with the enrolment of 22 ADR monitoring centres across the country in the year 2010. To ensure implementation of this programme in a more effective way, the National Coordinating Centre was then shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.) in April, 2011. After that AMCs increased to 90 by the end of 2012, 60 of which are phase I AMCs and 30 are phase II AMCs. All the 90 AMCs are categorised into

four zones i.e. North, South, East and West as per zonal offices of CDSCO in India and are functioning under NCC. Now NCC-PvPI added 60 more AMCs by the end of 2013 and now total 150 AMCs for ADR reporting.

The Pharmacovigilance Program of India (PvPI) was launched with a broad objective to safe guard the health of 1.27 billion population of India. Adverse drug Reactions (ADRs) are reported from all over the country to NCC-PvPI, which also work in collaboration with the global ADR monitoring centre, World Health Organization-Uppsala Monitoring Centre (WHO-UMC), Sweden to contribute in the global ADRs data base. NCC-PvPI monitors the ADRs among Indian population and helps the regulatory authority of India (CDSCO) in taking decision for safe use of medicines.

The mission of PvPI is to safeguard the health of the Indian population by ensuring that the benefit of

use of medicine outweighs the risks associated with its use. Since there exist considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management - there is a need to engage healthcare professionals and the public at large, in a well-structured programme to build synergies for monitoring adverse drug reactions in the country.

In an effort to indicate its efforts to monitor the adverse drug reactions, the Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare created a Toll Free Number-1800-180-3024 facility under Pharmacovigilance Programme of India, to collect the adverse drug reactions with the use of medicines and to ensure patient safety.

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*Dr. G. N. Singh* is the Drugs Controller General of India

*Dr. V. Kalaiselvan* is Sr. Scientific Officer

*Ms. Archana Saurabh* is Pharmacovigilance Technical Associate at Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Govt of India

“Don't read success stories,  
you will only get a message.  
Read failure stories,  
you will get some ideas  
to get success”.

- Dr. A P J Abdul Kalam

# Rational use of medicines – Opportunities and challenges for Indian Pharmacists !



**Dr. Guru Prasad Mohanta**

*Professor, Department of Pharmacy, Annamalai University, Annamalai Nagar, TN*

Undoubtedly the medicines are a major component of healthcare and have helped significantly reducing the morbidity and mortality burden. In spite of having tremendous development in the field of science and technology including the area of drug discovery and development, there have been continued challenges in ensuring uninterrupted availability of essential or priority medicines to the ailing communities. Though India's pharmaceutical sector is very robust and immune to the recession, the access (availability and affordability) of medicines to the people of India is a cause of concern! It has been often estimated the access to medicines in India is just one third against the world average of two-third population's access to essential medicines. India is known as the pharmacy of third world and it exports medicines to more than 200 countries including USA, UK, and Canada etc. But millions of Indian households do not have access to essential medicines, a really unfortunate situation! Economic constraint is one of the main reasons of poor access to medicines in our country. The availability of quality essential medicines in public health facilities is always a matter of debate. Largely the people depend on private healthcare where they spend out of pocket to meet the expenditure. About 70% of Indians are spending their out of pocket expenditure on medicines and healthcare services compared to 30-40% in other Asian countries. Out pocket payments are considered catastrophic as this drives the people to reduce the expenditure on other basic necessities. 3.2% of Indians are vulnerable to fall below the poverty line just because of out of pocket medicine expenditure.

In one side the medicines are becoming increasingly unaffordable and the other side there is increased reports of adverse drug reactions harming the patients. Medicines are double edged weapons and if not used properly they harm the users. In short the medicines are not only valuable scarce commodities but are dangerous goods too! This warrants their rational use. The World Health Organization (WHO) defines Rational Use of Medicines (RUM) as "the patients receive medications appropriate to their clinical needs, in

doses that meet their individual requirements, for an adequate period of time, and the lowest cost to the patients and their community". This ensures five rights: Right patient, Right medicine, Right dose, Right duration and Right price. There are many issues associated with irrational use of medicines. Irrational medicine use may lead to increased cost to the patient and the health system, poor quality of services, increased exposure to adverse effects of medicine, contribute to the development of antimicrobial resistance and increased patients myth on there is a pill for every ill.

Realizing the importance of rational use of medicines and the consequences of irrational use, several strategies are advocated to promote rational use of medicines. The core strategies include: establishing a mandatory multidisciplinary national body to coordinate medicine use policies, developing, revising and implementing standard treatment guidelines, developing and implementing essential medicines list or hospital formulary, establishing pharmacy and therapeutic committee (drugs and therapeutic committee) at least in district level, introducing problem based pharmacotherapy in medical curriculum, ensuring in service educational programme (continuing professional development programme) for all categories of health professionals dealing with medicines and developing approaches to improve prescribing practices in private sectors in collaboration with professional associations. Though not significant, the Government of India and many state Governments have introduced several steps to promote rational use of medicines. These efforts include: development of standard treatment guidelines at national and state levels, developing and revising the essential medicines list at different level including part of public health standards, training programme on rational use and pharmacoconomics etc.

The pharmacists are uniquely positioned both in community and hospital sector that they are the final link between the medications and the patients. The

community pharmacists are often the first contact health professionals where they are consulted for health advice on problems of all kinds, and remedies are dispensed with almost every transaction. They have ample opportunities and can promote rational use of medicines both at community level and the health set up.

“Worldwide more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients fail to take them correctly”, a World Health Organization (WHO) survey reports. The situation though alarming provides good opportunities to educate patients on medicine use, health promotion and other aspects of healthcare. The patients counseling on medicine use is proved to be an effective method promoting adherence to medication for both acute and chronic conditions. They have been participating in the development of standard treatment guidelines, essential medicine list and National Formulary of India. Besides patient education, the hospital or clinical pharmacists are providing medicine information services to healthcare professionals at least in some hospitals. The hospitals undergoing accreditation process, have introduced the clinical pharmacy services. In public health facilities, it has been reported that on an average the physicians spend just less than five minutes with each patient in out-patients’ clinic. During this short period, it is impossible for the doctors to explain about the medicines to the patients. That provides the pharmacists an opportunity to impress patients on medicine use and adherence. During dispensing the pharmacists must ensure the right drug to the right

patient in right quantity and dose in right package to preserve integrity. If it does not happen, the whole process of health system fails.

However the road is not very smooth. There are many challenges to the pharmacists’ role or activities. One of the biggest issues is the pharmacists’ role in health system. It is not on par with that of physicians. Perhaps main reason for this is lower educational status of the pharmacists compared to that of doctor. The employment of PharmD qualified pharmacists may solve this issue. The educational and training background of diploma pharmacists is grossly inadequate to cope up with development. Even due to lack of adequate number of pharmacists in health facilities, the pharmacists too find difficult to spare time for patients counseling or education during dispensing. In the private sector at community pharmacy level, it is necessary to ensure the presence of pharmacists. Though some state Governments like Maharashtra have initiated procedures ensuring the presence of pharmacists and dispensing under their supervision, it requires a complete change in mind set not only of drugs control authorities but that of owners of community pharmacies.

The country’s health policy, national drugs policy and planning commission’s high level expert group on universal health coverage recommend the promotion of rational use of medicines. While these recommendations are the driving force, the pharmacists and their professional associations should come out proactively participating in this noble cause which would not only improve the professional image of pharmacists but also serves the society at a large.

*Dr. Guru Prasad Mohanta is Professor of Pharmacy in Annamalai University, Tamil Nadu and until recently a WHO consultant on pharmaceutical policies. Dr. Mohanta is an votary for rational drug use and has written several columns for educating the general public.*

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## Personalized medicine – Emerging field in targeted therapeutics

**Dr. Harsha Doddihal, MD**

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*harsha.doddihal@quintiles.com*

Everyday numerous individuals take one or the other medicine. Medicines either save lives, give relief, cause harm or do not make any difference. Will it not be better if we knew upfront how the medicine would act on a particular individual? Tailoring medicines or therapy to an individual can be called “Personalized Medicine”. Personalized Medicine is also defined as right drug at the right dose at the right time to the right patient.

People do argue that medicine has always been personalized in terms of doctors factoring in individual's social, financial, medical and personal history. What has changed is the understanding of the genetic underpinnings an individual harbours in health and disease. This genetic understanding has been due to Human Genome Project and subsequent research based on it. The knowledge of genetic basis is impacting all aspects of human health but the greatest impact so far has been in the treatment of cancer.

Herceptin (Trastuzumab) and Gleevec (Imatinib) were the earliest targeted drugs to be approved for breast cancer and chronic myeloid leukemia respectively. Herceptin was approved by FDA in 1998 while as Gleevec got approved in 2001. Herceptin targets HER2 receptor expressed by 20-30% of breast cancer patients. Gleevec (Imatinib) is a tyrosine kinase inhibitor which specifically blocks the action of BCR-ABL translocation which is also called as Philadelphia chromosome. With the success of Gleevec and the ability to effect cure in a subset of patients ushered in the era of personalized medicine. For most cancer patients “cure” is still a distant dream and there are side effects with targeted therapies also but the way an individual patient is viewed along with the cancer she/he has, has changed. The below table captures few of the targeted agents.

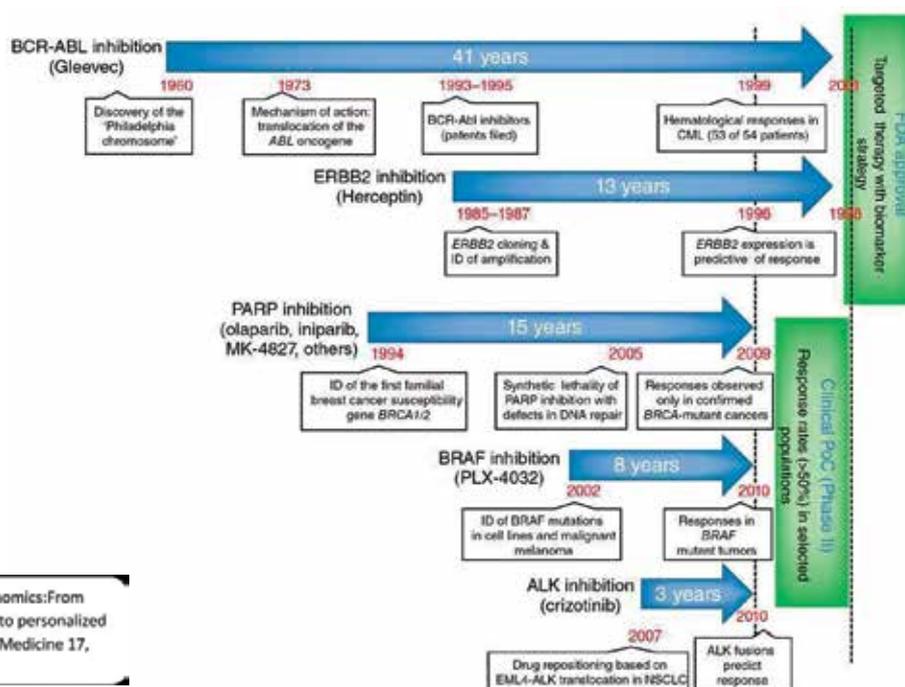
Disease	Mutation /Amplification	Therapy
Breast Cancer	Her-2 amplification	Trastuzumab, Lapatinib, Pertuzumab, Trastuzumab-DM1
Gastric Cancer	Her-2 amplification	Trastuzumab
GI Stromal Tumor	KIT, PDGFR mutation	Imatinib
NSCLC	EGFR mutations	Erlotinib, Gefitinib
NSCLC	EML-4/ALK translocation	Crizotinib
Melanoma	BRAF	Vemurafenib
Acral Melanoma	CKIT	Imatinib
Colorectal Cancer	KRAS	Cetuximab, Panitumumab
CML	BCR-ABL translocation	Imatinib, Nilotinib, Dasatinib, Bosutinib
CML	T315I mutation	Ponatinib
NHL	CD-20	Rituximab

*Abbreviations: GI-gastrointestinal, NSCLC-Non small cell lung cancer, CML-chronic myeloid leukemia, NHL-Non-Hodgkin's Lymphoma.*

Pharmacogenomics is another emerging field which is personalizing medicine. It promises improvements in efficacy and fewer side effects of drug. Few drugs require enzymatic transformation inside the body, increased or decreased enzymatic activity can be potentially harmful. We are today in better position to understand this for few drugs.

Drug	Gene/test	Disease Condition
Clopidogrel (Plavix)	CYP2C19	Cardiovascular-blood thinner
Abacavir (Ziagen)	HLA-B*5701	HIV
Coumadin	CYP2C19	Cardiovascular-blood thinner
Azathioprine (Imuran)	TPMT	Rheumatoid Arthritis
Carbamazepine (Tegretol)	HLA-B*1502	Epilepsy
Opioid drugs(codeine, morphine)	CYP2D6	Pain relief

We do need to thank the advancements in computational ability-faster computers, better drug modelling software, which has accelerated the development process. New genome sequencing (NGS) and Whole genome sequencing (WGS) are set to make a difference to understanding of health and diseases in revolutionary manner. This needs to be aided by implementation of Electronic Health Records (EHR) which will correlate the genomics to phenotypic expression.



Credit-Cancer Genomics:From discovery science to personalized medicine: Nature Medicine 17, 297-303 (2011)

## Conclusion:

Personalized medicine presents opportunities and challenges in plenty. We are just scratching the surface of the emerging field and there is lot of personalization which still needs to happen. From discovering potential new targets in disease conditions, mapping them to specific diseases, developing molecules which have high specificity to the intended target, doing appropriate pre-clinical studies, adapting the clinical research from phase 1 to phase 3, developing companion diagnostics and marketing the drug to the right population, each area offers tremendous learning, research and employment opportunities. We need to prepare ourselves and be ahead of the curve to reap the benefits.

## Further reading:

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## The significance of branding in the Pharma industry

**Shri. Kiran Shankar**

*Vice President, Marketing - Wintac*

Traditionally, and for last many decades, consumer goods companies (FMCG) have relied heavily on branding to successfully market their products. Off late, pharmaceutical companies have started recognizing the need and importance of branding of pharmaceutical products. Most of the pharmaceutical companies in India have strengthened their marketing department by inducting experienced brand manager/product manager for their products.

### What is a brand?

A brand is a collection of perceptions in the mind of the consumer, who has the power to begin, sustain or terminate relationships with it; in fact, a brand is the most valuable real estate in the world - A corner of the consumer's mind. A brand also is a seller's promise to consistently deliver a specific standard or service. The mega brands always convey quality image and as such the hope is to be able to command a higher profit.

### History of Brand:

The word 'Brand' comes from the old word 'Brandr', meaning to burn and is of Anglo-Saxon origin. The Etruscans, Romans and Greeks used to claim their ownership by stamping their pottery with the visuals of fish, star or cross etc. Also farmers used to brand the cattle to claim their ownership over a specific herd of cattle. The word brand was first introduced in the world of advertising in the late 1950's, by David Ogilvy, who created brand usage advertising.

Over 100 years ago Thomas Beecham recognised the importance of branding his safe and effective laxatives 'Beecham pills'. This started a new trend in the marketing of medicines attaching a personal guarantee of products' efficiency, quality and consistency.

Brand definition: The American marketing association defines the term brand as a name, term, symbol or design or combination of them which is intended to signify the goods or service of the seller or group of sellers and to differentiate them from those of competitors.

### Brand Image:

When a person buys certain brand he believes that he or she is buying quality at acceptable (certainly not cheapest available) price, when the buyer gets the taste, style, accomplishment, and the perception of status. However, in pharmaceutical brands, the focus is more on efficacy, safety, quality, consistency etc. When it comes to life saving drugs nobody would like to take any chance.

In the world of consumer goods & services, companies have used branding techniques to achieve competitive advantage for many decades. In the Fast Moving Consumers Goods industry (FMCG) brands are viewed as the key asset\* of the company and all resources are utilised to create and develop brands. While core principle and strategies for branding a medical product is somewhat same as that of any other consumer products but there are some differences in the pharmaceutical industry due to difference in regulations (which is required to safeguard the interest of ultimate consumers) of promoting of drugs. Many of the strategies used (exaggeration of claims) to market consumer products are unacceptable practices in healthcare industry.

### "Our biggest asset is four letters"

Nori Ohga, *Chairman Of The Board, Sony Corporation*

\*John Stuart, co founder of Quaker oats said "If this business were to split up, I would give you land and bricks and motor, and I would take the brands and trademarks and I would fare better than you".

As compared to the FMCG industry, the pharmaceutical industry has not been as efficient in leveraging the power of their brands. This is primarily because pharmaceutical products have always competed against each other brands based on functional attributes & features. However, with patent expiry or compulsory licensing this has become a difficult situation as generics create severe price competition in the market adversely affecting the sales of the original brand.

As drugs switch from 'prescription – only medicines' ( ) to "Over The Counter" (OTC) products, consumer power in the drug industry is increasing substantially. Many pharma companies are slowly accepting that the medicine (at least in certain categories) are also becoming like FMCG goods. Higher healthcare costs, the rise in consumer knowledge about medicines and various electronic media providing information on medicines in a simple and interesting form to the consumers, have encouraged the self medication by them. These facts have compelled the companies to rethink their conventional way of marketing operations and strongly focus on the brand building process.

#### Top 10 Brands in the World-wide

Note: Not a single Pharmaceutical company/products are featuring among top 100 brands world-wide

### Top 10 brands of Pharmaceuticals in the World-wide

Note: Only American companies & their brands are dominating in the top 10 list.

### Top 10 Pharmaceutical brands in India

#### JUL'13 Ranking

Mat			Val Crs.
	TOTAL MARKET		75,542.49
1	Phensedyl Cough	Aventis Pharma	298.36
2	Corex	Pfizer Inc	298.01
3	Augmentin	GlaxoSmithKline	291.90
4	Voveran	Novartis	263.64
5	Human Mixtard30/70	Novo Nordisk	263.02
6	Monocef	Artisto Pharmaceuticals	246.92
7	LIV-52	Himalaya	218.24
8	Betadine	Purdue Products L.P.	200.40
9	Dexorange	Franco Indian Pharmaceutical	195.46
10	Volini	Ranbaxy	191.57

Source: IMS Health TSA, July 2013

<http://pharma.financialexpress.com/latest-updates/2544-indian-pharmamarket-posts-growth-of-13-5-per-cent-ims-health>

Note: The adage that 'Old is Gold' is fully applicable for top brands of pharmaceuticals in India.

### Brand Debate:

In the earlier days pharmaceutical companies used to concentrate on managing patents and not the brands. On the other hand pharma companies should focus on branding right from the onset and develop a plan early to leverage it beyond patent expiration. It goes without saying that the lasting success of a pharma product is enhanced by the ability of a company to build a global brand rather than to the protective strength of a patent alone. Well designed brands unlike patents do not have an expiry date and gain their strength from a successful name.

Pharmaceutical companies tend to focus primarily on healthcare professionals as their only (or the most important) customers. Majority of pharmaceutical companies sell 'pills', whereas patients want 'therapy solution'. Pharma brand managers must consider developing 'therapy solution' as opposed to 'product only solution', to enhance patients wellbeing while differentiating the offerings of the product to the customer. For the physician the corporate brand name stands for certain reputation, commitment, R&D, quality control & availability, while for patient the product name plays more important role in terms of quality of life, improved condition, freedom from disability, longer life etc. (intangible or emotional attributes).

### Your brand should aim for following qualities:

1. Attributes - A brand brings certain attributes for example, faster dissolution, prolonged action, dual mechanism of action, bioavailability, no adverse effects etc.
2. Benefits - A brand is more than a set of attributes, customer do not buy attributes, they buy benefits such as, relief (efficacy) safety, convenience, compliance, etc.
3. Values - A brand also says something about the product values. It is up to the brand manager/ product manager to target specific buyer group. Your product/services needs to say strongly

what your values are for your patients (consumer group) Eg: To what extent your company will go extra miles to give a product quality, consistency or dependability irrespective of cost involved.

4. Culture - A brand may represent a certain culture. Eg. A company may like to create a perception of their R&D culture by spending of huge amount in bring out new research molecules or formulations.
5. Personality- A brand can also project a certain person as A brand Ambassador Eg- Well know film star Amitabh Bachchan modelling for Glaxo Smith Klein for their range of aerosols for asthma, he being an asthmatic patient.
6. User - A brand suggests the kind of consumer who buys or uses the product. As a matter of fact, the users will be those who respect the value of the product. Companies seek the support of regular users for giving feedback on their personal experience of the products. In pharma industry companies use the renowned doctors as 'Key Opinion Leaders'. (KOL)

7. Brand depth - If a company treats a brand only as a name, it will miss the point of branding. The real challenge in branding is to develop a deep set of meanings for your brand. When your audience can visualize all the above six dimensions of a brand we call this a 'Deep Brand'.

### Conclusion:

Pharma industry in India is in the nascent stage, as for as building their brands are concerned. Our brands are often termed as 'Branded generics'. If Indian companies have to emerge as global companies and build global brands they have to learn the process of brand building and focus their time, energy & money on this meticulous process with right earnest. Let us hope & wish that some of you will sincerely pursue this professional task and emerge as a successful brand manager/product manager in coming years in the Indian pharma industry.....

Wish you all the Best!

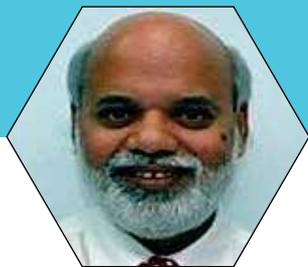
*Shri. Kiran Shankar is Vice President - Marketing of Wintac/BPRL Group of Companies , a leading USFDA approved pharmaco and a leader in parenteral segment.*



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## Challenges and Opportunities in Pharmacy Profession

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*President of Association of Pharmaceutical Teachers of India*

Since independence Indian Pharma profession has grown tremendously and has become self-sufficient industry known for producing Quality Medicine at economic price worldwide. There are 26,000 pharmaceutical companies in India and out of them 300 are organized sector. Domestic sale of Medicine is Rs. 42,000 crores and will reach to Rs.1, 00, 000 crores around 2012. First 50 companies produce 75% of total sales.

Export of Drugs and Medicine is around Rs. 15000 crores and around 2012 it will go to 50,000 crores. 70% of Export is bulk drug (active ingredients) and companies like orchid (Chennai based) and Dr. Reddy's Laboratories (Hyderabad based) are the leading giants in this category. There are 85 therapeutic segments and 80,000 brands (Ex. Crocin is a brand which contains Paracetamol). Therapeutic segment means drugs useful in specific category for ex. Diabetes, Cancer etc. Due to product patent acceptance and implementation from Jan 2005 many Indian pharmaceutical companies like Ranbaxy, Dr. Reddys Laboratories, Lupin Ltd, Sun Pharma, Glenmark, Wockhardt, Zydus Cadila, Torrent, started investment in tune of 10% of sales in Research and Development. R and D investment will reach to Rs.40,000 crores around 2012.

Today 40% of the world's bulk drugs requirement is met by India. 15% Scientists working in drug discovery laboratories in USA are Indians. Clinical Research Industry will be around Rs. 40, 000 crores around 2012, opening many job opportunities. India is emerging as a global source of vaccines (SERUM, BIOCON, SHANTA, BHARAT). Biotech product market will be around Rs. 23,000 crores in 2010. Herbal Drugs Market around 2012 will be around Rs. 6,000 crores. Companies like Dabur, Zandu, Himalaya, Sami Chemicals are leading exporters. Global players are looking at India for tremendous outsourcing opportunities and various other activities.

Indian Pharmaceutical Industries' Global ranking in volume terms is 4th and in terms of value it is 13th. Quality of Indian pharmaceutical products is

appreciated world wide and more than 70 plants are approved by U.S. Food and Drugs Administration and we export bulk drugs to around 100 countries. Advantage of India is world-class quality Pharma products manufactured at 8 to 10% of international prices. Average life expectancy of 37 years is now shifted to 61 years within 50 years of independence. This suggests that Indian Pharma profession has contributed substantially for life of the people and happiness. Today India has world-class recognition in Information Technology, Pharmaceutical Technology and Biotechnology. We have recognized international base for process chemistry. Around Rs. 6,40,000 crores of medicines are sold world wide and Pfizer is a no.1 company and Lipitor (Lipid lowering agent) is no.1 brand with a sale of Rs. 40,000 crores. In India Ranbaxy is a no. one company with the turnover of Rs. 3600 crores and Corex is a leading brand with a sale of Rs. 88 crores.

Looking at this foundation and growth rate of 10% and strong R & D base, quality and economy of medicines, India will emerge out as a super power in pharmaceuticals around 2020 and will lead the world to serve humanity.

In line with current scenario, pharmacy profession has provided ample job opportunities and business opportunities for making a successful career.

### Job Opportunities in Pharmacy Profession

1. Production and Manufacturing: After passing B. Pharm you can start your career in manufacturing bulk drug, dosage form, Cosmetics, Biotech, Ayurvedic products, veterinary products, and Nutraceuticals. You have to implement Good Manufacturing Practices and be constantly aware of various regulatory standards of different countries while manufacturing dosage forms. Starting salary is in the range of Rs.5,000/- to Rs.10,000/- per month and you can reach to the level of a President Manufacturing, payment may be Rs. 1 crore per annum. Pharmaceutical

companies are mainly situated in Mumbai, Pune, Nashik, Aurangabad, Wapi, Ankleshwar, Baroda, Ahmedabad, Jaipur, Delhi, Chandigarh, Baddi, Goa, Hyderabad, Bangalore, Chennai and Kolkata.

2. **Quality Assurance and Control:** After passing B.Pharm you can take the career in Quality Assurance dept. Job involves In Process Quality Control, Analytical method development Training on GMP, and audits to improve systems. Starting salary is in the range of Rs. 5000/- to Rs. 10,000/- per month and as a Vice president Q.A you can earn Rs. 5,00,000/- per month in a leading pharma company.
3. **Pharmaceutical Sales and Marketing:** B. Pharm graduate can start his career as a Medical Representative with a start of Rs. 7000/- to Rs.15000/- per month and can become Marketing Director in leading pharma company with a salary of Rs. 1 crore per annum. Job involves Sales promotion, Product Management, Distribution Management, Market Research, Strategies, & Sales analysis. B.Pharm with Management Qualification is a synergistic qualification to lead in this career.
4. **Hospital and Clinical Pharmacist:** This branch has started developing in India but in developed countries like U.S., EUROPE, JAPAN, AUSTRALIA, pharmacists are more trusted professionals having respect and reward. In India B.Pharm can get a salary of Rs. 10,000 and he can become Chief Pharmacist of Hospital in a span of 10 years with a salary of Rs. 50,000/- per month. In developed countries, he may earn Rs. 60,000/- to Rs. 2,00,000/- per month. Job includes dispensing and compounding, Medical Records and History, Inventory Management, Drug information system. Nowadays 5 years Pharm D. program is compulsory to become pharmacist in U.S.A. Pharmacy Council of India is thinking to implement this programme from 2007-2008.
5. **Community or Retail Pharmacist:** D.Pharm is a minimum qualification to become Registered Pharmacist although B.Pharm and M.Pharm can take this career. Main job responsibility includes inventory management, patient record system, patient counseling. Salary varies from Rs. 3000/- per month to Rs. 15000/- for per month, depending on business. Looking at big giants entering in retail business like Reliance, Apollo, Medicine

Shoppe, Merc, Zydus Cadila, this is going to be remunerating career. There are almost 6,00,000 community pharmacist in India.

6. **Regulatory Affairs:** B.Pharm with 2 years of experience can start his career as Drug Inspector and can reach to position of Drug Controller of India. This is the govt. job having many advantages. Job involves approvals, Issuing licenses, sampling, audits to maintain the quality. Salary Range from Rs.17000/- to Rs. 40,000/- per month.  
  
In pharma Industry due to product patent, and laws and regulations related to medicinal product and various processes to register product in other countries regulatory knowledge has become a rewarding career. B.Pharm student with a Regulatory course qualification can take a career as Regulatory Manager in Pharma Industry.
7. **Clinical Research:** B. Pharm with a Clinical Research Diploma can join as a Clinical Research Associate or Quality Assurance Manager or Data Manager or Business Development Manager in Contract Research Organization. Starting salary is Rs.20,000 per month and person can become President with emoluments to the tune of Rs. 5, 00,000 per month. Person should be accustomed with Pre Clinical Research, and various phases of Clinical Research, Schedule Y, Bio-equivalence and Bio – Availability studies.
8. **Research and Development:** After M.Pharm or Ph.D. Pharmacy Student can take this as a career starting from Research Assistant to become President (Research). He is involved in New drug development, Process development, Formulation development, Natural Product Research, Biotechnology Research, Clinical trials, Bioequivalence studies, Toxicology etc. Starting salary is Rs.15000/- per month while President earns up to Rs. 1 crore per annum.
9. **Pharma Education and Research:** B.Pharm. Graduate can become a teacher in D.Pharm college while M.Pharm, Post graduate in degree college. To become professor and principal Ph.D is essential. There are more than 500 colleges in India for D.Pharm and more than 700 Degree colleges and around 200 Post Graduate colleges. There is a huge scarcity of teachers and demand is more than availability. After B.Pharm, student can go abroad for M.S., Ph.D. Programme by giving

G.R.E. and TOEFL examination. Lecturer salary is Rs 17000/- per month while Professor and Principal earns around Rs. 50,000/- per month.

Pharma Associations Contribution: Indian Pharmacy Congress Association (IPCA) is a body representing following association and conducts congress every year. 59th Indian Pharmaceutical Congress will be held at Varanasi in Dec. 2007.

1. Indian Pharmaceutical Association (IPA)
2. Association of Pharmaceutical Teachers of India (APTI)
3. Indian Pharmacy Graduate Association (IPGA)
4. Indian Hospital Pharmacist Association (I.H.P.A.)
5. All India Drug Controller Organization Confederation (AIDCOC)

Besides these, we have Indian Drug Manufacture Association (IDMA), Organization of Pharmaceutical Producers of India (OPPI) and All India Organization of Chemist and Druggist (AIOCD).

These all associations are continuously contributing for the growth of pharma profession.

### Business or Entrepreneurship Opportunities in Pharmacy

1. Retail (Community) Drug store
2. Wholesale Drug store

3. Repackaging Unit
4. Drug Distribution
5. Manufacturing dosage forms
6. Marketing formulations (Loan/Contract)
7. Manufacturing Bulk Drugs and Excipients
8. Cultivation of Medicinal Plants
9. Public Testing Laboratory
10. Pharmaceutical consultancy
11. Starting Pharmacy college
12. Pharma Journalism and publications
13. Pharma Trading.
14. Pharma Allied Business.
15. Clinical Research Organization

### Qualifications to do:

D. Pharm	12th Science with Physics, Chemistry, and Mathematics or Biology
B. Pharm	12th Science with Physics, Chemistry and Mathematics or Biology with minimum 50% Marks. Central Examination Test 20% seats for Management Quota

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## Advances in nose to brain delivery of therapeutics

**Dr. Maya George**

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The worldwide market for therapies for CNS (central nervous system) disorders is estimated at greater than \$50 billion, yet CNS therapeutic research and development is associated with considerable challenges. It takes a significantly longer time to get a CNS drug to the market (12–16 years) compared to a non-CNS drug (10–12 years), in addition to higher attrition rates for CNS drug candidates during clinical trials. Reasons for this include the complexity of brain and CNS side effects which are undetectable in preclinical and early clinical development. One of the biggest challenges in neurotherapeutic development lies in the limited ability of many compounds intended for CNS action to cross the BBB (blood brain barrier). The BBB serves to protect the brain and spinal cord from a variety of pathogens and toxic substances, but also limits the entry of many molecules for treating neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, stroke and brain tumor. Although some small molecules administered by traditional routes reach the brain by crossing the BBB, usually high systemic doses are required to achieve therapeutic levels, which can lead to adverse effects throughout the body. It has been estimated that less than 2% of all small molecule drugs and virtually no large molecules can get past the BBB in appreciable amounts. Drugs can be introduced directly into the CNS by intracerebroventricular or intraparenchymal injections, yet these techniques are invasive, risky, and expensive requiring surgical expertise for accurate placement. Therefore, it is of great importance to identify drug delivery strategies that can bypass the BBB and directly deliver drugs to the brain. In this context, the use of the intranasal route to deliver drugs to the CNS provides a promising alternative that has attracted considerable interest amongst the scientific community. Recreational drugs such as nicotine (from tobacco smoke), cocaine, or amphetamines are commonly "sniffed" through the nose to achieve CNS effects. Additionally, the cumulative evidence suggests that drugs are able to enter the brain directly from the nose through an olfactory or a trigeminal pathway. The olfactory or trigeminal nerve systems originate in

the brain, innervate the nasal cavity and are exposed directly to the external environment outside of the BBB. Therefore, the nasal route forms the most direct and non-invasive method of entry into the brain.

The introduction of the nasal route as a promising alternative to other conventional routes for systemic delivery of drugs is associated with a number of advantages such as convenience, easy access, rapid absorption, avoidance of intestinal and hepatic first-pass metabolism and high potential for drug transfer to the brain. However, this delivery route faces challenges with respect to dose reproducibility due to two major drawbacks: (1) mucociliary clearance, which reduces the residence time of the drug in the nasal cavity and (2) nasal metabolism, where many compounds (e.g. peptides, nitrosamines, cocaine) undergo some degree of nasal metabolism, decreasing their bioavailability following this route of administration.

Recent developments in nasal drug delivery have suggested the potential of this route as a means to target the brain, especially for neurotherapeutics with limited blood–brain permeability. To understand the feasibility of the nasal route in the direct CNS delivery of a compound, it is important to take into consideration the potential barriers between the nose and the brain. The nasal cavity can be divided into three anatomical regions, namely the vestibular, respiratory and olfactory regions of the nasal cavity. The vestibular region is the least important of the three regions with regard to drug absorption. The respiratory region is the major site for systemic drug absorption owing to its high degree of vascularity and significant absorptive surface area. The olfactory region appears to be the most important site for direct CNS delivery, since the presence of a direct connection between the olfactory and respiratory submucosa and the brain via the olfactory and trigeminal neural pathway is well established.

Knowledge regarding the existence of an intranasal pathway to the brain involving the olfactory epithelium and olfactory bulb dates back to the middle of last century. Faber et al. identified the localization of

poliomyelitis virus in the central nervous system after intranasal inoculation in monkeys. The transport of a number of agents such as horseradish peroxidase, wheat germ agglutinin–horseradish peroxidase conjugate and colloidal gold across the olfactory epithelium into the CNS in animals has also been reported by numerous investigators. Similarly, a large number of studies have been performed where drugs such as estradiol, cephalexin, lidocaine and cocaine have been shown to reach the CSF, the olfactory bulb and in some cases distant parts of the brain after nasal administration. Studies have also been directed to investigate the mechanism of transport of drugs across the olfactory epithelial membrane to identify the important physicochemical characteristics that contribute to the CNS disposition of the drug following nasal administration where the bioavailability or permeability of compounds >1 kDa, was directly correlated to the molecular weight of the compounds.

Although a significant number of small molecules have been studied for potential nose to brain delivery in animal models, such as the rat and the monkey, only a handful of them have shown promise. Increasing the drug hydrophilicity, molecular weight and the degree of ionization can reduce drug transport into the CNS after intranasal administration. In addition, low molecular weight drugs can be affected by the active efflux transporters at the apical membrane surface (P-gp, MDR, MRP) in the olfactory epithelium.

Various formulation approaches have also been studied, such as microemulsions and nanoemulsions to improve drug solubility and mucoadhesive formulations to decrease mucociliary clearance. Emulsion formulations of clonazepam, sumatriptan, risperidone, zolmitriptan, or nimodipine demonstrated an increased brain uptake. For clonazepam, sumatriptan, and risperidone, the increased brain uptake was accompanied by an increased uptake into the blood.

Successful nose to brain delivery has also been reported for neuropeptides and proteins. An olfactory mediated transfer of hexarelin has been reported in rabbits. Vasoactive intestinal peptide, known to rapidly degrade in blood, was found in significant amounts in the trigeminal nerve pathways when administered nasally, and a glucagon-like peptide-1 antagonist was detected in high levels in the olfactory bulb, hippocampus, cerebellum and brainstem following intranasal administration. Intranasally administered

desferoxmine was found to have increased targeting (200-fold) to the cortex compared with intravenous delivery, and has been proposed for use in the treatment for stroke.

Although most of the studies were performed in rodent models, a handful of studies have also been conducted in humans. No difference in CSF levels was observed for melatonin, irrespective of the route, nasal versus intravenous, indicating that the drug may be entering the CSF via the bloodstream in both cases. Nasal administration of insulin in human volunteers were observed to give increased levels in the CSF with no associated increase in serum levels. Phase II clinical trials of intranasal insulin, showed promising results in improving cognitive function in adults with amnesic mild cognitive impairment in Alzheimer disease 50.

The exact pathways underlying the direct nose-to-brain delivery of drugs are not completely understood, but the olfactory neurons connecting the nasal passages to the brain have been postulated to play a role. In addition, pathways involving blood vessels, cerebrospinal fluid, and the lymphatic system may also play a part in the transport of molecules from the nasal cavity to the CNS. It is likely that a combination of these pathways operate, with one outweighing the other, depending on the properties of the drug, formulation and/or delivery device.

The nasal mucosa is highly vascular, with the olfactory mucosa receiving blood from small branches of the ophthalmic artery and the respiratory mucosa supplied by the capillaries of a branch of the maxillary artery. The relative density of blood vessels is greater in the respiratory mucosa compared to the olfactory mucosa making the former region an ideal site for systemic absorption of drugs. Delivery to the CNS following absorption into the systemic circulation and subsequent transport across the BBB is possible, especially for small lipophilic drugs, which enter the bloodstream more easily and cross the BBB more readily compared to large, hydrophilic therapeutics such as peptides and proteins.

The neuronal connection for the mammalian olfactory system commences as the olfactory receptor neurons (ORNs) in the olfactory epithelium. The axons from the ORNs form the olfactory nerve which projects on to the olfactory bulb and forms synapses with the apical dendrites of mitral/tufted cells, giving rise to the olfactory bulb glomeruli. The axons of the mitral and tufted cells project directly into the primary olfactory

cortex and the primary olfactory cortex projects to the hypothalamus, thalamus, hippocampus, septal region, substantia innominata and the orbitofrontal cortex. It has been observed that large proteins and nanoparticles were transported via axons through the olfactory bulb into the olfactory cortex and from there to the cerebrum and the cerebellum. Hence, all these regions form potential delivery sites for the nose-to-brain transport drugs via the olfactory epithelium. Additionally, the ophthalmic and maxillary branches of the trigeminal nerve innervate the respiratory and olfactory epithelium of the nasal passages. It has been shown that these neurons can deliver the neurotrophic factor, IGF-1 (MW 7.65 kDa), to the brainstem and spinal cord areas of rats. Hence, in contrast to rostral entry of drug via the olfactory pathway, the trigeminal nerve was shown to enhance nose-to-brain delivery to caudal brain areas. Since a portion of the trigeminal neural pathway, the ophthalmic nerve enters the brain through the cribriform plate alongside the

olfactory neurons, it is difficult to distinguish whether intranasally administered drugs reach the olfactory bulb and other rostral brain areas via the olfactory or trigeminal pathways or both.

The presence of anatomical connections between the nose and the brain makes the nasal route a promising alternative for the targeted delivery of small hydrophilic drug molecules that are unable to cross the BBB through commonly used routes of drug administration to reach the CNS. Many small molecules have been shown to have preferential uptake into the brain following nasal administration. Consequently, a tremendous potential exists in exploring the mechanisms controlling the brain disposition of drugs following intranasal administration. In general, nasal delivery represents a promising route of drug administration offers a tremendous opportunity to bypass the blood brain barrier to efficiently deliver therapeutic treatments for CNS based diseases.

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# In Depth Insight on Analytical Quality by Design in Dissolution Testing

**Dr. Mukesh C. Gohel**

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Quality by design (QbD) can be critically defined as: Predefined Quality (QC)/accuracy, Safety (avoidance of dose dumping) and Clinical efficacy (biorelevancy for floating DDS, IVIVC) of the product or method by Design. The principles of QbD are generally applied in the manufacturing environment but it can also be extended to analysis (i.e. in QC and QA departments). The term "AQbD" is used when the principles of classical QbD are extended to QC/QA departments. For example, the concept of QbD can be extended to dissolution test as well as to the HPLC analysis.

Dissolution test is considered as a potential performance test since it is linked with the performance of the product in human body. The classical uses of dissolution test are: in formulation and development department for screening of formulations, for establishing IVIVC, to simulate food effects (e.g. dissolution test in milk), to study integrity of matrix in presence of alcohol (up to 40%), in vitro surrogate for BE studies and as a QC tool in the analytical department. The future roles of the dissolution test are: sensitive to changes in the formulation/processing conditions, mimic the conditions prevailing in human body (e.g. for floating DDS). The test should be predict in vivo performance of the product and thus reduce unnecessary human trials. QbD facilitates the adoption of Process Analytical Technology (PAT).

The outcome of the dissolution test is dependent on many variables and hence precise control of the test conditions is required to get reproducible results. Physicochemical properties of API, product formulation/processing conditions, factors associated with dissolution apparatus and storage conditions influences the dissolution pattern of API. The important independent variables are: temperature, shaft wobble, rotation speed, vessel centering, vessel tilt, paddle height, base plate levelness, vessel types, and level of deaeration.

The experimental conditions, except the temperature of the dissolution medium (37°C), are product dependent in the dissolution test. Each solid oral dosage form is evaluated in a unique way (e.g. Pharmacopoeial specifications- e.g. paddle, basket,

flow through cell, etc.). High reproducibility and low variability is desirable in the dissolution from the analytical view point. From the view point of clinical response, clinical relevance is desirable.

Formation of an efficient QbD team is the first step to monitor the dissolution test. The QbD team should include thinkers (contributors) from various departments such as QC/QA representatives, statistician, regulatory representatives, R & D scientists, clinician, marketing, management and others. The changes in formulation and processing conditions should be reflected by the dissolution test (manufacturing view point).

The key elements of QbD are quality target product profile (QTPP), critical quality attributes (CQA), risk assessment, analytical design space, control strategy and life cycle management. QTPP should include the patient and labeling specific requirements. CQA includes critical material attributes, critical process attributes. Variations in the dissolution test can be considered as an important point in CQA. It is worthwhile to note that analytical design space is optional but necessary. Risk assessment requires consideration of every point related with the performance of dissolution test. Control strategy is planned to keep the important variables within control. One of the best resource materials to learn QbD is to study the material put on the website of US FDA (e.g. acetipatan IR and SR tablets). Beside many points, dissolution specifications are included under QTPP (see FDA website).

The first duty of the QbD team is to draw the cause and effect diagram (fish bone diagram) after getting input from every team members. Based on the experience and available literature, the team should select critical factors (from the fish bone diagram) affecting the dissolution test. The next step is to apply the design of experiments. Generally the Placket and Burman design and/or fractional factorial design is used for screening of independent variables (IV). Three or four most vital factors (IV) are identified screening exercise. The next step is the use of a suitable design (full factorial or central composite design) with suitable

number of levels (two or three or more). Contour plot and response surface plot are drawn using suitable software.

The overlaid contour plot can be used for eliminating failures before they occur. The components of Failure Mode and Effect Analysis (FMEA) are: Severity ( ranking 1 (NS) to 25 (disastrous) ), probability (ranking 1 (high degree) to 9 (no detectability)), detectability (ranking 1 (unlikely) to 9 (high probability)). The RPN is calculated using the following equation.

$$\text{Risk Priority Number} = S * P * D$$

The factors with high RPN number shall be critically monitored to minimize the variations in the dissolution test.

The contemporary area in the pharmacy is the use of advanced chemometric tools to get full insight in the matter (dissolution test, refinement of PK parameters – Ka, Kel, etc.,).

Monte Carlo simulation and principal component analysis (PCA – multivariate data analysis tool) are the most popular chemometric tools. The use of Monte Carlo simulation (MCS) is preferred when: the mathematical model is complex, the mathematical model is non-linear, and the mathematical model involves many terms. MCS is also useful in six sigma. The essential elements of six sigma are Define, Measure, Analysis, Improve, and Control - DMAIC. PCA can be simply defined as a data reduction technique. In the dissolution test, the sampling time can be selected using the science of PCA to cut down the cost of analysis. FDA will raise minimum query if science (QbD, chemometric tool) is adopted in the dissolution test. PCA can be used for justifying the use of a particular dissolution medium (pH 1.2, 4.5 or 6.8) or a particular speed of agitation (50, 75 rpm).

The chief goals of QbD are Safety and Efficacy. Many drugs are taken after ingestion of food and alcohol is an integral part of food in the developed cold countries. Alcohol consumption by patients along with MR dosage forms is a concern for safety. The officers at US FDA learnt that dosage forms containing strong opioids resulted in dose dumping from generic dosage form when alcohol was consumed (as a part of food) along with the dosage form. Hydromorphone resulted in toxic effects when alcohol was consumed with the drug. The FDA currently demands the dissolution data in zero to 40% alcohol for the modified release formulation. More than 50 % of the poorly soluble API's displays three fold or higher apparent solubility in FaSSiF containing 20 % ethanol. The use of aqueous

alcohol as a dissolution medium is recommended for MR products and for the dosage form containing BCS class 2 and 4 compounds. The most important application of dissolution test is the prediction of in vivo performance and selection of bio-batch. On an average 50% of the BE study shows bio-inequivalence. By combing the outcome of the dissolution test and known PK parameters (Ka, Kel, Vd, etc.) of the drug, one can intelligently select a bio-batch and save a lot of money and time of the company. Incorporating IVIVC into QbD allows developers to rely on the dissolution method to move within the Design Space while maintaining relevance in vivo

The next step after full implementation of QbD is the adoption of Process Analytical Technology (PAT). There are ample opportunities of PAT. Some of them are use of NIR, in-situ de-aeration, autosampler, X-ray, etc. Dissolution test can be replaced with a calibrated NIR instrument (RTRT: Real Time Release Test). Slower analytical technique is replaced with a faster and accurate in-situ analytical tool (Saving of time and PAT compliant). If the particle size of API correlates with dissolution during development, then particle size measurement could be used in lieu of the dissolution (RTRT) . This is very much feasible for BCS I drugs. Disintegration can be used as a surrogate test for a few products on a case to case basis, provided mechanisms are well understood (e.g. mouth dissolve tablets of BCS class I drugs).

It is concluded that systematic scientific approach is required in required in Analysis. The Food and drug control authority will evaluate the ANDA or other dossiers without raising many queries. The findings of AQbD in dissolution testing can be useful if the company has multiple plants. The variations between laboratories can be minimized if AQbD is adopted. QbD brings in economy due to identification of CQA , adoption of sound control strategy, and reduced re-analysis and reduced batch rejection rate. QbD is directly proportional to delta SOP and Delta GMP. Dissolution test is beyond the QC test in the present scenario. Quality should be built in the dissolution test to minimize variations in the results.

*The extension of this article can be discussion of AQbD in HPLC. The references to the text included in this article are available on request from the author.*

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## Good Samaritan – Pharmacist 24 x 7

**Shri. Mike Sreshta** RPh

*Director of Pharmacy of NorthEast Ohio Neighborhood Health Services, Inc. (NEON)*

NorthEast Ohio Neighborhood Health Services, Inc. (NEON), was organized in 1967, exceeding a hallmark of over 45 years as a network of community health centers. NEON is a not-for-profit Federally Qualified Health Center, is the oldest and the largest one of its kind in the USA.

Expanding the availability of primary care services, its seven centers treat thousands of greater Cleveland area residents. The health centers offer the entire family accessible, comprehensive services including Adult Medicine, Pediatrics, Family Medicine, OB/Gyn, Behavioral Health, Dental, Optometry, and Podiatry services. Ancillary services such as laboratory, X-ray, nutrition and Pharmacy are also available at our centralized neighborhood locations, meeting a wide array of our patients' needs. Its mission is to enhance the quality of life to Northeast Ohio residents by providing comprehensive and excellent health care services in a culturally sensitive and caring environment. It provides healthcare to everyone regardless their ability to pay.

Our providers are committed to a service delivery model that emphasizes accessible, personalized care. Each patient has access to a primary care provider who coordinates all of their health care needs. NEON provider staff currently includes 14 Physicians, 10 Dentists, 6 Nurse Practitioners, and 4 Certified Nurse-Midwives. In addition to clinical services, patients have access to social work, health education, family planning, and nutrition counseling to provide a multi-disciplinary approach to care and improved health outcomes.

NEON maintains a history of collaboration with our community partners since its inception to assure the provision of comprehensive health care services of the highest quality to the residents of Northeast Ohio.

### Pharmacy

NEON is considered a "safety net" provider since it provides care to everyone regardless their ability to pay. The U.S. government mandates a lower price to all these safety net providers so that our clinic could purchase drug at a lower price and use the savings to reach more eligible patients and provide more comprehensive services.

Neon pharmacy department comprises of four pharmacies servicing all the 7 clinics. Pharmacy located at Hough is open for extended hours on Monday, Wednesday and Saturday and all the other pharmacies are open 8.45 am -5.45pm from Monday to Friday. The patient profiles are integrated into one server, enabling the pharmacists to check patient profiles of patients going to any site instantly. This prevents duplication of therapy, sharing of all pertinent information and prevents drug abuse.

Pharmacy does participate in institutional drug replenishment patient assistance programs. These programs facilitate prompt procurement of needed pharmaceutical products to deserving patients. Patients pay nominal amount for their medications and for those in a higher income bracket a sliding scale payment is used. However all patients regardless of their income can obtain their medications at NEON. All pharmacies are staffed with registered pharmacists and registered pharmacy technicians.

Patients, from all the NEON clinics can also go to any of the six contracted walgreens pharmacies in the neighbourhood after hours. This is a tremendous help for our patients to get 24 hour service for their pharmaceutical needs. There is currently discussion for adding more contract pharmacies to improve our service even further. Please visit our website at <http://www.neonhealth.org> for more information.

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## Role of Pharmacist beyond dispensing: A pharmacovigilance perspective

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Pharmacy as a profession has made significant progress in the recent years. It has seen a shift from product orientation to patient focus. Pharmacist should realize it's no more a task carried out behind the curtains. This article introduces aspiring pharmacists to one such profession where they can extend their roles as providers of service than mere handling medicines.

### The past and present

Pharmacy is not mere preparing or dispensing of drugs. The professional practice reaches far beyond serving community. Since the inception of the concept "pharmaceutical care," coined by C. D. Hepler and L. M. Strand, the profession has seen itself extending far beyond dispensing. It emphasizes and recognizes the role of pharmacist as an integral part of the healthcare system. WHO explains pharmaceutical care as "a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. Pharmaceutical care focuses on the attitudes, behaviors, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life."

Speaking globally, the role of pharmacist has changed or grown, perhaps now it has become more patient-centric. Pharmacists have an important responsibility in monitoring the ongoing safety of medicines as part of their professional practice. The agreed common aspect known about pharmacists is counseling patients on potential side effects. This one-on-one two-way interaction can be utilized further by asking them to report back any undesirable occurrence which can serve as an effective feedback system. Adding to this, pharmacist's expertise can play a vital role in early detection of unintended side effects. But does that indicate drugs are unsafe – definitely not. A drug needs to be considered as a concept, with benefit-risk profile, applied to treat patients through proven or commonly agreed measures where benefits outweigh risks.

Unless otherwise proven, mere existence of negative data can never be conclusive or deemed irrelevant for further use. Numbers speak volumes about ubiquity and are never actual. A drug's benefit-risk profile is better derived from clinical judgment. Here comes the role of pharmacists on a global perspective called Pharmacovigilance.

### Drug safety and Pharmacist

History of drug goes way back to 5000 B.C with suggested use of opium. But not until 1960s after the thalidomide tragedy that it was deemed necessary to closely control the quality, efficacy and safety of medicines. This ultimately led to the discipline called pharmacovigilance.

WHO defines pharmacovigilance as science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. It's an activity contributing to the protection of patients' and public health. It would be prudent to say pharmacovigilance deals with the collection of adverse drug reaction (ADR) reports from various stakeholders responsible for monitoring the safety profile of the drug. Adverse drug reaction is a noxious and unintended response to medicinal product. It may arise from use of the product within or outside the terms of the marketing authorization, and a pharmacist knows it better why drugs are non-inclusive of safety profile in entirety before it enters market. Pharmacists have an important contribution to make with regards to post-marketing surveillance. Whether it is a non-prescription drugs or a prescribed therapy, most drugs accessible to the patients are made available through the pharmacists. India still has traditional pharmacy practice where it sees more floating prescription and over-the-counter (OTC), which remains a challenge.

### A step beyond

So, how can pharmacists be proactively involved? Well, the answer is simple. The whole purpose of

pharmacovigilance is to minimize the potential for harm that is associated with the drug. Pharmacists form the core of interdisciplinary healthcare system where safety monitoring is the integral part of clinical practice. It would be a myth to consider a drug entirely safe and a misperception to consider it entirely harmful. From pharmacovigilance perspective, healthcare professionals need both good clinical judgment of the adverse drug reaction and sound insight into effectiveness of the drug to arrive upon the metacenter creating a relationship between benefit and risk.

### Safety as a concept

Safety when defined can be “relative absence of harm.” But that doesn’t mean safety is never doing anything and hoping nothing has happened. In pharmacovigilance, safety means collection of reports of adverse effects of drug. Safety can mean generating data and arriving upon a solution to decide further usage of drug. Apart from the routine ADRs being reported, a pharmacist must also be involved in the collection of data that might be useful in longitudinal pharmacoepidemiological studies. There is a trendy rule where manufacturers deem their drugs as safe until proven harmful, and the regulatory authorities consider every drug might be harmful until proven safe. As a matter of fact, the pharmacists should consider both. Their roles are not just confined to reporting adverse events but there has to be a proactive approach in preventing the drug related adverse events.

### Staying vigilant

One of the safety concerns is timely identification of the early warnings of side effects. The process is usually dependent on doctors suspecting something and trying to find an association between the drug and disease. This gives an opportunity for the pharmacists to step in and make a difference by identifying the initial users of new drugs through prescriptions and to monitor systematically rather than waiting for someone to recognize a possible adverse effect. This concept is better known as prescription event monitoring.

In addition to the pharmacist’s responsibilities relating to the reporting of adverse events, they can also involve themselves in areas such as record keeping, education and monitoring the over-the-counter drugs. A major step in empowering the pharmacists is by providing access to the medication records of the patient, thereby maximizing the benefit and minimizing the

risks of medication use. As a result, assessments of potential drug interactions and any adverse event are possible. In case of changes in the labeling or when a drug has been withdrawn from the market, it becomes absolutely necessary for the pharmacist to ensure that patients get a change in therapy but continue to take medications for chronic conditions.

### In-clinical practice

Pharmacists are one of the major stakeholders along with the physicians, patients and other healthcare professionals. Pharmacists play a key role in management and prevention of the adverse events associated with the drug. Safety concerns are often considered to be implied when drugs are approved or authorised. The scope has widened now. It includes all safety-related activity right from the moment humans are first exposed to the new drug. It should be noted that the pharmacists has an added advantage of getting in direct contact with the patients who may not be involved in the clinical trials for ethical reasons.

To be more precise, hospital pharmacists can play a significant role in ADR reporting because the most serious adverse drug events occur in hospitals. In addition, a number of publications reiterate the fact that adverse events account for a considerable percentage of all hospital admissions. Pharmacists can actually help in substantially reducing the incidence of the adverse events by recording as well as timely communication of adverse events occurring in hospitals to further control the harmful effects of these events. This can be achieved through direct involvement in patient care and a proper reporting system in place. The adverse event information obtained from hospitals can be quite advantageous because of their high-quality documentation. In fact, hospital pharmacists have access to sophisticated computer systems and databases which augers well for effective retrieval of information.

### Indian framework

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of the Ministry of Health and Family Welfare, Government of India in collaboration with Indian Pharmacopoeia Commission (IPC), Ghaziabad has initiated a nation-wide pharmacovigilance programme as Pharmacovigilance Programme of India (PvPI) in 2010. The programme is being coordinated by IPC as a National Coordinating Centre (NCC). The centre operates under the supervision of a Steering

Committee which has the Drug Controller General of India (DCGI) as its ex-officio chairman and the Officer-in-Charge (New Drugs), CDSCO, New Delhi as its ex-officio Member Secretary. PvPI currently has 150 functional ADR monitoring centres (AMCs) across the country. With increased nutritive interest shown by Government, regulators, and industry, the numbers are expected to soon increase involving both private and government medical colleges.

## Accessibility

It can be observed that underreporting can be significantly reduced by actively involving pharmacists in the surveillance of drug safety. It is highly recommended to increase the participation of pharmacists especially in a country like ours, where the unawareness is accounted for the decline in reporting. Negligence of reporting is also considered to be a factor for the steady dearth in reporting and seen as a major setback among Indian HCPs. The challenge now remains in creating awareness.

Back in the old days, information about possible adverse effects of drugs was spread through medical literature which was then the available effective way. Accessibility is far more accessible now and the needed information just a swipe away. Information technology can be used constructively to improve communication. Pharmacists have quick access to a pool of information on medication safety. PvPI now has a dedicated website with a PvPI toolkit for the stakeholders. PvPI recently launched toll free helpline (1800-180-3024) to facilitate reporting of adverse reactions. There are various national level workshops held to provide training to the stakeholders and generating awareness. Moreover, it has become almost imperative for pharmacists to use the Suspected Adverse Drug Reaction Reporting (SADRR) Forms to report suspected adverse drug events. The interaction of much of the stakeholders with the AMCs is primarily through the SADRR forms. This will be helpful for the AMCs to maintain a database of all the adverse events associate with the drug. Suggestions are being proposed at various levels to consider incorporation of PV concepts in education curriculum.

## Take a leap

Aspirants who wish to take up pharmacovigilance as their career; this might be the right time as future can see a demand in qualified pharmacovigilance specialists. Recently drug safety has earned concerns

by regulatory authorities worldwide. Stringent laws are being adopted. Global pharmaceutical companies are looking at India for their pharmacovigilance activities. This can be an added benefit to the existing outsourcing hub. There are various opening among leading PV service providers, clinical research organizations, and IT companies. India is one of the largest pharmaceutical industries with many major global players. Pharmaceutical companies are now setting up in-house units and they are in need of experts. With more AMCs being added, medical colleges and hospitals may see an ardent need for trained professionals. Besides, there are also chances to work for regulatory authorities like DCGI/CDSCO. The industry is all set to see much growth both in private as well as Government sector.

## Observation

A lifesaving drug today can be banned tomorrow. It is very unlikely that harm of medicines can always be predicted and prevented but limiting the numbers is surely approachable. A pharmacist can perhaps be entrusted as an effective tool in collection and reporting of ADRs for they are present at all levels of medical care, right from community pharmacy to primary healthcare centers, government hospitals to corporate hospitals. Most importantly, pharmacies work as a department at affordable and approachable locations. This can serve as best takeaway point as pharmacists are actively involved in the final stages of patient care. Pharmacists can create a trusted environment by counseling patients to reduce medication errors, improve safety and quality of care; above all, it gets all the attention a pharmacist deserves.

## Epilogue

Getting the pharmacists recognized as providers would help overcome the barrier to incorporate their role on the healthcare team. At the same time, pharmacists should step out; challenge themselves to take up the responsibilities while working in complex healthcare setting. Stay tuned, re-invent yourselves and be prepared. A budding pharmacist should realize clinical pharmacy is not just drug-drug, drug-food interaction, but it is also tracking adverse drug effects, reducing medication errors, monitoring patients' compliance, counseling patients. Healthcare is all about collective accomplishment and pharmacist do deserve a little credit. A bit of us lie in contributing back to society and if that giving involves our profession, what better a service can it be!



## Patient counseling in health care setting: where are we?

**Dr. Krishnamurthy Padebettu**

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The concept of patient management is undergoing a sea change. It has broadened its scope from medical to social: it sees the medical problem in a social context. This becomes more relevant in dealing with chronic diseases, both infectious and lifestyle related. The patient-centered, not disease-centered, approach demands active engagement of patient in dealing with the medical problem. This is easier said than done. While medical professionals are trained to deal with medical issues in the most dispassionate manner, it does not help in any way in engaging patient's participation in the therapeutic agenda. It needs different skill sets which are hardly there to see.

Several years back an interesting experiment was conducted by a social psychologist at a major hospital in Cairo, the capital of Egypt. He placed his associates at each of the strategic points where patients came in contact with the hospital staff-at the reception, doctor's consultation, laboratory and pharmacy. At each location the associate meticulously noted down the interaction between the patient and the medical professional. Finally, when the patients came out the associate who waited outside asked each patient one question, "What did the doctor, lab technician and pharmacist tell you?" About 90% of the time the answer was, "Nothing"! This came as a surprise because the records indicated that at each location there was lot of talking and garrulous advice.

When a patient goes to a hospital he carries with him several questions in his mind. While interacting with the professionals in the hospital he rarely gets an opportunity to ask these questions. Most of the time there is very little interaction or the talk is one way down. There is the position of dominance that is usually assumed by the professional. A sick person quickly finds out whether the Medical professional is interested in him or in his disease. The patient is not treated as intelligent being. The social and educational distance, if any, between the patient and the professional is further widened by the unnecessary use of jargons. "I know what is best for you". "You don't understand". "Do as you are told". These comments fly

thick and fast in consultation rooms and corridors of hospitals. A sick person's needs span a full range of issues from the physical, the emotional, the intellectual and the spiritual. He desires to be treated like a human being, with respect. He wants to be informed; he wishes to be empowered; he is willing to take part in decisions in his treatment.

In today's patient care scenario there is less space for communication and least for understanding. Communication means one should be able to convey the right information to the person across in the right way and to make sure that the person understands the message and is able to make the right choice. Good communication is important for good counseling and good counseling is important for patient empowerment and engagement in the medical care.

Counseling involves efforts to empower the patient to ably participate in disease management. It should be supportive, facilitatory, not confrontational and judgmental. Counseling is not advice. There are several issues in counseling which should be kept in mind. A sick person lacks confidence in the ability to cope with the illness. The Medical professional has to provide the necessary knowledge, skills and tools to equip the patient in dealing with the situation. The patient needs to be explained about the disease, the prognosis, against the background of his beliefs, his education and expectations and delivered in a language that is not open to misinterpretation. This is not easy. It needs efforts to coax relevant information out of the patient to know the knowledge and skill deficiencies and to determine the exact mechanism of transferring them to the patient. Often, one may have to encourage behavior shift in the patient which may demand immense skill. Understand, inform, encourage, support and advise- these are some of the key steps involved in counseling. Good communication, which means openness, willingness to listen and offer empathetic response, leads to better counseling which improves outcome by helping the patient understand his disease, enhancing his participation, and providing him with knowledge and skills needed to overcome

sickness, sustain and promote health. There is growing evidence that patient centered approach involving good communication and counseling improves satisfaction with quality of medical care, reduces the need for repeat visits and, most of all, delivers increased enjoyment and job satisfaction to the health care provider. This is not easy at a time when investigation and instruction have replaced history taking and counseling, and polypharmacy has replaced restraint in the use of drugs, and patient

becomes anonymous disease entity. Before things become worse and the situation becomes irretrievable, appropriate intervention is required. Health care needs to be transformed from a medical endeavour to a social enterprise with a patient-centered learning. One should remember that social tools and skills are as important as medical tools and skills. There is a strong and immediate need to build the capacity of health care professionals in helping patients overcoming barriers to accessing quality care in healthcare settings.

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## Auditing & Self Inspections : Effective tools in pharmaceutical industry

**Dr. Sarang Athavale**

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Before going into brief details about Auditing we will have to understand the basic definition of the term Audit. Historically, the word 'auditing' has been derived from Latin word " audire " which means " to hear ". Auditor word has been derived from the word Audit. If you see in this case the meaning of Auditor would be : a person who hears others and that other person is nothing but the Auditee. In initial days the auditing was carried out for accounts only to see that there are no mismatches in the entries made in the books. If there are any mismatches then those should be highlighted and problems should be resolved. But later Management Gurus introduced this system for almost each and every category of business and globally the standards were developed to follow the systems.

The general definition of an audit is a planned and documented activity performed by qualified personnel to determine by investigation, examination, or evaluation of objective evidence, the adequacy and compliance with established procedures, or applicable documents, and the effectiveness of implementation. The term may refer to audits in accounting, internal controls, quality management, project management, water management, and energy conservation etc. When we are dealing more with pharmaceuticals auditing becomes extremely important. The main reason is that we are into the business of life saving drugs. Saving lives of patients is our topmost priority.

There are various kinds of audits and one of them is Quality audits which is most important for pharmaceutical industry. The basic GMP according to all guidelines talks about quality audits. Safety, security, information systems performance, and environmental concerns are increasingly the subject of audits. There are now audit professionals who specialize in security audits and information systems audits. With nonprofit organizations and government agencies, there has been an increasing need for performance audits, examining their success in satisfying mission objectives.

Quality audits are performed to verify conformance to standards through review of objective evidence. A system of quality audits may verify the effectiveness of a quality management system. This is part of certifications such as ISO 9001. Quality audits are essential to verify the existence of objective evidence showing conformance to required processes, to assess how successfully processes have been implemented, and to judge the effectiveness of achieving any defined target levels. Quality audits are also necessary to provide evidence concerning reduction and elimination of problem areas, and they are a hands-on management tool for achieving continual improvement in an organization. Recent developments in pharmaceutical shows the introduction of ICH Guidelines which are more related to Management's role. The new guideline of ICH Q10 reflects the philosophy of FDA regarding role of Higher Management in Quality Management through the effective tool of Audits. These audits are also called Internal Audits in pharmaceuticals.

To benefit the organization, quality auditing should not only report non-conformance and corrective actions but also highlight areas of good practice and provide evidence of conformance. In this way, other departments may share information and amend their working practices as a result, also enhancing continual improvement. This principle should be applied in each and every aspect of various organizations.

Why audits are important for pharmaceutical industry needs to be understood first. There are several benefits of audits e.g. Benchmarking of your current performance ,better deployment or redeployment of your resources , standardization of systems and processes , minimizing the problems , better communication and awareness of facts , training to employees due to nonconformance and most important is the compliance to the systems as per GMP norms.

Audits are always viewed as fault finding missions by the auditees. It should not be viewed as a fault finding mission but fact finding mission. Once this philosophy

is spread all over the organizational structure , things become more easy and the growth takes place. Personal hindrance is one of the biggest drawback for audits. Probably this is one of the most important reason why Indian companies are not able to compete with US & EU pharmaceutical companies. Today Indian pharmaceutical industry is completely in shattered state. In last 66 years of our independence we could not launch even a single molecule as our own. Having business , earning good margins and creating wealth and fame are all different issues which needs to be understood by all of us.

We would like to understand first what should be the main objective of the Audits. It should be stressed that the quality system aims to bring transparency to all operations bearing on quality. It should be planned and documented activity with well defined objectives and a methodology communicated to all concerned. It is particularly important for top management to remove apprehensions at all personnel levels that internal quality audits are fault finding exercises. It should be made clear that audits are a tool for improving the system and personnel should be encouraged to bring their difficulties and problems into open, as well as to make suggestions about their areas of operations.

Let us see now what are the different steps involved in Audit process . The steps involved in the audits are as follows : Planning Quality Audits > Selection of auditors > Preparing for quality audits > Conducting quality audits > Preparation of audit reports > Follow up audits > Records of quality audits. Quality Head or Management Representative is responsible for the total activity and Higher Management is ultimate responsible for the activity and outcome of the activity (ICH Q10 – Pharmaceutical Quality Systems)

Who should conduct the Quality Audits? This is one of the biggest dilemma in Indian pharmaceutical industry. We think that any person having experience of more than two to three years can conduct the audits. But this is very delicate activity and needs to be handled very carefully. There are some personal qualities which the auditor needs to have in him/her. The qualities are as follows : Auditor should have good communication skills , should be professional , should have good interpersonal relations , should have analytical approach , should be assertive in nature , should be objective , should be tactful and diplomatic , should be firm and tenacious , should be logical and finally should be unbiased in nature. With

all these personal qualities justifying audits becomes meaningful. It is not easy to get people with all these qualities but Organization should make an efforts to train people and make them strong to carry out the activity of audits.

What are the different types of Audits? There are different types of audits and they are as follows :

- a) **First Party Audits** : When the sponsor, auditor and auditee are from the same organization it is called as internal or first party audits
- b) **Second Party Audits** : When the sponsor and the auditor are from the same organization. e.g. Regulatory audits
- c) **Third Party Audits** : The sponsor and the auditor will be examining the auditee on behalf of the sponsor.
- d) **External Audits** : When the sponsor and auditor are part of one organization and the auditee is part of an another organization.

Different Techniques by which the audits are performed

- There are three different techniques by which the audits are generally performed. The techniques are as follows :

Horizontal Audit : Selecting a department and carrying out audit in logical sequence

Vertical Audit : Selecting a product to see the work flow is smooth and efficient

Random Auditing : Need to examine closely a particular activity

Some important aspects which an auditor should keep in mind are as follows : It is fact finding mission and not Fault finding mission. There should be an opening meeting before conducting the audit with auditee department. There should be a statement of confidentiality. Scopes and objectives should be explained to the auditee. Lead auditor or team leader should prepare the program and it needs to be circulated to auditee department in advance. The audit can be trace forward or trace backward ( input to output or vice versa ). One should ask open ended questions and invite auditee to open himself/herself before auditor. One should not ask closed questions which ends in Yes or No. There should be 5 W ( What , Why , When ,Where & Who ) and 1 H ( How ) always available with auditors and they should be used logically to reach the conclusions. Listening to auditee is of utmost important to become really good auditor.

Many times we lack in listening to others. One should always verify the information, always take notes while auditing it will help you when you make your final report and finally the body language with auditee needs to be positive so that you get the correct information from him/her. Flow charts and checklist can be prepared by understanding the systems of the auditee department before auditing them. The observations you make as an auditor should be categorized viz. Critical , Major , Minor and Suggestions. But while doing this one you need to understand the consequences and categorize them accordingly. You should be reasonable with scientific rationale always.

Approach needs to be adopted by auditor for any investigation - If one wants to become successful auditor then he/she should have the following approach. There are five important factors which one should always keep in mind. The five factors are Science behind each and every activity , if it is a process which involves instrument/equipment then it's Engineering aspect , cGMP to be followed as per guidelines , Regulatory aspects involved for the process and finally the Risk factor involved. If these five factors are understood properly every audit can be more as a fact finding audit and less fault finding audit.

Lets us understand the difference between Quality Audit and Self Inspections now. A quality audit is an examination of all or part of quality system with specific aim of improving it. It is usually conducted by outside experts or team appointed by management. It is useful to supplement self-inspection programme with quality audits. It may be extended to suppliers and contractors. Where as self-inspection is a rehearsal of one's areas by either oneself or by someone belonging to the department so as to find out the existing unsafe conditions. The inspection should encompass every area that is occupied or used by members of such department on a regular basis. If we see the regulatory guidelines for following GMP , we will find that there is no mention of Audits but self inspections. As per chapter 9 of EU guidelines or TGA guidelines or MCC guidelines or PICS guidelines and various guidelines including USFDA & WHO, it talks about self inspection. What the EU guidelines says is as follows :

**Principle :** Self inspections should be conducted in order to monitor the implementation and compliance with Good Manufacturing Practice principles and to propose necessary corrective measures.

9.1 Personnel matters, premises, equipment, documentation, production, quality control, distribution of the medicinal products, arrangements for dealing with complaints and recalls, and self inspection, should be examined at intervals following a pre-arranged programme in order to verify their conformity with the principles of Quality Assurance.

9.2 Self inspections should be conducted in an independent and detailed way by designated competent person(s) from the company. Independent audits by external experts may also be useful.

9.3 All self inspections should be recorded. Reports should contain all the observations made during the inspections and, where applicable, proposals for corrective measures. Statements on the actions subsequently taken should also be recorded.

Recently MHRA has released a news under it's official website which is as follows :

MHRA expectation regarding self inspection and data integrity - 16 December 2013

The MHRA is setting an expectation that pharmaceutical manufacturers, importers and contract laboratories, as part of their self-inspection programme must review the effectiveness of their governance systems to ensure data integrity and traceability.

This aspect will be covered during inspections from the start of 2014, when reviewing the adequacy of self inspection programmes in accordance with Chapter 9 of EU GMP.

It is also expected that in addition to having their own governance systems, companies outsourcing activities should verify the adequacy of comparable systems at the contract acceptor.

This shows that Regulatory agencies are becoming more serious about the self inspections now a days. How we can interpret the self inspection activity ? If we want to understand this we will have to see the official ppt by WHO. It has shown self inspection as follows :

Self-inspection - informal (daily)	>	Immediate correction
Self-inspection - formal (quarterly)	>	Improve systems
QC - Internal (half-yearly)	>	Confirm compliance

The above details of self inspection tells about the philosophy needs to be adopted by the pharmaceutical organizations. But it is not to be limited to pharmaceuticals only. Each and every industry can gain if this approach is adopted. This also speaks about the cultural difference between Western countries and Asian countries.

Where do we stand as pharmaceutical industry as on today ? - This is really a very interesting question. We have very good manpower with us which is young and enthusiastic. But unfortunately after having all positives with us and extremely good cultural background since ages on our side , somehow we are not withstanding the challenges of today's pharmaceutical competitions. When I am writing this article Sun Pharma has already bought Ranbaxy for around \$3.0 billions. Ranbaxy is suppose to be the most valued company once upon a time and today they are totally in soup. It is not only Ranbaxy but

more and more Indian pharmaceutical companies are under scrutiny by Regulatory agencies. One needs to really think - what is happening with us as a country ? According to me we lack in self inspections at all levels. I would go ahead and say that even our personal life also we lack in self inspections or self introspections. We do not believe in accepting mistakes made by us and that is what is going to make a difference for our survival in near future. I was reading a newspaper and found that BPO industry is shifted its base to Philippines. It is not strange because we do not accept what wrong we are doing. The same can happen with pharmaceutical industry also. My sincere request to all my young Indian brothers and sisters to be more serious about their studies and ethical practices to be followed when we are trying to get into healthcare industry. If this happens I am very that India is going to have a great future ahead and we will definitely be one of the biggest Superpower in the world.

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## Entrepreneurship

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1. Entrepreneurship is a process of identifying and starting a business venture, sourcing and organizing the required resources and taking both the risks and rewards associated with the venture.
2. An entrepreneurial approach is vital for successful society, because entrepreneurship creates competitiveness, disruptiveness, improvement in living standards, market penetration, jobs, value for society and goods and services with value addition at competitive pricing
3. Enhances knowledge oriented attitude in society
4. Successful entrepreneurship begins by identifying target market and process for delivering value to the target market
5. For eg., in the case of pharmaceutical and healthcare products, communication through medical representatives is addressed to potential prescribers and pharmacies
6. In case of prescription based products (which may be manufactured under drug license or food license), value should be delivered to the prescribers who will create demand for the promoted product through their prescriptions
7. All in all, it means roping opinion builders is essential for successful marketing of the entrepreneurial venture/products (in case of intangible products, ensure there are tangible components)
8. Opinion builders in case of nonprescription oriented products can include housewives, chefs, sport stars and other influential people
9. Blue ocean strategy is ideal in today's context for entrepreneurial ventures: it essentially means you market unique products or you are a part of uncrowded and unique market segments. For eg., electrolyte energy fruit drinks (caffeine free) in ready-to-drink, Tetra Pak packaging, for prescriber markets: is a blue ocean strategy
10. In case of me-too product markets, price and service delivery becomes all important competitive aspect
11. Providing a compelling unique selling proposition (USP) is vital for a successful business venture
12. Success of Indian pharmaceutical industry is through arbitrage opportunity: low cost high quality generic drugs for global markets, this was the compelling USP
13. Successful entrepreneurship requires an open mind and humility for adaptation and learning, particularly by listening to vendors, intermediaries and customers. Also learn to read with attention business books to soak in business wisdom that will help your entrepreneurial working
14. Entrepreneurship involves constant improvement to engage prospects and customers successfully
15. Entrepreneurs should follow the basic rule:  
$$\text{Income or profit} = \text{Revenues} - \text{Expenses}$$
  
Try to improve revenues and keep expenses at minimum comfort level
16. So keep accurate records of financial transactions (on real time basis, with proper formats) and prepare the financial statements like balance sheets, cash flow and profit and loss statement
17. Learn to make presentations and improve communication (body language, written and oral)
18. Make regular presentations to stake holders on present status of enterprise and future plans/prospects, so that you can obtain inputs from them for improving business results (Stakeholders include important customers, financial entities, associates, vendors, intermediaries etc), this is a constant confidence building process: everything is ultimately about confidence or absence of fear. When you give confidence to customer, he will buy the product, when you give confidence to lender, he will give finance at a low level of interest

19. Learn to negotiate and establish win-win relationships, so that you get a good deal when transacting
20. Entrepreneurship is not a rocket science, it is more a matter of discipline, meticulousness and focus on outputs (such as customer satisfaction, sales etc)
21. Get 360 degree feedback on yourself, employees and the firm so that areas for improvement can be identified
22. Use the KRA (Key Result Area) approach on a routine basis for focused and progressive working
23. Essence of entrepreneurship is creating assets through resource mobilization
24. Successful business ventures follow a simple rule:  
Buy cheap, add value, improve perceived value and sell dear!  
  
Value addition can come from keeping stock for selling at right time, modification to ingredients, packing, communication etc
25. Never burn bridges, you never know who will be of help! Give respect and recognition to people, take respect & recognition in an assertive way
26. Focus on financial aspects and do not get carried away by emotion, in judging or negotiating or decision making process, consider all alternatives and implications, remember when the chips are down, you are alone!
27. Always remember entrepreneurship is calculated risk – Not a gamble. Take informed decisions, knowledge is vital: bring facts to the table
28. Analyze each issue with Edward De Bono multi-hat method: black for negative thinking, yellow for positive thinking, white for information oriented thinking, green for creative thinking, red for intuitive thinking and finally blue for organizing the thinking process (either individually or through the team): try to picture both the best case scenario and worst case scenario for taking appropriate decisions
29. Always have team approach, not a single man show! Teams give synergistic results. Build a network of relationships of people who can help: associates, mentors, academic faculty etc
30. Believe in give and take: this ensures longevity of relationships
31. Business ventures need not run totally on your money: banks/lenders (such as venture capitalists, private equity investors, trusts etc...) provide finance depending on your credibility, persuasive sophisticated communication, tautness of business plan and pleasing behavior
32. Business plan should be comprehensive, covering target markets, the process for value delivery, invoicing details, payment collection system etc... Plan your business work and work your business plan, constantly fine tuning and improving the same (Nothing is carved on stone!)
33. Never let your or team's morale down: ups and downs in business are common, focus on being responsible, honest and devoted to your entrepreneurial work, never let your enthusiasm whittle down, everything will pass on! Learn to expect the unexpected!!
34. Use quantitative planning – analyze each rupee and paisa flow, understand market size and behavior in both quantitative and qualitative paradigms
35. Learn to build brands and positive imagery
36. PQRST (Sushil of Mantri developers said) Punctuality, Quality, Reliability, Speed & Transparency are vital to be a good entrepreneur.

### Reference definitions:

A chronological List of the Definition of 'Entrepreneur'

- 1734: Richard Cantillon: Entrepreneurs are non-fixed income earners who pay known costs of production but earn uncertain incomes
- 1803: Jean-Baptiste Say: An entrepreneur is an economic agent who unites all means of production land of one, the labour of another and the capital of yet another and thus produces a product. By selling the product in the market he pays rent of land, wages to labour, interest on capital and what remains in his profit. He shifts economic resources out of an area of lower and an area of higher productivity and greater yield.
- 1934: Schumpeter: Entrepreneurs are innovators who use a process of shattering the status quo o the existing products and services, to set up new products, new services

- 1961: David Mc Clelland: An entrepreneur is a person with a high need for achievement (N-Ach). He is energetic and a moderate risk taker.
- 1964: Peter Drucker: An entrepreneur searches for change, responds to it and exploits opportunities. Innovation is a specific tool of an entrepreneur hence an effective entrepreneur converts a source into a resource.
- 1971: Kilby: Emphasizes the role of an imitator entrepreneur who does not innovate but imitates technologies innovated by others. Are very important in developing economies.
- 1975: Albert Shapero: Entrepreneurs take initiative, accept risk of failure and have an internal locus of control (Citation needed)
- 2013: Ronald May: An Entrepreneur is someone who commercializes his or her innovation.

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## Pharmacogenomics – an overview

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Pharmacogenomics is the technology that analyses how genetic makeup affects an individual's response to drugs.

This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that will be tailored to a person's genetic makeup.

Foundation for Pharmacogenomics was laid in 1865 with Gregor Mendel proposing the Laws of Genetics. In 1909, Garrod published "Inborn errors of Metabolism" explaining the individual abnormalities of drug metabolism due to mutations in genes controlling enzyme synthesis.

Isoniazid therapy for tuberculosis caused peripheral neuropathies in few patients who were sensitive to the neurotoxic effects of the drug. This toxicity was due to high concentrations of drug due to impaired activity of the enzyme N-Acetyl transferase.

Ground breaking genetic and biochemical studies by Werner Kalow and others showed that polymorphisms in genes encoding the drug metabolising enzymes serum cholinesterase, cytochrome P-450, and N-acetyltransferase lead to adverse drug reactions.

These observations laid the foundation for pharmacogenetics and pharmacogenomics.

Now it is well established that adverse drug reactions are a significant cause of hospitalization and can even cause deaths in patients. The genetic differences among human beings will be used to predict whether a medication will be effective for a particular patient and to help prevent adverse drug reactions.

Researchers need to identify the markers that can correlate drug response and genetic make up. These markers are Single-Nucleotide Polymorphisms (SNPs). SNPs are the variations in DNA at a single base which are found in at least 1% of the population.

Regions of chromosomes that are likely to contain a risk gene can be identified by a method called Linkage. In linkage studies, researchers are searching for markers that are consistently present in those patients with given disease conditions but are not present in those without the condition/s. When a marker is identified in the presence of a condition, the marker and the disease causing gene are said to be linked.

Possible genetic markers for diseases such as cancers, heart diseases, diabetes, bipolar disorders, schizophrenia etc. have been identified.

Individualized antibiotic treatment can be initiated overcoming resistance by considering variations in drug-metabolizing enzyme, haplotypes, SNPs and modeling of individual immune response.

Pharmacogenomics aims to develop rational means to optimize drug therapy, with respect to the patients' genotype, to ensure maximum efficacy with minimal adverse effects.

The field of pharmacogenomics is still in its infancy. Its use is currently quite limited, but new approaches are under study in clinical trials.

In near future, it is possible that pharmacogenetic tests may be in the form of a kit comprising of drug and diagnostic agents. These kits will provide genetic information that will be useful for taking the decision regarding personalized therapy.

Pharmacogenomics will allow the development of tailored drugs to treat a wide range of health problems, including cardiovascular disease, anti coagulant therapy, Alzheimer disease, cancer, HIV/AIDS, and asthma.

The goal of personalized medicine is to provide the Right Dose of the Right Drug for the Right Indication for the Right Patient at The Right Time and pharmacogenomics is the answer for this.

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## Hobbies – A Gift to Your Present

**Shri. Uday Arur**

*Business and lifestyle coach*

I recently read of a young man, the son of an illustrious lawyer father, and a partner at a law firm. People around him admire him for his ability to be patient; his eye for detail; and the ability to stay cool in critical situations. During client transactions, he is able to patiently wait for others to put their point on the table and at the same time quickly grasp the matter and come out with solutions. These are invaluable skills and abilities and how where did he learn them? From his passion for wild life photography – a passion that takes him to various tiger habitats, to spend time clicking the wildcats. All the long hours spent waiting for just the right moment to take the right picture, keeping his cool in difficult situations, and responding with the right actions at the right time have proved to be time well spent. They have ingrained in him the right attributes to assist him in his professional life.

In another instance, a well known figure in the US, left school at 12, as he didn't fit the traditional academic environment. However, he bred and sold dogs, collected and swapped stamps, made model aeroplanes and joined a club where he flew his planes each Sunday. While these hobbies were hardly mainstream, the skills he learned through these interests set him up for life. His breeding venture taught him valuable business skills, including the basics of profit and loss, marketing and bookkeeping. His stamp collecting taught him the value of marketing and networking. Through his interest in model aeroplanes he learned the value of sticking to a task until it was finished. He was shy, but his model aeroplane club brought him into contact with like-minded souls and he learned to make friends for the first time. His hobbies had made him feel as though he was in control and learn a range of organisational skills.

My own hobbies - reading, writing, music, and attending learning events have contributed a lot to my personal life invaluable for me. They have enriched me in innumerable ways and most importantly, taught me resilience, and provided me peace of mind. In difficult times, my hobbies have been of immense help in coping with stress – and fuelled my hopes of good times returning soon. In good times they have elevated my mind and given me much happiness and fulfilment.

### Student Alert

For students, hobbies provide not only pleasure and learning; they can also serve you well in your efforts to land a job. Putting hobbies in your CV can prompt the interviewer to ask you about your hobbies and give you an opening to make a favourable impression. Before that, be sure to think thorough carefully about how the hobby has shaped your personality, or helped you become a better person. You can then explain to the interviewer the benefits which you had already thought through. If the interviewer fails to ask you this question, be proactive and steer the conversation towards it in some way.

Hobbies help us not only to become better persons, but also increase our chances of getting a good job, and becoming good at it. Besides, they also help in dealing with bad times by serving as fulfilling distractions.

A fascinating testament to the value of hobbies and interests!

### References:

*The Economic Times* - Hobbies can teach kids valuable skills, Body and Soul



# Role of Pharmacist in Geriatric Pharmacy Practice

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In our society, the percentage of elderly people in the population has increased dramatically during recent decades and is likely to increase further in the coming decades. However, a large proportion of older people are confronted with one or more disabilities or disease condition. The older population consumes more number of drugs when compare to younger adults.

## Pharmacotherapy for older people

The Hippocratic Oath tells us, "First, do no harm". In the older population, the susceptibility to the Adverse Drug Reactions (ADRs) is higher than younger adults. The principle of Geropharmacology is based on the appropriate use of drugs to give most benefit to older person while avoiding or decreasing ADR and drug interactions.

## Use of medication by seniors

Nineteen percent of hospital admission are over the age of 60 years, mainly due to medication. In India the elderly constitute about 6% of the population and in some states the percentage is even higher. (For eg, Kerala, it is as high as 10%). Figures relating to drug consumption in India are not available, but with increasing access to modern medical care it can be surmised that this is likely to be substantial. Geriatrics is more susceptible to the ADR due to risk factors. The risk factors for adverse drug effect include altered pharmacokinetics and pharmacodynamics, multiple disease and drugs, problems with medication adherence and inappropriately ordered drug dosages.

## 1. Pharmacokinetic Alteration

### Absorption

Absorption is a process that is most affected by age. Absorption is usually slower than in younger individuals, but complete. It results in the lower peak concentration of the drug and increase the time to onset of action. This can be important in symptom relieving drugs. An important example is a drug used for pain relief.

With age there occurs, an increase in the gastric pH. This can lead to a decrease in absorption of acidic drugs like aspirin. The same change can also cause a decrease in absorption on some solid formulation.

Absorption may be significantly affected by disease. An example is congestive heart failure, where decreased gastric motility can lead to slower drug delivery to the site of absorption and mucosal edema can lead to decreased absorption. Apart from this, the edematous mucosa is also more prone to damage from prolonged contact with the drug.

### Distribution:

There are significant differences at the level of distribution. With aging there occurs a decrease in body weight. This necessitates a decrease in the loading dose of a drug and also requires dosing adjustments. Examples are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), narcotics and low molecular weight heparin. Body water decreases with aging; this necessitates a decreased loading dose of water soluble drug like lithium, and amino glycosides. Lean mass decreases and necessitate lower loading dose of muscle binding drugs like Digoxin. The relative proportion of fat increases as the age increases. Example of a commonly used drug is diazepam.

### PROTEIN BINDING:

The two principal proteins that bind drugs are albumin (binds to acidic drugs) and alpha-1 acid glycoprotein (binds to basic drugs). Alterations in the level of these proteins occur in the presence of diseases. It is free drug concentration that determines the drug action. Prescribers and clinical pharmacists must take this factor in to account while prescribing and monitoring the drugs, especially in hypo-albuminergic states. Important drugs in this regard are warfarin, digoxin, phenytoin and diazepam.

### METABOLISM:

Metabolism occurs mainly in Liver. There are many extraneous factors affecting liver metabolism. Drug interactions are a very important consideration in selecting drugs, as they can cause very significant

differences in the rate of metabolism, especially in elders who are more likely to be taking multiple drugs.

#### **EXCRETION:**

Another important area which influences drug action is excretion. With age there occurs a decrease in renal mass and blood flow. It is important to adjust dosage based on creatinine-clearance, as serum creatinine values may not always estimate the degree of renal impairment in older adults due to their low lean mass.

## 2. Pharmacodynamic Alteration

Pharmacodynamic changes in the elderly occur mainly due to the decrease in neurotransmission activity related to acetylcholine, DOPA, serotonin. Receptor site also altered and CNS receptors are decreased in the elderly. CNS stimulants show decreased activity and CNS depressants shows increased activity. All these lead to various types of ADRS.

#### **POLYPHARMACY:**

Polypharmacy (i.e., the use of multiple medications and/or the administration of more medications than are clinically indicated, resulting in unnecessary drug use) is common among the elderly, because they are likely to have multiple medical problems. It is therefore crucial to bear in mind, when adding new medication for an older patient, how the medication may interact with the medications the patient is already taking.

#### **UNDERTREATMENT:**

Sometimes under-treatment can be a problem in older adults. Misunderstanding of Geropharmacology principles may lead the clinicians to prescribe inappropriate doses of medications.

#### **DOSING OF DRUGS IN ELDERLY:**

Drug dose should be reduced in elderly patients because of a general decline in body function with age. A general equation that allows calculation of maintenance dose for a patient of any age is follows:

$$\text{Patient's Dose} = \frac{(\text{Weight t in KG}) 0.7 \times (140 - \text{age in years})}{1660} \times \text{Adult dose}$$

#### **PRINCIPLES OF PRESCRIBING IN THE ELDERLY:**

- Review -patient's medical record
- Avoid prescribing prior to diagnosis.
- Follow Beers Criteria Start with a low dose and titrate slowly.
- Avoid starting 2 agents at the same time.

- Reach therapeutic dose before switching or adding agents.
- Consider non-pharmacologic management
- 'Old drugs for old people' – It is safer to use drugs that have been time tested
- Keep in mind possible drug interactions including Over The Counter preparations
- Use less frequent dosing intervals (OD or BID dosing is preferable)
- Use formulations that are easy to administer
- Drugs should be dispensed in easy-to-open containers
- Clear instruction about how to administer the drug should be given
- Treat adequately; do not discontinue a drug without achieving adequate therapeutic concentration unless ADR intervene.
- Always continuously evaluate the need for each of the drugs that the patient is taking
- Be sensitive to the patient's concerns and reports of ADRs
- Foster a good Physician-Pharmacist-Patient relationship

#### **Summary:**

Successful pharmacotherapy means using the correct drug with the correct dose for the correct indication and for correct duration in an individual patient. Age alters Pharmacokinetics and Pharmacodynamics. Dose adjustment for renal & hepatic impairment must be strictly followed. Polypharmacy & drug-drug, drug-food interaction should be avoided; ADRs are common & preventable among the elderly.

#### **Conclusion:**

The clinical pharmacists' consultations can improve geriatric patients' drug regimens and compliance. One important aspect of quality care for older adults is managing their medications to assure the maximum beneficial results from medication therapy while avoiding adverse complications. The main guidelines to prescribing medication for the older patient are "to start with a low dose of medication and step up the dose as one goes along to achieve an optimum therapeutic end point". The prescriber must keep the principles in Geropharmacology in mind if their prescriptions are to have intended effect and not to create iatrogenic problems.



## Humble Leadership: The New Mantra

**Prof. Rahul Sharma**

*Dean, Krupanidhi School of Management, Bangalore*

With a historic general election just behind us and a new PM taking oath of office next week, leadership has been the flavour of the year thus far in India. And it is an issue that touches every aspect of our lives including work.

As results from the general election came in, we saw how the Indian electorate voted in someone who seemed decisive and courageous and voted out what they perceived as weak leadership. But political considerations aside, being a leader at the workplace also requires similar qualities.

A recent study conducted by the research company Catalyst that asked 1500 respondents about what are the traits they want in a leader found that two of the most important ones were humility and courage.

A leader is someone who is not afraid to take bold and tough decisions but at the same time needs to be open to dialogue and be humble because there is no learning without humility. For example if he makes a mistake, a good leader is not afraid to accept the mistake and be willing to learn from it. More importantly, a good leader admits mistakes and shares the learning with his or her subordinates.

Mistakes are not a sign of incompetence or weakness; they are part of what makes us human. And sometimes the leader needs to be seen as someone who is only human so that subordinates can connect to him or her.

In any workplace you walk in, at some point in time you will have to walk this tight line between courage and humility as a superior or a boss. You may sometimes not want to show your weaker side thinking the subordinates will have an inferior opinion of you and that a leader has to be infallible. But therein lies the most important lesson. A leader cannot always be perfect and that is ok.

The easiest way to navigate this dilemma of whether you as a leader should take a bold decision whose outcome is not entirely certain is to put the larger interest first. Leaders, by definition, look at the big picture - 'How does this affect us?' Not 'How does this affect me?' - and they walk that talk. That is how they earn respect of their colleagues and subordinates. We see the lessons right in front of us whether it was a Narayana Murthy at Infosys or a Ratan Tata or a Barack Obama or of course most recently, Narendra Modi.

India is entering an era of change and if there is one thing that will define you as a leader it will be how you handle change. The trick is to be able to handle it with humility by accepting uncertainty (you cannot be 100% right in your decision making) but at the same time being courageous enough to accept mistakes and make others believe that the change is worth embracing.

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*Prof. Rahul Sharma is the Dean of Krupanidhi School of Management, Bangalore*



## Pharma Inc. India: It's growth potential

**Dr. Sonal Dubey**

*Professor & Vice Principal - Krupanidhi College of Pharmacy, Bangalore*

The global pharmaceutical market is undergoing rapid transformation. As many blockbuster drugs come off patent, there are fewer new products in the pipeline to replace them. New drugs are facing regulatory challenges and pricing pressures. This has led to a paradigm shift towards the emerging markets of Asia, Australia, Africa and Latin America, which are growing three times faster than the current growth rates experienced in the industry's leading markets of North America, Japan and Europe. It is expected that these emerging markets over the next decade to come shall contribute over 40% of the global Pharma industry's incremental growth. The Indian Pharma industry is on the threshold of becoming a major global market by 2020. Many experts believe that the Industry has the potential to grow at an accelerated 15 to 20% CAGR (Compound Annual Growth Rate) for the next 6 years to reach between US\$52 billion to US\$74 billion in 2020.

The Indian pharmaceuticals market is witnessing dynamic changing trends such as large acquisitions by multinational companies in India, increasing investment by domestic and international players in India, big mergers, deeper penetration into the rural markets, growth and availability of healthcare and incentives for setting up special economic zones (SEZ's). These trends combined with increased purchasing power and access to good quality medical care will continue to propel the domestic pharmaceutical industry to new heights.

Indian Pharma companies are already major outsourcing partners of global Pharma companies. Research & Development in India is getting more innovative. Domestic companies have strengthened their position in the world for supplying solutions across the pharmaceutical value chain. They are likely to become a competitor of global Pharma in the areas of manufacturing and R&D, and a potential partner in others.

### India's Advantages:

- India's domestic pharmaceutical market has recorded a CAGR of 13.5% over the past five years. With considerable expertise in manufacturing of generics and vaccines, Indian companies have now also started significant research and development (R&D) with major players like Dr. Reddy's, Cadilla and Sun Pharma as front runners.
- India has the world's second biggest pool of English speakers and a strong system of higher education, all this has well-positioned India to become an outsourcing partner in manufacturing and R&D, and as a location for clinical trials.
- Significant cost arbitrage: Basic production cost in India is 50% less than that in US, which includes 30-50% lower depreciation in term of construction cost and equipments; and 85-90% manpower cost saving.
- Upswing in revenues due to increase in export and outsourcing business in form of contract research and manufacturing services (CRMS).
- Foreign direct investment (FDI) into the Indian pharmaceutical sector has more than doubled during the April-December 2013 period at US\$ 1.26 billion, which stood at US\$ 589 million in 2012, according to the data from the Department of Industrial Policy and Promotion (DIPP).
- The pharma sector in India is expected to clock total sales of US\$ 27 billion by 2016, according a recent report by Deloitte. The study also reports that India stood at US\$ 22.6 billion in 2012 and has risen to 23.6 billion in 2013.
- The pharma exports from India will be more than the size of the domestic sales by FY15, according a recent report by India Ratings & Research.
- Indian drug firm Sun Pharma is acquiring Ranbaxy Laboratories from Daiichi Sankyo for US\$ 3.2 billion.

This deal will make the new entity India's largest and world's fifth largest drug maker. The combined entity will have operations in 65 countries with 47 manufacturing plants spread across five continents along with a strong base in generics and specialty products including 629 abbreviated new drug applications (ANDAs).

- The World Health Organization has strongly endorsed India's patent laws and no country including the United States has challenged it at the WTO claiming that the laws infringe trade related intellectual property rights, which proves that Indian patent laws are sound.

### Challenges:

- India is one of the most price-controlled markets in the world, as under the DPCO (Drug Prices Control Order), prices and margins are monitored carefully by National Pharmaceutical Pricing Authority (NPPA). There were originally 347 price controlled drugs included in 1979, which were then reduced to 143 in 1987 and currently, there are 65 bulk drugs under the DPCO. Price controlled drugs are essential medicines, such as antibiotics and painkillers, and drugs used for the treatment of diseases such as cancer and asthma. However, 90% of drugs are currently outside of any price controls in India. Consumer organizations maintain their stance of urging the government to continue to expand the umbrella of the DPCO, but the industry believes that price caps would inhibit the development of R&D in the country as companies would be less inclined to invest in R&D without the possibility of high returns.

- Infrastructure has always been mentioned as a barrier to growth of the Pharma industry in India. Poor energy and transport infrastructure has traditionally posed a problem for companies.
- Counterfeiting of drugs has been a major issue in the Indian Pharma space. In a study conducted by the International Pharmaceutical Federation and financed by the WHO that said 3.1% of all drugs sold in India were spurious.
- There is an increasing concern in the domestic industry regarding a shortage of skilled labour in critical areas. This causes a demand-supply imbalance.

### Overcoming the challenges is imperative for future growth.

India holds over 10 per cent share in the global pharma production with over 60,000 generic brands across 60 therapeutic categories and manufacturing over 400 different active pharmaceutical ingredients (APIs). There is no doubt on the growth potential of the Indian pharma industry. In fact, the Indian companies can be expected to garner US\$ 40 billion in sales as close to 46 US drug patents will expire by 2015.

With so much opportunity lying ahead of us the success factor depends on Innovation, reframing and constantly evolving policies, increasing use of technology and out of box thinking. Let's garner our potentials and move towards a brighter and better future.

*Dr. Sonal Dubey is the Professor & Vice Principal of Krupanidhi College of Pharmacy, Bangalore. She is a leading researcher in Medicinal Chemistry and has received research grants. She is an Associate Editor for *RGUHS Journal of Pharmaceutical Sciences*.*



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## Aspirations of an Indian Pharmacist

**Shri. Arshad Bashir Khan**

*Associate Professor, Department of Pharmaceutics, Krupanidhi College of Pharmacy, Bangalore.*

The "Perfect Pharmacist" is the theme of "Expressions 2014". It is a theme, a challenge, a goal, a target, a dream and an aspiration towards which every pharmacist strives or needs to strive! Perfection in any field is an elusive and ever-changing target, always coveted but seldom achieved. The paradigm of perfection yesterday may not hold true today and may become obsolete tomorrow. Yet, it is laudable that we dare to dream and achieve that which is apparently unachievable.

Pharmacists have been rendering untiring services in the field of health sector, industrial sector, academic sector and research sector. We started out as dispensers of medicines and have evolved to become designers of drugs and drug delivery systems, providers of quality-assured medicines, drug regulators, patient counsellors and care givers, educators, and myriad other roles.

The opportunities are there, more need to be created and the existing ones need to be expanded. The budding pharmacists studying in the colleges have to be particularly made aware of those opportunities. Their aspirations, ideas, suggestions and opinions have to be respected and accommodated. Their confusions, complaints and frustrations need to be addressed. In this regard, systematic and periodic surveys need to be undertaken by institutional authorities. The surveys need to be ideated, planned, organised and executed in such a manner that the student pharmacists can convey their varied opinions, feedback and suggestions effectively. The students, especially in their final year of graduation can be given a questionnaire where some fact-finding questions can be asked. Some model questions can be framed such as below:

1. Are you satisfied with the course?
2. Are you satisfied with your course content?
3. Do you want more clinical/practical sessions?
4. Do you want to continue higher education in the field of pharmacy?
5. If yes, which branches are you interested and why?
6. If no, what field of work will you choose?
7. What motivates you to achieve success?
8. Are you interested in research?
9. If yes, what particular area of research?
10. Are you planning to go abroad further studies?
11. Which countries attract you for further research and why?
12. What kind of facilities do you expect in a research institution?

The above questions are just examples which can be always rephrased or rewritten according to the need. The answers can guide our policy makers into making informed decisions and they in turn can press on the government to make favourable changes for the promotion of the field of pharmacy.

India is a resource-rich land, and our greatest resource is our people. This has been proven time and again, as Indians have contributed immensely to the world with regards to scientific achievements. We have with us our own pool of young aspiring pharmacists, and if we want India to experience their full potential, then their aspirations cannot be neglected.

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*Shri. Arshad Bashir Khan is an Associate Professor, Dept. of Pharmaceutics at Krupanidhi College of Pharmacy, Bangalore.*



## The Verdict

(This poem is dedicated to the recent rape victims of our country)

**Prof. P. M. Shyjan**

*Principal, Krupanidhi Residential P U College, Bangalore*

"My Lord, Do you really want me to answer his question?"  
"You should if you anticipate justice". The Judge affirmed.  
"What did you notice when you felt you were raped?"  
I mean what did he do to you before you realized you were sexually abused?" the prosecutor savored the question and the thoughts beyond...  
People held their breaths as they breathlessly waited.  
She looked at the Courtiers and at the floor then at the Judge , finally at a point in the vacuum. Sank desperately, yet mustered all her courage to answer. "My Lord..."

"Had it all he my master. Fine defined me a maid- no rights but Fed to serve and satisfy, Like a daughter in the house unaware of his intents, strolled in the house to become prey to his lustful eyes. Had it he my master in his thoughts, looks to spot and corner me In the house to find me alone. I cleaned his cloths, plates after his meal, Stealthily he intruded in the kitchen side storeroom as I knelt there to Collect grain for cooking the evening meal. Held he in his six pack strong arms, still unaware what's going on, thought he played a prank. Pushed me on the ground, all attempts futile as his arms tightened, All attempts futile .

Betrayed my innocent trust.  
Feelings terrible, inexplicable. He walked over me thirsting a bunch of notes in to my quivering hand and with a guilty plea and order not to disclose this wicked act to anybody. He had it all, he had it all. That's all my Lord....." crying inconsolably she collapsed inside the witness box. People nursed her not!

The judge sat up, wrote the verdict with a hurrying pen and a vague guilt,  
Read it aloud "the accused has been found guilty of raping the girl, even the forensic department reports support this fact. Hence he shall be hanged till death before tomorrow morning" the court heard it all.

The court adjourned. Early next morning, Hangman greased the lift of the hanging device then tightened the noose with a new rope...

The jailer waited for the Judge for the execution, a messenger came running and with an explosive sad news, the judge committed suicide by hanging on to the fan of his bed room in the wee hours of the morning .....and his family found a death note in his pocket,

" I-----, the Judge of the court should have been hanged till death and he the accused should have been let free, For he did rape the girl once, but I witness a few hundred rapes every year. But did little to stop them!!! I QUIT, I QUIT"

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*Prof. P. M. Shyjan is the Principal of Krupanidhi Residential P U College, Bangalore*

# Krupanidhi College of Pharmacy invests Rs. 5 lakh to set up pharmacovigilance centre at MVJ MC & RH

**PHARMABIZ.com**  
In-Asia most comprehensive pharmacy portal

## Krupanidhi College of Pharmacy invests ₹5 lakh to set up pharmacovigilance centre at MVJ MC & RH

**Our Bureau, Bengaluru, Tuesday, March 11, 2014, 13:15 Hrs [IST]**

The Krupanidhi College of Pharmacy has established Pharmacovigilance and Drug Information Centre (DIC) at MVJ Medical College and Research Hospital (MVJ MC & RH), Hoskote in Bengaluru at an investment of ₹5 lakh.

The college is also attached to MVJ MC & RH for conducting its Doctor of Pharmacy (Pharm D) course. The 900-bed multi specialty facility is equipped with advanced diagnostics to offer the required therapeutics and act as a major medical centre for the patients of this area.

The preference for MVJ MC & RH was because it was a teaching medical college hospital, according to officials from the Krupanidhi College of Pharmacy. The establishment of a pharmacovigilance and drug information centre will improve the therapeutic management of diseases and enhance the patient care, said Prof Syed Imam Rabbani, head department of pharmacovigilance and Pharm D programme, Krupanidhi College of Pharmacy.

Pharmacovigilance and drug information centre will be monitored by senior physicians and well-trained clinical pharmacists. The centre provide information regarding drug interactions, side effects and other drug enquiries to pharmacists, physicians, nurses, and other allied health care professionals. The DIC routinely responds to requests regarding appropriate therapy for specific patients, adverse reactions to drugs, efficacy of drugs, intravenous additive incompatibilities, biopharmaceutical and pharmacokinetic parameters of drugs, information on new drugs, etc. The services of the centre are also open for the general public and patients, he added.

There are totally 60 students in Pharm D and 6 will be trained per batch. The activities of Pharm D students from fourth-year onwards are trained on rotation basis at the centre to get real-world experience on literature survey and critical analysis that goes to answer centre enquires. The internship students will be stationed at the center and under the supervision of experience faculty they are trained to carry-out the professional activities on daily basis from Monday to Friday, said Prof Rabbani.

The centre was inaugurated by Dharani Mohan, chief administrator, MVJ MC & RH in the presence of Geetha Nagpal, vice chairperson, Krupanidhi Group of Institutions along with the directors, principals, heads of various departments, faculty and students of both Krupanidhi College of Pharmacy and MVJ Medical College and Research Hospital.

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## Pharmacy & Life...

**Shri. Kashyap**

*Alumnus from the M Pharm class of 2013*

- Telling the bitter truth with sugar coating is called effective communication.
- Blending of oil & water can happen only with a surfactant. Effective communication is the surfactant, which helps us blend with people.
- Opportunities lie in problems like medicament in a capsule. Acceptance of the realities helps dissolve the outer shell and exposes us to opportunities.
- Problems, like vaccination, helps to increase our resilience
- W.B.C Willingness, Belief & Courage help us to take action and face the challenges of life with confidence. Balancing a healthy growth becomes easy.
- Problems, like the Antigens, stimulate our thinking and release ideas called Antibodies which help one to circumvent through life.
- ECG: Life is a flux and will never remain the same. Ones ECG – Enthusiasm, Confidence & Good feelings will keep fluctuating.
- Think big: Narrowing of blood vessels lead to hypertension. Narrow thinking creates tension in life.
- Adulteration: in drugs happens due to adulterated thoughts & thinking
- The dosage of a medicament is very vital. While lower dose won't have effect, higher dose becomes lethal. Similarly, with lower ego, people will trample over you and the opposite is true with higher ego... you will trample over many. Having an appropriate ego helps 'live and let live' yet contribute to the societal good.

### Rx for Life:

- P Purpose oriented living gives meaning to life
- H Hone relevant skills to complete tasks
- A Accept the realities in life which helps face life confidently
- R Respect one and all to work in and as a team
- M Motivation which is intrinsic and in my control helps better
- A Attitude of Gratitude helps one feel good for better productivity
- C Courage to face life as it is in spite of not having experience
- Y YOU – be your own CEO and manage your life rather than handing it over to the others

Our very human bodies are pharmacy manufacturing units as it produces all the necessary medicines in our body. And the quality is of high standards and are produced just as per the needs. As I was doing my post-graduation in pharmacy, I realised how our thoughts & thinking, and our way of life impacts our life. Instead of helping people cure their dis-ease post taking the drugs manufactured by us pharmacists, I decided to become a preventive pharmacist and got into helping my participants release the right chemicals through my classes.

Discussing the right pathway and making them feel good has helped many prevent the various illnesses that they go through. I am very happy that I am able to work with not only children but the youth, women and executives too. Helping them to anchor to wellness rather than illness has been a very rewarding experience.



## An overview on Intellectual Property Rights and how these useful for Pharma students and researchers

### Shri. Kedarinath

Alumnus of the M Pharm Class of 2013, is an Intern - Clinical Data Management with Quintiles.

Intellectual Property Rights (IPRs) are becoming an essential knowledge for the all types of subject's especially for the Pharma students and researchers. If want to run with the competition in the world one should get the knowledge and utilise these IPRs, if you want to get benefit from these IPRs, you not need to be an IPR expert, at least having a basic knowledge is sufficient to enjoy the benefits of IPRs, especially PATENTS for Pharma students.

#### Introduction to IPRs:

Intellectual Property Rights (IPRs) are LEGAL rights which are granted to a person for CREATIONS of the mind or intellect which have commercial value.

#### Why the word Property?

- IPRs also have commercial value & can be BOUGHT and SOLD
- It Is Intangible

#### Essential features which define Property:

- Documentation
- Legally authorized gov. issuing agency
- Description
- Ownership
- Time duration
- Fee
- Commercial value

#### Why IPRs are important?

- "The person who has put in ORIGINAL EFFORT must be REWARDED."
- To Encourage INNOVATION and CREATIVITY.
- If IPRs Not There Who Is The Looser???
- Your invention was copied by others & they get credit, will you be motivated for another NEW INVENTION???
- So PROTECTION is required for the creations of mind.

#### Mechanisms for IPP (intellectual property protection)

Is it possible to have only one mechanism? To protect all creations of mind?

1. Patents
2. Copyright
3. Trademark
4. Industrial designs
5. Layout designs of integrated circuits
6. Geographical indications
7. Registration of plant varieties
8. Trade secrets.

#### PATENTS:

"A patent is an exclusive right granted by the gov. to the original inventor/developer/researcher of an invention, which prohibits others from making, using or selling that invention."

#### What is patentable?

As per Indian patent act 1970, MUST satisfy 3 basic criteria:

1. Novelty
2. Inventive step
3. Industrial application

#### Benefits:

- Grant of exclusive rights, encourages new invention.
- Apart from profitability, respect and recognition

#### Precautions:

- Patents granted for specified period, must be kept alive by payment on regular basis.

Term: 20 years

#### Registration:

- Patent application in India consist of 4 forms (form 1, 3, 5, 18)
- At 4 places in India Kolkata, Mumbai, Chennai and Delhi.

#### How long does it take to get a patent?

- Normal route: approx. 30 months
- By fast route: approx. 12-15 months.

#### Is it possible to Protect your invention in a number of countries?

- By 'patent co-operation treaty (PCT)' - 140 countries.

#### What is 'convention patent application' ?

176 countries designated by India as convention countries.

## Copyrights:

"Copyrights are a set of exclusive rights granted by law to the creators and procedures of forms of creative expressions such as literary, musical and cinematographic works."

### Best forms:

- Authored & edited books.
- Can't be reproduce without the permission of person.
- It got only limited protection.

### Benefits:

- Protection from copying
- Commercial value
- Recognition

### Precautions:

- Copyright rules....update yourself.
- Aware of loopholes.

e.g.: In biotechnology, wobble sequence.

Term: life time of author and 50 years after his death.

Registration at Delhi.

## Trademarks:

"A trade mark is a word or a symbol adopted and used by a manufacturer or a merchant to identify his goods and distinguish them from those manufactured or sold by others."

All pharmaceutical products should bear distinctive trademarks.

### Benefits:

- Quickly recognized symbol
- Enhances market value
- Maintain particular level of excellence So that they have significant commercial value and must be protected.

### Precautions:

- Must be proper i.e., used as an adjective followed by noun describing product.
- Duration may vary from country to country.

Term: 10 years & renewed.

Registration at Mumbai.

## IPRs Vs Regulatory Issues:

"The emergence of WTO & signing on agreement on TRIPS made industry realize that without adequate knowledge on these areas, becoming a global player is not possible."

## IPRs :

- These are rights associated with property which is intangible, but it has commercial value.
- This will expire after time period.
- These are not compulsory for person or organization.
- Giving protection to invention and encourage person.

## Regulatory Issues:

- These are laws which have to be followed and complied with.
- But these never expire as long as mfg. is going on.
- These are compulsory for manufacturing products.
- Ensures safety and quality of products.

## Significance of IPRs for research:

1. Prevent duplication of work.
  - Searching patent data bases.
  - Save precious time and money.
2. Help researchers to focus on commercial relevant research.
  - What is 'HOT' & what is 'NOT'.
  - Patent work not present in journals.
3. Prevent exploitation of work.
  - By enabling 'legal rights' to inventor.
4. Help in revenue generation.
5. Important source of technical information.
  - Unlikely to be available anywhere else.
6. Stimulate creativity.
  - Impose challenges for researchers.
7. Prevent infringements & help to avoid litigation.
8. Help in identification of career for opportunities.
  - Knowledge of IPRs can help to locate industries working in specific area.

## Conclusion:

Lack of IPRs knowledge causes the duplication of work there by causes time and money waste, and lose of various opportunities.

"The Pharma students and researchers must know about these IPRs, which can help to improve their research, better innovation and better career opportunities."

## Reference:

IPR hand book for Pharma students and researchers by Parikshit Bansal.

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# Happenings @ KCP

2014  
EXPRESSIONS

# Happenings@KCP

## FOUNDERS DAY

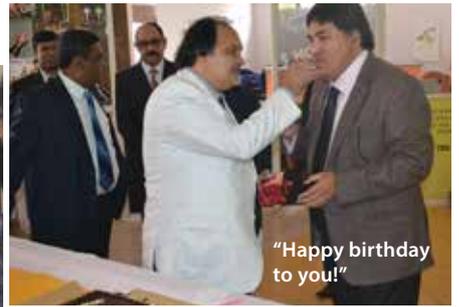
July 17, 2013



17th July Founders Day of Krupanidhi Group of Institution



"Tum jiyo hazzaro saal, saal ke din ho pachas hazzar"



"Happy birthday to you!"



"Greeting from staff to our beloved chairman"



"Waiting for food"

## TEACHERS DAY

September 5, 2013



The Principal speaks...



Sir, please cut a bigger piece for me



Yes! Dr. Naira you deserve it!



Felicitating the teacher of teachers, our beloved Chairman Sir

## PHARMACY WORKSHOP

September 28, 2013



"Thank you, Prof. Uday Arur for bringing out the "leaders in us"



This is a better seating arrangement! I hope they have the same for the examinations.

# Happenings@KCP

October 01, 2013

## ETHNIC DAY



"Unity in diversity" demonstrated on Ethnic Day



"Hey! Watchout I am a Milkha Singh localite"



"As-salamu aleykum" from Iran



The Charming Three



"Nigeria's greeting to all"



"Pretty ladies"



Only flowers for me? I spent so much on the costume!



"Enthusiastic audience"



Shake hands for a better tomorrow



"Yes, I am keeping an account"

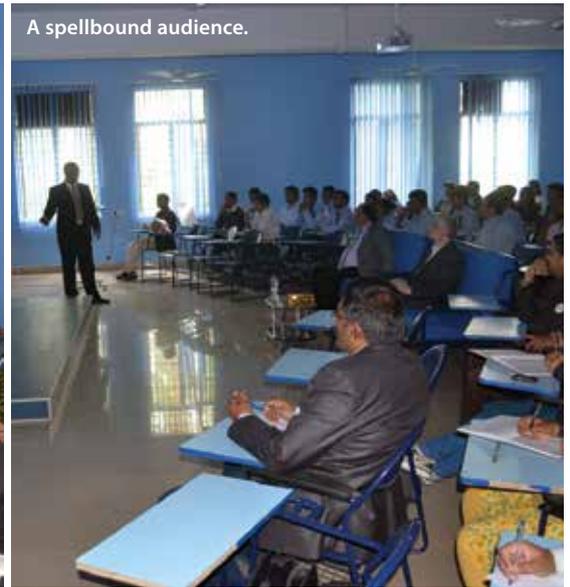
# Happenings@KCP

**NATIONAL  
PHARMACY  
WEEK  
CELEBRATION**

November 11, 2013



Mallya Sir in his full glory and style.



A spellbound audience.



Yes. This is a true leadership style. Dr. Shenoy.



Okay, so this is the concept. Great.



Dr Dinesh Shenoy @ KCP during National Pharmacy Week

**SEMINAR  
FOR  
TEACHERS AT  
PHARMACY**

November 11, 2013



Prof Anila explaining "Understanding Effectiveness" for teacher at Pharmacy College.



Dr. Prem Kumar. I never knew you are even good at making butterflies on the wall. Wow!

## AIDS AWARENESS DRIVE

December 02, 2013



"Taking oath to stay safe"



The enthusiastic lot. Always.



"Take the lead and pledge your support for World AIDS day."



Thank you. We promise to be careful.



Wear it with pride. Help save lives.



Show it to your Papa. Let him play safe.

Stand up. Make a difference



Full participation and strength.



"Let's join hands... to fight. To protect.. To give... our loved ones healthy tomorrow"

# Happenings@KCP

FRESHERS DAY

December 14, 2013



Our chairman, THE great orator BLESSING THE FRESHERS.



Dignitaries gracing the freshers day



Chaand mera dil chandni ho tum.....



Who is next



The Blue brigade.....Pride of Krupanidhi



Artistic acrobats



Welcoming Freshers is a tradition here.



Nigeria rocks



Koel boli duniya doli..... marvellous Nikitha



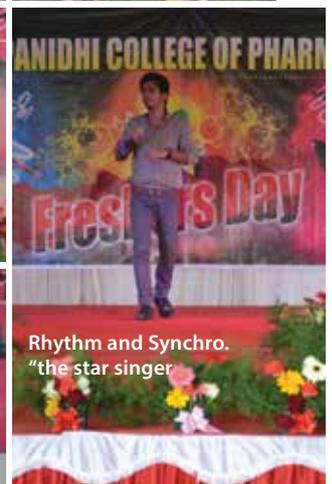
Talent unlimited. Keep it up.



"One two three four, get on the dance floor"



Aaj kal paun zameen par nahi padte mere



Rhythm and Synchro. "the star singer"

# Happenings@KCP

## CHRISTMAS @ KCP

January 04, 2013



Singing Carols



Hey children! who took my Santa dress.



Snowman at KCP



Waiting for the Santa to bless us

## INDEGENE PLACEMENTS

January 17, 2013



Ms Surabhi delivering the pre-placement talk on the occasion of Indegene recruitment drive.



Mr Rikshikesh explaining global presence of Indegene



Attending THE DRIVE.... Seriously.

## SARASWATHI POOJA @ KCP

February 04, 2013



Saraswati pooja on occasion of Basanth panchmi



Oh God! Where is Puja ki Samagiri



Abhishekum to the Goddess Saraswati



Seeking blessings from Goddess



Will the fire in the tray also grow.



The organizers



Oh! Saraswati Ma fill our life with eternal light of knowledge



Panditji! Please tell who has to sit first.

# Happenings@KCP

VALENTINES DAY

February 14, 2013



Happy Valentine's Day. We celebrate all events.



Somebody took my scooter instead of the heart.

February 17, 2013

RELGARE CAMPUS DRIVE



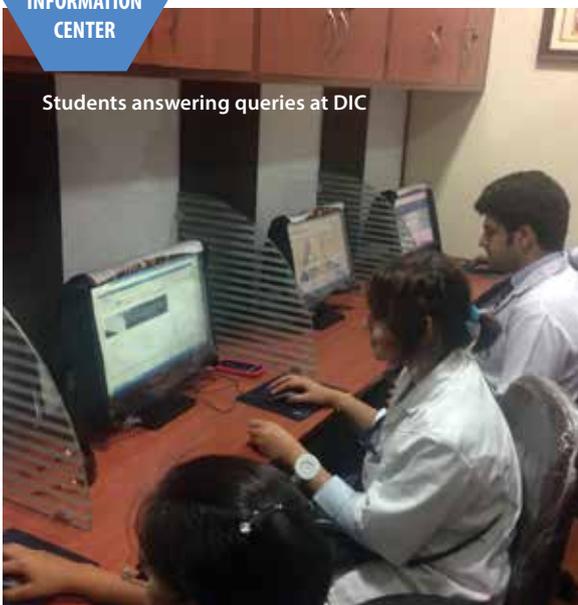
Students attending pre-placement talk.



Mr sudheer. Conducting one to one interview

DRUG INFORMATION CENTER

March 5, 2013



Students answering queries at DIC



Mrs. Dharani Mohan, inaugurating Drug Information Center (DIC) set up by KCP at mvj hospital



DIC Library

# Happenings@KCP

## INAUGURATION OF GENTS & LADIES ROOM AT PHARMACY

March 15, 2013



Yes. Boys too have a room



Inauguration of the renovated ladies room.

## TALENT DAY

April, 2013



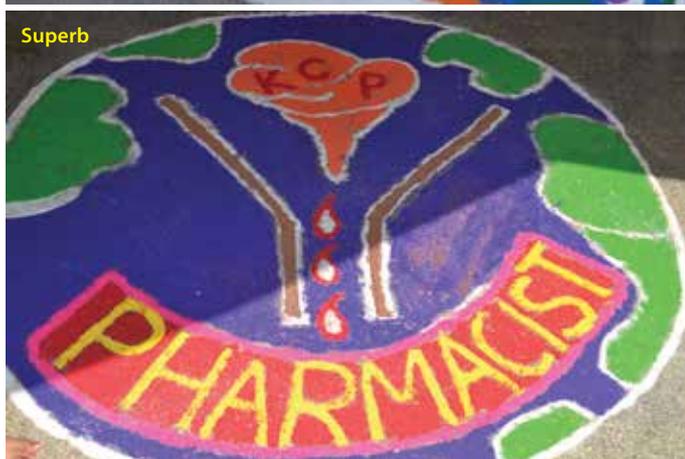
Nursing Principal Mrs Prabha and Mrs Geetha our admin officer ponder what is this?.....



Who put the drums on me



Superb



Wow. Lovely peacocok indeed



Sad but true. Please do not abort



Mehandi competition. The dress too is matching. Great

# Happenings@KCP

TALENT DAY

April, 2013



# Happenings@KCP

SPORTS DAY

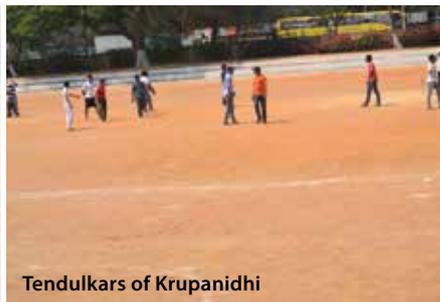
April 04, 2013



Only after you run I will blow the whistle!



Lemon and spoon race, The balancing Act



Tendulkars of Krupanidhi



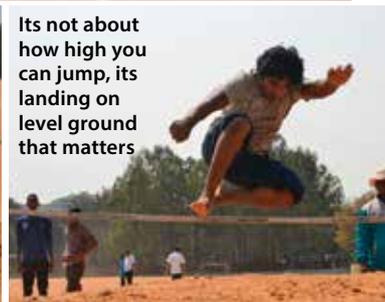
Awesome Duo, Dr Dang and Dr Karvekar



From Mauritius, With Love!



Wow! What A Jump



Its not about how high you can jump, its landing on level ground that matters



Mrs Geeta Nagpal. The vice chairperson Speaks



Congrats Dr Sonal, True inspiration for young faculty



The virtuous office staff, relaxing for the day!



Sports rolling trophy goes to..... goes to..... 2nd BPharm



Good Job Muniappa, !



Uma ,Satyamma, Savita ,have it all for your rangoli competition

## FINISHING SCHOOL

2013



Finishing School by Prof Prakash Mallya , the Director of Center for Pharmaceutical Professional Advancement



Zealous participation in finishing school



On the spot artistic creation during finishing school

## LIGHTER MOMENTS



"Happy Birthday Ranganath sir"



Ms Teena Seeking Blessings From Dr Thakur On Her Birthday



"Aare hold the gift first Dr. Rabbani

# KCP's unique advantage CPPA - Center for Pharmaceutical Professional Advancement

The Indian Pharmaceutical Industry has become global with operations in India and almost all the Regions of the world, and is growing exponentially. Companies are looking for candidates who are smart and can present themselves well. Students are not able to catch up with the pace of growth opportunity as they lack employability skills or soft skills. Soft Skills training has become a must for the students who want to go for job or higher studies. Most employers these days want to hire, retain and promote persons who are dependable, resourceful, ethical, self-directed having effective communication, willing to work and learn and having positive attitude.

With this in mind the Krupanidhi College of Pharmacy has commenced a new and a positive initiative based on finishing and polishing concepts for Student centric, Student focused and Student development activities called CPPA- Center for Pharmaceutical Professional Advancement. CPPA lays emphasis on Hard Skills as well as soft skills.

Soft skills or Emotional Intelligence Skills strengthen the students from within. Soft skills are about enabling and empowering. These skills empower them to understand their own SWOT - Strengths, Weakness, Opportunities, Threats- and how best they can come across as competent individuals in any given situation. At CPPA, coaching is imparted to fine-tune the students' attitudes, values, beliefs, motivation, desires, feelings, eagerness to learn, willingness to share and embrace new ideas, goal orientation, flexibility, persuasion, futuristic thinking, compassion, diplomacy, and various skill sets of communication, manners, and etiquette so that they will be able to deal with different situations diligently and responsibly.

Soft skill is not a visible skill like the domain subject content the student learns in his Academic career, but it helps in improving the personality of the person. It gives finishing touch to the personality. Soft skills will help the students increase their employability potential and face the challenges of the present time.

Hard skills are technical skills whereas soft skills are at the surface providing finishing touches for success. The blend of both skills is essential for personal, professional and social success. The significance and relevance of soft skills equip the students with adequate ammunition to face corporate battles and challenges.

## CPPA Curriculum and Objectives

The Curriculum and Modules have been developed. In consultation with the Institutes Governing Council,

Corporate Panel, Subject Experts, the Industry -Institutes Partnership Centers and with support and co-operation from distinguished people from the industry.

### Industry Modules :

1. Value added short professional courses designed as per the requirement of the industry
2. Regular Guest-lectures, Seminars, Workshops, the faculty selected from Pharmaceutical Industry, Hospitals and Subject experts in respective branches to sharpen the skills of students.
3. On Job Training programs at Hospitals, Industry .
4. Participating in Conferences, Symposiums, Exhibitions etc
5. Training based on learning-by-doing philosophy.

### Personality Development Modules :

1. Exclusive faculty resource to impart soft skill training.
2. Become self-confident individuals by mastering interpersonal skills, team management skills, and leadership skills
3. Stress, Strain and Conflict management through simple techniques.
4. Develop broad career plans, evaluate the employment market, identify the organizations to get good placement, match the job requirements and skill sets
5. Develop effective communication skills , presentation skills, business correspondence .
6. Develop all-round personalities with a mature outlook to function effectively in different circumstances
7. Take part effectively in various Interview and selection procedures adopted by the Pharma Companies, Campus Interviews etc

The Periodic training programmes which is unobtrusive to their Regular Academic Time-Table is conducted in a very informal, interesting, and interactive manner, which gives ample scope for the students to interact with each other and face a wide variety of issues, topics, and situations that they are likely to come across as entry-level Officers, Executives, Associates. Etc. in the Working and Corporate environment.

Since its inception in 2009, CPPA is envisioned, mentored and coached by Prof. Prakash V Mallya; with over 40 years of Pharmaceutical Industry experience in India and over 60 Countries around the world, ably assisted by industrial luminaries and team motivators from the Krupanidhi College of Pharmacy College and Krupanidhi Business School.



# CPPA Activities - June 2013 - March 2014

Topic	Speaker
<b>JUNE 2013</b>	
WHO – Rational Drug Use	Dr. Guru Prasad Mahanta – Annamalai University.
Clinical Pharmacy – Pharm D	Dr. Wafa Y Dahdal – Director of International Programs, Asst Director of Professional Development, American College of Clinical Pharmacy- USA.
Nanotechnology Application in Medicine & Pharmaceutical Sciences	Dr. Anupama Rangan – Vivekananda College of Pharmacy – Bangalore.
Opportunities in Nutraceuticals	Dr. Shrinivasan S, Sr. VP- Medreich Labs, Bangalore
<b>JULY 2013</b>	
Drug Discovery Studio	Dr. Anand Krishnamurthy & Mr. Shrikant – Accelrys
Preparing for NAAC Accreditation Presentation	Prof. K R Maruthi, Principal Krupanidhi Degree College
Plant Visit – Medreich Labs- Bangalore	KCP Staff & Students
<b>SEPTEMBER 2013</b>	
Leader In me Workshop	Prof. Uday Arur – Biz Mantra Management Consultant, Mumbai
<b>NOVEMBER 2013</b>	
Understanding Effectiveness for Teachers	Prof. Anila, Director CLHRD/Mangalore.
Building Competence	Prof. Anila, Director CLHRD/Mangalore.
Overview of the Pharmaceutical Industry	Mr. Krishna Kumar, Head QA- Biocon- Bangalore.
National Pharmacy Week Celebrations SEMINAR SERIES – Biogenerics, QbD, Process Engineering, Product Development, Advanced Analytical Techniques,, Enhancement of Drug Delivery, Writing Research & Review Articles	Dr. Dinesh Shenoy, Sr. GM- Mylan Labs.
<b>DECEMBER 2013</b>	
KCP Staff Visit to Green-Chem , Bangalore	Dr. MD. Karvekar, Dr. Prem Kumar, Dr. Sonal Dubey, Prof. Prakash V Mallya
65th IPC New-Delhi, Amity University Noida	Directors, Principal, Dean, M Pharm & B Pharm Students were Registered Delegates. The KCP contingent was jointly lead by Prof. Mallya & Dr. Raman Dang.
Seminar Presented By Prof. Prakash V Mallya, Lead Mentor, CPPA KCP – ENHANCING LEARNING THROUGH MOTIVATION	
<b>JANUARY 2014</b>	
Visit to GROUP PHARMACEUTICALS - Malur/Bangalore	All MPharm Students & Prof. Mallya
Advances in Diagnosis and Imaging of Cancer Impacting Treatment.	
	Dr. Harsha Doddihial, VP Quintiles, Consulting Oncologist , Bangalore.
Finishing School & Skill Development	All MPharm, Final BPharm,
IPR Lecture Series 1	Mr. Ravi Syam Madhira, Deputy General Manager & Head – IPR, Jubilant Organosys, Bangalore.
<b>FEBRUARY 2014</b>	
IPR Lecture Series 2	Mr. Ravi Syam Madhira, Deputy General Manager & Head – IPR, Jubilant Organosys Bangalore
QC, IPQC, GLP, Ranbaxy Issues	Mr. Sarang Athavale, Pharma Industry Consultant.
Teleradiology, Image Radiology in Clinical Trials and New Drug Development	Dr. Arjun Kalyanpur, CEO, Teleradiology Solutions, Image Core Labs, Bangalore.
From Research Topic to Publication	Dr. G Jagadeesh, USFDA, Maryland-USA.
Industrial Visit Tejkamal Pharma, Bangalore	D.Pharm, B.Pharm, Pharm.D
Campus Drive- Religare Wellness	D.Pharm, Final B.Pharm
Finishing School Training, Defining Decade, Case Study	Final B.Pharm, M.Pharm
Life Skills, Motivation, Communication, Personality Development Training	Mr Kasyap, Buoyancee, Bangalore
Introduction to Marketing and Marketing	Prof. Vinay Rao, Krupanidhi College of Management
<b>MARCH 2014</b>	
Visit to Karnataka Antibiotics & Pharmaceutical Ltd. Plant, Bangalore	Staffs and Students
Visit to Medopharm Plant, Bangalore	M.Pharm Students



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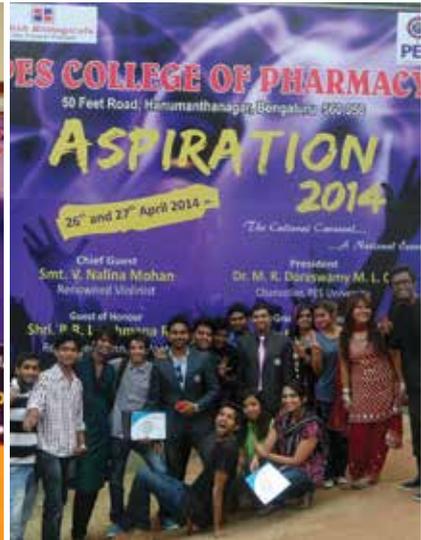




## Outside KCP

2014  
EXPRESSIONS

# Student participation in Intercollegiate competition



# Seminars and Workshops



PVPI Workshop organised By PSM India



One week course organized by St. John's Research Institute, in Collaboration with Mc.Master University, Canada



Dr. Thakur presiding National Pharmaceutical Scientific Seminar at Kozhikode, Kerala.



5th INDIAN PHARMACEUTICAL CONGRESS  
20th - 22nd December 2013

KCP team at 65th Indian Pharmaceutical Congress, New Delhi



# Seminars and Workshops



CME program by MVJ Med Coll and Res Hosp, Bangalore



Indian Congress of Pharmacy Practice 2014 at Hotel Sheraton, Bangalore



# Seminars and Workshops



3 days symposium on NDDS at Al Ameen College of Pharmacy.



Two day training on "Advanced Good Manufacturing Practice" Jointly organized by WHO & Central Drug Standard Control Organization



At 'Recent advances in Pharmacy Practice' organised by Oxford College of Pharmacy



Short Course on "Educational Methodology" at RGUHS



Nigerian Dignitaries at "Kwankwasonians In Diaspora" SRM University, Indian Chapter, at Taj West-End, Bangalore



"Phyto Zoo medicine and AYUSH Therapy" in Oriental College of Pharmacy, Navi Mumbai





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# Creative Canvas

2014  
EXPRESSIONS





## Dreams and You

Rajdwip Ghosh

*III B.Pharm*

If dream were given to a lonely man  
and a lonely man's dreams came true  
I would force myself to sleep all the time  
just so i could dream of u

If wishes were given to lonely man  
and I was given just two,  
I would wish for you to always love me  
and the other I would give to you

If my tears could write a love song  
I would write a love song for you  
It would explain just how i feel inside  
and how much i love you too

But, dreams are only dreams  
and wishes seldom come true  
my tears can't write a love song,  
but when they fall, they fall for you!

# Around the World in 22 Pics



**Vijay Yadav** III B Pharm

*Hobbies:* Traveling, Photography, Adventure

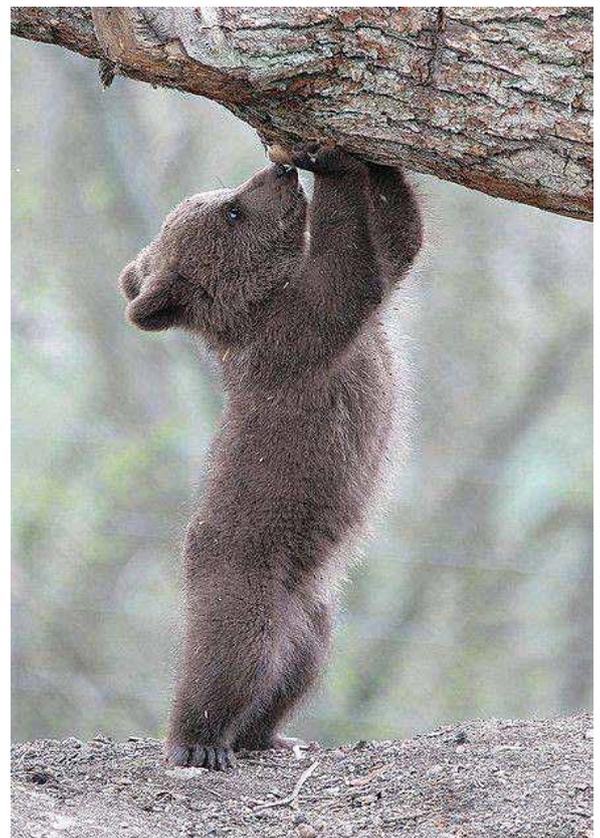
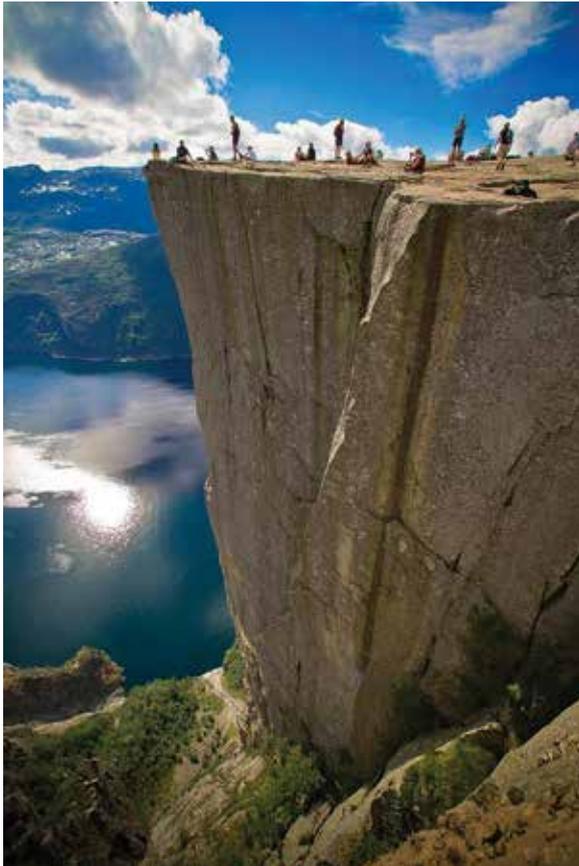
*Countries Traveled:* Denmark, Norway, Germany, Holland, Belgium, Sweden, Finland, Iceland, France, United Kingdom, Austria, Greece and Thailand

*Inspiring Personalities:* Sir Edmund Hillary and Ansel Adams

*"I have a real passion in photography and traveling since my childhood. To me, photography is an art of observation. It's about finding something interesting in an ordinary place... I've found it has little to do with the things you see and everything to do with the way you see them. As the ace photographer Berenice Abbot says, "photography can only represent the present. Once photographed, the subject becomes part of the past".*



# Around the World in 22 Pics





# Antibiotic Resistance and Policies in the Control of Antibiotic Resistance

Arun Roy

III Pharm D

## Abstract

Antibiotic resistance occurs when an antibiotic has lost its ability to effectively control or kill bacterial growth, in other words, the bacteria are 'RESISTANT' and continue to multiply in the presence of therapeutic levels of an antibiotic.

Only through certain level of awareness, antibiotic policies and judicious use of antibiotic can overcome this deadly problem.

## Introduction

It is difficult to imagine undertaking today's surgical procedures, transplantation, cancer chemotherapy or care of critically ill or HIV infected patients without effective antimicrobial agents. Bacteria are champions of evolution and a few microbes have adapted to a point where they pose serious clinical challenges for human. Antibiotic resistance is a direct consequence of antibiotic use. Both continue to escalate despite many calls for moderation of antibiotic use, in the hospital and in the community.

Now we need antibiotic policies and other control measures to overcome this deadly problem. Despite the lack of properly controlled studies, which would be very difficult to perform, there is no doubt that policies can be efficacious in reducing cost and levels of use without being detrimental to patient care.

## How do Bacteria Become Resistant?

Natural Resistance some bacteria are naturally resistant to certain types of antibiotics. They lack the metabolic process or target site which is affected by the particular drug.

Example 1: Gram negative bacilli are normally unaffected by penicillin.

Example 2. M. tuberculosis is insensitive to tetracycline.

This type of resistance does not pose a significant clinical problem.

However, bacteria may also become resistant by two other mechanisms:

1. By a genetic mutation.
  2. By acquiring resistance from another bacterium.
1. Genetic Mutation: It is a stable and inheritable spontaneous change of the bacteria's genetic material, thought to occur in about 1 in 1 million to 1 in 10 million cells. Different genetic mutations yield different types of resistance. Some mutations enable the bacteria to produce potent chemical (enzymes) that inactivate antibiotics, while other mutations eliminate the cell target that the antibiotic attacks. Still others close up the entry ports that allow antibiotics into the cell, and others manufacture pumping mechanisms that export the antibiotic back outside so it never reaches its target.
  2. Acquiring resistance from another bacterium: Bacteria can acquire antibiotic resistant genes from other bacteria by following ways:

Conjugation > Sexual contact through the formation of a bridge or sex pilus is common among Gram-negative bacilli of the same or another species. Even non-pathogenic organism may transfer the 'resistance' or 'R' factor to pathogenic organisms, which may become widespread by contamination of food or water.

Example: Chloramphenicol resistance to typhoid bacilli, Streptomycin resistance of E. coli and many others have been traced to this mechanism.

Transduction > It is the transfer of gene carrying resistance through the agency of a bacteriophage. The 'R' factor is taken up by the phage and delivered to another bacterium which it infects.

Example: many staphylococcus aureus strains have acquired resistance by transduction.

Transformation > A resistant bacterium may release the resistance carrying DNA into the medium and this may be imbibed by another sensitive organism becoming unresponsive to the drug.

Example: pneumococcal resistance to penicillin.

## Various factors responsible for antibiotic resistance

**The patient:** Factors likely to the development of resistance in individual patients include a large inoculum infection which increases the potential for pre-existing resistant mutants. Any process that lowers the drug concentration at the site of infection is also likely to cause resistance as will slower eradication of infection due to a foreign body or a compromised immune system. While the normal flora is usually forgotten about, or ignored, when treating specific infection, its exposure to the antibiotic is inevitable. Development of resistance in normal flora is probably of great significance clinically, as this resistance may spread to more pathogenic organism.

**The organism:** Whether resistant survivor organisms revert to full sensitivity on removal of antibiotic selective pressure depends on the several factors. On rapid removal of selective pressure, reversion to sensitivity will probably occur, although taking longer than the initial process of development to resistance. We know, however, that, genetic compensation for the cost of resistance can occur, i.e. the resistant survivors can undergo separate mutation over several hundred generation that favor maintenance of the resistant gene.

**The drug:** The antibiotic itself is likely to be important regarding development of resistance. Narrow spectrum agents should be beneficial as they have less effect on normal flora than broad spectrum agents. Dose regimen is also likely to be important. Higher doses, which will achieve higher drug concentrations at the site of infection, are less likely to select for resistance, although the effects of this strategy on the normal flora are unknown.

**Your favorite meat:** A report published by the food and drug administration of USA in February 2011, tested 480 samples each of ground turkey, pork chops, ground beef and chicken wings, breast and thighs and all contained antibiotic resistant strains of salmonella and campylobacter. It may be due to antibiotics are used by the meat industry to promote faster growth and keep their animals free from disease.

PATIENT	ENVIRONMENT
Inoculum	Quality of generics
Foreign body	cycling
Immune system – De novo or clonal	
Normal flora	resistance
Missed doses	Total use/ threshold
Eradication regimes	
DRUG	ORGANISM
Dose regimen	Compensation
Combination	Cost of resistance
Course length	on antibiotic withdrawal
Spectrum	
Revision	

(The dynamics of resistance > the patient, the drugs, the microorganism and the environment interact. It is difficult to identify any one factor as crucial on its own)

(The dynamics of resistance > the patient, the drugs, the microorganism and the environment interact. It is difficult to identify any one factor as crucial on its own)

**PREVENTION:** So what is fueling antibiotic resistance, you may ask? We are finding that the wide spread overuse as well as in appropriate use of antibiotic fueling antibiotic resistance. These complications of antibiotic therapy can have serious outcomes even death.

## So what can we do to prevent antibiotic resistance?

Patients, healthcare provider, hospital administrators, and policy makers must work together to employ effective strategies for improving antibiotic use ultimately improving medical care and saving lives.

### PATIENTS

Take antibiotics exactly as the doctor prescribes. Do not skip doses. Complete the prescribed course of treatment, even you start feeling better.

Only take antibiotics prescribed for you, do not share or use leftover antibiotics. Antibiotic treat specific types of infections. Taking the wrong medicine may delay the correct treatment and allow bacteria to multiply.

Do not save antibiotics for the next illness; discard any leftover medication once the prescribed course of treatment is completed.

Do not ask for antibiotics when your prescriber thinks you do not need them.

Prevent infection by practicing good hand hygiene and getting recommended vaccines.

### **HEALTHCARE PROVIDER S**

Do not treat viral infections with antibiotics even if the patients ask for them.

Prescribe antibiotics only when they are absolutely necessary and giving them at the right dose and only for as long as they are needed.

Avoid unnecessary overlaps in antibiotics. It is not usually necessary to give two antibiotics to treat the same bacteria.

Become familiar with resistance trends in your region.

Discuss and work with pharmacist regarding appropriate antibiotic use, antibiotics resistance and about adverse effects.

Utilize patient and provider resources offered by professional pharmaceutical organization.

When you prescribe an antibiotic take an antibiotic time out after 24 to 48 hours. This is the time to stop and assess the patient's treatment and use of antibiotics.

Are the culture results available?

How has the patient responded?

Are antibiotic still needed?

Is this the right drug and right dose?

## **Conclusion**

Antibiotics are losing their effectiveness of a rate that is both alarming and irreversible. While it is true to say that there is no absolute proof of a causative association between antibiotic use and resistance, most authorities believe the association to be 'Virtually certain'. Given this and the impossibility of controlling for all compounding factors in prospective trials, a programmatic approach to control of antibiotic resistance is essential. Given the recent worldwide escalation in resistance and the overwhelming evidence of much over-use of antibiotics ( and thus unnecessary resistance), the programmatic and essential approach to the control of antibiotic resistance is to control antibiotic use. The important question is: how much research is still needed in this area?

## **Reference**

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## How to make someone tell the truth

Ssozi Kenneth

III B.Pharm

“Cross your heart and hope to die.” It sounds childish, but asking someone to place a hand on their heart while answering your questions could result in more truthful answers.

Because your mind associates the gesture with morality and forthrightness, touching your ticker primes your brain for truth-telling. However this tactic wouldn't work if you try it on someone motivated to lie \_ like a lover who you suspect may be fooling around. It's more useful in situations when someone might be tempted to lie, but isn't motivated to bluff you. (for example, you ask your roommate if they took your dog to the park or just around the block.)

Here are more ways to coax the truth out of someone.

### Ask In a Text

People tend to respond more honestly in texts than in verbal phone conversations: since you don't have to hear the emotional consequences of your honesty \_ like your friend's disappointment when you tell them you can't make it to his bachelor party.

### Take Money off The Table

When people are exposed to cash or finance-related words, there's a 46% chance they'd lie than if they were primed with language unrelated to money. [shift his mind away from financial considerations.]

### Spritz a Little Cleaner

You behave more honestly in clean-smelling environments.

### Shine a Light

You are less inclined to lie or act unethically in bright spaces, as opposed to a dark room. Your brain equates light with openness and honesty. And when a room is brightly lit, you feel like your thoughts and actions are exposed.

### Make Him Go the Distance

When soldiers were told they'd earn an extra 30 minutes of leave on a Thursday evening for every point they scored in game of dice, they were much likely to cheat on a Wednesday or a Thursday \_ as opposed to a Monday, reveals an Israel study. whatever motivates someone to cheat \_ whether it's money, power or reputation \_ putting “temporal distance” (a.k.a more time) between the lie and the payoff decreases the likelihood of dishonest behaviour. [widen the time gap between when you ask your questions and the possible payoff of a dishonest answer.]



# Drug Poisoning

Binay Gupta

III Pharm D

## Abstract

Drug poisoning mainly refers to the condition of exposure of life to an overdose of either prescribed drugs or drugs that are brought over the counter. It can also be due to drug abuse or drug interaction. Some people may be more sensitive to certain medications so that the high end of therapeutics range of a drug may be toxic for them. Illicit drugs, used to get a high, may be taken in overdose amounts when a person's metabolism cannot detoxify the drug fast enough to avoid unintended side effect.

## Introduction

Drug poisoning describes the toxic effect due to the ingestion or application of a drug or other substance in quantities greater than recommended or generally practised. Reaction to a drug caused by an allergic sensitivity is not considered as drug poisoning. Worldwide, among more than 9 million natural and synthetic chemicals have been identified, fewer than 3000 cause more than 95% accidental and deliberate poisoning. Virtually, all drugs, especially in larger doses or when taken over long periods of time, can initiate a toxic condition.

## Drug poisoning causes

In many hospitals in the developed world, acute poisoning is one of the most common reasons for acute admission to a medical world, poisoning may be:

### A) Deliberate- It can be:

- 1) Self harm or suicide
- 2) Child abuse or Munchausen syndrome by proxy (a behaviour pattern in which a care giver deliberately exaggerates or induces physical, psychological, behavioural or mental health problem in those who are in their care)
- 3) Third party, example- homicide or illicit use of drug.

### B) Accidental-

- 1) In children
- 2) Dosage error by patient or doctor
- 3) Recreational use, example: heroin, methadone and cocaine.

### C) Occupational exposure

### D) Environmental exposure

Example- plants, food, stings and bites.

## Clinical features

Drugs have effects on the entire body, generally in an over dose, the effects of the drugs may be a heightened. Eighty percent of adults are conscious on arrival at hospital and the diagnosis of self poisoning is usually made from the history. In the unconscious patient a history from friends or relatives is helpful, and the diagnosis can often be inferred from tablets, bottles or a suicide notes brought by the ambulance attendants. Tablets identification may be helped by the use of TICTAC, a visual drug identification database with information and high-quality images on thousand of tablets, capsules and related products. The physical symptoms may also aid in the identification of the agent responsible for poisoning.

## Investigation

A blood sample should be taken at an appropriate time post the drug overdose. If the following drugs are likely to have been taken such as aspirin, digoxin, ethylene glycol, iron, lithium, methanol, paracetamol or theophylline, the determination of the concentration of these drugs will be valuable in management. Drug screens of blood and urine are also occasionally helpful in the seriously ill unconscious patient in whom the cause of coma is unknown. Further investigation depends on the drugs ingested and knowledge of their likely impact on metabolic and cardiorespiratory function and the clinical assessment of the patient, example: arterial blood gases in the comatose patient.

## Some physical signs of poisoning

Features	Likely poison
Constricted pupils	Opioids, Organophosphate insecticides Nerve agent.
Dilated pupils	Tricyclic antidepressant Amphetamines Cocaine Anti muscarinic drugs
Divergent strabismus (deviation of eye that patient cannot overcome)	Tricyclic antidepressant
Nystagmus (involuntary movement of eye)	Phenytoin Carbamazepine  Carbon monoxide Methanol
Loss of vision	Tricyclic antidepressants Theophylline Opioids Mefanmic acid Isoniazid Amphetamines
convulsion	Metoclopramide Phenothiazides
dystonic reaction	Antimuscarinic drugs Amphetamines Cannabis Recovery from tricyclic antidepressant overdose
Delirium and Hallucinations	Tricyclic antidepressant Antimuscarinic drugs
Hypertonia and Hyperreflexia	Theophylline
Tinnitus and deafness	Salicylates Quinine
Hyperventilation	Salicylates Phenoxyacetate herbicides Theophylline  MDMA(estacy) 3,4-methylene dioxy-n-methylamphetamine
Hyperthermia	Usually occur in comatose patients
Blisters (small pockets of fluids within the upper layer of skin)	Carbon monoxide poisoning.
Lips and skin 'cherry red'	

## Management

Most patients with self poisoning require only general care and support of vital system. The following

principles should be applied for the management of patients with self poisoning.

- 1) Emergency resuscitation
- 2) Prevent further drug absorption
- 3) Increase drug elimination
- 4) Administration of specific drug antidotes
- 5) Psychiatric assessment

Emergency resuscitation -

- Nurse the patient in the left lateral position to reduce the risk of aspiration.
- clear the airway and intubate if the gag reflex is absent.
- administer 60% oxygen by face mask in patients not intubated.
- Artificial ventilation is sometime necessary if ventilation is inadequate.
- measure temperature with a low-reading thermometer and treat hypothermia.

### 1) Prevent further drug absorption –

- These measures are reserved for those who have taken a potentially serious (life threatening) overdose by mouth.
- Gastric lavage is rarely used due to the risk of complications and only if the procedures can be undertaken within 1hr of ingestion. 200-300ml of warm water or 0.9% saline are repeatedly instilled and aspirated from the stomach via a large bore oro-gastric tube with the patient in the left lateral decubitus position. It is contraindicated if the airway is not protected or overdose of corrosive, petrol or paraffin taken. Complications include pulmonary aspiration and oesophageal perforation.
- Activated charcoal (50g orally) absorbs unabsorbed poison still present in the gut. It is given if the patient has ingested a drug absorbed by charcoal (example- aspirin, digoxin, paracetamol, barbiturates) up to 1hr previously.
- Whole bowel irrigation is orally for potentially toxic ingestions of iron, lithium, sustained release or enteric coated drugs and ingested drug packets. Polyethylene glycol electrolyte solution, eg- Klean-prep is infused via a nasogastric tube (1-2L/hr) until the rectal effluent is clear (usually 3-6hrs).

### 2) Increasing drug elimination

Multiple dose activated charcoal (50g 4-hourly until charcoal appears in the faeces or recovery occurs)

interrupts the entero-hepatic or entero-enteric recirculation. It is only used in patients who have ingested a life-threatening amount of carbamazepine, phenobarbital, dapsone, quinine or theophylline.

- Urinary alkalinisation increases the urine pH and enhances the elimination of salicylates. It is rarely used now.
- Haemodialysis is used with severe lithium, ethanol, methanol, ethylene glycol and salicylate poisoning.

### 3) Antagonizing the effect of poison -

- Specific antidotes are available for a small number of drugs:

Antidotes	Likely poison
100% oxygen or hyperbaric oxygen therapy (HBOT)	carbon monoxide poisoning and cyanide poisoning
Activated charcoal with sorbitol	used for many oral toxins
Adenosine	Theophylline antidote for adenosine poisoning
Atropine	organophosphate and carbamate insecticides, nerve agents, some mushrooms
Beta blocker	theophylline
Calcium chloride	calcium channel blockers, black widow spider bites
Calcium gluconate	hydrofluoric acid
Chelators such as EDTA, dimercaprol	heavy metal poisoning
(BAL), penicillamine, and 2,3-dimercaptosuccinic acid (DMSA, succimer)	
Cyanide antidote (amyl nitrite, sodium nitrite, or thiosulfate)	cyanide poisoning
Cyproheptadine	serotonin syndrome
Deferoxamine mesylate	Iron poisoning
Digoxin Immune Fab antibody (Digibind and Digifab)	digoxin poisoning
Diphenhydramine hydrochloride and benztropinemesylate	Extrapyramidal reactions associated with antipsychotic
Ethanol or fomepizole	ethylene glycol poisoning and methanol poisoning
Flumazenil	benzodiazepine poisoning
Glucagon	beta blocker poisoning and calcium channel blocker poisoning

Insulin with Glucagon	beta blocker poisoning and calcium channel blocker poisoning
Leucovorin	methotrexate and trimethoprim
Methylene blue	treatment of conditions that cause methemoglobinemia
N-acetylcysteine	Paracetamol (acetaminophen) poisoning
Naloxone hydrochloride	opioid overdose
Octreotide	oral hypoglycemic agents
Physostigmine sulfate	anticholinergic poisoning
Phytomenadione (vitamin K) and fresh frozen plasma	warfarin poisoning and indanedione
Pralidoxime chloride (2-PAM)	organophosphate insecticides, followed after atropine
Protamine sulfate	Heparin poisoning
Prussian blue	Thallium poisoning
Pyridoxine	Isoniazid poisoning, ethylene glycol
Sodium bicarbonate	ASA, TCAs with a wide QRS6

### 4) Psychiatric assessment

All patients with Deliberate self harm must be taken seriously and an assessment made of suicidal intent. In some patients, often young females, the act was not premeditated, they have no wish to die and the tablets were taken in response to an acute situation, example: an argument with the girl friend/boy friend. The risk of suicide is low and formal psychiatric assessment is not always necessary. In the absence of potential medical problems these patients may not necessarily need to be admitted to hospital, provided there is the necessary social and emotional back up at home. In other patients there is clear suicidal note was written and effort was made not to be discouraged. These patients must be assessed by a psychiatrist before they leave hospital.

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# Biotechnological approaches for better utilization of medicinal plants

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## Introduction

Medicinal and aromatic plants represent a consistent part of the natural biodiversity endowment of many countries around the world. These species provide an important contribution to health, local economies, cultural integrity and ultimately the well being of people, particularly the rural poor and fragile social groups, e.g., the elderly, children and women.

Interest in natural products research is strong and can be attributed to several factors:

1. Unmet therapeutic needs
2. The remarkable diversity of both chemical structures and biological activities of naturally occurring secondary metabolites
3. The utility of bioactive natural products as biochemical and molecular probes
4. The development of novel and sensitive techniques detect biologically active natural products
5. Improved techniques to isolate, purify and structurally characterize these active constituents and
6. Advances in solving the demand for supply of complex natural products

## Indian – medicinal plants

In India 15,000-20,000 species are reported to have medicinal value. Out of these, 7000-8000 is used in ISM (4700 as folklore remedies, 1800 in Ayurveda, 500 in Siddha, 400 in Unani, 300 in Tibetan). However, Herbal Pharmaceutical Industry largely uses only 400 species. In Indian context the herbal medicines are of great importance as the allopathic drugs are not available to the masses especially in rural & tribals around 80% of the population from the developing countries rely on traditional medicines, mostly plant based drugs for their primary health care needs. Also, it is stated that modern pharmacopoeia still contain at least 25% drugs derived from plants and many others which are synthetic analogues built on prototype compounds isolated from plants. The fact that these products are

easily available at affordable prices and sometime the only source of health care

## Chemical Features of Medicinal Plants

Medicinal plants display diverse pharmacological activities (e.g., antimicrobial, adaptive, stimulatory, and sedative properties). They are used as cholagogic, hypotensive, capillary-enforcing, antiulcer, anticholinesterase, anticancer, spasmolytic, analgesic, and analeptic medications. An advantage of medicinal plants is that they provide patients with a complex of natural compounds, have smoother action and are better tolerated than synthetic drugs, and produce few allergic reactions. They do not accumulate and therefore can be administered for a long time. Medicinal plants and phytopreparations are used for therapy and prevention of various human diseases, including cardiovascular, gastrointestinal, nervous, and skin diseases, and even malignancies

## Engineering the plant cell factory for secondary metabolite production

Plant secondary metabolism is very important for traits such as flower color, flavor of food, and resistance against pests and diseases. Moreover, it is the source of many fine chemicals such as drugs, dyes, flavors, and fragrances. It is thus of interest to be able to engineer the secondary metabolite production of the plant cell factory, e.g. to produce more of a fine chemical, to produce less of a toxic compound, or even to make new compounds, Engineering of plant secondary metabolism is feasible nowadays, but it requires knowledge of the biosynthetic pathways involved. To increase secondary metabolite production different strategies can be followed, such as overcoming rate limiting steps, reducing flux through competitive pathways, reducing catabolism and over expression of regulatory genes. For this purpose genes of plant origin can be over expressed, but also microbial genes have been used successfully.

Over expression of plant genes in microorganisms is another approach, which might be of interest for

bioconversion of readily available precursors into valuable fine chemicals. Several examples will be given to illustrate these various approaches. The constraints of metabolic engineering of the plant cell factory will also be discussed. Our limited knowledge of secondary metabolite pathways and the genes involved is one of the main bottlenecks.

## Bioreactors

Bioreactors are vessels designed for large-scale cell, tissue or organ culture in liquid media. Functionally, plant culture bioreactors can be divided into two broad types: those in which the cultures are immersed partially or temporarily in the medium, and those in which the cultures are continuously submerged. Bioreactors provide more precise control of the plant growth gaseous exchange, illumination, medium agitation, temperature and pH than the conventional culture vessels. Bioreactor based propagation of plants can increase rate of multiplication and growth of cultures and reduce space, energy and labour requirements in commercial micropropagation. They can therefore be attractive to developing countries as regards new or expanding plant culture facilities, in combination with a conventional laboratory. However, to be cost-effective, use of bioreactors requires indexed plant cultures, and attention to aseptic procedures during handling of plant material. Hence, the integration of bioreactors into production systems should only be attempted by facilities with skilled and experienced propagators.

## Biotechnology for the production of plant secondary metabolites

Plant cell culture systems represent a potential renewable source of valuable medicinal compounds, flavors, fragrances, and colorants, which cannot be produced by microbial cells or chemical synthesis. Biotechnological applications of plant cell cultures presents the most updated reviews on current techniques in plant culture in the field. The evolving commercial importance of the secondary metabolites has in recent years resulted in a great interest, in secondary metabolism, and particularly in the possibility to alter the production of bioactive plant metabolites by means of cell culture technology. The principle advantage of this technology is that it may provide continuous, reliable source of plant pharmaceuticals and could be used for the large-scale culture of plant cells from which these metabolites

can be extracted. In addition to its importance in the discovery of new medicines, plant cell culture technology plays an even more significant role in solving world hunger by developing agricultural crops that provide both higher yield and more resistance to pathogens and adverse environmental and climatic conditions. This paper describes the callus and suspension culture methods that we have established in our laboratory for the production of bioactive secondary metabolites from medicinal plants.

The production of plant secondary metabolites by means of large-scale culture of plant cells in bioreactors is technically feasible. The economy of such a production is the major bottleneck. For some costly products it is feasible, but unfortunately some of the most interesting products are only in very small amounts or not all produced in plant cell cultures. Screening, selection and medium optimization may lead to 20- to 30-fold increase in case one has producing cultures. In case of phytoalexins, elicitation will lead to high production. But for many of the compounds of interest the production is not inducible by elicitors. The culture of differentiated cells, such as (hairy) root or shoot cultures, is an alternative, but is hampered by problems in scaling up of such cultures. Metabolic engineering offers new perspectives for improving the production of compounds of interest. This approach can be used to improve production in the cell culture, in the plant itself or even production in other plant species or organisms. Studies on the production of terpenoid, indole alkaloids have shown that the over expression of single genes of the pathway may lead for some enzymes to an increased production of the direct product, but not necessarily to an increased alkaloid production. On the other hand feeding of such transgenic cultures with early precursors showed an enormous capacity for producing alkaloids, which is not utilized without feeding precursors. Over expression of regulatory genes results in the up-regulation of a series of enzymes in the alkaloid pathway, but not to an improved flux through the pathway, but feeding loganin does result in increased alkaloid production if compared with wild-type cells. Indole alkaloids could be produced in hairy root cultures of *Weigelia* by over expression of tryptophan decarboxylase and strictosidine synthase. Alkaloids could be produced in transgenic yeast over expressing strictosidine synthase and strictosidine glucosidase growing on medium made out the juice of *Ymphoricarpus albus* berries to which tryptamine is

added. Metabolic engineering thus seems a promising approach to improve the production of a cell factory.

### Why Plant Cell Culture for Pharmaceuticals?

- Historical success and future promise of natural products as therapeutics
- Increasing constraints on bioprospecting and wild biomass collection
- Emerging technologies increase utility as research tool and feasibility for commercial use
- Identification of high-value products with supply problems Success and Promise of Natural Products
- 75% of world population relies on plants for treating illness/ disease
- 25% of U.S. pharmaceutical market from plant-derived compounds, including state-of-the-art drugs, e.g. Taxol
- Only 2% of the >250,000 plant species have been extensively evaluated as therapeutics
- Unparalleled diversity of complex, novel molecular structures constraints on bioprospecting
- Geo-political impediments to access
- Difficulty of reliable resupply
- Unrealistic expectations of many source countries
- Development vs. preservation of biodiversity, disappearance of rainforest, extinction of many species

### Emerging Technologies

- Transgenic plants proteins (Abs, insulin) and Agrobacterium species vectors and Onco gene Guno technology
- Improvements in analytical chemistry, robotics, and micro research
- Improvements in bioreactor design for enhanced mass High Value Products/Supply Problem
- Skikonin and naphthoquinone for skin ailments and as a dye in cosmetic and silk industry
- Paclitaxel (Taxol) and diterpenoid for cancer therapy

### Advantages of Plant Cell Culture

- Environmentally benign
- Faster growth compared to plants
- Controlled, reliable supply of high quality bulk
- Quick response to variability in demand
- Culture conditions controlled easily
- Simplified downstream processing
- Novel metabolites

### In Vitro Propagation Techniques

The biotechnological tools are important to select, multiply and conserve the critical genotypes of medicinal plants by adopting techniques such as micropropagation, creation of somaclonal variations and genetic transformations. Biotechnological tools can also be harnessed for production of secondary metabolites using plants as bioreactors. In vitro propagation involves cell culture systems of a range of ex-plant tissues and mostly micropropagation is achieved from organised tissues by multiplication of meristems and auxiliary buds. In many cases it provides an opportunity to maintain type-to type plant species and the propagation system can produce a large number of plants from a single clone. Plant regeneration from shoot and stem meristems has Yielded encouraging results in medicinal plants like *Catharanthus roseus*, *Cinchona ledgeriana* and *Digitalis* spp. The production of tropane alkaloids by hairy root culture has been resorted in several medicinal plants like *Atropa*, *Datura* and *Hyoscyamus*. Plant cell suspension culture is the selection of variant cell lines for the genetic improvement of plants. High secondary product yields in plant cell cultures of medicinal plants like *Catharanthus roseus*, *Coleus blumei*, *Coptis japonica* and *Panax ginseng* have been reported. Cryopreservation has been used successfully to store a range of tissue types, including meristems, anthers/pollens, embryos, calli and even protoplasts. Cryopreservation is already reported for many medicinal plants like *Rauwolfia serpentina*, *Datura* spp., *Atropa*, *Hyoscyamus* spp. etc. Protoplast fusion or somatic hybridization has been used to bypass the sexual process. The objective is to transfer important genes which can not be transferred through sexual means due to the operation of incompatibility systems. Somatic hybrids between *Atropa belladonna* and *Datura innoxia* were reported which showed higher amounts of tropane alkaloids. Biotransformation of psychotrine cephaline to emetine production from cell cultures of Ipecac needs to be shown economically viable when compared with synthetic process of production of emetine.

Plant cell culture is of importance of improvement of medicinal plants. Complete plants have been regenerated from callus cultures, excised anthers and isolated protoplasts of many medicinal and aromatic plants. Many of the regenerated plants showed somoclonal variation and selections were

made for high active principle yielding cell lines. Protoplast fusion has been plant is regenerated; micropropagation techniques can be used to multiply and clone the desired species. Gene transfer is possible from wild and related species to desired cultivars through wide hybridization including embryo rescue systems. Thus, to sum up, various components of the application of tissue culture technology would be:

- Micropropagation
- Conservation through Cryopreservation
- Bioproduction of value added secondary metabolites
- Biotransformation of bioactive molecules
- Genetic upgradation for improvement
  - Somatic hybridization
  - Somoclonal variations
  - Transgenic plants

The only limiting factor in commercialization of large number of medicinal plants has been the cost of cultivation. As for other annual/biennial crops per acre requirement of planting material is very large, cost of propagule is of major concern. Tissue culture can thus be adopted for species which are:

- difficult to regenerate by conventional methods and the only way to save them from extinction is to propagate them by tissue culture;
- species where population has decreased due to over exploitation and thus initial bulking of the stock can be taken up by tissue culture
- Species which show lot of variability in terms of the active principles with medicinal properties. Tissue culture of selected clones will help in sustainable harvest and fetching better prices both in the domestic and international market.
- Trees with medicinal properties or elites can be identified based on their potential of yielding higher amount of active principle.

Tissue culture protocols have been developed for several plants but there are many more species which are over exploited and need conservation through in vitro techniques. Scarcity of planting material for large number of species is the limiting factor for expanding area under the cultivation.

### Commercial Tissue culture

Commercial application of plant tissue culture started in USA with micropropagation of orchids in 1970s. It has seen tremendous expansion globally from 1985 to 1990 in the number of production units as well as the number of plants produced. With an estimated

global market of 15 billion US dollars per annum for tissue cultured products, even with exponential expansion in the industry, the demand far exceeds production, leaving enough scope for expansion. This industry appears to be undergoing a pause in growth presently in developed countries as it is finding difficult to remain cost-effective. In US, only half the production capacity is being utilized currently due to high labour costs. In developing countries, with lower wage scales, plants are being produced at much cheaper rates. Indian micropropagation industry, though a late starter by almost a decade, compared to its western counterparts, has expanded exponentially from 5 million annual capacities in 1988 to 190 million in 1996. The facilities now created are at par with the best in leading countries like the Netherlands and USA. To remain in profitable business and to earn the much needed foreign exchange, Indian units need to judiciously mix steady revenue generating items with unique specialty items based on demand in domestic and international markets.

### Future directions

While much work has been done on the isolation of new lead compounds and the investigation of bioactive constituents of plants, there are still many avenues to be explored. More representative bioassays need to be introduced with suitable targets. Faster and more efficient dereliction techniques are continuously being sought for.

Some Challenges for the Future of the Natural Product Sciences

- Catalog and preserve the bio- and chemo-diversity of the rainforests and the oceans
- Catalog the eco- and ethno-information on plants and their products
- Maintain equitable access to the biome and assure intellectual property rights
- Develop medicinal plant germ banks
- Develop integrated global information systems on medicinal plants
- Develop medicinal plants in a sustainable manner
- Enhance drug discovery technology in the areas of automation, genomics, and bioassay targets
- Develop genomics-based, in-field bioassays
- Optimize the chemical diversity of natural products
- Produce vaccines and drugs in fast growing secondary sites

- Assure the safety and efficacy of traditional medicines
- Develop integrated global alliances for plant product development
- Develop the facilities, the infrastructure and the personnel to conduct the above programs

### Natural Products in Drug Discovery – the Future

It is appropriate to consider what must be the role of natural products in health care systems globally for the next fifty years. For the past fifty years we have forgotten an important axiom: that what we do for drug discovery and natural products is of prime significance for our descendants, not for us. We must be sure to leave these generations the tools for their health care. Chemicals and chemical reagents are typically a non-renewable resource, and their use depletes our future resources. Consequently, a fundamental precept for all drug discovery programs, be they synthetic or natural, must now be the concept

of sustainability. Considering our future situation with respect to plant drugs, we can observe some striking polarities. There is a global population which is anticipated to reach at least 9 billion by 2050, and a rapidly increasing technology base in the areas of automation and biological assessment. By contrast, bio- (and therefore chemo) diversity in the world's hardwood forests is being irreversibly degraded at an alarming rate. And finally, oil stocks, a staple for the production of synthetic drugs, are projected to last only another 70-75 years at current rates of usage. In exploring facets of the future focus of natural products in the drug discovery process in particular, there are six aspects:

- i) Access to the biome,
- ii) Acquisition and analysis of traditional knowledge and on-going research,
- iii) Biotechnology development,
- iv) safety and efficacy of plant medicinal agents,
- v) Dereliction studies, and
- vi) Natural product structure diversification



# Soil Fertility Evaluation and Maintenance of Soil Quality

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Soil fertility has been considered in the past in a restricted sense as a physico-chemical phenomenon or as an index of available nutrients for plants, but the modern usage of the term connotes the capacity of the soil to produce crops of economic value to man and maintain the quality of soil for long term sustainable use. Therefore, any system soil fertility management will ultimately consider all aspects of soil-plant relationships and pollution of the environment as well. Soil fertility evaluation may be defined as the soil system's nutrient supplying capacity. It helps in adopting appropriate measures for overcoming various limitations and at the same time ensures optimum crop production.

Soil testing and plant analysis both are important tools for making fertilizer recommendations to crops. In case of soil testing, it will give a measure of the available nutrient status while plant analysis indicates actual removal of nutrients from the soil system. In addition to these, some other important facets of soil fertility evaluation and soil quality are being discussed in this chapter.

It is evident that the fertility problem cannot be met up by mere supply of plant nutrients but their efficient management has also to be given a due thought as a fertilizer being one of the earliest inputs a well balanced scheduling for optimizing levels of fertilizers to derive maximum remunerative returns.

## Techniques employed for assessing the soil fertility status:

There are usually four techniques used for the soil fertility evaluation namely,

- i) Nutrient deficiency symptoms of plants
- ii) Plant analysis
- iii) Biological tests where higher plants and certain micro-organisms are used
- iv) Chemical soil tests

### **Nutrient deficiency symptoms**

In this technique plants act as integrators of all growth factors. The appearance of abnormalities in the growing plants is caused by a deficiency of one or more nutrient elements. The visual method of evaluating

soil fertility is good because it involves no expenditure and no laboratory tests. Nutrient deficiency symptoms may be classified as follows:

- i) Complete failure from the beginning of the crop growth i.e. at the seedling stage
- ii) Stunting of crop growth
- iii) Nutrient specific leaf symptoms
- iv) Internal abnormalities within the plant body
- v) Delayed or off time maturity
- vi) Yield reduction without exhibiting deficiency symptoms on plants
- vii) Poor quality of crops

## Hidden Hunger

Hidden hunger may be defined as to a situation in which a crop requires more of a given nutrient element without exhibiting deficiency symptoms on plants. The concentration of an element is above the deficiency level but still considerably below that required to permit the most profitable crop performance.

### Critical limits:

There are two critical limits- lower critical limit and the upper critical limit. The lower critical limit is defined as that concentration of a nutrient element in plant or soil below which the plant can not complete its life cycle. The upper critical limit refers to that concentration above which the sufficiency range sets in. Hidden hunger may be eliminated by performing plants and soil testing which are useful for planning or modifying plant nutrient programmes for the subsequent crops.

## Seasonal Effects

Deficiency of nutrients in soils also results due to variation in weather and climatic conditions. As for an example, in drought and excessive moisture or unusual temperature very frequently affect the uptake of nutrients adversely which in turn results deficiency of nutrients on plants.

## Plant Analysis:

There are generally two types of plant analysis, i) Tissue testing-which involves testing of fresh tissues in the field and ii) total analysis which involves tests in the

laboratory with the help of instruments and reagents; it is a cost involving method. The total plant analysis is more accurate compared to tissue testing.

### Reasons for tissue tests and plant analysis:

- i) To help in determining the nutrient supplying power of the soil.
- ii) To help identify the deficiency symptoms and even more important, to determine nutrient shortages days or weeks before they appear.
- iii) To determine the effect of fertility treatment on the nutrient supply in the plant.
- iv) To study the relationship between the nutrient status of the plant and crop performance.
- v) To survey large areas.
- vi) To create interest among peoples about sound soil testing programmes.

### Soil Quality:

Soil quality is used to describe the ability of soil to perform the following functions:

- i) Supporting the growth and diversity of plants and animals by providing a physical, chemical and biological environment for the exchange of water, nutrients, energy and air
- ii) Regulating the distribution of rain or irrigation water between infiltration and runoff, regulating the flow and storage of water and solutes, including nitrogen, phosphorus, pesticides and other nutrients and compounds dissolved in the water
- iii) Storing, moderating the release of and cycling plant nutrients and other elements
- iv) Acting as a filter to protect water quality, air and other resources and
- v) Supporting structures and protecting archeological treasures.

The USDA Natural Resources Conservation Service defines soil quality as "The capacity of specific kind of soil to function, within natural or managed ecosystem boundaries to sustain plant and animal productivity, maintain or enhance water and air quality, and support human health and habitation. Changes in the capacity of soil to function are reflected in soil properties that change in response to management or climate"

Maintaining the functions of soil is thus central to the achievement of sustainable development. However, no soil is likely to provide all those above functions, some of which occur in natural ecosystems and some of which are the results of human modifications. Soils have an inherent quality as related to their physical, chemical and biological properties within

the constraints set by climate and ecosystems, but the ultimate determinant of soil quality is the land manager. Perceptions of what constitutes a good soil vary depending on individual priorities with respect to soil function, intended land use and interest of the observer. The assessment of soil quality can be viewed as a primary indicator of the sustainability of land management.

### Soil Quality Assessment:

Basically, two types of approach are employed for evaluating the sustainability of a management system: a) comparative assessment and b) dynamic assessment. A comparative assessment is one in which the performance of the management system is evaluated in relation to alternatives at a given time only. In contrast, in a dynamic approach, the management system is evaluated in terms of its performance over time. However, soil is not directly consumed by humans and animals, and it is difficult to relate measurable soil quality indicator properties to specific soil functions or management goals. The assessment of soil quality or health has been likened to a routine medical examination for a human being, when a doctor measures a number of key parameters as basic indicators of overall system function. Because soils perform many simultaneous functions, however, the objectives of relating indicator properties to specific functions or processes are very difficult.

Over last several years, researchers and farmers alike have tried to establish what are now widely called minimum data set of physical, chemical and biological properties that can be used as quantitative indicators in soil health assessments. Indicator properties that are frequently used are presented in table 1.

**Table 1. Soil quality indicator properties**

Physical properties	Chemical properties	Biological properties
Bulk density	Soil reaction or pH	Microbial biomass carbon
Rooting depth	Electrical conductivity	Microbial biomass nitrogen
Water infiltration rate	Cation exchange capacity	Earthworms
Water holding capacity	Organic matter	Enzymes
Aggregate stability	Mineralisable nitrogen	Disease suppressiveness
	Exchangeable potassium	
	Exchangeable calcium	

Characterization of soil health using these indicators can be quite time consuming and expensive, and is not

feasible as a general practice for everyone. A number of soil health scorecards have also been developed as qualitative tools for characterizing soil health.

Soil organic matter (SOM) content is frequently identified as a primary attribute of soil quality assessment. SOM influences many soil properties including infiltration rate, bulk density, aggregate stability, cation exchange capacity, and biological activity, all of which are related to a number of key functions. SOM serves as a slow release reservoir for plant macronutrients especially nitrogen and also helps in plant micronutrient nutrition. It facilitates the infiltration of water and air into the soil, increases water retention by the soil, and it's important in maintaining soil tilt. Over time, increases in SOM can lead to a greater and more diverse population of soil micro-organisms and may thus enhance the biological control of pests and plant diseases. Large quantities of fresh organic matter that are added to the soil, however, may stimulate plant pathogenic organisms and seed and seedlings pests such as cabbage maggots and wireworms, which can cause serious losses.

#### Methods for calculating soil quality:

Among methods, the following two methods are generally used for calculating soil quality indices i) Statistical and ii) Conventional methods.

Statistical: Soil quality indicators so determined are to be reduced to a minimum data set (MDS) through a series of uni- and multivariate statistical methods using SPSS 10 software. Both parametric (Randomised Block Design) as well as nonparametric statistics (Kruskal-Wallis  $\chi^2$ ) are to be used to identify quality indicators with significant treatment differences. Only variables with significant differences between treatments are to be chosen for the next step in MDS formation. For each statistically significant variable Principal Component Analysis (PCA) may be performed. Within each principal component, only highly weighted factors i.e those with absolute values within 10 % of the highest weight, are to be taken for the MDS. For the reduction of redundancy and rule out spurious groupings among the highly weighted variables within each principal component, the multivariate correlation co-efficients may be used to determine the strength of relationships among variables. Well correlated variables are to be considered as redundant and also for the elimination

from the data set. Summing up absolute values of well correlated groups, the highest correlation sum is the best representing group. Apart from this, any non-correlated highly weighted variables are also to be considered important and retained in the MDS.

#### MDS validation:

Multiple regression analysis using final MDS components as independent variables and each management goal attribute as a dependent variable is to be made. These regressions serve to check the MDS representation of management system objectives.

#### Indicator transformation (Scoring):

After determining variables for MDS, every observation of each MDS indicator needs to be transformed for the inclusion in the soil quality index (SQI). Linear scoring technique may be used. However, soil quality indicators are to be ranked in ascending or descending order depending on whether a higher value a higher value considers "good" or "bad" with respect soil functions. For more is better indicators, each observation divides by the highest observed value such that the highest observed value receives a score of 1. For less is better indicators, the lowest observed value divides by each observation such that the lowest observed value receives a score of 1.

#### Indicator integration into indices:

Two soil quality indices may be used for comparison: an additive SQI and a weighted additive SQI. The additive index is the summation of scores from MDS indicators. From the summed scores, the additive soil quality index treatment means and standard deviations are to be calculated. In the weighted additive index after transformation, the MDS variables for each observation are to be weighted based on PCA results. Each PC explains a certain amount of the variation in the total data set. The percentage is to be standardized to unity, provided the weight for variables chosen under a given PC. Then summing up the weighted MDS variable scores for each observation and calculated the treatment means and standard deviations. For all the indexing methods, SQI scores for the management treatment are to be compared using a two way ANOVA. Higher index scores are considered to be a mean better soil quality.

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