ISSUE No. 37

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

This Issue dedicated to IPA Convention 2017-18

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2018

Delvin Formulations

Destiny for Innovation

Moving Globally

- R & D and Manufacturing of API
- R & D and Manufacturing of Formulations
- International Marketing
- Domestic Marketing
- Medical Devices
- Surgicals

Our Group of Companies

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We wish all our readers a very **HAPPY TAMIL NEW YEAR.**

We are happy to publish the 37th issue of Pharma Web Newsletter for **Jan – March 2018.**

This issue dedicated to Indian Pharmaceutical Association, National Convention 2017 – 18 held in Chennai on **10th & 11th February 2018** at B. S. Abdur Rahman Crescent Institute of Science And Technology, Vandalur.

The Indian Pharmaceutical Association National Convention envisaged the theme **"PHARMA VISION 2030: Planning the Future"**. The main aim of Pharma vision 2030 is to achieve the enhancement of production of Pharmaceuticals $ 35 to 130 billion, to achieve this target two days scientific sessions were held, eminent speakers from Industry, Academicians, Research Scientist and Regulatory officials participated in the conference and delivered lectures. The foremost important lecture was given by Dr. B. Suresh, President, Pharmacy Council of India, about the broad outline of Pharma Vision 2030.

This issue consists of the all the lectures held in the convention programme. The convention was well attended by more than 2000 delegates. This issue covers all the important lectures, events and also Photos. The important outcome of the conference is narrated as summery in this issue. We thank for Mr. J. Jayaseelan & Mr. T. Sathish, for providing the article and Photos for publication.

We are very much thankful to M/s. Fourrts (India) Laboratories Pvt. Ltd., M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,
R. NARAYANASWAMY
Chief Editor

INDIAN PAHRMACEUTICAL ASSOCIATION
NATIONAL CONVENTION 2017 – 18

Indian Pharmaceutical Association, Tamilnadu Branch conducted IPA National Convention 2017 – 18 on 1**0th & 11th February 2018** at Dr. B. S. Abdur Rahman Crescent Institute of Science and Technology, Vandalur, Chennai on the theme of **"Pharma vision 2030: Planning the Future".**

The members of the core committee for the convention were: Chairman - Dr. S. Manivannan, IPA Convention Co-coordinator – Mr. J. Jayaseelan, Secretary – Mr. T. Sathish, Treasurer – Mr. Rajesh H Bhandari, Co-Chairman's – Mr. R. Narayanaswamy, Mr. R. Sabapathy, Mr. M. M. Yousuf & Dr. B. Jayakar.

On 10th February 2017 morning, the convention was inaugurated by chief guest **Dr. S. R. Rao**, Senior Adviser, Department of Biotechnology, Ministry of Science and Technology, Govt. of India. **Dr. B. Suresh,** President, Pharmacy Council of India, Vice Chancellor, JSS University, Mysore, **Shri. Abdul Qadir Abdul Rahman Buhari**, Chancellor, B. S. Abdur Rahman, Crescent Institute of Science and Technology and Dr. Rao Vadalamudi, President, Indian Pharmaceutical Association, were Guest of Honour's

Dr. S. Manivannan, President – IPA TN Branch, and Chairman, IPA Convention 2017 – 18, welcomed the members, Mr. J. Jayaseelan, Vice President – IPA TN Branch, Convener, IPA Convention 2017 – 18 briefed about the convention, Dr. B. Suresh, President, Pharmacy Council of India, Vice Chancellor, JSS University, Mysuru, spoken about the theme "Pharma vision 2030: Planning the Future". Dr. Rao Vadalamudi, President, Indian Pharmaceutical Association, Dr. K. Bangarurajan, Joint Drugs Controller (India), CDSCO, New Delhi, Shri. K. Sivabalan, Director of Drugs Control, Tamilnadu, Shri. S. V. Veerramani, Immediate National Past President, IDMA, Shri. Abdul Qadir Abdul Rahman Buhari, Chancellor, B. S. Abdur Rahman, Crescent Institute of Science and Technology gave their address. Chief Guest Dr. S. R. Rao, Senior Advise, Department of Biotechnology, Ministry of Science and Technology, Govt. of India gave his address. Mr. T. Sathish, Secretary, IPA TN proposed vote of thanks.

Registration : Around 2000 delegates including students, Faculties, Industrialists and Regulators participated in the convention.

Cultural : On the inaugural day evening Cultural program was organized and the various pharmacy colleges participated and entertained all.

Valedictory Function : The valedictory function was held on the afternoon of Sunday, 11th February 2018 that was presided over by Dr. Rao Vadalamudi, President, Indian Pharmaceutical Association. Dr. V. K. Subburaj, IAS (Retd), Former Secretary, Department of Pharmaceuticals, Govt. of India, was the chief guest of the function. The guest of honor was Prof. K. Chinnaswamy, President, Tamilnadu Pharmacy Council.

Scientific Table

Program Schedule - Day 1: Saturday, Febrauary 10, 2018

Venue: Convention Hall, B. S. Abdur Rahman Crescent Institute of Science & Technology, Vandalur, Chennai

10.35 -12.30 PM	Inaugural Session & Theme Address	
	Pharma Vision 2030:Planning the Future	by Dr. B. Suresh

Session Time	Name of the Speaker	Topic of the Presentation	Name of the Chair Persons
Track 1 - IPA's Oration Lecture			
12.30 -1.00 PM	Dr. T. V. Narayana, Chairman, Educational Division, Indian Pharmaceutical Association, Mumbai & Secretary, Indian Pharmaceutical Congress Association.	Pharma Vison 2030: Educational Perspectives	Dr. K. Chinnasamy, President, Tamil Nadu State, Pharmacy Council, Chennai & Dr. VSV Rao Vadlamudi, President, Indian Pharmaceutical Association, Mumbai & Common Wealth Pharmaceutical Association
1.00 -2.00 PM	Lunch		
Track 2 - Industry Session			
2.00 -2.15 PM	**Opening Remarks**		
2.15 -2.30 PM	**Shri. Annasamy Vaideesh,** President - OPPI; Vice President, South Asia & Managing Director, India, M/s.Glaxosmithkline Pharmaceutical Ltd., Mumbai	Pharma Vison 2030: Global Perspectives	Mr. S.V. Veerramani, CMD, M/s. Fourrts India Laboratories Pvt. Ltd., , Chennai & Immediate Past President, IDMA & Shri. Kaushik Desai, Hony . Secretary, Indian Pharmaceutical Association, Mumbai
2.30 - 2.45 PM	**Shri. Tushar A Korday,** Director of M/s.Emil Pharmaceutical Industries Pvt Ltd., Mumbai	Pharma Vision 2030: Role of SME's	
2.45 -3.00 PM	**Shri. Rajiv Gulati,** Founder & CEO, M-Chemist	Pharma Vision 2030: Future of Pharmaceutical Marketing	
3.00 -3.15 PM	Panel Discussion		

Session Time	Name of the Speaker	Topic of the Presentation	Name of the Chair Persons
Track 3 - Regulatory session			Dr. B. Suresh, President, Pharmacy Council of India, New Delhi & Dr. S. Manivannan, DDC, CDCSCO, New Delhi & LOC Chairman – IPA Convention, Chennai
3.15 - 3.30 PM	Opening Remarks		
3.30 - 4.00 PM	Dr. S. Eswara Reddy, Joint Drugs Controller (India)	Pharma Vision 2030: Import, Export Registration of Drugs & Medical Devices	
4.15 PM	Dr. K. Bangarurajan, Joint Drugs Controller (India), CDSCO, New Delhi	Pharma Vision 2030 : Prospects of Clinical Trials in India and Developing Strategies	
4.15 - 4.30 PM	Shri. C. Venkataraman, Director - Corporate Support, Lupin Ltd.	Pharma Vision 2030: Future of Pharmaceutical Pricing	
4.30 -4.45 PM	Dr. R. K. Sanghvi, Chairman - Nutraceutical & Medical Committee, IDMA Mumbai.	Future and Growth of Nutraceuticals & its Regulations towards the emergence of Pharma vision 2030	
4.45 - 5.00 PM	Panel Discussion		

Session Time	Name of the Speaker	Topic of the Presentation	Name of the Chair Persons
Track 4 – Education Session			Dr. B. Jayakar, Registrar, Vinayaga Missions University, Salem Shri. T. Jayapal Reddy, Director ,St.Peters Institute of Pharmaceutical Sciences, Warangal & Dr. T. K. Ravi, Advisor, Scientific Committee, IPA Convention, Chennai
5.15 - 5.30 PM	Opening Remarks		
5.30 -5.45 PM	Dr. George Patani, Chairman - Industry institution Interaction & Director, Inga Labs	Strengthening of Industry-Institute Interaction to meet Pharma Vision 2030	
5.45 -6.00 PM	Dr. Vijaya Sagar, Professor & Head, Dept of Anatomy, Sri Ramachandra Medical College & University	E-Learning : Strategies for Implementation In the Indian Scenario	
6.00 -6.15 PM	Panel Discussion		

06.30 to 08.00 PM Culturals

Program Schedule - Day 2: Sunday, Febrauary 11, 2018

Session Time	Name of the Speaker	Topic of the Presentation	Name of the Chair Persons
Track 5 – Pharmacy Practice Session			Dr. S. Anandan, Dean, Sri Ramachandra Medical College & Research Institute, Chennai & Shri. T. Sathish, Hon. Secretary IDMA & IPA, Organising Secretary, IPA Convention, Chennai
9.00 – 9.15 AM	Opening Remarks		
9.15 - 9.30 AM	Dr. S. Sriram, Professor and Head, Department of Pharmacy Practice, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore.	Pharma Vision 2030: Professionalism in Clinic Intervention	
9.30 - 9.45 AM	Dr. Ganachari, Professor & Head, Dept of Pharmacy Practice, KLEU's College of Pharmacy, Belgaum.	Pharmacists in Clinical Trials : Transformation of Skills for effective Patient Care	
9.45 -10.00 AM	Dr. M. Suresh Kumar, Professor, Research Director & Coordinator- TIFAC CORE Herbal Drugs JSS College of Pharmacy, Ooty	Precision Pharmacy by 2030 : A Smooth or Bumpy Road Ahead	
10.00 -10.15 AM	Panel Discussion		

Session Time	Name of the Speaker	Topic of the Presentation	Name of the Chair Persons
Track – Other Session			Mr. R. Thiruvengadam, Joint Managing Director, Tablets (India) Limited, Chennai & Shri. J. Jayaseelan, Chairman IDMA-TNPKSB & IPA Convention Coordinator
10.30 – 10.45 AM	Opening Remarks		
10.45 -11.00 AM	Dr. Gopakumar G. Nair, Past President & Chairman – IPR Committee, IDMA Mumbai.	Pharma Vision 2030 - Futuristic Aspect on Patents	
11.00 -11.15 AM	Dr. V. Kalaiselvan, Principal Scientific Officer,Indian Pharmacopeia Commission.	Pharma Vision 2030 - Pharmacoviligance	
11.15 -11.30 AM	Shri. Shailesh Patel, Director, Medikoe Mumbai.	Digital Healthcare, New Age Pharmacies & Patient Centricity	
11.30 – 11.45 AM	Panel Discussion		

11.45 - 1.30 PM

Valedictory ceremony followed by Vote of Thanks

(Summing Up of Pharma Vision 2030 by Shri. J. Jayaseelan, Chief Guest: Dr. V. K. Subburaj, IAS;

Guest of Honour: Dr. K. Chinnasamy)

Indian Pharmaceutical Association - National Convention 2017-18

Venue

Welcome address by Dr. S. Manivannan

Inauguration of IPA Convention

Inauguration of IPA Convention

Overview of IPA Convention by Mr. J. Jayaseelan

Address on the Theme by Dr. B. Suresh

Felicitation Address by Mr. S. V. Veerramani

Guest of Honour address by Mr. Abdul Qadir Abdul Rahman Buhari

Release of Souvenir

Chief guest address by Dr. S. R. Rao

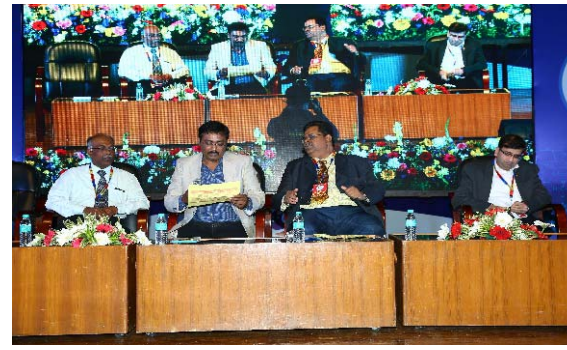
Audience

Audience

IPA's Oration Lecture

Scientific – Industry Session

Scientific - Regulatory Session



Scientific – Education Session

Scientific – Pharmacy Practice Session

Scientific – Other sessions

Cultural

Cultural

Felicitation of Judge's of Cultural

Valedictory

Address by Prof. Dr. K. Chinnaswamy

Valedictory

INDIAN PAHRMACEUTICAL ASSOCIATION
NATIONAL CONVENTION 2017 – 18

Summary

PHARMA VISION 2030:

Envisage increasing the Pharma industry turnover from the present $ 35 to 130 billion. To achieve the target, the 5 facets of Pharmacy profession namely, Pharmaceutical Industry, Pharmacy Education, Regulatory Affair, Pharmacy Practice, and Innovation need to co-ordinate each other.

PHARMACEUTICAL INDUSTRY

Investments need to be made for sustainable development and develop clusters that support need of the industry and to promote competitive environment and to provide level playing ground to the Indian Industry to compete globally. To shift towards knowledge driven evidence based innovation in Medicines and Biologics. In order to improve the manufacture of API production, Government needs to provide land and pollution treatment issues. Govt. need to support the API production units to reduce the cost of production in order to compete with the Chinese production. Industry need to invent more new drugs and also production of generic drugs and to become leader in biological route.

PHARMACY EDUCATION

Develop competent Human Resources to ensure safe and rational use of Medicine, to implement dynamic curriculum. Collaborate with Pharmaceutical Industry Research and providing quality medicine at affordable cost. The Research & Development and qualified teachers are to be encouraged in the institutions. In order to have a proper education control Govt. may avoid dual control. The education institution may induct part time faculties from industries. To train Pharmacy students with latest technologies and to make them as experts in Pharmaceutical and Biotechnology Science. To become a global destination for Pharmacy education by making our Curriculum at par or better than the international Curriculum.

REGULATORY

Realistic and effective Rules & Regulations and Harmonization with other countries regulation are to be implemented. The intellectual property rights, evaluation of regulatory effectiveness including training the stake holders for effective compliance of regulatory requirements are to be accelerated. It is foremost important to implement all the regulatory requirements through online process by all states as well as Central Govt. Further the regulation should be more transparent. Regulatory control should include Pharmaceutical drugs, Biological, Veterinary drugs, Natural drugs, Medical device and CRO etc. This can be achieved by including experts of respective field in to the regulatory stream.

PHARMACY PRACTICE

The Pharmacy Practice should be on team based inter-professional Pharmaceutical care and responsibility to be given to the Pharmacist for efficient, safe and effective delivery of medication. The Clinical information system needs to be improved. By 2030 we should make the minimum qualification for practicing Pharmacists at least to B Pharm Degree. To ensure that "Drugs are not sold but dispensed" professionally by pharmacists by proper pharmacy practice.

RESEARCH & INNOVATION:

To invest in research infrastructure, collaborate, increase in spending in R & D, access to industry with Research Intuitions and Academic.

PHARMA POLICY / GOVERNMENT ROLE

To create an environment this should provide quality medicines at affordable price. Support the Industries with growth driven policies and to encourage Innovation and R & D. To create science based legal environment to deal with patent issues.

ARTICLES

PHARMA VISION 2030: PLANNING THE FUTURE

by

Dr. B. Suresh,
Vice Chancellor, JSS University, Mysore
President, Pharmacy Council of India New Delhi

Pharma Vision 2020

'In the year 2020, Pharmacists and Pharmaceutical scientists working within various disciplines of Pharmacy will be established and recognized as the medicines expert and an expert in health promotion and disease prevention.'

Mission 2020

'To optimize health of all members of society through the promotion of safe, effective and rational medicine use, patient counseling and monitoring of disease management (through pharmaceutical care).'

Pharma Vision 2020

Have we realised yet our Vison 2020?

How far are we from our goal?

What needs to be done?

India can realise Pharma Vision 2020 and emerge as a leader in drug production if it accomplished a few "missions" essential to achieve the goals, including increasing the pharma industry's turnover from the present $17 billion to $100 billion in the next 10 years.

Dr APJ Abdul Kalam
10th June, 2010

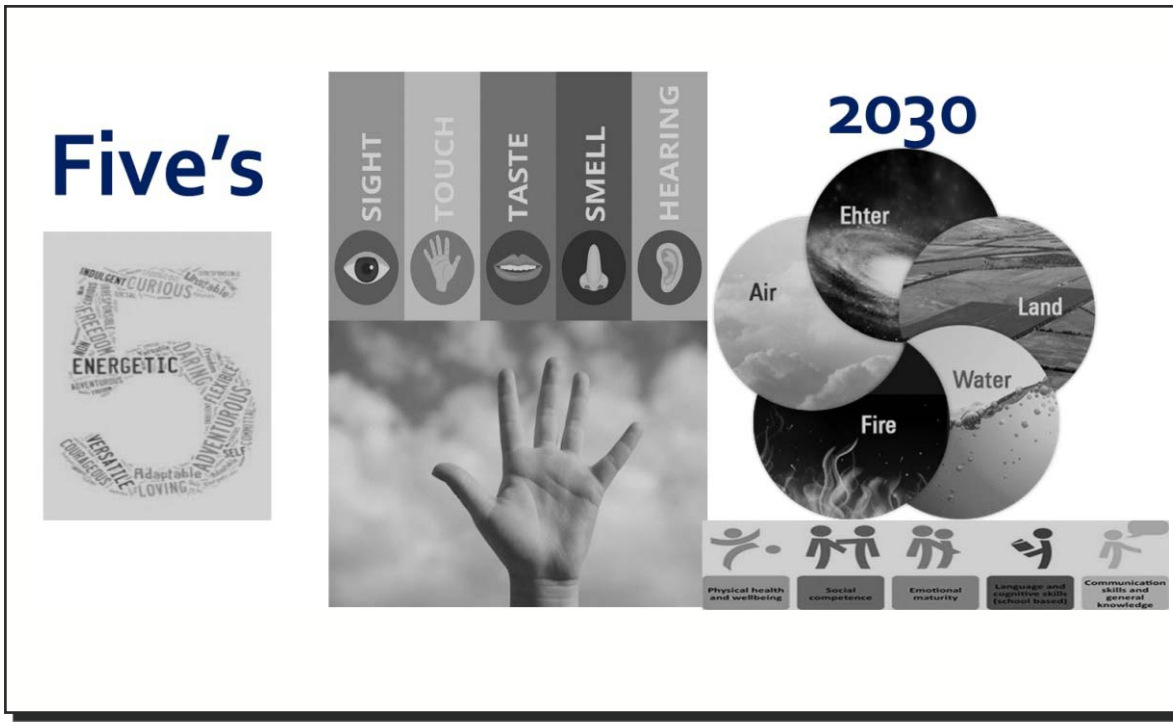
What Could the Role of the Pharmacist be in the Future?

PHARMACY PRACTICE

Pharmacists will bear responsibility for the initial assessment of patients to inform the choice of medication, as well as the continual monitoring of the clinical performance and adverse effects of the medicines, making adjustments to dose and drug to optimise their safe and effective use

PHARMACEUTICAL INDUSTRY / SCIENCES

The Pharmaceutical Industry of India will emerge as a leading destination for drug discovery and innovation and achieve the distinction of being the world's preferred supplier of low-cost generic medicines signifying the Made-in-India brand in therapeutics and Biomedical Innovations with the highest standards of quality and sustainability at a scale unprecedented in the history of medicine.



Five Facets of Pharmacy Profession

Pharma Vision 2030: Pharmacy Practice

Hospital and Clinical Pharmacy

- Team-Based "Interprofessional" Pharmaceutical Care
- Responsibility for therapeutic outcomes given to and accepted by pharmacists
- Clinical Information Systems
- Evidence-Based Drug Therapy
- Outcomes Driven, Cost Effective

Pharma Vision 2030: Pharmacy Practice

Community Pharmacy Practice

- Efficient, safe, and effective delivery of services.
- Improving patient medication use, health, and wellness
- Collaboration with physicians and other health care providers
- practice information systems and technology that support patient care services, medication safety, and medication fulfilment
- continuous quality improvement

The Pharma Success Pill

- Have the ability to grow and increase output in tough economic times and provide high-wage, good quality jobs
- Be innovative and deploy the latest technology to generate competitive advantages
- Generate significant exports; create a strong supply-chain that drives further economic growth
- Encourage capital flow with sustained growth
- And be profitable and provide funds for reinvestment into the R&D cycle.

Pharma Vision 2030: Pharmaceutical Industry

Therapeutics

- The development of regulatory ecosystem that stimulates the Pharmaceutical industry to invest in sustainable development of the sector.
- Development of clusters that support the needs of the industry
- Promoting a competitive environment and provide level playing ground to the Indian industry to compete globally

Pharma Vision 2030: Pharmaceutical Industry

Biomedical Innovation

- Catalyse convergence of technologies and fields biology, engineering, IT, synthetic biology, nanotechnology.
- Mandate digitisation of biomedical and health data, information and knowledge
- Provide access to multiple sources of data and to make these interoperable.
- The shift towards knowledge-driven, evidence based innovation in medicine and biology.
- Development of platform technologies/ standards as globalisation accelerates

Pharma Vision 2030: Regulatory Affairs

Policy Research & Innovation

- Realistic and effective rules and regulations
- Harmonisation of regulations
- Intellectual property and Trade agreements
- Controlling alternative and illegal distribution channels (counterfeit and spurious drugs)
- Evaluation of regulatory effectiveness.

Pharma Vision 2030: Regulatory Affairs

Global Regulatory compliance

- Comply with regulatory requirements with regions
- Act on changes and updates
- Track and understand the changes
- Provide training for stakeholders to ensure compliance
- Provide regulatory input before and during inspections

Pharma Vision 2030: Research and Innovation

Research Environment

- Invest in research infrastructure
- Nurture human resource that that can drive research environment
- Collaborate
- Catalyse spending in R & D
- Capitalise on the unique resources and heritage.

Pharma Vision 2030: Research and Innovation

Research Infrastructure

- Industry academia collaboration
- Pooling and sharing of resources
- Identification of thrust areas and areas of national importance
- Access to national research funding

Pharma Vision 2030: Pharmacy Education

Pharmacy Practice

- Nurture and develop a competent human resource that can provide pharmaceutical care that ensures safe and rational use of medicines
- Innovate, ideate and implement a dynamic curriculum that supports life long learning

Pharma Vision 2030: Pharmacy Education

Pharmaceutical Sciences

- The Pharmaceutical sciences that are contemporary with the pace of the growth and the needs of the Pharmaceutical Industry that supports its vision to evolve as a world leader in providing quality medicines at affordable costs

Announcing shortly the –

Pharma Vision 2030 : The Charter and Roadmap

VISION 2030

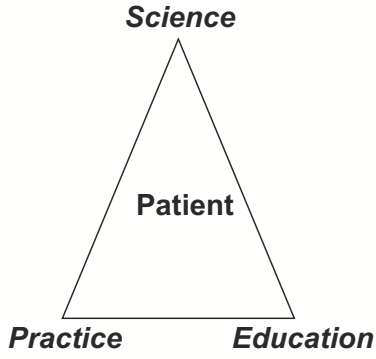
PHARMA VISION 2030: PLANNING THE FUTURE

by

Dr. T.V. Narayana,
Chairman, IPA Education Division

- Practiced since ages –
  --- colonial period – 18th century
  --- during 2nd world war
- People were trained to treat wounded soldiers and called compounders.
- Selected people were trained at MMC and Bengal Medical college

3 Areas of Pharmacy Profession



Pharma Industry

- No Manufacturing units
- Import Dependent Industry till Independence
- Started with 10 crore INR in 1947
- 1st Industry- Days Chemicals, Kolkatta

The Indian Pharmaceutical Industry

- Over 23,000 units
- 260 organized sectors
- 6,000 to 8,000 small scale sectors with more than 60,000 formulations
- Highly fragmented with market share < 6%
- Top ten accounts for 49% globally

IPA CONVENTION 2018

Pharmacy Profession in India:

UG Programme Started from 1939

No changes for 79 yrs

No Vision & Mission

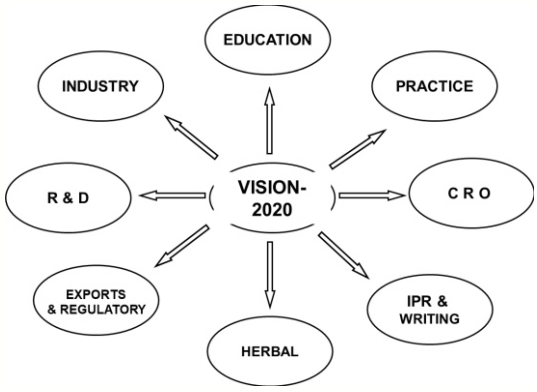
His Excellency Dr. A.P.J. Abdul Kalam, President of India, releasing the Charter for Pharma Vision 2020 on 17th December 2003 at Chennai during 54th Indian Pharmaceutical Congress with PCI & IPA Presidents

THE VISION- 2020

By the year 2020, Pharmacists and Pharmaceutical scientists working in various disciplines of pharmacy will be recognized as experts in medicine, health promotion and disease prevention.

THE MISSION- 2020

To improve the health of all members of society through the promotion of safe, effective and rational use of medicine, patient counseling and monitoring of disease management through proper pharmaceutical care



PHARMA INDUSTRY: VISION – 2020

The Indian pharmaceutical industry shall ensure that essential drugs at affordable prices are available to the vast population of this sub-continent and also continue to provide employment for millions

PHARMA R & D : VISION – 2020

The pharmacy profession shall provide intellectual capital to make available safe, cost-effective, contemporary, quality therapeutics to the people of India, to help reduce percentage of mortality and morbidity and to emerge as a significant player in the global market

PHARMA CRO : VISION – 2020

The pharmacy profession will make the clinical trial industry in India to grow to over a billon dollars over the next five years and position itself as a destination of choice for CRO services by way of strict implementation of patent laws, single window clearance of clinical trial protocols by regulatory Agencies and shall accord “industry status” to this sector

PHARMACEUTICAL EXPORTS : VISION – 2020

- Major global player in the field of pharmaceutical exports and as a provider of quality medicines at low costs.
- Provide leadership to developing countries in combating their health care issues.
- Emerge as a major player in the generic drugs market in USA and Europe

HERBAL DRUGS : VISION – 2020

Attain new heights in herbal drug research by shaping Indian systems of medicine into a popular system of medicine of the future for holistic health care and ensuring health care for all especially for the welfare for the poor

PHARMACEUTICAL REGULATION : VISION – 2020

Implement all the rules and regulations, which guide, monitor and control the activities of the providers of the healthcare system in the country and shall examine the way to bring them up to international standards.

PHARMACEUTICAL IPR : VISION – 2020

- Indian Patents Act should ensure that it does not exceed the requirements of TRIPS
- Prioritizes access to medicines and public health, while retaining the right to participate in the compulsory license scenario
- Lead a movement of developing nations and create a TRIPS south and G-20 alliance

PHARMACEUTICAL WRITING : VISION – 2020

- Understanding the basis and rules of editing medical documents
- Knowing how academic medical articles are constructed
- Mastering the rules of scientific evidence
- Understanding and interpreting bio-statistics
- Commanding a thorough knowledge of medical nomenclature

PHARMACY EDUCATION : VISION – 2020

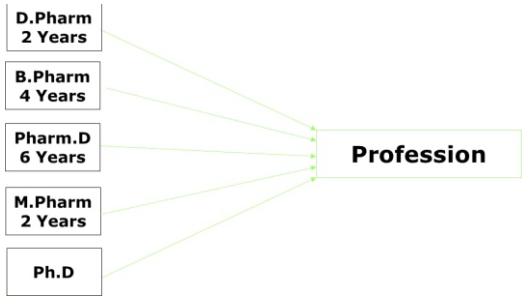
"Preparing the Future Pharmacist" (Vancouver 1997): identified roles and responsibilities (8 star)

- Care giver
- Decision maker
- Communicator
- Leader
- Manager
- Life-long learner
- Teacher
- Researcher

PHARMACY EDUCATION : VISION – 2030

- Pharmacy education traditionally has been industry and product oriented. In India.
- There has been a surge in the number of institutions offering Pharmacy degrees at various levels and a practice oriented Doctor of Pharmacy (Pharm D) Program.

Present levels of Pharmacy Education in India



Present registrable qualifications under the Pharmacy Act 1948 : Pharm D., B. Pharm, D. Pharm (minimum qualification)

Source : PCI

IPA CONVENTION 2018

Planning the future

Pharmacists are health care professionals whose of advances in the pharmaceutical industry, the health sector professional responsibilities, maximum therapeutic benefit from their professionals. treatments with medicines.

As the world grows smaller , present and future professionals including technocrats, managers, administrators need to plan out careers on global lines rather then regional or national lines demanding the human resources to be sharper than ever to survive and succeed.

Change will not come if we wait for some other person, or if we wait for some other time.

We are the ones we've been waiting for.
We are the change that we seek."

------Barack Obama

Dr. B. Suresh
President, Pharmacy Council of India

Pharm D regulations 2008

B Pharm regulations 2014

M Pharm regulations

Pharmacy Practice regulations

Pharmacy teachers regulations

D.Pharm Regulations

To Equip the Future Pharmacist as a Knowledgeable Professional with skills of not only Manufacturing, dispensing of medicines, but also to serve as counselor

Unfortunately, in the eyes of the public, the role of the Pharmacy profession and its contribution to health care are often not duly recognized and even misunderstood. This is possibly because both public and policy makers believe that pharmacists' role is restricted to merely buying and selling of medicines.

- The pharmaceutical industry in India is one of the largest and most advanced among the developing countries.
- Besides providing employment to millions, it ensures that essential drugs are available at affordable prices to the vast population of India.

PHARMACISTS IN PRACTICE SETTINGS

Pharmacists form a vital link between the Doctors, Nurses and the Patients

COMMUNITY PHARMACY

- Community pharmacists are the heath care professionals most accessible to the public.
- They work in chain stores or independently owned pharmacies
- They ensure accurate supply of medicines after verifying the safety of the medication record.
- They are also involved in extemporaneous preparations, drug utilization monitoring and promoting patient care.

HOSPITAL PHARMACY

- Hospital Pharmacy:- practice of pharmacy inside a hospital close to the patient' in an environment where doctors, nurses and other health care professionals interact with the pharmacists on matters related to medicines, surgical and other patient care items required.
- Are responsible for purchasing, manufacturing, dispensing and quality testing of medication stock.
- In India there are more than 15000 hospitals and around 9 lakh hospital beds. Most of these hospitals have pharmacies run by pharmacists. Pharmacists thus work both in private and public hospitals across the country.

CHALLENGES IN EDUCATION

- Mushroom growth of institutions
- Shortage of qualified teachers
- No TOT (Training of trainers)
- Dual control of regulatory bodies
- Less research activity
- Weak industry – academia interaction

NEED OF THE HOUR:

A new model for Pharmacy Education

The student should be trained to create, transmit, and apply new knowledge based on cutting-edge research in the pharmaceutical, social, and clinical sciences.

As members of clinical care teams, their expertise extends to advising patients and prescribers with regard to potential drug interactions, the changes in management of chronic and acute illnesses, and assessing and improving outcomes of drug therapy.

FOCUS ON:

- Problem solving Skills
- Case studies
- Creative thinking
- Communicative skills
- Reasoning

Concept – based teaching methodology & Career - based Education

Training to Transform learners into thinkers who create, challenge, evaluate and make decisions

Acquaint with innovation, patenting and selling ideas ----

To become a new breed of technocrats – Entrepreneurs

- Pharmacy is a rewarding career, in terms of personal satisfaction and financial compensation, as well as service to the people.
- Holding such a respected place in the healthcare system (most trustworthy profession as per Gallup poll in USA) earned through their career options and job opportunities helped to make informed suffering.

So start planning from today.
As the old Chinese saying goes

'A JOURNEY OF A THOUSAND MILES
BEGINS WITH ONE SMALL STEP'.

ACKNOWLEDGEMENTS

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Dr. B. Suresh, President, PCI
Prof. K. Chinnaswamy
Pharmacy Council of India, New Delhi
IPA, Mumbai

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FUTURE OF THE PHARMACEUTICAL INDUSTRY

by

Shri. A. Vaidheesh
President – OPPI & Vice President, South Asia & Managing Director, India, GSK Pharmaceuticals

"The future cannot be predicted, but futures can be invented."
– 1963 Dennis Gabor "Inventing the Future" (Nobel Laureate in Physics for holography

Future Challenges: Demographic trends are putting healthcare systems under pressure

Growing Populations

+1Bn by 2030

About 8.5 billion people are expected to inhabit the planet by the year 2030

Rapid Aging

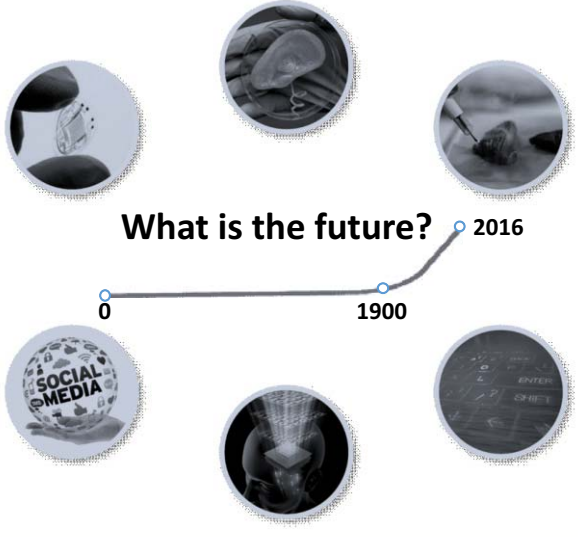
+500m over 60 by 2030

About 1.4 billion people worldwide are projected to be 60 or older by the year 2030, fueling a rise in chronic illness

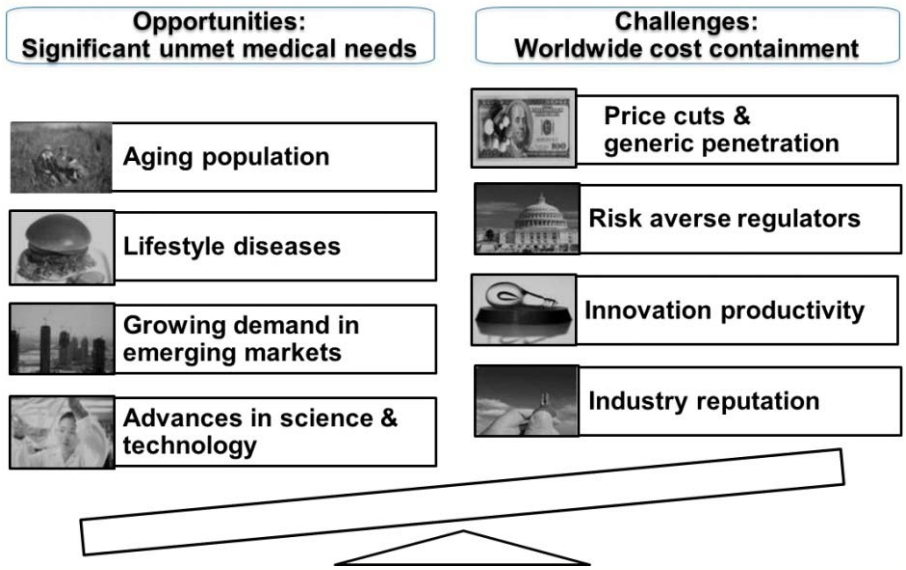
Increasing Healthcare Demand

13T by 2025

If growth trends continue, global healthcare outlays could rise 70% by 2025 to USD 13 trillion



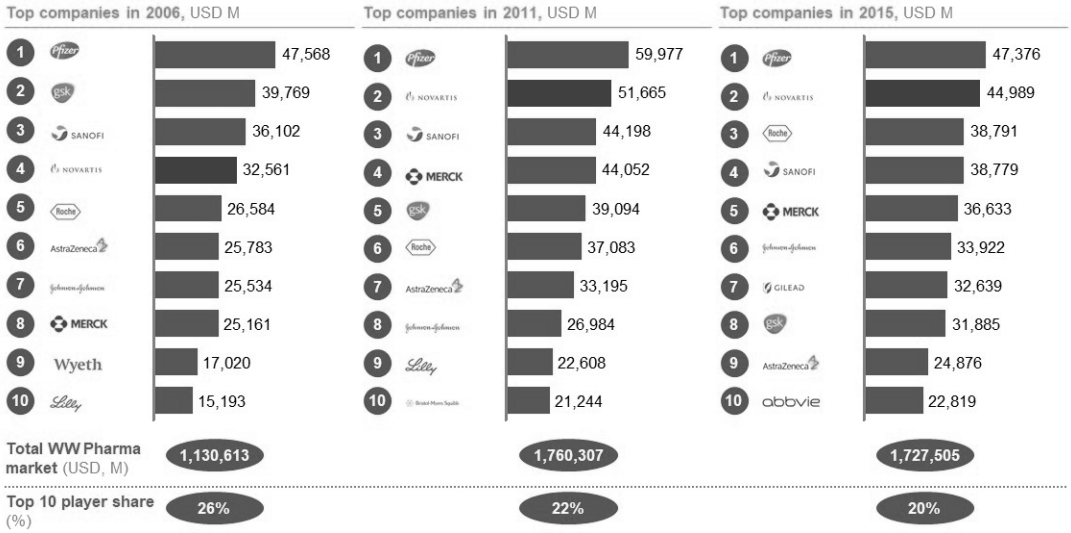
Key trends shaping the future of Pharma



Trends

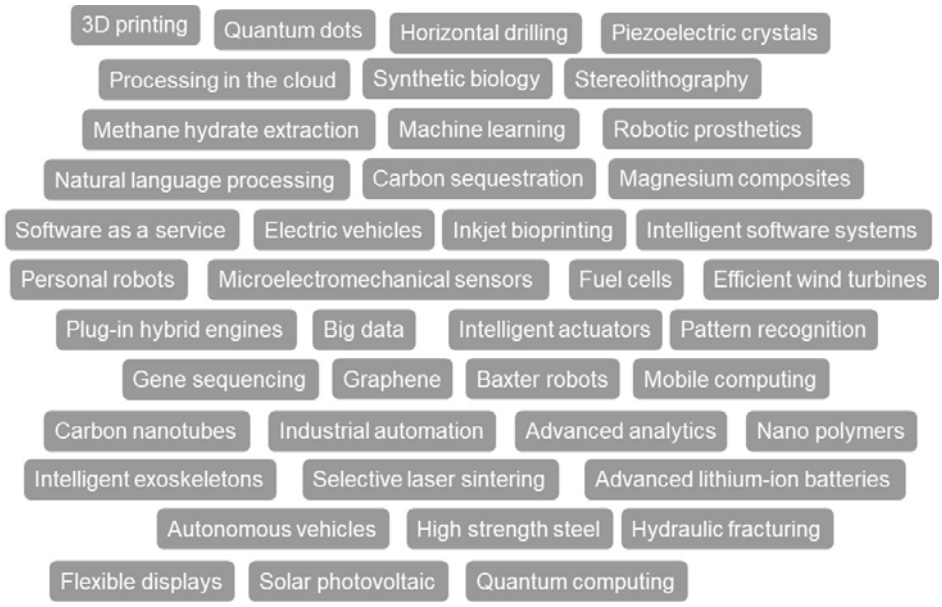
1	Lots of unmet needs remain
2	Poor lifestyle leads to increased demand for drugs
3	Explosion of biological knowledge
4	Wealth – People are getting richer and will spend more on health care
5	Demographics – Aging and growing populations
6	Information – Rise of consumerism and the informed patient

Industry has become more fragmented



- Decline in top 10 pharmacos' aggregate market share suggests there is still room for significant consolidation
- Pure bios players and specialized companies are taking market share from top companies in a market that has been flat overall (e.g., AbbVie, Gilead already in top 10; Teva, Novo Nordisk in top 20); this is resulting in a more diffuse industry

Disruptive technologies

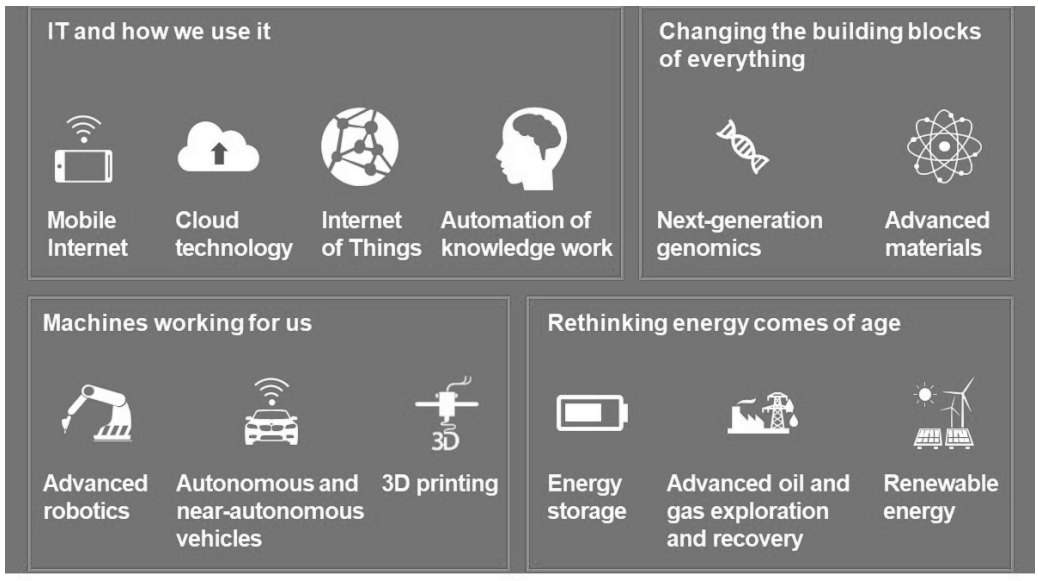


Adoption of new technologies is also accelerating

Time to reach 50 million users

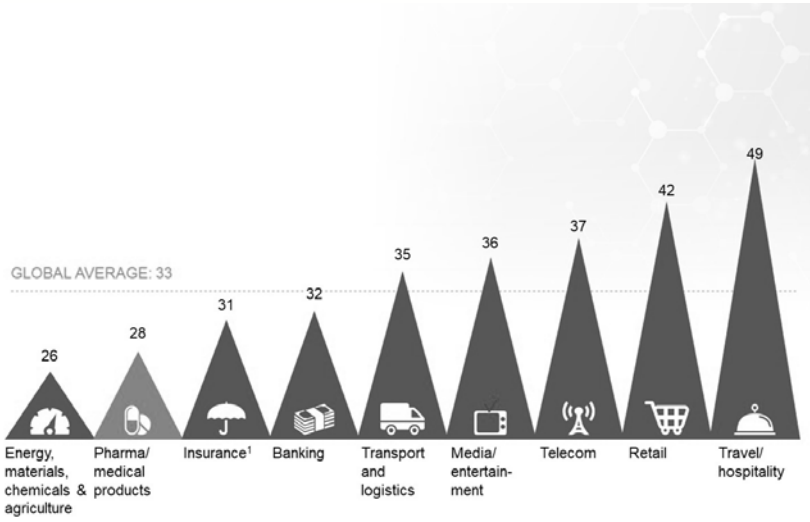
Twelve technologies have significant potential to disrupt

The disruptive Dozen



Pharma is among the most immature sectors in applying Industry 4.0…

Distribution of Digital Quotient score by industry (Global)2; Points out of 100



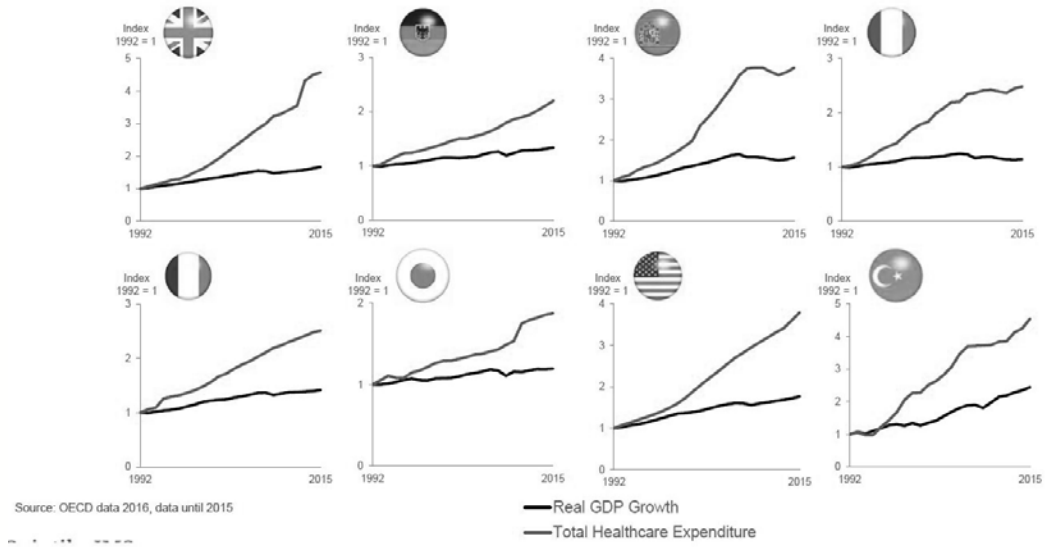
1 Includes P&C and Life insurance;
2 The McKinsey Digital Quotient is a proprietary tool used to assess companies across 18 practices, which have measured the digital readiness of 200+ companies

SOURCE: McKinsey Digital Quotient

Key challenges

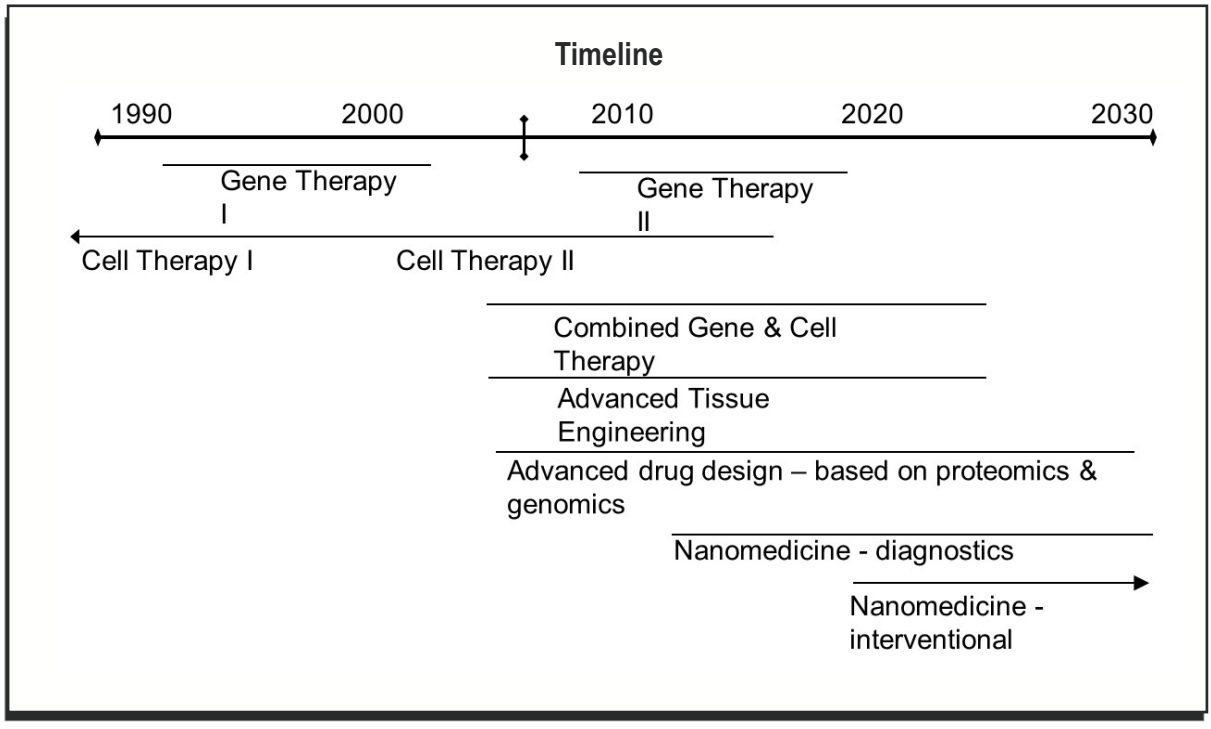
1. R&D costs pulling ahead of output
2. Government pressure on price
3. Unmet medical needs remain
4. Commercial model in transition
5. Pharma's negative image a real challenge

Healthcare expenditure trends have deviated from GDP growth over the past 25 years without answering the question of sustainability



The "5 P's" of Future Medicine

Predictive	**Pharmacogenomics and Pharmacoproteomics**
Preventive	Acting proactively with preventive medicine
Point of care	Mobile communications & ubiquitous computing
Parametric	Multiple parameters over time referenced to patient's own baseline and genetic profile compared to standard model
Personalized	Individual treatment for each patient



"Our generation may be the last to have to accept death and taxes as inevitable."

– Commander Shaun Jones, US Navy, DARPA

Whatever happens, it will be an interesting place to be…

ROLE OF PHARMACISTS IN SMEs

by

Mr. Tushar A Korday
Director, Emi Pharmaceutical Industries Pvt Ltd., Mumbai

Definition of "Pharmacist"

- Dictionary meaning is, " A person who is professionally qualified to prepare and dispense medicinal drugs" – in hospital or shop.
- **Medical Dictionary**
  A person Licensed to prepare, compound and dispense drugs upon prescription from a licensed practitioner

Definition of "Pharmacist"

- **Wikipedia**
  Pharmacist or chemist are health care professional who practice in pharmacy, the field of health sciences focusing on safe and effective medication use.
- We usually consider pharmacist as pharmacy graduates or pharmacy diploma holder - Dispensing drugs / medicines
  - Manufacturing drugs / medicines including quality control and assurance .

MSME's

Definition of SME's was based upon Investment in Plant and Machinery.	
Small Scale	Less than Rs 5 cr
Medium Scale	Between Rs 5 cr to Rs 10 cr
Large Scale	Above Rs 10 cr
Now the definition is changed Based on Annual Turn over (Attuned to GST)	
Micro Enterprise	Annual Turnover Less than rupees 5 cr
Small Enterprise	Between Rs 5cr to Rs 75 cr
Medium Enterprise	Between Rs 75 cr to Rs 250 cr

FEATURES OF MSME's

Total Pharmaceutical production in India
- $ 32 Billion or Rs 2.10 Lakh Cr

Exports
- $ 16 Billion or Rs 1.05 lakh Cr

- SME's are playing crucial role.
- SME's also provide employment to lakhs of people, including Chemists and operators.
- Production by SME's is 85% by volume and 40% by value.
- SME's are thus backbone of Pharmaceuticals industry in India.
- India is Pharmacy to the World

FEATURES OF MSME's (contd.)

- SME's are the growth engines of Indian Pharmaceutical Industry. Contribute 35-40% of industry.
- Yesterday's SME's have become today's Pharma giants.
- SME's provide competition and price reduction.
- SME's are engaged in contract manufacturing, very few have their own marketing
- SME's are significant contributors to export.

FEATURES OF MSME's (contd.)

- There are more than 9000 SME's in India and many of them have been started by Pharmacy graduates.
- Thus many Pharmacists have become entrepreneurs and they need all the encouragement.
- While most of SME's are Schedule M compliant, several hundreds are WHO-GMP compliant, a few even US FDA approved units.

SME GROWTH STORY

FROM 1947 to 2000

- Till early 70's we were dependent on imported medicines.
- Indian Patent Law 1970 led to self – reliance, leading to several start-ups in Pharmaceuticals industry.
- Most of these were SME's started by Pharmacists and Science graduates.
- Entrepreneurs tied up with technocrats and the industry was built up, brick by brick.

SME GROWTH STORY

- Led to development of Associate industries including Engineering, Equipment, Manufacturing, Packaging, Testing Labs and also R&D.
- Several Pharmacy Colleges set up.
- By 1990 India became self sufficient in medicines and very soon started exporting medicines. Both in API's and Formulations.
- A revolution carried out by our able Pharmacists, with supportive Government policy

SME GROWTH STORY (contd.)

2001 TO PRESENT

- Investment in API's started floundering. API production became expensive compared to large size plants in China. India has slowly and steadily become significantly dependent on China for API's and Intermediates.
- The Government failed to resolve land availability and pollution treatment (CETP) issues, which has compounded the problems

SME GROWTH STORY (contd.)

- Indian Formulations Industry continued its Stellar growth. India today is 3rd in the world on volume basis and 10th on value basis . SMEs are exporting to Regulated markets, Semi-Regulated markets and Un-regulated markets.
- Regulatory concerns in recent times have affected exports to Regulated markets, diminishing image of our industry. Needs to be addressed quickly.

Reasons for Past Success

- Low investment
- Simple manufacturing processes – API and Formulations
- Easy Regulatory Requirements
- Low labour costs, leading to lower manufacturing cost.
- Lower competition within India and even outside India
- Large pool of qualified technical manpower - pharmacists, science graduates, engineers and accountants.
- Technical Entrepreneurs - Many pharmacists became promoters.
- Contract Manufacturing, Loan license activities for large marketing companies.

Challenges to be recognised for future

- Investment costs are much higher.
- Labour cost have gone up. Manufacturing costs no longer an advantage
- Manufacturing parameters have become complex
- Stringent Regulatory Requirements to be followed diligently
  - Quality Assurance Tougher
  - Quality Testing as per latest IP / BP / USP monographs
  - Data Integrity
  - Comprehensive Systems Required
- Stiff competition – within India and from out side India
- Contract Manufacturing, Loan License operations continuing
- Role of Pharmacist has become more vital and crucial for the survival and growth of SME's in Pharmaceutical Industry

Factors for API Industry

- India has lost substantial ground to China over last 15 years due to
  - Large sized plants in China – Economies of Scale
  - Subsidies given by China govt. Cheap labour and finance
  - Easy pollution control, production and quality control norms.
- However scenario is now changing as China has clamped down on polluting Industries leading to closure of several factories. This has resulted in shortage of many items and rise in prices.

Factors for API Industry

- This is an opportunity for Indian manufacturers , especially SME, which we must seize -
- Setup new, large sized plants
- Set up CETPs with the help from Govt.
- Deliver superior quality products, with assured performance.
- Re-establish image of BRAND INDIA

MAJOR TRENDS FOR 2030

- New Technologies are coming up for manufacturing and packaging.
- Harmonization of regulatory requirements
- New fields such as Bio-similars.
- Most of today's patents will be expired. Generic market to boom.
- New Drugs, New Therapies will come in the forefront.
- Regulatory norms to be increasingly tougher. Indian companies have to adapt to these norms. Data integrity, Documentation, Bio-equivalence studies and Quality Compliance will be more stringent.

MAJOR TRENDS FOR 2030

- All units will have to be WHO-GMP compliant, even EU-GMP or US-FDA level especially for export markets, as we aim for higher exports.
- R&D activity will have to be stepped up. Only F&D or reverse engineering will not suffice.
- Competition from China and other countries in formulations will be stiff. China will be in formulations mfg in big way with mass production.

Major Trends for 2030 (contd.)

- Tremendous Price Pressure due to
  - Competition
  - Govt. Pressure for Public Expenditure
  - Insurance Companies will dominate healthcare.
- Cost escalations - Our cost advantage has disappeared
- Spend on healthcare will increase substantially
- Niche Products to be focussed
- Novel Drug Delivery system
- Personalized Healthcare Management
- Contract Research
- Nutraceuticals and Nutracosmetics

TRENDS IN PHARMA (INDIA)

- Manifold rise in Public and Private Healthcare Spending
- Rising Patient Awareness
- National Healthcare Insurance recently announced for low income families.
- Several new players/expansion projects in manufacturing.
- Indian manufacturers are likely to be more competitive and highly reliable compared to Chinese in APIs.
- Mass therapies will constitute 50% market.

TRENDS IN PHARMA (INDIA)

- Hospital segment will increase its share to 25%
- Unprecedented pace of innovation - new drugs, therapy and techniques.
- Multinational companies have become more aggressive in Indian market.
- Spate of Merger and Acquisitions.
- Metro and Tier I markets will drive growth while rural market will increase its share
- Disposable income levels set to rise significantly in rural markets
- MSMEs have to be aware of these challenges and be prepared to overcome them successfully.

INDIAN ECONOMY & MSME

- Expected to touch $5 trillion by 2025, may be $7 trillion by 2030
- Indian Pharmaceuticals Market projected to reach $ 55 Billion by 2020 and $ 120 Billion by 2030.
- Growth Rate 7%- 8% expected in Pharma industry
- MSME which forms backbone of industry is expected to play a significant role in this growth story.
- Further it will nurture and support development of new age entrepreneurs.

INDIAN ECONOMY & MSME (contd.)

- Initiatives such as "Make in India", "Digital India", "Start-ups", "Ease of Doing Business", "Easy Finance" are expected to boost MSME
- Share of MSME in GDP in India is 42%
- Compared to developed countries share of 48-60%
- Thus there is tremendous scope for MSME sector in India.
- Onset of GST will bring good tidings for MSME sector

INDIAN ECONOMY & MSME (contd.)

- Exports by MSME Sector
  2013-2014 42.42%
  2014-2015 44.76%
  2015-2016 49.86%
- Contribution of MSMEs to GDP
  2012-2013 37.54%
  2013-2014 42.38%
- Employment in MSME is 106 million which is 40% of India's work force.
- Number of SME's is 42.50 million which forms 95% of total industrial units.
- Growth rate - Over 10%
- Bank lending - 16%
- Fixed Asset Investment by MSMEs - Rs 14.72 lakh Cr.

SKILLS SET FOR PHARMACISTS

- Pharmaceutical industry is under constant change and description . Complacency does not work here. Pharmacists have to constantly upgrade themselves with newest technology and skills.
- Pharmacist should possess core technical knowledge and master regulatory practices, but they must also have requisite skills to survive in this changing world.
  - Communication
  - Resilience
  - Creative and Critical thinking
  - Risk based decision making
  - Leadership
  - Crisis management
  - Problem solving

CAREER CHOICES TO PHARMACISTS

Pharmacists, Chemists and Engineers have several career options in the Pharma industry including SME's.

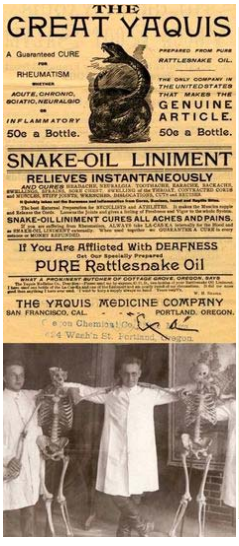
- Entrepreneur
- Quality Control
- Regulatory/ Documentation
- R&D
- Consultancy
- Government Analyst/Officer
- Clinical Research
- Manufacturing
- Quality Assurance
- F&D
- Process Development
- Teaching
- Testing labs

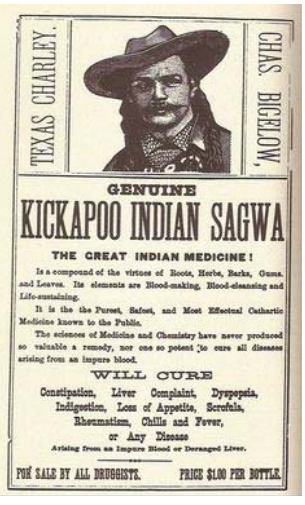
Depending upon individual's attitude, capability and interest, suitable career can be chosen. But in any professional field updating of knowledge ,skill set, training is mandatory and must be pursued rigorously.

PHARMA VISION 2030: FUTURE OF PHARMACEUTICAL MARKETING

by

Shri. Rajiv Gulati
Founder & CEO, M-Chemist





There is nothing Permanent, except Change

- Heraclitus of Ephesus

History

- 1970: Patents abolished in India
- 1978: Patents introduced in Italy
  - Launch of New Molecules
  - API Mfg in India
  - Export of API
  - Formulation Export
  - IP Challenges (Para IV)
  - Acquisitions
  - 505(b)(2)
  - Brands

What Next?

Global Headwinds

- Changing Regulatory Environment
- Rising Protectionism (Russia 2020)
- Increasing Competition
- Growing FDA Expectations (Predictive)

Local Headwinds

- NPPA
- Code of Conduct
- Genericization/Substitution/Jan Aushadhi
- One Plant-One Molecule-One Brand-One Price
- Proposal for fixed margins

National Health Insurance Scheme
- A Game Changer?

Differentiate or Die
(Existing Market)

- Complex Chemistry
- NDDS
- Technology
- Therapy Focus
- Form focus
- OTC/FSSAI

Extreme Focus on Patients and Outcomes

Existing Challenges - New Opportunities

- More than half the country has no access to Healthcare
- Indian patients pay 'out of pocket'
- Consolidation of Distribution post GST
- Potential consolidation of manufacturing and marketing post GMP and Bio-equivalence
- Increasing band-width and technology makes telemedicine possible
- Modicare

PHARMA VISION 2030 - PROSPECTS OF CLINICAL TRIALS IN INDIA & DEVELOPING STRATEGIES

by
Dr. K. Bangarurajan
Joint Drugs Controller (I), CDSCO, New Delhi

Definition of Clinical Trial

Rule 122DAA. Definition of clinical trial- For the purpose of this Part -

"Clinical Trial" means a systematic study of new Drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and/or efficacy of the new drug."

Different Phases of Clinical Trial

- Pre-Phase-1 (Phase "0")
- Phase-I
- Phase-II
- Phase-III
- Phase-IV

Stages of Clinical Trials

Pre-Phase-1 (Phase "0")

- Very low dose pharmacokinetic study to help in early drug candidate selection.
- Reduces failure relating to pharmacokinetic parameters in early drug development
- Generally dose administered is less than 100mcg

Phase-I (Human Pharmacology)

- To estimate safety and tolerability
- May be conducted in healthy volunteers
- If the drug is significantly toxic, study is usually carried in patients
- To determined maximum tolerated dose (MTD)
- Pharmacokinetics
- Pharmacodynamics
- Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) study

Phase-II
(Therapeutic exploratory Trials)

- To evaluate effectiveness of a drug
- To determine short-term side effects
- Dose finding study to determine the dose for Phase-III trial
- Conducted on limited number of patients

Phase-III
(Therapeutic confirmatory trials)

- To confirm the evidence of safety & efficacy generated in Phase-II
- To explore the use of drug in wider population, in different stage of disease, safety & efficacy of the drug in combination with other drugs

Phase-IV
(Post Marketing Trials)

- Conducted after drug approval in approved indication
- To determine additional drug interaction, dose response, safety to support the use of the drug under approved indication

Designs of Clinical Trial

- Randomized
- Double-blinded
- Open-labeled
- Cross over
- Parallel
- Double blind Double dummy
- Active Controlled study
- Placebo Controlled study

Double Blind Double Dummy

Example-:

- Active tablet (A)
- Active injection (B)
- Placebo tablet (C)
- Placebo injection (D)

Each Patients will receive either A+D or B+C so that blindness is maintained

Key Activities for Clinical Trials

- Development of the Study Protocol
- Development of Written Standard Operating Procedures (SOPs)
- Development of Support Systems and Tools
- Generation and Approval of Study-Related Documents
- Selection of Study Sites and Qualified Investigators
- Ethics Committee Review and Approval of the Protocol.
- Review by Regulatory Authorities

Key Activities

- Enrollment of Subject: Recruitment, Eligibility, and Informed Consent
- The Investigational Product(s): Quality, Handling, and Accounting
- Conducting the Study: Study Data Acquisition
- Safety management and Reporting
- Monitoring the Study
- Managing Study Data.
- Quality Assurance of Study Performance and Data
- Reporting the Study

Regulatory Aspects of Clinical Research in India

- India is a widely preferred location for the pharmaceutical companies in conducting clinical research for several reasons. Currently available regulatory guidelines for clinical research in India are:
  - "Schedule-Y" of the Drugs and Cosmetics Act (1940) and Rules (1945)
  - "Good Clinical Practices for Clinical Research in India" of CDSCO
  - "Ethical Guidelines for Biomedical Research on Human Participants" of Indian Council of Medical Research [ICMR])

Regulatory Aspects of Clinical Research in India (Cont...)

- Conducting any clinical trial in India essentially requires approval from the registered ethics committee. The DCGI will not sanction the permission to begin the study without EC approval. The EC carefully reviews each of the clinical trial protocol submitted to them as per Schedule Y, the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding rights, safety and well-being of the trial subjects
- With the ethical clearance and other related essential documents the sponsor prepared a dossier for the regulatory submission. In India, trial can be started only after the regulatory (DCGI) permission

Good Clinical Practices (GCP)

- Good Clinical Practices (GCP) is an ethical and scientific quality standard for designing, conducting and recording trials that involve the participation of human subjects. Compliance with this standard provides assurance to public that the rights, safety and well being of trial subjects are protected, consistent with the principles enshrined in the Declaration of Helsinki and ensures that clinical trial data are credible.
- The Drug Technical Advisory Board (DTAB), the highest technical body under D&C, Act, has endorsed adoption of this GCP guideline for streamlining the clinical studies in India.

Good Clinical Practices (GCP)

- This guideline have been evolved with consideration of WHO, ICH, USFDA and European GCP guidelines as well as the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research.

Schedule Y

- Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials
- Drugs and Cosmetics Rules, 1945 applicable for Clinical trial study:

Rule	Permission for
122 A	To import new drug
122 B	To manufacture new drug
122 D	To import or manufacture fixed dose combination
122 DA	To conduct clinical trials for new drug/Investigational new drug
122 DDA	Definition of Clinical trial
122DAB	Compensation in case of injury or death during clinical trial

Application for permission of Clinical trial

- It shall made in Form 44 accompanied with the following data in accordance with appendices name, namely
  - Clinical and pharmaceutical information
  - Animal pharmacology data
  - Animal toxicology data
  - Human clinical pharmacological data
  - Regulatory status in other countries
  - Prescribing information etc.
- Form 12 – To import study drug for examination, test or analysis

Recent Initiatives by CDSCO

- Digitization of Clinical Trials towards ensuring the data credibility and patient safety
- Mandatory registration of all new clinical trials in the Clinical Trials Registry of India (as of 2009)
- Registration of ethics committees; and use of language encouraging respect of participants' cultural, educational, and economic backgrounds
- Formation of New Drug Advisory Committees (NDACs) and Technical Review Committee (TRC)
- Audio visual recording of Informed Consent Process
- Time frame of SAE reporting etc.

Current market scenario of Clinical trial in India

- Clinical trial and research is now a major business in India. Over 100 companies are currently conducting the clinical trials in India
- Top multinational pharmaceutical companies like Pfizer, Glaxo Smith Kline, Aventis, Novartis, Novo Nordisk, Astra Zeneca, Eli Lilly are conducting clinical trials in India apart from the Indian companies like Dr. Reddys, Nicholas Piramal, Cipla and Lupin
- The following factors make India a critical destination to conduct clinical research and pave the way for it to emerge as a clinical research hub in future:

i. There are numerous government funded medical and pharmaceutical institutions with state-of the-art facilities, which can serve as ideal centres for multi-centred clinical trials.
ii. India boasts of well-trained and qualified manpower, well versed in English. In terms of the cost efficiency, India is better as the cost to conduct a trial here is lower by 50 to 75% than in the United States or the European Union.
iii. R&D costs in India are substantially less than those in the developed world and it is possible to conduct both new drug discovery research and novel drug delivery system programmes at competitive rates.
iv. Clinical trials cost approximately US$ 300 to US$ 350 million abroad, they cost about INR 100 crore in India.

Total no. of CT permission granted by CDSCO

- The number of clinical trial permissions granted by Central Drugs Standard Control Organization (CDSCO) during 2014 to 2017 are as follows:

Year	No. of Permission granted
2014	198
2015	216
2016	129
2017 (Till Nov.)	211

- As per the requirement of Rule of 122DAC under Drugs and Cosmetics Rules, 1945 clinical trail shall be registered at Clinical Trial Registry of India maintained by ICMR before enrolling the first patient for study,

Future development in Clinical trials by CDSCO

- To make time bound Clinical trial and new drug approval
- To promote growth of Clinical trial research industry
- To safeguard trial subject rights
- To ensure timely accessibility of new drugs in India
- Promote innovation in the country
- To streamline with contemporary good Regulatory practices

- Time lines will be fixed for processing application for
  - CT (in general)
  - CT (innovated in India)
  - CT (if drug already approved by other country)
  - New drug
- Provision for interim compensation
- Post trail access of new drugs to CT subjects

"I think in some ways the recent initiative and new proposal of CDSCO in the existing regulations in clinical trial, if applied in the right spirit will be a guide across globe"

Key Activities in details for Clinical Trials

1- Development of the Study Protocol

The sponsor, often in consultation with one or more clinical investigators, generally designs the study protocol; clinical investigators may also design and initiate clinical studies as sponsor-investigators.

The sponsor and clinical investigator(s) should be aware of national regulations pertaining to designing, initiating, and conducting the study.

2- Development of Written Standard Operating Procedures (SOPs)

Sponsors, clinical investigators, independent Ethics Committees/ Institutional review Boards (IECs/IRBs) monitors, contract research organizations (CROs) should develop and follow written standard operating procedures (SOPs) that define responsibilities, records, and methods to be used for study-related activities.

Development of Written Standard Operating Procedures (SOPs)

Sponsors should consider preparing SOPs including those for:

- Developing and updating the protocol, investigator's brochure, case report forms (CRFs), and other study-related documents;
- Supplies procurement, shipping, handling, and accounting for all supplies of the investigational product;
- Standardizing the activities of sponsors and study personnel (e.g. review of adverse event reports by medical experts; data analysis by statisticians);
- Standardizing the activities of clinical investigators to ensure that trial data is accurately captured;
- Monitoring to ensure that processes are consistently followed and activities are consistently documented;
- Auditing, to determine whether monitoring is being appropriately carried out and the systems for quality control are operational and effective.

Development of Written Standard Operating Procedures (SOPs)

- Clinical investigators should consider developing SOPs for common trial-related procedures not addressed in the protocol. These may include communicating with the IEC/IRB; obtaining and updating informed consent; reporting adverse events; preparing and maintaining adequate records; administering the investigational product; and accounting for and disposing of the investigational product.

- IECs/IRBs should develop and follow written procedures for their operations, including membership requirements; initial and continuing review; communicating the investigator(s) and institutions; and minimizing or eliminating conflicts of interest.

3 - Development of Support Systems and Tools

- Support systems and tools include, but are not limited to, trial-related information documents (e.g. investigator's brochure, case report forms (CRFs), checklists, study flow sheets, drug accountability logs;

- The sponsor is generally responsible for developing, maintaining, modifying and ensuring the availability of support systems and tools

4- Generation and Approval of Trial-Related Documents

- The sponsor generally develops, designs, and provides various standardized forms and checklists to assist the clinical investigator and his/her staff in capturing and reporting data required by the protocol
- Investigator's brochure;
- Checklists to identify and document the required steps for each of the various clinical trial activities.
- Investigational supplies accountability forms
- Case Report Forms (CRFs) for each scheduled study
- Informed consent documents;
- Adverse Event or safety reporting forms;

5- Selection of Study Sites and Qualified, trained & experienced investigator & study personnel

- Clinical investigators must be qualified and have sufficient resources and appropriately trained staff to conduct the investigation and be knowledgeable of the national setting and circumstances of the site and study population(s).

6- Ethics Committee Review and Approval of the Protocol

- Studies must be reviewed and receive approval/favourable opinion from an independent Ethics Committee (IEC)/Institutional Review Board (IRB) prior to enrollment of study subjects.
- The investigator generally assumes responsibility for obtaining IEC/IRB review of the study protocol. Copies of any approval / favourable opinion are then provided to the sponsor.

7- Review by Regulatory Authorities

- Studies must undergo review by regulatory authority(ies) for use of the investigational product or intervention in human subjects and to ensure that the study is appropriately designed to meet its stated objectives, according to national regulation
-
- The sponsor is generally responsible for ensuring that the applicable regulatory authority(ies) review and provide required authorizations for the study before the study may proceed.

8- Enrollment of Subjects: Recruitment, Eligibility, and Informed Consent

- The clinical investigator has primary responsibility for recruiting subjects, ensuring that only eligible subjects are enrolled in the study, and obtaining and documenting the informed consent of each subject. Within GCP, informed consent must be obtained from each study subject prior to enrollment in the study or performing any specific study procedures.

9- The Investigational Product(S): Quality, Handling, and Accounting

- Sponsors control access to the investigational product and also document the quantity(ies) produced, to whom the product is shipped, and disposition (e.g return or destruction) of any unused supplies. Investigators to control receipt, administration, and disposition of the investigational product.

10-Conducting the Study: Study Data Acquisition

- Research should be conducted according to the approved protocol and applicable regulatory requirements.

11- Safety Management and Reporting

All clinical trials must be managed for safety. Although all parties who oversee or conduct clinical research have a role/responsibility for the safety of the study subjects, the clinical investigator has primary responsibility for alerting the sponsor and the IEC/IRB to adverse events, particularly serious/life-threatening unanticipated events, observed during the course of the research. The sponsor, in turn, has primary responsibility for reporting of study safety to regulatory authorities and other investigators and for the ongoing global safety assessment of the investigational product. A data and safety monitoring board (DSMB) may be constituted by the sponsor to assist in overall safety management

12- Monitoring the Study

- The Sponsor may perform such monitoring directly, or may utilize the service of an outside individual or organization [e.g. contract research organization (CRO)]
- The "on site" monitors review individual case histories in order to verify adherence to the protocol, ensure the ongoing implementation of appropriate data entry and quality control procedures, and verify adherence to GCP

13- Managing Study Data

- Managing clinical trial data appropriately assures that the data are complete, reliable and processed correctly and the data integrity is preserved. It includes all processes and procedures for collecting, handling, manipulating, analyzing, and storing/archiving of data from study start to completion.
- The sponsor bears primary responsibility for developing appropriate data management systems. The sponsor and the investigator share responsibility for implementing such systems to ensure that the integrity of trial data is preserved.

14- Quality Assurance of Study Performance and Data

Quality assurance (QA) verifies through systematic, independent audits that existing quality control systems (e.g. study monitoring) are working and effective.

Sponsors bear primary responsibility for establishing qualify systems and conducting quality assurance audits.

15- Reporting the Study

The results of study should be summarized and described in an integrated clinical study report containing clinical data and statistical descriptions, presentations, and analysis. The report should be complete, timely, well-organized, free from ambiguity, and easy to review.

The sponsor is responsible for preparing clinical study reports.

PHARMA VISION 2030: FUTURE OF PHARMACEUTICAL PRICING

by

Shri. C. Venkataraman
Director – Corporate Support, Lupin Ltd.

BRIEF HISTORY OF PRICING POLICY IN INDIA

- **POST INDEPENDENCE:** The entire industry was decontrolled. In 1962, with the aggression of China on India, an emergency was declared. The Govt. feared that due to Chinese aggression, there could be shortages of essential medicines, as a result the prices might rise. Accordingly for the 1st time statutory control on prices of drugs and pharmaceuticals was imposed under **THE DEFENSE OF INDIA ACT OF 1915.**

BRIEF HISTORY OF PRICING POLICY IN INDIA

- The Drugs (Display of Prices) Order 1962 and Drugs (Control of Prices) Order 1963 were promulgated. Under the Drugs (Display of Prices) Order 1966, it was made obligatory for the manufacturers to obtain prior approval from Govt. before increasing the price of any formulation.

DPCO 1970

- DPCO 1970 was the 1st comprehensive price control order promulgated under the section 3 of Essential Commodities Act of 1955.
- The said DPCO mainly focused on controlling the profitability of the Pharmaceutical business in India. The order fixed that a Company can earn maximum of 15% pre tax profit of Pharma sales (net of Excise Duty & Sales Tax).

DPCO 1970

- No individual product price approvals were required. Thus there was less bureaucratic hurdles.
- If a Company's pre tax profit exceeds 15%, the Company has to deposit the surplus with the Govt.
- The main salient features were that the individual Companies can have their own pricing for their respective products.

THE HATHI COMMITTEE, 1974 & DPCO 1979

- The Govt. Of India appointed a Committee under the Chairmanship of Rajya Shaba MP Mr. Jaisukhlal Hathi to look into the aspects of Pharmaceutical Industry in the country. The said report which was submitted in 1975 was known as Hathi Committee Report.
- The report emphasized on encouraging the Public Sector for manufacturing bulk Drug and also to control the prices of Bulk Drug & Formulations.
- Based on the recommendation of the report, the Govt introduced a new DPCO on 31st March 1979.

DPCO 1979

- DPCO 1979 for the 1st time introduced price fixation for both Bulk Drug & Formulations based on bulk drugs listed in the schedule.
- For formulation the concept of MU (MARK UP) was introduced to cover distribution cost, manufacturers margins, trade margins etc.
- DPCO 1979 had 3 categories covering 370 drugs. The drugs were categorized based on the essentiality and the need to keep the price affordable. The categories & their MU were as under:-

DPCO 1979

CATEGORY I: 40%
CATEGORY II: 55%
CATEGORY III:100%

- For the 1st time control on overall profitability of the Company as well as individual product price controls were introduced. Thus pharma companies were subjected to dual control.

Under DPCO the prices were fixed & monitored by BICP. They introduced a 4th Category (not specified in DPCO) with an MU of 60%.

- The period 1979 to 1987 was the worst years faced by pharmaceutical companies.

DPCO 1987

- The same pattern continued but with little relief to the industry. The number of categories were reduced to 2 from 3.
- The new concept of MAPE (Maximum Post Allowable Expenses) term was introduced. Category I was granted 75% and Category II 100%.
- The number of drugs under price control was reduced from 370 to 142.

DPCO 1995

- DPCO 1995 also continued the same pattern as set under DPCO 1979 & 1987. However, the number of Categories were reduced to ONE with 100% MAPE.
- Also the number of Bulk drugs under price control were also reduced from 142 to 76.
- Pricing of API's and its formulations to please NGO's & Parliament members killed API industry during this period and gave an upper hand to Chinese API manufacturers.
- Since the pricing by NPPA were unrealistic in most of the cases, Manufacturers were forced to find out ways & means to circumvent DPCO.

DPCO 2013

- The DPCO 2013 made a paradigm shift in the approach of price control.
- The concept of Cost based pricing was discarded by adopting market base pricing.
- API's were taken out of price control.
- Due to this game changer move, Companies were less inclined to circumvent DPCO and the Industry as whole welcomed the move.
- However NGO's were not happy with the move and they wanted more control as well as the same should be based on cost and not market based.

MAIN SHORTCOMINGS IN THE DPCO 2013.

- Implementation of the price reduction with immediate effect even on all pre manufactured stocks available in the market / distribution channel.
- Compelling manufacturers whose prices are lower than Ceiling Price to continue at lower price permanently.
- In case of Scheduled formulations the WPI increase has to be taken in the month of April every year.
- No provisions / methodology were inbuilt to grant price revision in case of abnormal increase in input cost.

DIFFERENTIAL INTERPRETATION: NPPA V/S INDUSTRY

- CATEGORISATION: NPPA does not differentiate between innovative dosages like SR/ER vis a vis Plain Tablet. Thus NPPA clubs all formulations for working average prices unless specified in NLEM.
- NPPA considers all packs viz. hospital supply packs and small packs for averaging the price. This makes all small packs unviable.
- No difference in different drug delivery viz MDI & DPI. For NPPA both are having same strength and hence same price.

DPCO IMPLEMENTATION BY NPPA

- Going beyond provisions of DPCO. A few examples are listed hereunder:-

1. Frequent changes in Form I, which are not in compliant with the DPCO.
2. Not strictly following provisions for fixation of price under Para 4.
3. Not disposing off Review orders in a timely manner.
4. Issuing guidelines after actions have been taken viz with reference to WPA cases.
5. Issuing SCN without going into details of submission made by manufacturers.

VISION 2030

- Industry cannot expect freedom from price controls. Price control will be there and industry has to learn to live with it as it has to plan its growth as done in last 60 years with price regulations.

- What Industry would like?

1. Industry is not against price regulations. But once a policy / order is in place, it should be followed meticulously and the same should be stable for a considerable period of time say 5 to 10 years. This would help the manufacturers to plan strategy and to decide on the area of focus.

2. Policy / actions should encourage investment and growth of the industry and not stifle the growth.

3. Encourage local production of API to reduce dependency on China. Even if the local cost is higher, local production needs to be encouraged for national security.

- The role of the regulator should be only that of monitoring.

- •Govt. may adopt a three level controls for making drugs affordable. Viz:

NLEM being the most essential drugs as drafted by experts, the said molecules could be price controlled. To make it affordable, Govt. may supply it free of cost to all patients visiting Govt. / Municipal hospitals / dispensaries. For those who don't wish to visit Govt. hospitals may buy the same from retail outlet at Govt. notified price. Rest of the formulation should be decontrolled. A cap on price increase per year can be continued as followed now.

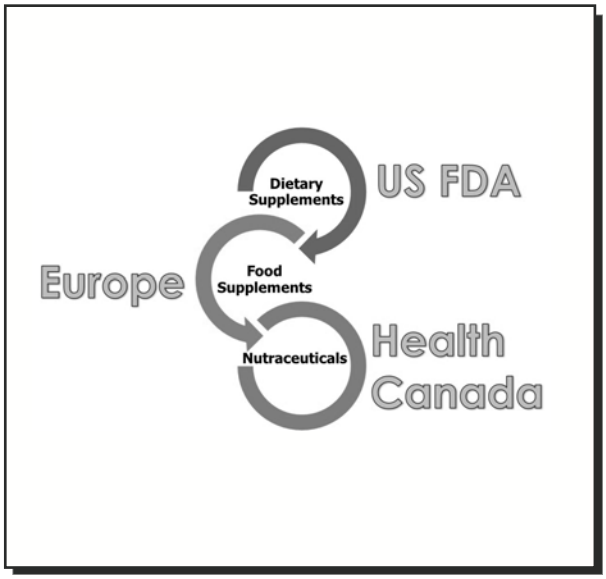
Increase insurance cover to citizens of the country. This would be in addition to price control so that cost of medical expenses are limited.

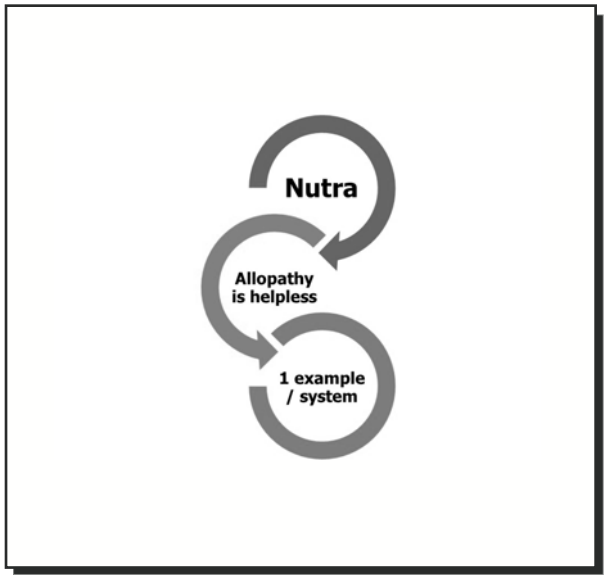
Introduce a concept of self regulation. i.e. manufacturers will have to have self regulation as per the parameters set by the Govt. In case Govt. finds that the parameters are not followed, Govt. can fix the price.

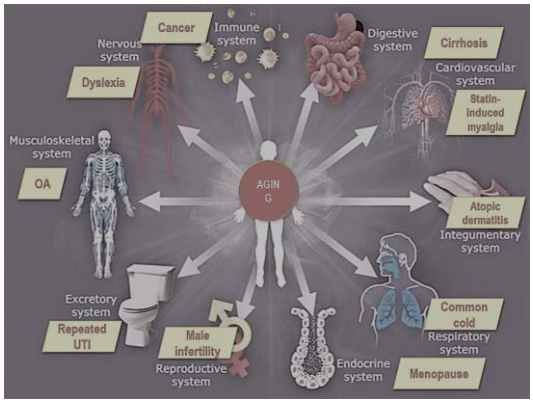
•The industry may lookout for price control regime for all medical devices, Diagnostics as well as hospitalization charges to make health care affordable.

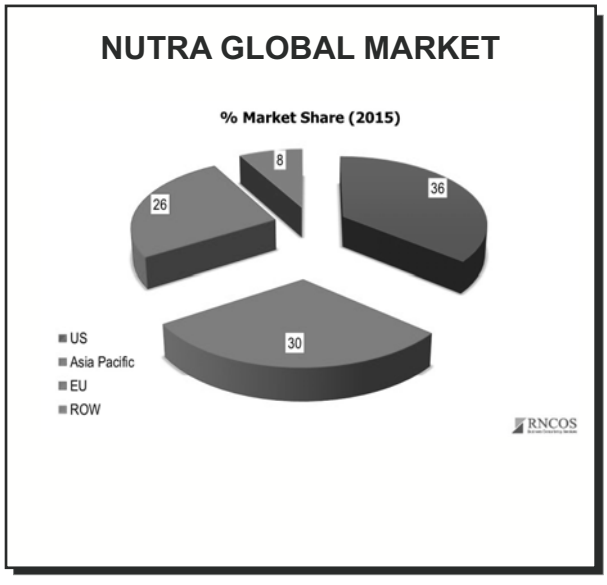
FUTUE & GROWTH OF NUTRACEUTICALS & ITS REGULATIONS TOWARDS THE EMERGENCE OF PHARMA VISION 2030

by
Dr R K Sanghavi
Chairman – Nutraceutical & Medical Committee, IDMA, Mumbai

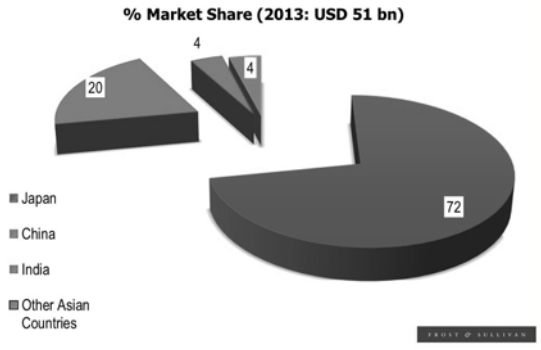




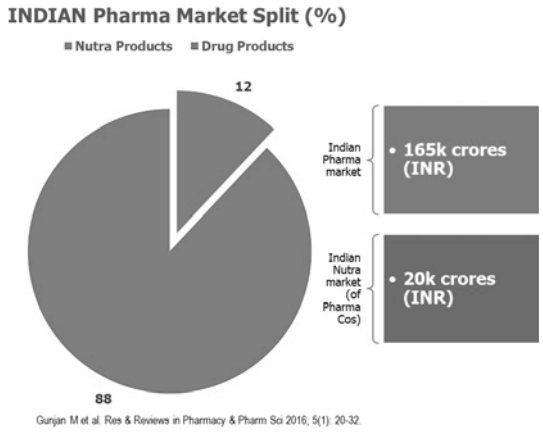




NUTRA ASIA MARKET

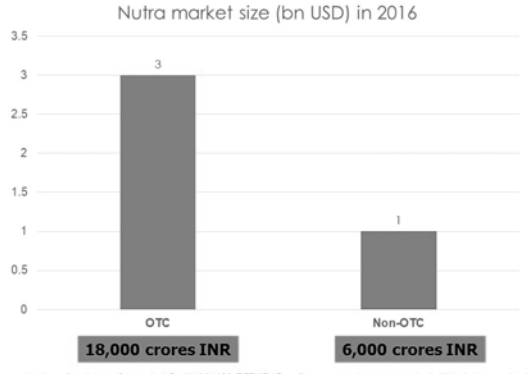


NUTRA vs DRUG



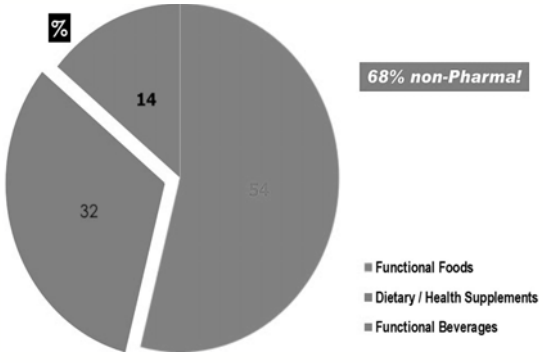
Gunjan M et al. Res & Reviews in Pharmacy & Pharm Sci 2016; 5(1): 20-32.

INDIAN NUTRA MARKET

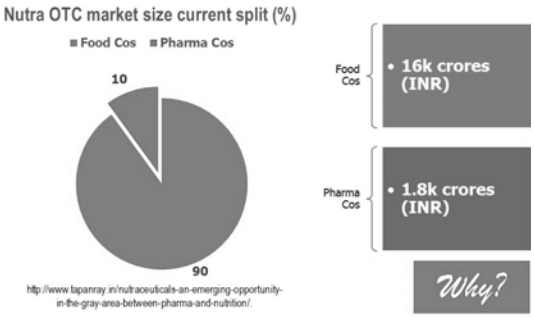


http://www.livemint.com/Companies/hPcoVzKYVpjO6xTlZBKjDJ/Drug-firms-eye-overthecounter-market-in-bid-to-buttress-gr.html

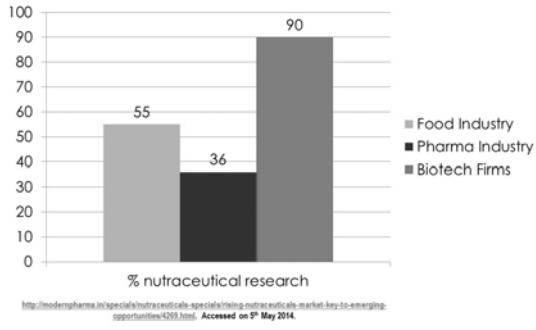
INDIAN NUTRA MARKET



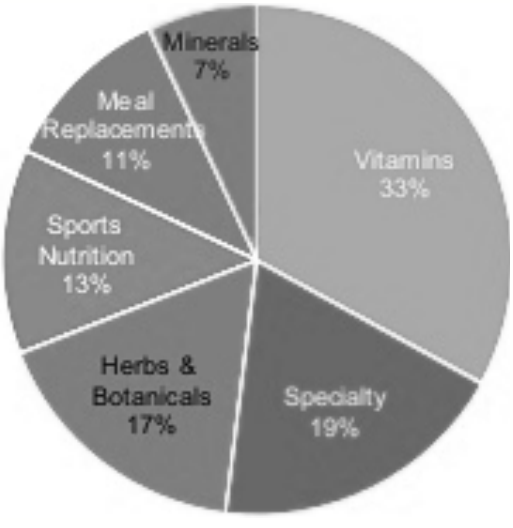
INDIAN NUTRA OTC MARKET



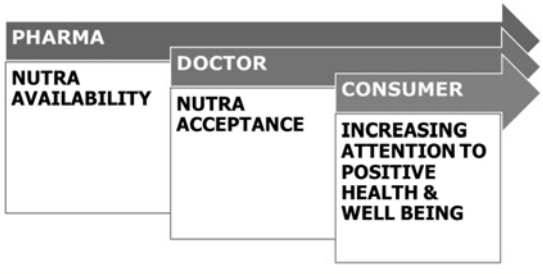
NUTRA RESEARCH THRUST



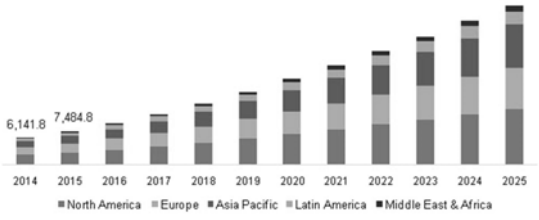
NUTRACEUTICALS, NUTRITIONALS & NATURALS MARKET



PROLIFERATING NUTRA SEGMENT IN INDIA

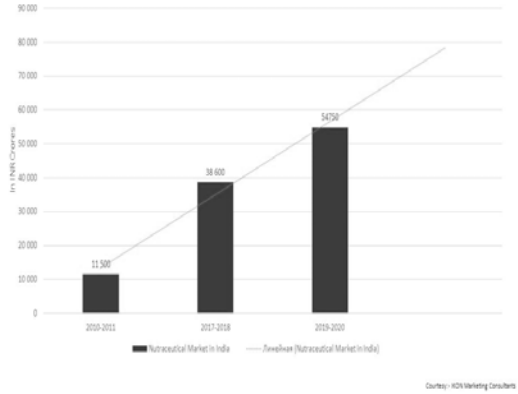


NURACEUTICALS GROWTH



Highest growth rate in US followed by Asia Pacific and then Europe!

INDIAN NUTRA GROWTH



FSSA SCHEDULES (I)

Sch I: Vitamins & Minerals	Sch II: Amino Acid & Other Nutrients	Sch IV: Plant or Botanicals
16+15=31	50+7=57	400
Tocotrienols		+39 (439)

fssai

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

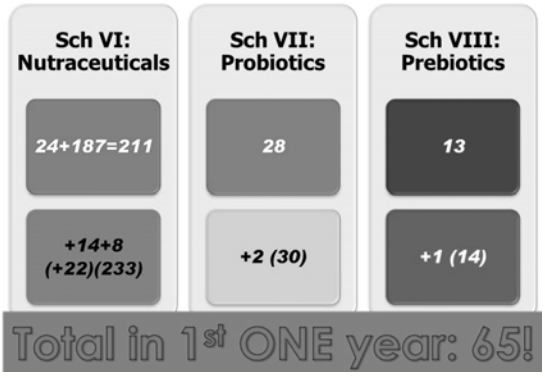
Ministry of Health and Family Welfare, Government of India

FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (23rd December)

vs

Amendment, 29th December 2017

FSSA SCHEDULES (II)



FSSAI – 29th Dec 2017 Order (I)

- Ingredients declared not approved but not harmful.
  - Already manufactured / imported products permitted to continue till 6 more months.
- Re-review of disallowing mere vitamins & minerals combinations.
  - Inspite of disallowing in the regulations order stating the same to be permitted for marketing TILL re-review is DONE & COMPLETE.

FSSAI – 29th Dec 2017 Order (II)

- Footnote under the Schedule – I (Vitamins, Minerals & their components)
  - Suitable esters and salts of vitamins and salts and chelates of minerals may be used.
- Altered to ...
  - Suitable esters, derivatives and salts of vitamins and salts and chelates of minerals may be used.

FSSAI – 29th Dec 2017 Order (III)

- Footnote under the Schedule – II (Amino Acids & other nutrients)
  - Suitable esters and salts of amino acids may be used.
- Altered to ...
  - Suitable esters, derivatives, isomers and salts of amino acids may be used.

FSSA 2006

- **Section 18:** General principles to be followed in Administration of Act.
  The Central Government, the State Governments, the Food Authority and other agencies, as the case may be, while implementing the provisions of this Act shall be guided by the following principles namely:-
- (2) The Food Authority shall, while framing regulations or specifying standards under this Act–
  - (a) take into account –
    - (ii) international standards and practices, where international standards or practices exist …

INDUSTRY EXPECTATION

Adopt the list of ingredients as under -

CODEX ALIMENTARIUS International Food Standards (World Health Organization, Food and Agriculture Organization of the United Nations)

FDA DSHEA Dietary Supplement Health Education Act

JECFA JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

FDA GRAS GENERALLY RECOGNIZED AS S

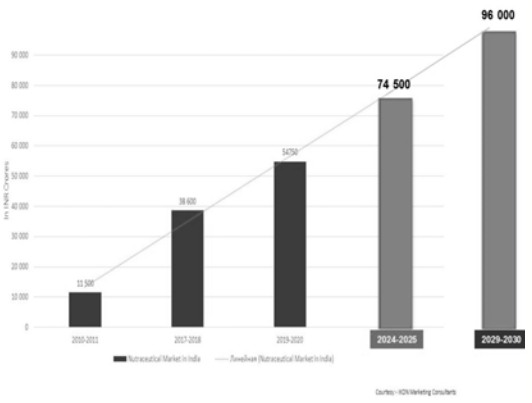
Health Canada

efsa European Food Safety Authority

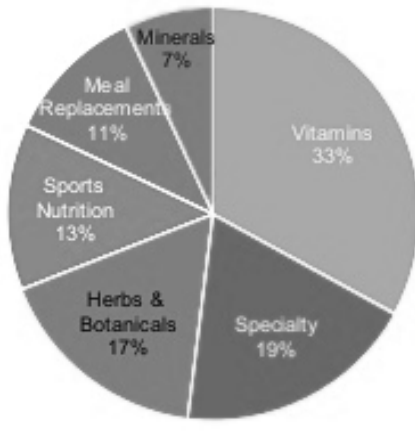
FOOD STANDARDS

FSANZ Food Standards Australia and New Zealand

INDIAN NUTRA GROWTH



2012E SUPPLEMENT SALES BY PRODUCT TYPE



STRENGTHENING INDUSTRY INSTITUTE INTERACTION TO MEET PHARMA VISION 2030

by

Dr. George Patani
Director, Inga Laboratories P. Ltd. Chairman Industry Institute Interaction Committee, IDMA

Need for Industry Institute Interaction (III)

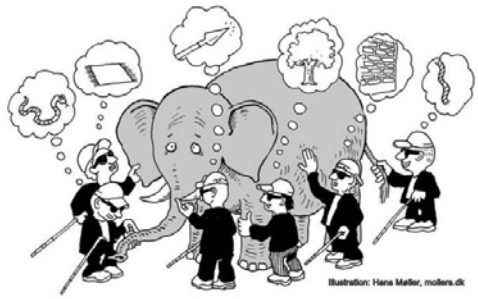
- Liberalization and Globalization – industrial scenario is fast changing
- Great focus on Quality Products and Skilled and Qualified Man Power
- Training (Retraining) of the work force has become a major activity for all industries
    - Technical skills, Team work, Communication (Patil, BMB, IJLTET, Vol. 3, Issue 4, March 2014)
    - Learning Agility, Result Orientation, Integrity & Values (CII Skills Report 2017)
- Need for industries to depend on institutions for technical and skilled man power and solutions to technical problems

III - Nature of Interaction

- Internships, Placements
- Industrial Tours
- Interactive Workshops/Seminars
- Curriculum Development
- Part time faculty from Industry
- Research Projects – Technology Transfer
- Continuing Education Programs
- Incubation Centers
- Centers of Excellence

Benefits of III – Skill Development

- Institute
- Greater Resource generation
- More relevant curriculum
- Better placements



- Industry
  - New Trained Personnel
  - Skill Upgradation of the Workforce
  - Applied Research gets done collaborative research
  - Important Impact on process innovation and new products and services
    - Chile and Colombia
      - III increased propensity of firms to introduce new products and patent (Marotta, Blom and Thorn 2007)

Challenges– Collaborative Research

- Industries lack information about technology universities have to offer
- Industries - Low level of engagement with universities (12%)
- Quality of information regarding innovation once contact is made
- Mismatch in terms of relevance, time horizons (SMEs) & expectations
- Demand centers on highly applied technical issues
- Lack of interest for the academic concerned

Howells, J., Ramlogan, R., Cheng, S. L. Benefits and Challenges of University –Industry Interactions : A Critical Perpesctive University of Manchester

Drugs discovered and marketed in India*

Drug	Discoverer	Use	Marketed by	Year of approval
Sintamil	Ciba-Giegy Research Centre, Mumbai	Anti-depressant	Novartis, Mumbai	1976
Satraindizole	Ciba-Giegy Research Centre, Mumbai	Anti-protozoal	Alkem Laboratories, Mumbai	1980
Guglip (phytopharmaceutical)	CDRI, Lucknow	Hypolipedimic	CIPLA, Mumbai	1988
Centchroman (Ormeloxifene)	CDRI, Lucknow	Contraceptive, dysfunctional uterine bleeding (DUB), emergency contraception	Hindustan Latex Ltd, Thiruvananthapuram Torrent Pharmaceuticals Ltd, Ahmedabad	1989 1990
Bacosides (phytopharmaceutical)	CDRI, Lucknow	Memory enhancer	Nivaran Herbals, Chennai	1997
Arteether	CDRI, Lucknow	Anti-malarial	Themis Medicare, Mumbai	1997
Risorine	IIM, Jammu	Anti-tubercular	Cadila Pharma, Ahmedabad	2009
Synriam	Ranbaxy Laboratories Ltd, New Delhi	Anti-malarial	Ranbaxy Laboratories Ltd, New Delhi	2011
Lipaglyn™ (Saroglitazar)	Zydus Cadila, Ahmedabad	Diabetic dyslipidemia or hypertriglyceridemia	Zydus Cadila, Ahmedabad	2014

* Curr. Sci., 2016; Vol 111, No. 2, 252-255

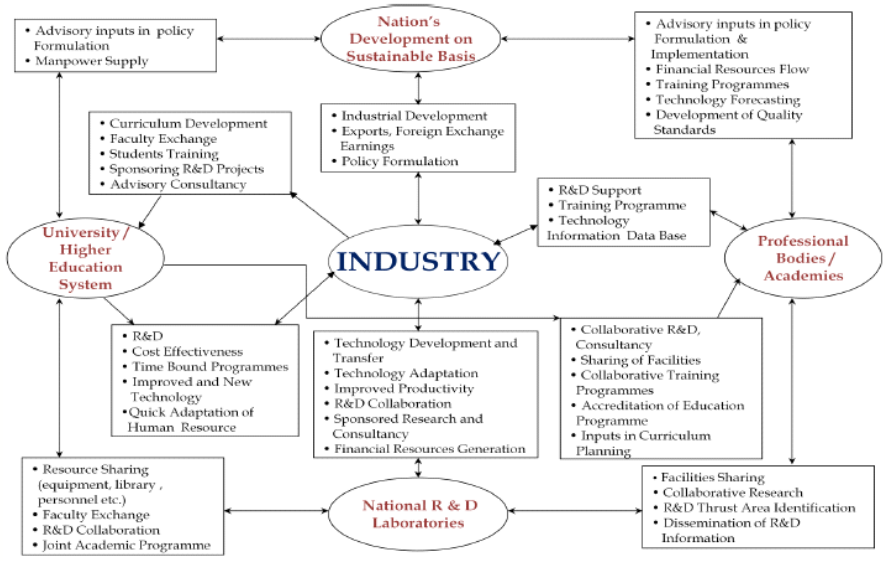
Drugs discovered but not marketed in India*

Drug	Discoverer	Use	Licensed to	Year of approval
Centiminazone	CDRI, Lucknow	Anti-thyroid	Unichem Laboratories, Mumbai	1972
Nonaperone	Ciba-Giegy Research Centre, Mumbai	Anti-psychotic	Novartis, Mumbai	1980
Amoscanate	Ciba-Giegy Research Centre, Mumbai	Anti-parasitic	Novartis, Mumbai	1980
Enfenamic acid	Regional Research Laboratory (now IICT), Hyderabad	Anti-inflammatory	–	1982
Cent-bucridine	CDRI, Lucknow	Local anaesthatic	Themis Medicare, Mumbai	1987
Cent-butindole	CDRI, Lucknow	Neurolaptic	Themis Medicare, Mumbai	1987
Chandonium iodide	CDRI, Lucknow, and Panjab University, Chandigarh	Neuro-muscular blocker	CIPLA, Mumbai	1994
Cent-propazine	CDRI, Lucknow	Anti-depressant	Themis Medicare, Mumbai	1996
Bulaquin	CDRI, Lucknow	Anti-malarial	Nicholas Piramal, Mumbai	1996

Successful industry-institute collaboration must support the mission and motivations of all partners

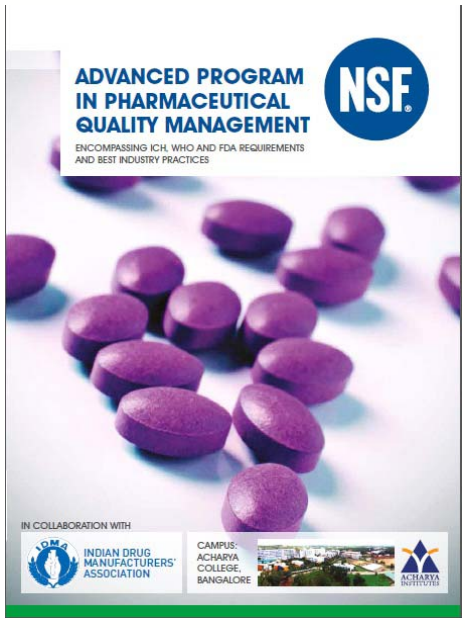
* Curr. Sci., 2016; Vol 111, No. 2, 252-255

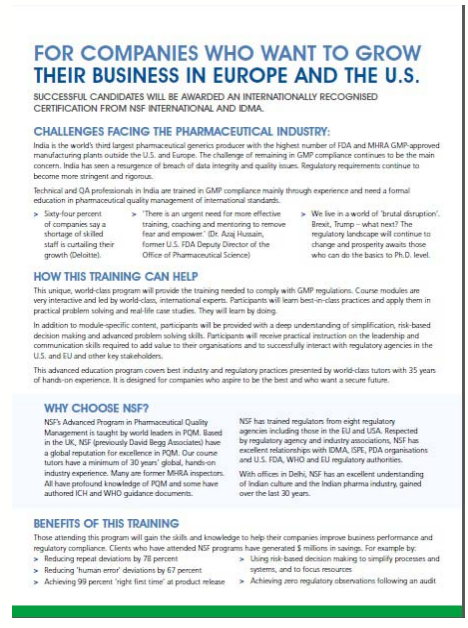
Model for Institute-Industry-National R&D Labs and Other Organisations Interaction



Visvesvarya National Institute of Technology

Training Program – Associations (IDMA)





Intensity-University Industry Links

High (Relationships)	Research partnerships	Inter-organizational arrangements for pursuing collaborative R&D, including research consortia and joint projects.
	Research services	Research-related activities commissioned to universities by industrial clients, including contract research, consulting, quality control, testing, certification, and prototype development.
	Shared infrastructure	Use of university labs and equipment by firms, business incubators, and technology parks located within universities.
Medium (Mobility)	Academic entrepreneurship	Development and commercial exploitation of technologies pursued by academic inventors through a company they (partly) own (spin-off companies).
	Human resource training and transfer	Training of industry employees, internship programs, postgraduate training in industry, secondments to industry of university faculty and research staff, adjunct faculty of industry participants.
Low (Transfer)	Commercialization of intellectual property	Transfer of university-generated IP (such as patents) to firms (e.g., via licensing).
	Scientific publications	Use of codified scientific knowledge within industry.
	Informal interaction	Formation of social relationships (e.g., conferences, meetings, social networks).

Jose Guimon, Promoting University-Industry Collaboration in Developing Countries, World Bank 2013.

Economic Development - University Industry Partnership

	Most developed countries	**Least developed countries**
Teaching University	• Private participation in graduate programs • Joint supervision of PhD students	• Curricula development to improve undergraduate and graduate studies • Student internships
Research University	• Research consortia and long term research partnerships to conduct frontier research	• Building absorptive capacity to adopt and diffuse already existing technologies • Focus on appropriate technologies to respond to local needs
Entrepreneurial University	• Spin-off companies, patent licensing • Entrepreneurship education	• Business incubation services • Entrepreneurship education

Jose Guimon, Promoting University-Industry Collaboration in Developing Countries, World Bank 2013

University of Tokyo – School of Pharmaceutical Sciences Research Programs

Department	Research Program	Duration	Sponsor Name	Value (million yen)
Graduate School of Pharmaceutical Sciences	Laboratory of Drug Informatics/Drug Lifetime Management	2015.10-2020.03	Nichi-Iko Pharmaceutical, Ikeda Mohando Ltd., Toho Pharmaceutical, Watami no Kaigo Co., Ltd., Wakaba Corporation, Ain Pharmaciez, Hojin-yakkyoku Inc., Recruit Medical Career, Medisere Co., Ltd., Yuyama Co.,Ltd	222.5
	Drug Policy and Management	2011.04-2015.09	Towa Pharmaceutical	150
	Pharmaco-business Innovation	2012.09-2016.03	Ain Pharmaceiz, Nippon Flour Mills, Kyowa Hakko Kirin Co., Ltd., Takeda Pharmaceutical, Sakura Global Holding, Jonson & Johnson Medical Company, Terumo Corporation, Hitachi Ltd.	109
	Pathological Cell Biology	2012.10-2017.09	Funakoshi Co., Ltd.	100

Attributes - Industry and Institute Interactions must

- Result Orientation
- Learning Inclination
- Integrity & Values
- Team Work
- Communication
- Technical Skills
- Incentivize Collaboration
- Globalize (MNCs, Universities)

INDIAN PHARMACEUTICAL MARKET

Indian Pharmaceutical market

- 1950s-1960s

MNCs 80-90 %

- Government Actions – 1970s
  - Abolition of Product Patents
  - Limitation of Multinational equity in Pharmaceutical companies
  - Establishment of 5 state owned pharmaceutical cos.

Indian Pharmaceutical market

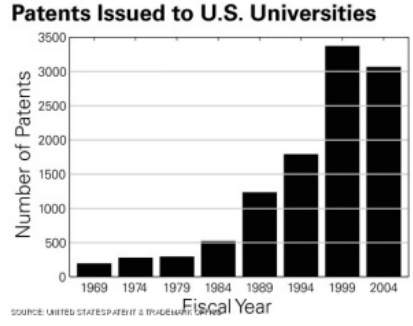
- 1980s-1990s-2000s

Indian Pharma 80-90 %

India – Self sufficient and the pharmacy of the world

TRIGGERS OF GROWTH FOR III IN THE U.S.

- Bayh Dole Act 1980
- The key change made by Bayh–Dole was in ownership of inventions made with federal funding. Bayh–Dole permitted a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government.



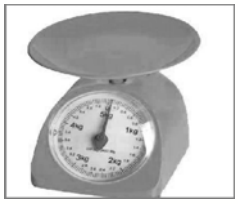
E-LEARNING STRATEGIES FOR IMPLEMENTATION IN THE INDIAN SCENARIO

by

Dr. Vijay Sagar
Professor & Head, Dept of Anatomy, Sri Ramachandra Medical College & Research Institute

How does it all weigh up

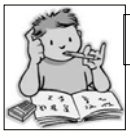
- Self directed motivation
- Solitary
- Monotonous
- Impersonal
- Inability to clarify doubts
- Poor attendance
- Robust technology
- High investment costs



How does it all weigh up

- Flexible
- Self paced
- Covers basics
- Consistent delivery
- Time savings
- Captures Knowledge
- Reusable
- Scalable
- Distance education

E-learning culture



Self Directed, Motivated, Self regulating

Upgrade skills, understand learning, facilitate, create new opportunities

Believe, willing to spend time and money

Getting e-content

Commercial products

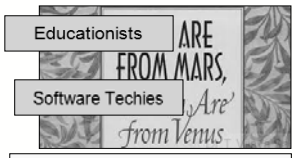
- Cross sectional anatomy tutor
- Defiore atlas of histology
- Ackland video atlas of anatomy
- Simbryo - Langmans

Internet

- Online resources
- Najeebs, Khan academy
- You tube
- Youtube downloader.

Software Team

- Advantages
- Expensive
- Different Languages
- Specialisation
- Educational technologist



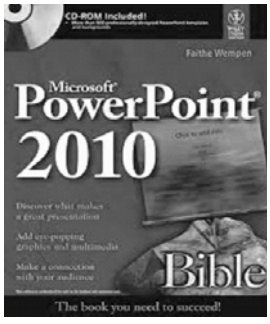
How to make e-content

- Power point
- Build interactivity
- Audio Narrations
- Video clips
- Multimedia content

- Tailor made for e-learning
- Customise tabs
- Group slides into sections
- Improved picture crop

Power point

- Broadcast via skydrive
- Insert online videos
- Make bookmarks
- Trigger events on reaching bookmarks
- Remove background from picture



Powerpoint

Great for a classroom environment

Does it fit into an e-learning environment ?

Rapid authoring tools

Software which allow integration of multimedia objects and creation of interactive learning materials.

Helps create e-content in a short time, in an easy way and at highly reduced cost.

Allows non programmers to create multimedia content

Multiple export options, support online environment

Allows endless possibilities

Big 5

Adobe Captivate

Articulate

Knowledge presenter

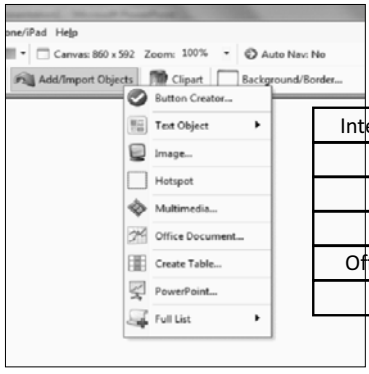
Camtasia studio

Lectora

Start up screen

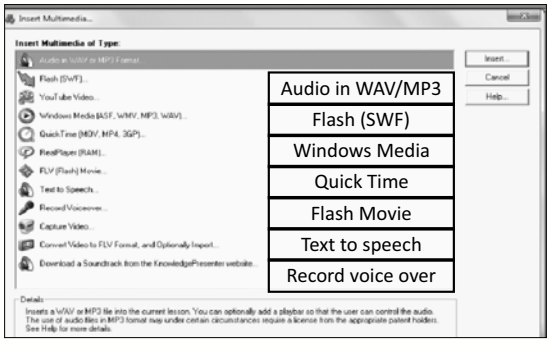
User Interface

Import options



- Interactive buttons
- Text
- Images
- Multimedia
- Office documents
- PointPoint

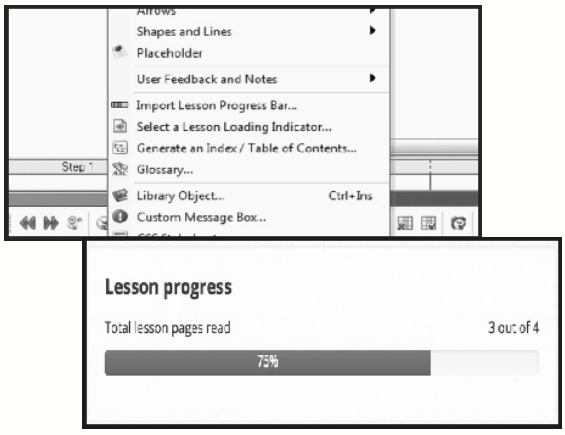
Import multimedia



- Audio in WAV/MP3
- Flash (SWF)
- Windows Media
- Quick Time
- Flash Movie
- Text to speech
- Record voice over

Import PowerPoint

Other inserts



Apply events to Objects

When clicked on this object, perform the action

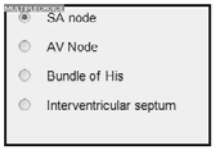
- display a picture
- display a text box
- play an audio file
- play a video file
- Jump ahead to _____ slide
- Jump back to _____ slide

- Go to you tube link_____
- Display a Pdf document
- Enlarge a picture
- Conduct a Multiple choice quiz
- Assess the multiple choice quiz and give report
- e mail results

Demo

MCQs

Where is the cardiac impulse generated ?



Single best response

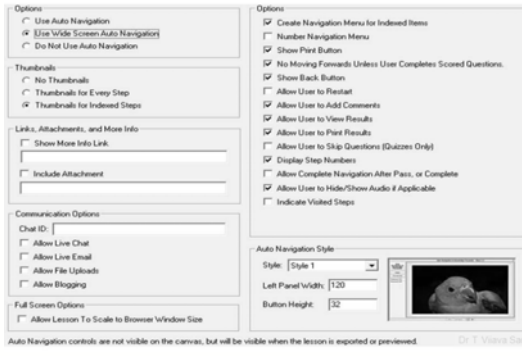
Multiple best response

Matching and sequencing

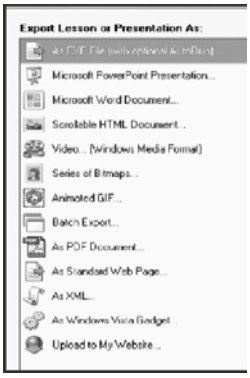
Fill in blanks

Demo

Final selection



Export



- .exe file
- Standard export for web
- Ppt
- Scrollable document for net
- Video
- iphone app/ipad app

Develop basic multimedia skills

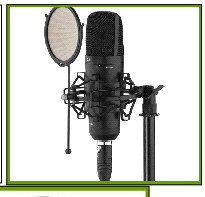
•Video editing and processing software
•Procure genuine software
•USD 150-200

Audio equipment

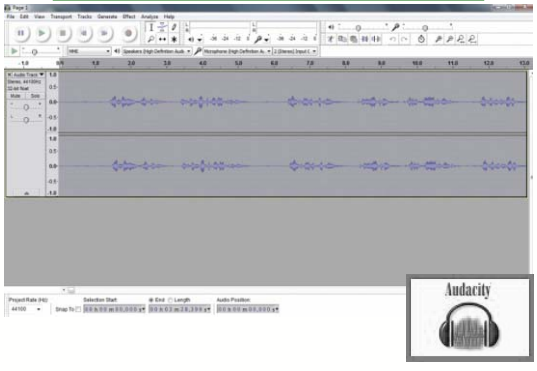
• High quality Condensor type microphone

•Audio interface

• Studio – ideal



Post recording audio processing



Central Multimedia hub

How to deliver content ?

Offline Delivery

- Pen drives
- CD/DVD ROMS

Online delivery

- Static website
- Dynamic website using a LMS

Infrastructure is **THE** pre-requisite

Learning Management Systems (LMS)

- Heart of e-learning
- Customised for plug and play
- Free Vs Paid
- Upload to your website
- Populate with users and content

Learning Management Systems

1. Registration
2. Delivery
3. Scheduling, tracking and reporting

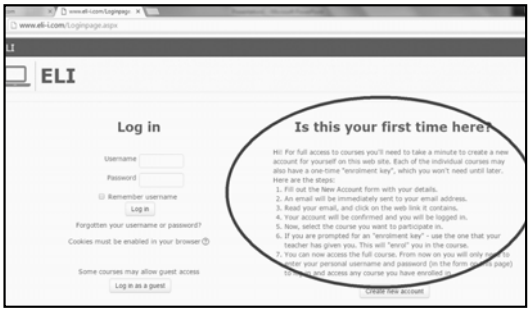
Moodle

- Modular object oriented dynamic learning environment
- Open source software
- Tailored for e-learning and course administration
- Basic themes
- Plug-ins, Free / Paid
- Supports activities at university level

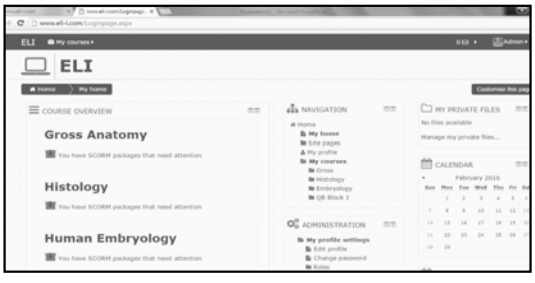
FREE !!

Website

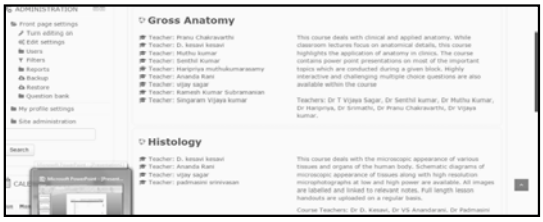
Secure Access



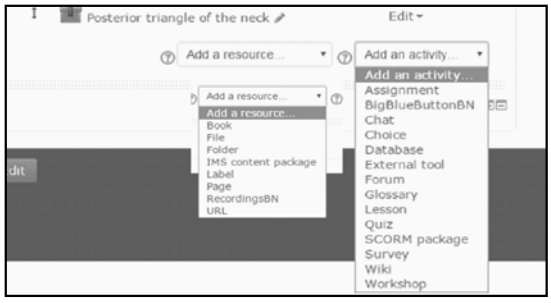
Available Courses



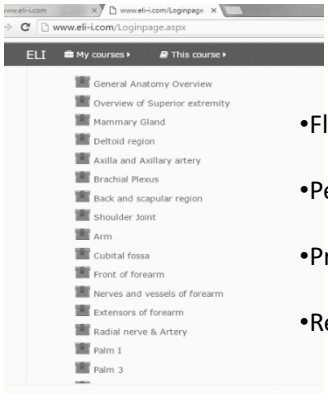
Course descriptor and teachers



Upload resources/activities

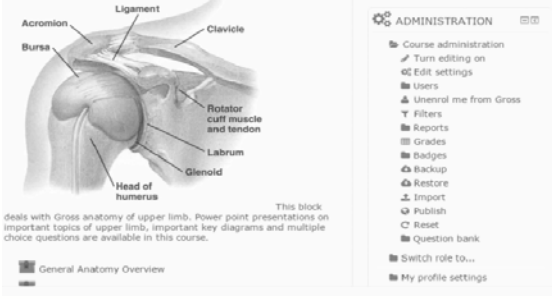


Topics inside course

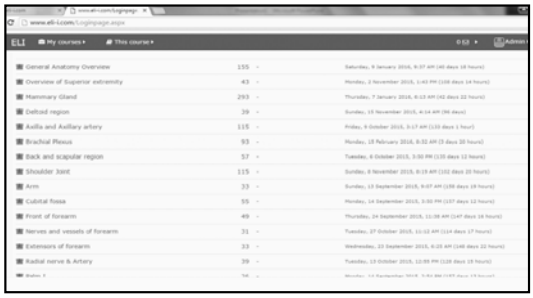


- Flexibility
- Permit downloading?
- Print ?
- Restrict attempts ?

Course Administration



Tracking User's progress



Schedule activities

Change initiatives

- Inertia
- Convince faculty
- Organise adequate FDPs
- Enforce change ?

Successful Implementation

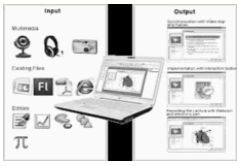
Support from Senior administrative levels

Technology has to deliver

Create impacting change initiatives

Conclusion

- Single route which supports all types of learners
- Human interaction is a vital ingredient
- Magic is in the mix
- Increasing computer literacy



The future…….

- Pedagogical shift is inescapable
- High speed Internet
- Futuristic e-learning environments
- e-Centres of excellence
- Consortium of colleges

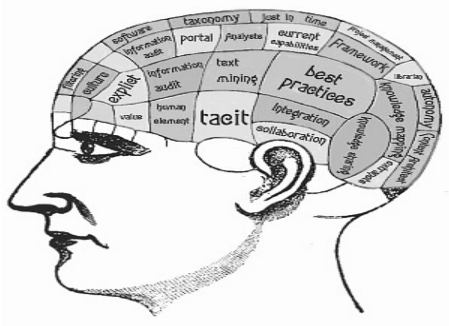
"I am not a teacher, only a fellow traveller of whom you asked the way. I pointed ahead, ahead of myself and you……."

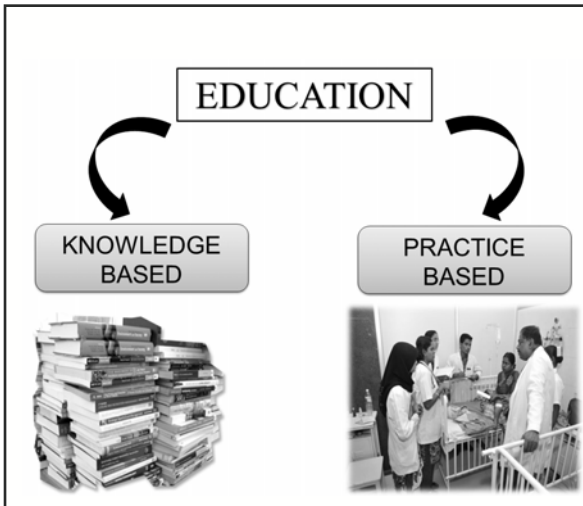
George Bernard Shaw

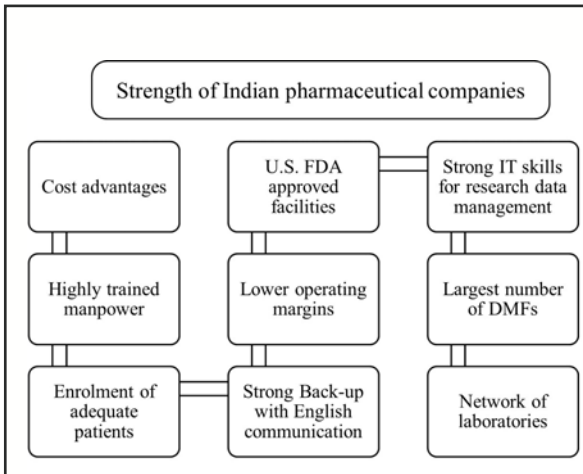
PHARMA VISION 2030: PROFESSIONALISM IN CLINICAL INTERVENTION

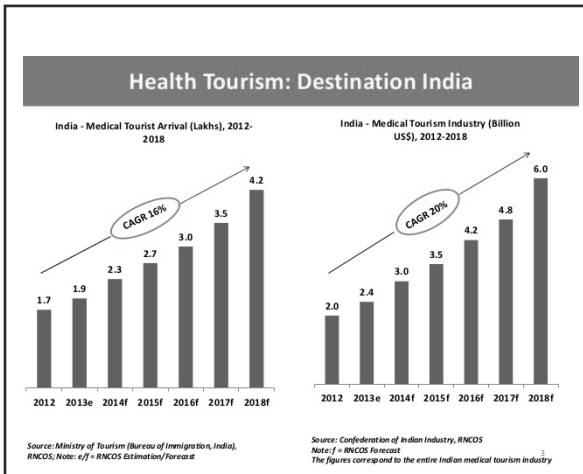
by

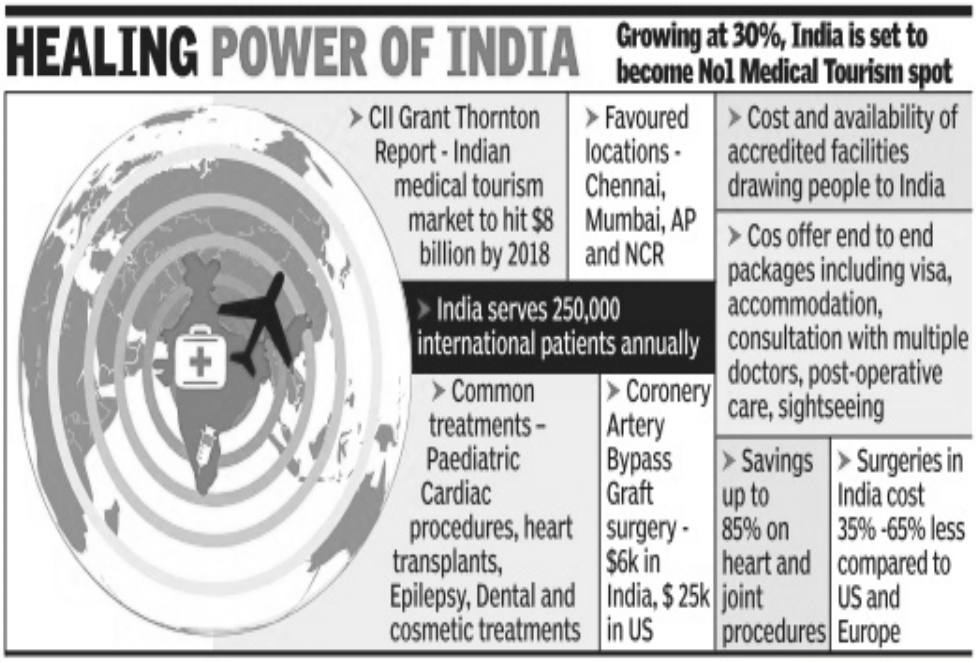
Dr. S. Sriram
Prof & Head, Dept. of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore

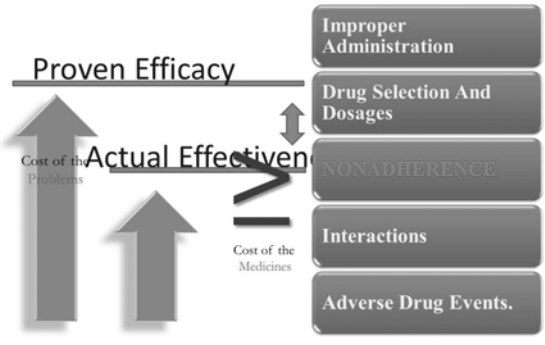


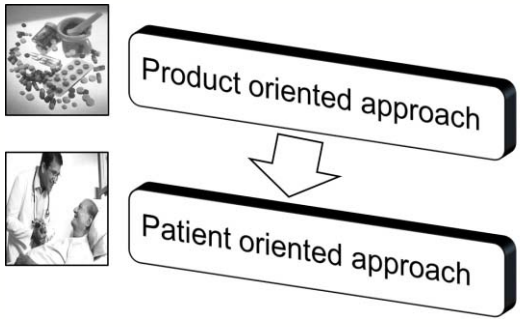







HEALING POWER OF INDIA
Growing at 30%, India is set to become No1 Medical Tourism spot
CII Grant Thornton Report - Indian medical tourism market to hit $8 billion by 2018
Favoured locations - Chennai, Mumbai, AP and NCR
Cost and availability of accredited facilities drawing people to India
India serves 250,000 international patients annually
Cos offer end to end packages including visa, accommodation, consultation with multiple doctors, post-operative care, sightseeing
Common treatments – Paediatric Cardiac procedures, heart transplants, Epilepsy, Dental and cosmetic treatments
Coronery Artery Bypass Graft surgery - $6k in India, $ 25k in US
Savings up to 85% on heart and joint procedures
Surgeries in India cost 35% -65% less compared to US and Europe

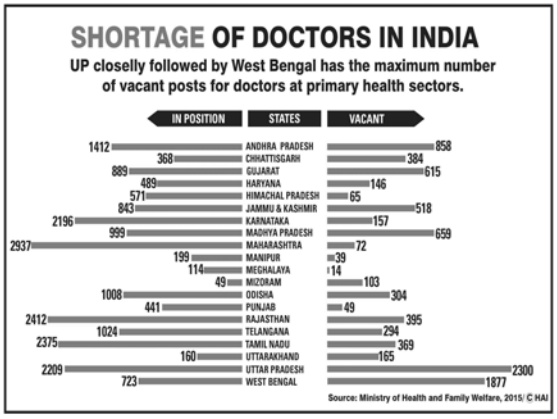

Proven Efficacy
Actual Effectiven
Cost of the Problems
Cost of the Medicines
Improper Administration
Drug Selection And Dosages
NONADHERENCE
Interactions
Adverse Drug Events.

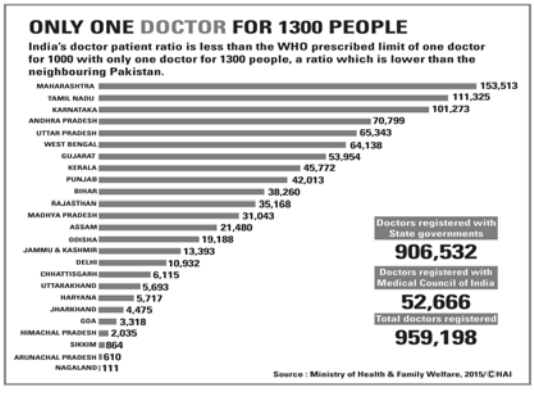

Product oriented approach
Patient oriented approach

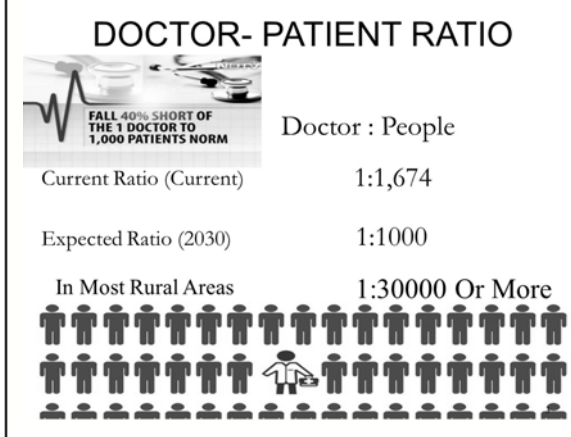
MEDICINES

when not used appropriately become

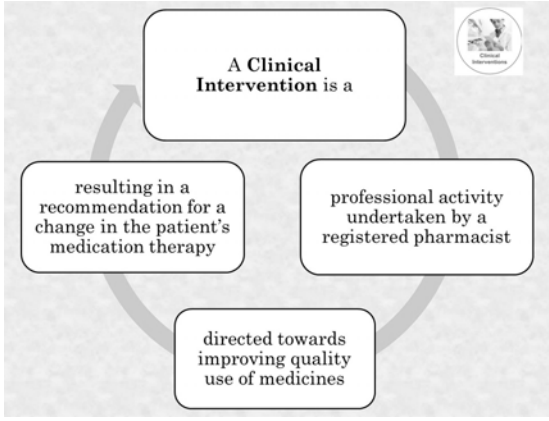
MEDISINS



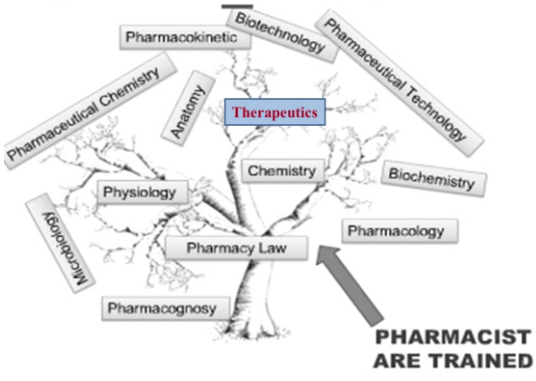


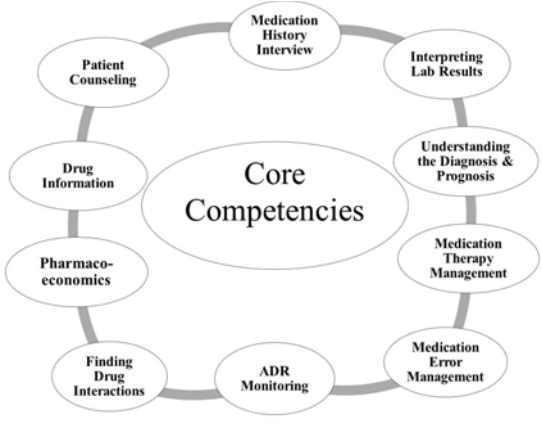


MEDICATION ERRORS MAKING HEADLINES!

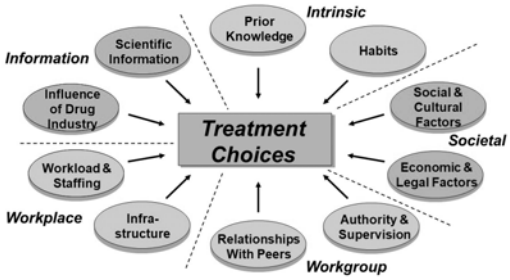


Application oriented Pharmacy education

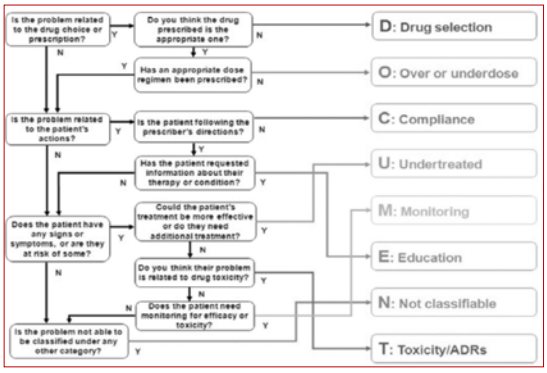


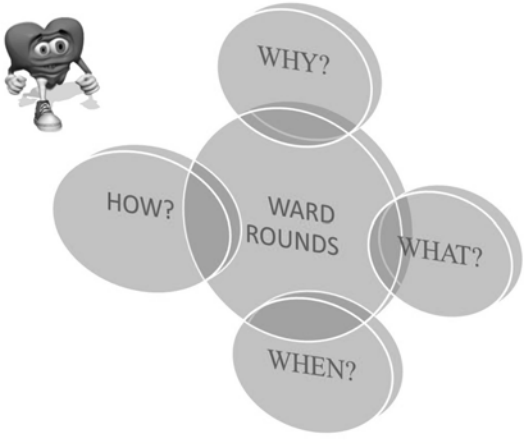


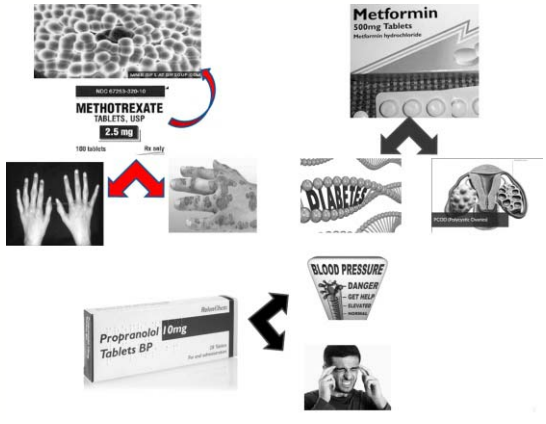
Many Factors Influence Use of Medicines

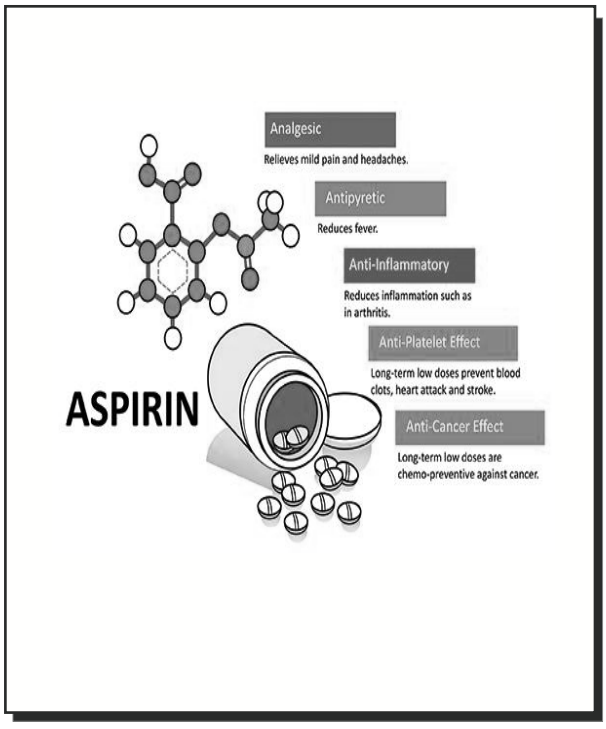


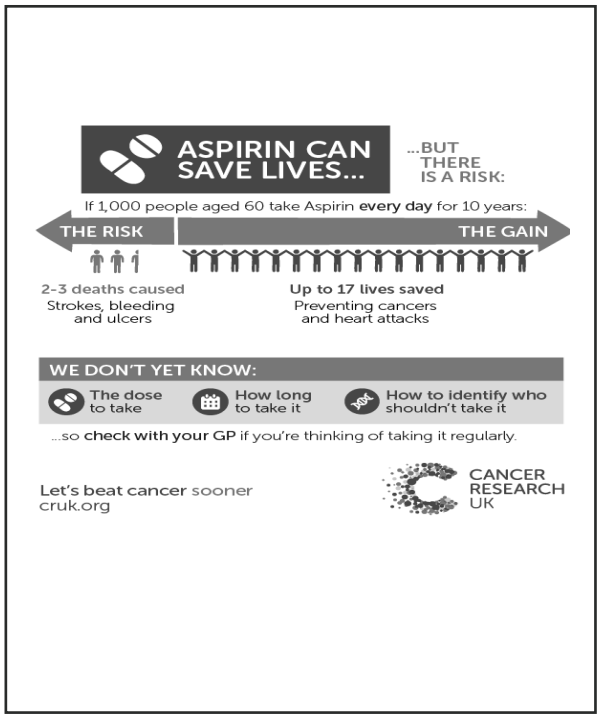
Stepwise Intervention

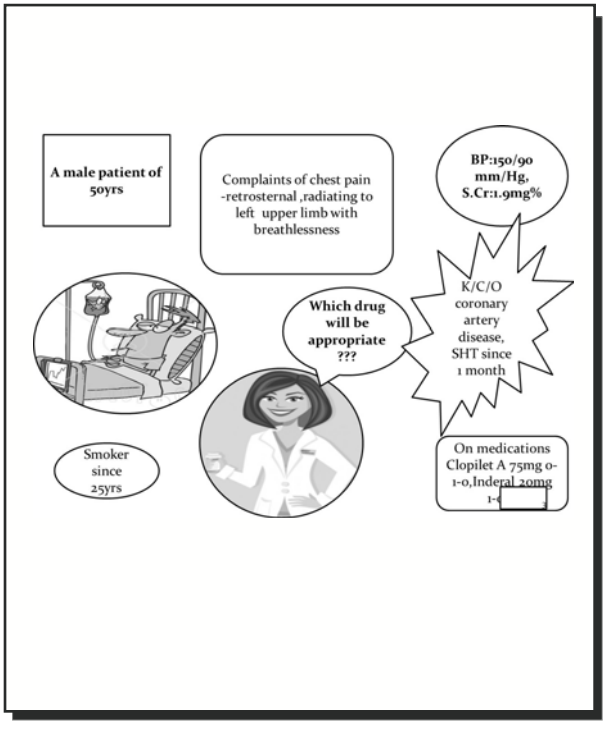


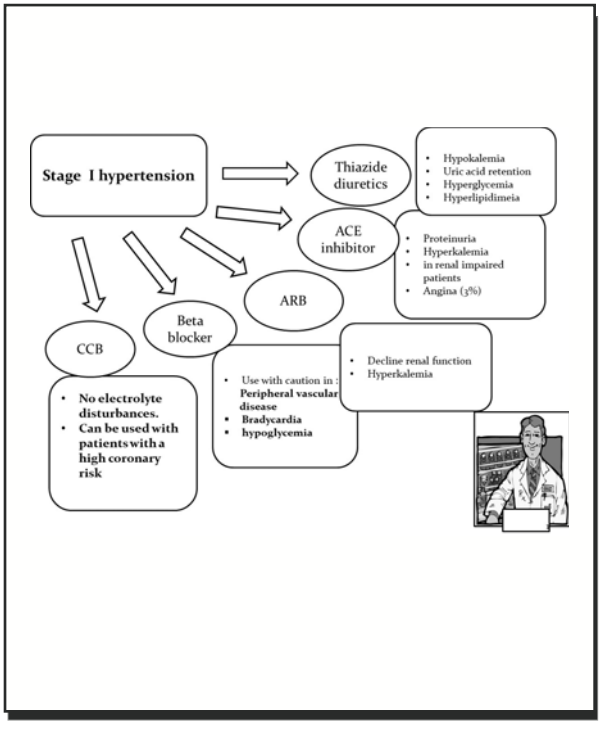


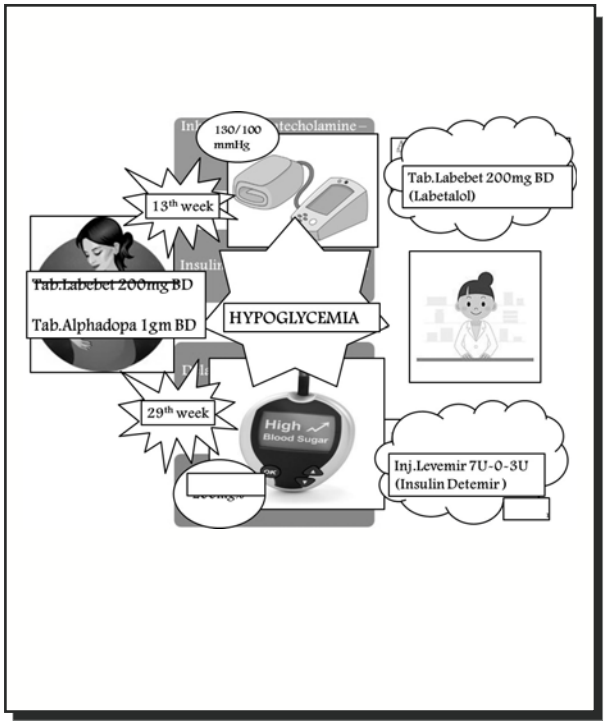


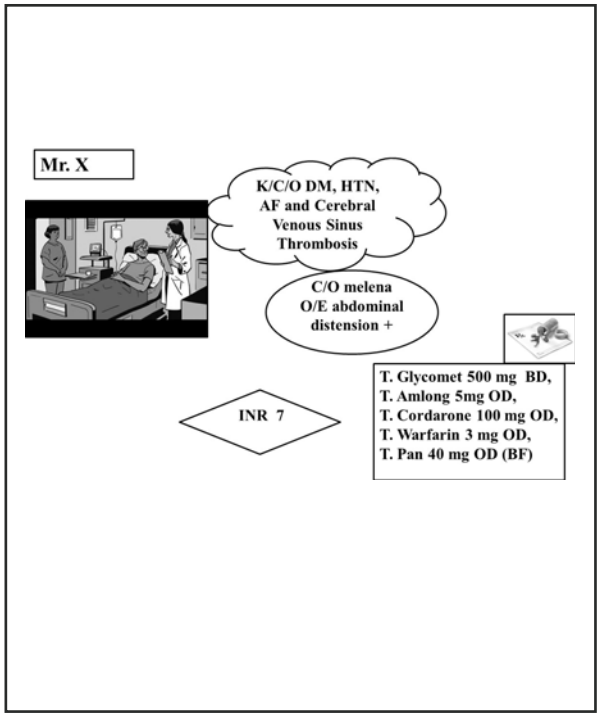

Analgesic
Relieves mild pain and headaches.
Antipyretic
Reduces fever.
Anti-Inflammatory
Reduces inflammation such as in arthritis.
Anti-Platelet Effect
Long-term low doses prevent blood clots, heart attack and stroke.
Anti-Cancer Effect
Long-term low doses are chemo-preventive against cancer.
ASPIRIN

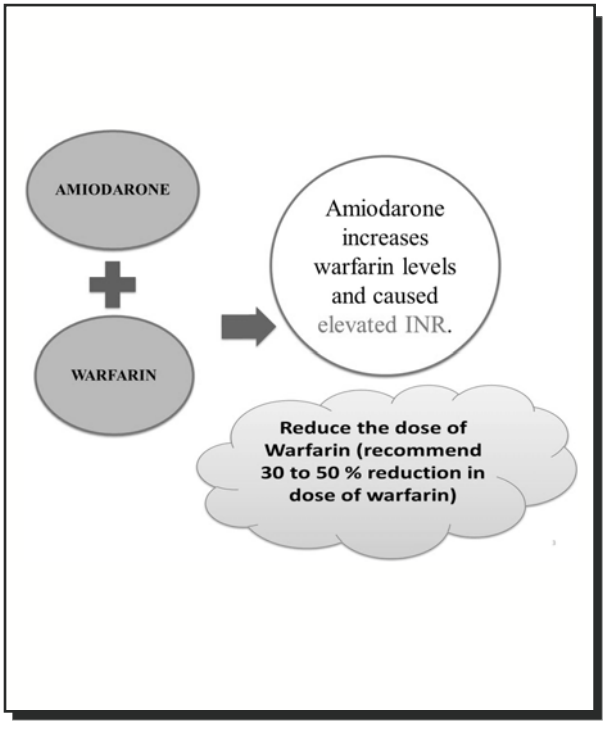

ASPIRIN CAN SAVE LIVES...
...BUT THERE IS A RISK:
If 1,000 people aged 60 take Aspirin every day for 10 years:
THE RISK
THE GAIN
2-3 deaths caused
Strokes, bleeding and ulcers
Up to 17 lives saved
Preventing cancers and heart attacks
WE DON'T YET KNOW:
The dose to take
How long to take it
How to identify who shouldn't take it
...so check with your GP if you're thinking of taking it regularly.
Let's beat cancer sooner
cruk.org
CANCER RESEARCH UK

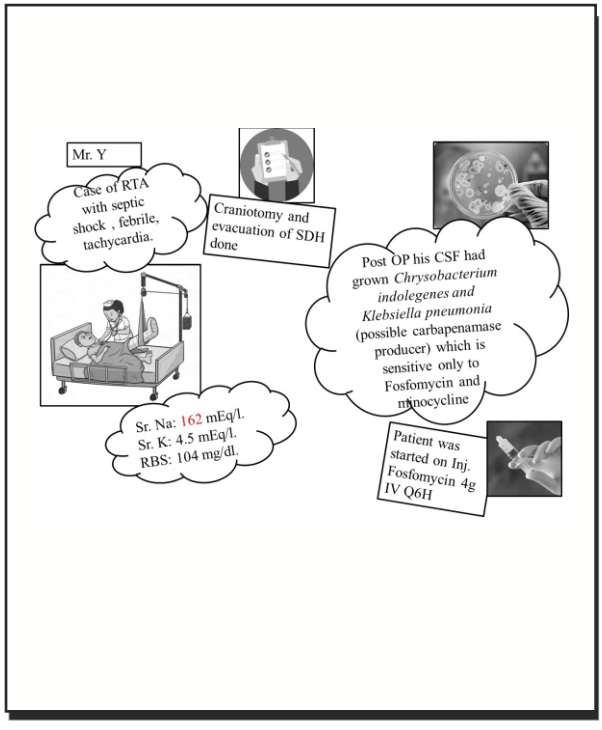

A male patient of 50yrs
Complaints of chest pain -retrosternal ,radiating to left upper limb with breathlessness
BP:150/90 mm/Hg, S.Cr:1.9mg%
K/C/O coronary artery disease, SHT since 1 month
Which drug will be appropriate ???
Smoker since 25yrs
On medications Clopilet A 75mg 0-1-0,Inderal 20mg 1-

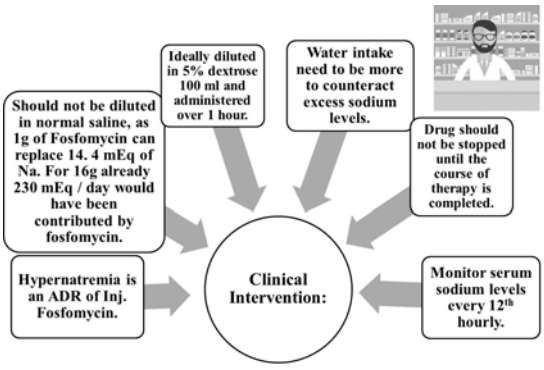

Stage I hypertension
Thiazide diuretics
Hypokalemia
Uric acid retention
Hyperglycemia
Hyperlipidimeia
ACE inhibitor
Proteinuria
Hyperkalemia
in renal impaired patients
Angina (3%)
ARB
Beta blocker
CCB
Use with caution in : Peripheral vascular disease
Bradycardia
hypoglycemia
Decline renal function
Hyperkalemia
No electrolyte disturbances.
Can be used with patients with a high coronary risk


130/100 mmHg
13th week
Tab.Labebet 200mg BD (Labetalol)
Tab.Labebet 200mg BD
Tab.Alphadopa 1gm BD
HYPOGLYCEMIA
29th week
High Blood Sugar
Inj.Levemir 7U-0-3U (Insulin Detemir)


Mr. X
K/C/O DM, HTN, AF and Cerebral Venous Sinus Thrombosis
C/O melena O/E abdominal distension +
INR 7
T. Glycomet 500 mg BD,
T. Amlong 5mg OD,
T. Cordarone 100 mg OD,
T. Warfarin 3 mg OD,
T. Pan 40 mg OD (BF)


AMIODARONE
WARFARIN
Amiodarone increases warfarin levels and caused elevated INR.
Reduce the dose of Warfarin (recommend 30 to 50 % reduction in dose of warfarin)


Mr. Y
Case of RTA with septic shock , febrile, tachycardia.
Craniotomy and evacuation of SDH done
Post OP his CSF had grown Chrysobacterium indolegenes and Klebsiella pneumonia (possible carbapenamase producer) which is sensitive only to Fosfomycin and minocycline
Sr. Na: 162 mEq/l.
Sr. K: 4.5 mEq/l.
RBS: 104 mg/dl.
Patient was started on Inj. Fosfomycin 4g IV Q6H



Every ill has got a pill

But every pill shouldn't create an ill

Format: Abstract

J Infect Chemother. 2003 Dec;9(4):314-20.

Effects of anti-inflammatory drugs on convulsant activity of quinolones: a comparative study of drug interaction between quinolones and anti-inflammatory drugs.

Hori S[1], Kizu J, Kawamura M.

Author information

Abstract

Quinolones have been reported to possess potent convulsant activity, which is enhanced when they are administered concurrently with anti-inflammatory drugs. To define the individual drug interactions of quinolones with anti-inflammatory drugs, we studied the convulsant activity of six quinolones with or without 13 anti-inflammatory drugs and 3 analgesic/antipyretic drugs in mice. Intraventricular injections of norfloxacin (NFLX), enoxacin (ENX), ciprofloxacin, lomefloxacin (LFLX), levofloxacin, and gatifloxacin induced convulsions in mice in a dose-dependent manner. Concurrent administration of biphenylacetic acid strongly enhanced the convulsant activity of NFLX, ENX, and LFLX. Flurbiprofen also strongly enhanced the activity of NFLX and ENX, and ketoprofen strongly enhanced the activity of ENX. However, mefenamic acid, piroxicam, tenoxicam, meloxicam, etodolac, sulpyrine, isopropylantipyrine, and acetaminophen had no effect on the convulsant activity of quinolones. These results suggest that each quinolone has an individual drug interaction with each anti-inflammatory drug. It was suggested that we should know which anti-inflammatory drugs enhance the convulsant activity of individual quinolones, and which quinolone has no/weak drug interaction with different anti-inflammatory drugs when these drugs are used concurrently for the treatment of patients with infectious diseases.

Published in final edited form as:
Stroke. 2015 March ; 46(3): 722–731. doi:10.1161/STROKEAHA.114.006866.

Comparative risk of ischemic stroke among users of clopidogrel together with individual proton pump inhibitors

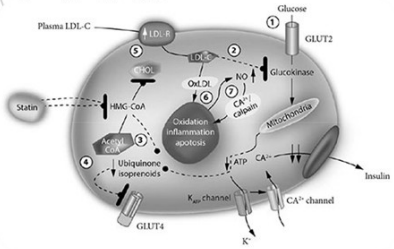
Charles E. Leonard, Pharm.D., M.S.C.E.[1,2], **Warren B. Bilker, Ph.D.**[1,2,3], **Colleen M. Brensinger, M.S.**[1], **David A. Flockhart, M.D., Ph.D.**[2,4], **Cristin P. Freeman, M.P.H., M.B.E.**[1,2,†], **Scott E. Kasner, M.D., M.S.C.E.**[5], **Stephen E. Kimmel, M.D., M.S.C.E.**[1,2,6], and **Sean Hennessy, Pharm.D., Ph.D.**[1,2,7]

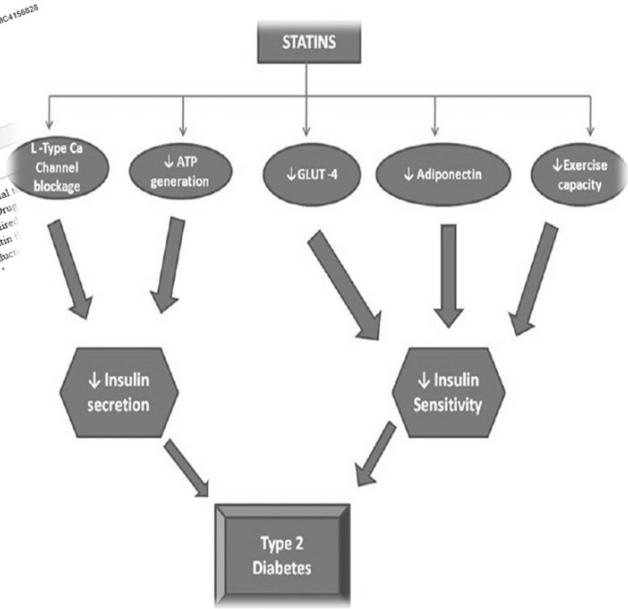
Leonard et al.

Abstract

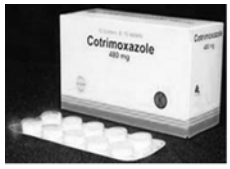
Background and Purpose—There is controversy and little information concerning whether individual proton pump inhibitors (PPIs) differentially alter the effectiveness of clopidogrel in reducing ischemic stroke risk. We therefore aimed to elucidate the risk of ischemic stroke among concomitant users of clopidogrel and individual PPIs.

Methods—We conducted a propensity score-adjusted cohort study of adult new users of clopidogrel, using 1999–2009 Medicaid claims from 5 large states. Exposures were defined by prescriptions for esomeprazole, lansoprazole, omeprazole, rabeprazole and pantoprazole—with pantoprazole serving as the referent. The endpoint was hospitalization for acute ischemic stroke,



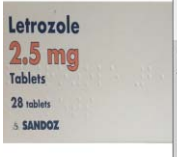


INCREASED RISK OF QT INTERVAL PROLONGATION



MAJOR INTERACTION

INCREASED RISK OF QT INTERVAL PROLONGATION



Indication	Breast cancer •Early: Adjunctive treatment with tamoxifene •Advanced • 2.5mg once daily
Precautions	• Cirrhosis or CrCl<10mL/min: 50% dose reduction • Decreased bone mineral density • High cholesterol
ADRs	Hot flashes, night sweats, nausea, arthralgia, headache, dizziness, edema
$T^{1/2}$	Terminal ~2 days

INSULIN DOSE CALCULATION FOR DIABETES MELLITUS

Total Daily Insulin Requirement (TDD in units)

0.2-0.4 units/kg

OR

- **Weight in Pounds ÷ 4**
- **0.55 X Total Weight in Kg**

Example:

If 160lbs, 160/4 = 40 units

If 55kg, 55× 0.55 =30 units

SLIDING SCALE INSULIN

BLOOD GLUCOSE LEVEL	UNITS OF INSULIN
<150	0
150-200	2
201-250	4
251-300	6
301-350	8
351-400	10
401-450	12
>450	14

CALCULATING INSULIN SENSITIVITY FACTOR (CORRECTION FACTOR)

__ mg/dl drop in your blood glucose caused by 1 unit of insulin

'RULE OF 1500' for regular insulin

'RULE OF 1800' for rapid acting insulin

1500/TDD or 1800/TDD = **Expected amount of glucose lowering per unit of insulin**

Example:

If TDD=30 UNITS

1500/30 = 50mg/dl reduced by 1 unit of insulin

If BG= 320mg/dl

(320-120)/50 = 4 units of insulin required

INDIA'S REJECTION OF SECONDARY PATENTS HAS KEPT BLOCKBUSTER MEDICINES AFFORDABLE FOR MANY

HUMIRA
- Rs.85,000 in USA.
- Rs.13,500 in India.

GLIVEC
- Rs.1.6 lakh in USA.
- Rs.11,000 in India.

SPIRIVA
- Rs.19,100 in USA.
- Rs.250 in India.

ADMINISTRATION ERRORS

Drugs involved	Error caused	Actual Procedure
Amoxicillin + clavulanate potassium (1.2g)	Reconstituted with **5ml sterile WFI** and administered in **10 sec**.	Reconstitution in **20 ml of WFI**, used immediately and given by slow i.v. injection over a period of **3-4 min**.
Gentamicin Rx - 60mg; Available as 80mg/2ml amp.	**2 ml** was administered	**1.5ml** should be administered instead of 2 ml.
Cefoperazone + sulbactam	Reconstituted with **5ml of 0.9% sodium chloride**	Reconstitution with **8ml of 5% dextrose in water** (or) **0.9% sodium chloride**

Drugs involved	Error caused	Actual Procedure
Etophyllin + Theophyllin	Administered as IV injection in **10 seconds**	Should be administered as IV injection at the rate of **2ml/min**
Ornidazole (100ml)	Administered as IV infusion in **10 minutes**	Should be infused over **15-30 minutes.**
Ofloxacin (100ml)	Administered as IV infusion in **10 minutes**	Administer infusion only. Avoid rapid (or)bolus IV infusion. It should be administered as IV infusion over a period of **30-60 minutes**

In silico clinical trials:
Drugs or components could be tested on these without limitations which would make clinical trials faster and even more accurate

Nanotechnology:
Due to their microscopic size, nanoparticles can easily travel around the human body in the blood stream, which have already been shown to assist in the delivery of anti-cancer drugs and to reduce toxicity.

Medical 3D printing:
It has the great potential to revolutionize the field of drug delivery with its inherent advantages of customizability and the ability to fabricate complex solid dosage forms with high accuracy and precision.

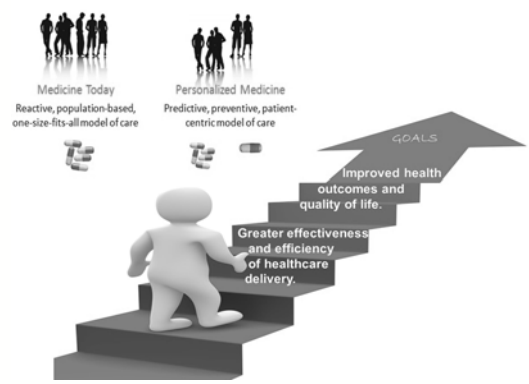
Genomics:
Aims at the complete mapping and understanding of all the genes of human beings and personalized medicine in which everyone gets customized therapy with customized dosages.

Wearables and beyond:
Biometric tattoos such as VivaLNK's eSkin Tattoo can transmit medical information discreetly which can be implanted under the skin and serve as an identification device.

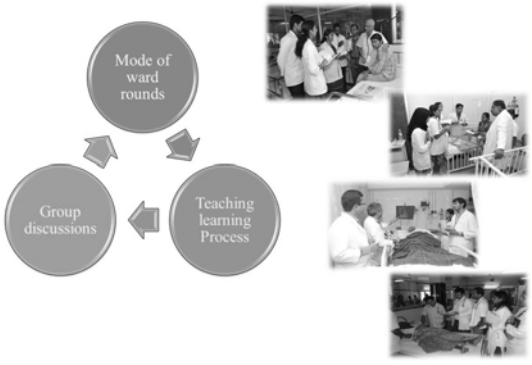
Augmented reality:
With an application using augmented reality during operations, surgeons can see through anatomical structures such as blood vessels in the liver without opening organs therefore they can perform more precise excisions.

Real-time diagnostics:
With the iKnife, the vaporized smoke is analyzed by a mass spectrometer to detect the chemicals in the biological sample which can identify whether the tissue is malignant real-time.

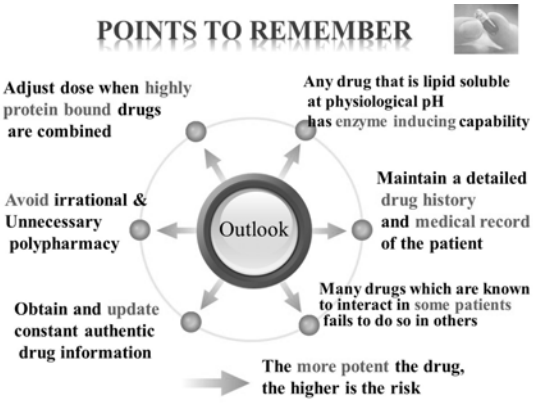
Google Brain:
We will be able to create digital selves based on neurological information and we could upload our minds to a computer and live on in a digital form.



Discussion with Preceptors



POINTS TO REMEMBER



- Ward Round Participation
- Medication History
- ADR & Drug Interaction
- Medication Error Reporting
- Pharmaco-economic
- Quality Of Life
- Patient Counseling
- Dosage Individualization
- Drug Information
- Medication Therapy Management

Clinical Pharmacist

PHARMACISTS IN CLINICAL TRIALS: TRANSFORMATION OF SKILLS FOR EFFECTIVE PATIENTS CARE

by
Dr. Ganachari
Professor & Head, Department of Pharmacy Practice, KLEU's College of Pharmacy, Belgaum

Futurology of Pharmacy Practice

What will be my Salary

What will be MY Designation

How will be work space

Will I be Hired ?

Are you Worth Hireing ?

Why Clinical Trials Need Pharmacist & Skills

Clinical Drug Trial without Pharmacist

!!** #$ @@ */- <>:"

Oath of Pharmacist

Pharmacists are the undisputed custodians of drugs

Current Scenario

- Clinicians
- Nurses
- Dieticians
- Allied science graduates
- Trained any graduates

Ideal Research Team

- Principal Investigator
- Research Pharmacist
- Research Nurse
- Research Phlebotomist
- Dietician

PHARMACIST'S OATH

- I swear by the code of ethics of Pharmacy Council of India, in relation to the community and shall act as an integral part of health care team.
- I shall uphold the laws and standards governing my profession.
- I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
- I shall follow the system which I consider best for Pharmaceutical care and counseling of patients.
- I shall endeavor to discover and manufacture drugs of quality to alleviate sufferings of humanity.

PHARMACIST'S OATH

- I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
- I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organizations.
- While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times !
- Should I trespass and violate this oath, may the reverse be my lot !

Clinical research

- Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical Research is different from clinical practice. In clinical practice one uses established treatments, while in clinical research evidence is collected to establish a treatment.

Scientific Aspects of Clinical Trial

Phases of Clinical Trial

- Phase I : First in man safety
- Phase II : First in patient dose, dosage form
- Phase III : Efficacy, ADRs
- Phase IV : [Post marketing surveillance] Evaluation in the real clinical setting

Phase I

- Objectives
  1. To assess a safe & tolerated dose
  2. To see if pharmacokinetics differ much from animal to man
  3. To see if kinetics show proper absorption, bioavailability
  4. To detect effects unrelated to the expected action
  5. To detect any predictable toxicity

– Inclusion criteria
  - Healthy volunteers : Uniformity of subjects: age, sex, nutritional status [Informed consent a must]
  - Exception: Patients only for toxic drugs Eg AntiHIV, Anticancer

– Exclusion criteria
- Women of child bearing age, children,

Phase I contd...

- Methods:
  - First in Man : Small number of healthy volunteers
  - First in a small group of 20 to 25
  - Start with a dose of about 1/10 to 1/5 tolerated animal dose
  - Slowly increase the dose to find a safe tolerated dose
  - If safe in a larger group of up to about 50 –75
  - No blinding
  - Performed by clinical pharmacologists
  - Centre has emergency care & facility for kinetics study
  - Performed in a single centre
  - Takes 3 – 6 months [70% success rate]

Phase II

- First in patient [different from healthy volunteer]
- Early phase [20 – 200 patients with relevant disease]
  - Therapeutic benefits & ADRs evaluated
  - Establish a dose range to be used in late phase
  - Single blind [Only patient knows] comparison with standard drug
- Late phase [50 – 500]
  - Double blind
  - Compared with a placebo or standard drug

Phase II

- Outcomes
  - Assesses efficacy against a defined therapeutic endpoint
  - Detailed P.kinetic & P.dynamic data
  - Establishes a dose & a dosage form for future trials
- Takes 6 months to 2 years [35% success rate]

Phase III

- Large scale, Randomised, Controlled trials
- Target population: 250 – 1000 patients
- Performed by Clinicians in the hospital
- Minimises errors of phases I and II

Phase III

- Methods
  - Multicentric Ensures geographic & ethnic variations
  - Diff patient subgroups Eg pediatric, geriatric, renal impaired
  - Randomised allocation of test drug /placebo / standard drug
  - Double blinded:
  - Cross over design
  - Vigilant recording of all adverse drug reactions
  - Rigorous statistical evaluation of all clinical data
- Takes a long time: up to 5 years [25% success]

Role of Pharmacist

Protocol

- Review the clinical trial protocol:
  - Is the dose appropriate for all trial participants?
  - Are all contra-indications listed in exclusion criteria?
  - Are all drug/disease interactions listed in exclusion criteria?
  - Have all expected side effects been included in protocol/patient information leaflet?

Review of trial protocol

- Discuss any protocol omissions or issues that need clarifying with Sponsor or Investigator
- Request a copy of the manufacturing and/or import authorisation to ensure that IMP manufactured/imported in compliance with Directive
- When all issues clarified and protocol amended (if necessary) trial can be approved from pharmacy perspective

Legalities

- Will the IMP be manufactured or imported under the terms of a manufacturing authorisation?
- IMPs must be manufactured to good manufacturing practice (GMP) Manufacturer must have a manufacturing license
  - Protects against poor quality or badly prepared medicines

Practicalities

- Do we have the facilities required for the trial?
  - Aseptic preparation?
  - Storage?
- Does the IMP pose a risk to staff?
  - Cytotoxic
  - Handling precautions
- Is the trial blinded?
  - Unblinding procedures

Finances

- Costing Template
- Are all services accounted for?
- Are the theoretical activity times realistic?
- Do standard prescription charges apply?
- Extra charges e.g. excess storage, drug destruction

Trial Approval

- Ethics committee
- DCGI
- DBT/DST
- HOSPITAL AUTHORITIES

IMP receipt

- Check temperature on any monitoring devices with delivery

  If out of range follow instructions with device and quarantine IMP

- Reconcile items delivered with delivery note
  Notify supplier of any discrepancies

- Ensure QP (IMP) release statement and Certificate of Analysis held in pharmacy for each batch of IMP delivered

- Acknowledge shipment as instructed on delivery note

IMP storage

- IMPs should be delivered directly to the pharmacy department

- IMP should be stored separately from normal pharmacy stock in area with restricted access
  - not stored on ward/clinic area unless used in emergency care

- Returned or expired IMP should be stored separately from unused IMP

- Regular temperature monitoring
  - Temperature deviations reported to CRA and medication quarantined

IMP Dispensing

- PI (or delegated Doctor) prescribe IMP on drug chart/prescription

- Signed prescription sent to pharmacy for dispensing

- IMP taken from dedicated IMP storage area

- Temperature checked to ensure in range

- If outside of range IMP must not be used

- Medication prepared

Labelling

- Pharmacy
  - Patient initials and subject number
  - Medication
  - Administration instructions
  - “keep out of sight and reach of children”
  - Address of pharmacy

Accountability

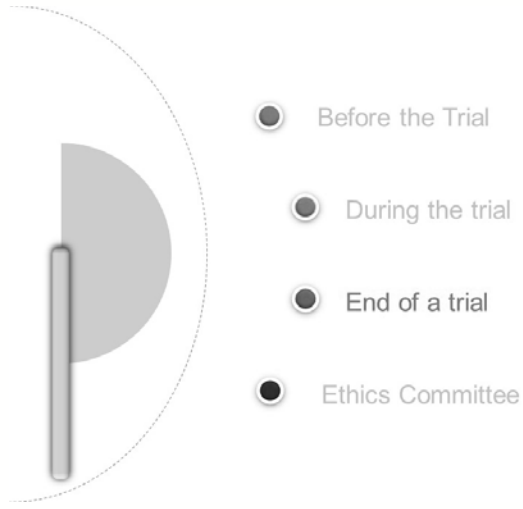
- Accountability form completed when medication removed
  - Number of products issued
  - Batch number and expiry date
  - Patient initials and trial number
  - Signature of person dispensing and checking medication

IMP dispensing

- All staff dispensing and checking IMP must be trained in GCP and procedures for dispensing IMP.
- Trial specific dispensing procedures should be followed by all staff dispensing and checking IMP
- IMP should only be dispensed on receipt of a prescription signed by the Investigator or delegated prescriber
- IMP accountability logs are completed when IMP dispensed

IMP returns

- All used or unused IMPs should be returned to pharmacy
- On return medication should be checked to determine the quantity and this should be logged in the accountability records
- Medication can be destroyed from pharmacy or sent back for destruction
- Must be checked by CRA



Filing and accountability

- Ensure all documentation is accurate
- Everything filed in Pharmacy Folder
- End of trial monitoring visit

Other pharmacy roles during trial ?

•Emergency unblinding

- Code breaks
  - Is unblinding actually necessary?
  - Who can unblind?
  - Who is blinded/unblinded?
  - Where are code breaks kept?

Other Pharmacist roles

- Notify investigator and/or sponsor if subject admitted to hospital or reports adverse reaction
- IMP recall
- Monitoring visits and audits
- Principal Investigator

Positions/Designations in Clinical Research

- Sponsor : Pharmaceutical/ Biotech/ Medical Device/ Cosmetic/ Academic Body … etc.

- Director/ Scientist
- Manager
- Team Leader
- Monitor/ CRA I, II III
- Statistician etc.

Positions/Designations in Clinical Research(contd..)

CRO:

- Director/Head – Clinical Operations/ Business Development
- Manager Clinical Research
- Project Manager
- CRA I, II III
- Data Management Specialist/ Data Manager
- Quality Assurance Auditor/ Quality Assurance Specialist
- Bio Statistician etc

Positions/Designations in Clinical Research(contd..)

SMO/ Investigative Site:

- Director/ Head - Clinical Operations/ Business Development
- Investigator
- Co Investigator
- Sub Investigator
  - Manager Clinical Research
  - Project Manager/ Team Leader
  - Study Coordinator/ Clinical Research Coordinator etc.

Major Employers in India

Sponsors

- Pfizer
- Eli Lilly
- Wyeth
- Dr Reddy's
- Ranbaxy
- Novartis
- Torrent
- Nicholas Piramal
- Orchid
- GSK
- Merck
- Biocon
- Bharath Biotech International
- Sandoz
- Sun Pharma
- Aventis
- Johnson and Johnson etc.

Major Employers in India

CROs:

- Quintiles
- Chiltern
- Omnicare
- Kendle
- Pharmolam
- Clininvent Research
- Vimta Labs
- Lotus Labs
- Lamda
- Siro
- Orange
- i3 Global
- Quest Life Sciences
- Apothecaries
- CliniRx
- GVK
- Actimus Bio
- Trident Life Sciences
- Jubilant
- Clinigene etc.

Major Employers in India

- SMOs:
  - KLES Dr.PK Hospital and MRC, Belgaum
  - AHERF (Apollo Hospital Education and Research Foundation, formerly called as SPECTRA)
  - Neeman Asia
  - Odyssey Research
  - Metropolis India
- St. John's Hospital
- Nimhans
- Gangaram Hospital
- Batra Hospital etc

Major Employers in India

- Investigative Sites:
  - KEM Hospital
  - Manipal Hospital Group
  - Nizam's Institute of Medical Sciences
  - AIIMS
  - SJPGI
  - JIPMER

(Almost all Medical College Teaching Hospitals are involved in Clinical Research work; Scientific and/or therapeutic)

Clinical Pharmacy Practice areas

- Ambulatory care
- Critical care
- Drug Information
- Geriatrics and long –term care
- Internal medicine and subspecialties
- Cardiology
- Endocrinology
- Gastroenterology
- Infectious disease
- Neurology
- Nephrology
- Obstetrics and gynecology
- Pulmonary disease
- Psychiatry
- Rheumatology
- Nuclear pharmacy
- Nutrition
- Pediatrics
- Pharmacokinetics
- Surgery

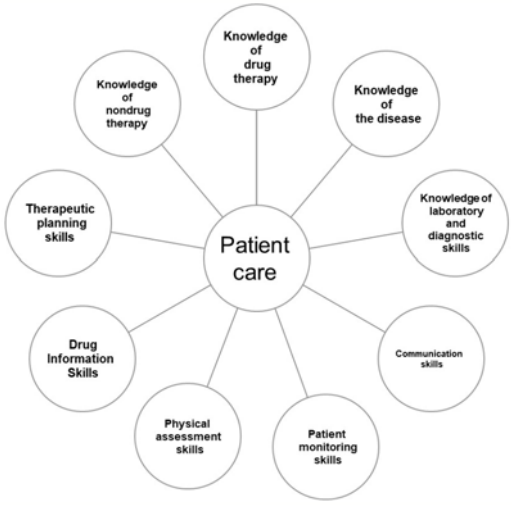
Are You Qualified to Be Professional ?

Typical Salaries in Clinical Research Arena

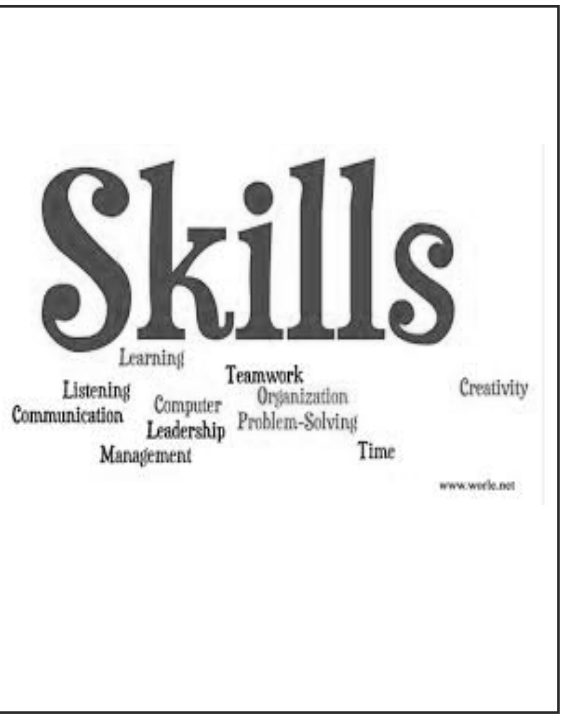
- North America and EU : USD 40,000 to 200,000 per annum
- India : INR 8000 to 4 lakhs per month

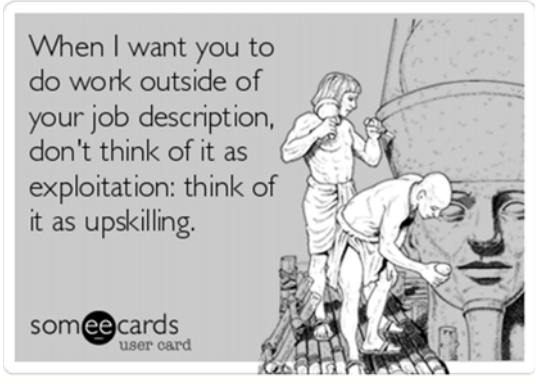
Note: These salary ranges refer to start up salaries to top positions.

Requirements




What is Required for Success ??
• Facilities
• Skills
• Attitude
• Opportunity
Your attitude is like a price tag, it shows how valuable you are.
Success.
SKILLS
ABILITIES
KNOWLEDGE
SKILLS


Skills
Learning
Listening
Communication
Computer
Leadership
Management
Teamwork
Organization
Problem-Solving
Time
Creativity
www.wcrlc.net


When I want you to do work outside of your job description, don't think of it as exploitation: think of it as upskilling.
someecards
user card


Yes, I did it !
I WILL DO IT
I CAN DO IT
I'LL TRY TO DO IT
HOW CAN I DO IT ?
I WANT TO DO IT
I CAN'T DO IT
I WON'T DO IT
WHICH STEP HAVE YOU REACHED TODAY?

summary of the studies conducted

Total Submission	Approved	Under Review	Withdrawn before approval
71	65	4	2

Approved	Ongoing	Completed	Withdrawn after approval
65	22	31	12

Clinical Operations Manager at Novo Nordisk A/S
Egypt
Pharmaceuticals

Current 1.Novo Nordisk
Previous 1.Novo Nordisk
Education 1.KLES college of Pharmacy, Belgaum

Kamlesh AmesarQuality Reviewer-Senior Drug Safety Associate at Tata Consultancy Services
Quality Reviewer-Senior Drug Safety Associate at Tata Consultancy Services

Mahendra DaphaleDrug Safety Associate at Quintiles
Drug Safety Associate at Quintiles

Nidhi Zalavadia Shah
Freelance Medical Writer / Content Editor
Egypt Research

Previous 1.Clinigene International Ltd,
2.KLE's Dr. Prabhakar Kore Hospital and Medical research centre
Education 1.KLES's College of Pharmacy

Mrunal Daphale
Pharmacovigilance Scientist at Novartis
Hyderabad Area, India
Pharmaceuticals

Previous 1.Novartis,
2.KLE's Dr Prabhakar **kore hospital** and **medicalre search** centre.
Education 1.Rajiv Gandhi University of Health Sciences

If you aspire to become a leader in the near future, then you have to keep in mind that you will need to develop skills that can help you perform your job better and enable you climb up the ladder.

DECCAN HERALD

Hence, it is advisable to get experience in another field as well or start reading about a different industry of your choice which will also be important for your domain, and which could make you an attractive candidate for your dream job.

(The author is principal, KPB Hinduja College, Mumbai)

DECCAN HERALD

PRECISION PARMACY - A SMOOTH OR BUMPY ROAD AHEAD

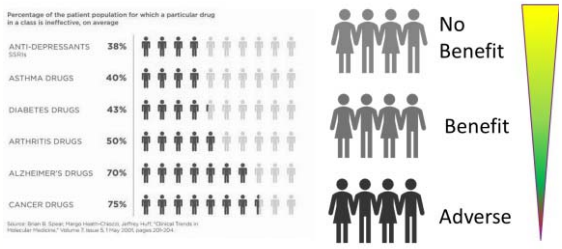
by

Dr. M. Sureshkumar
Professor, Research Director & Coordinator- TIFAC CORE Herbal Drugs JSS College of Pharmacy, Ooty

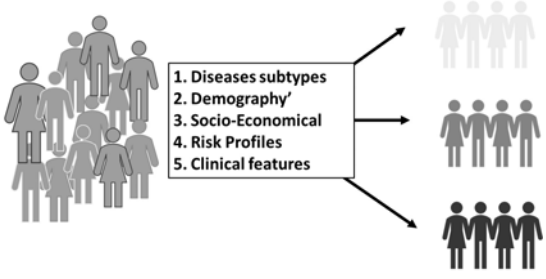
Summary

- Overview of Precision Medicine (PM)
- Global stand and initiatives
- Opportunities & Challenges (India)
- Emerging role of Pharmacist in PM
- Possible initiatives

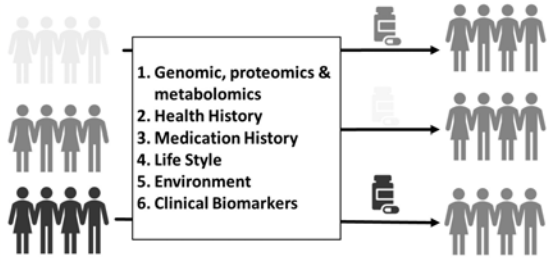
Conventional Therapy: "ONE-SIZE-FIT-ALL"



Personalised Therapy: "Stratification"



Precision Therapy: "Individualisation"

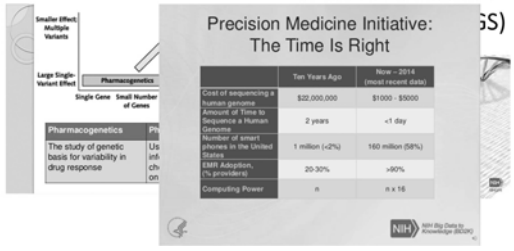


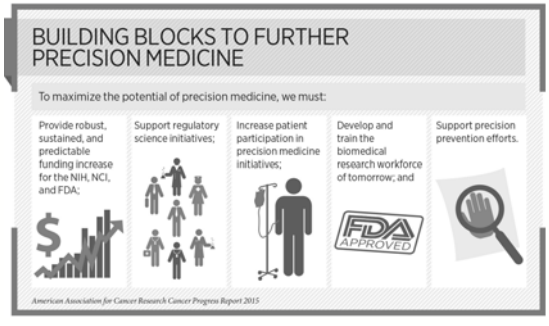
Precision medicine

‘Drug’
‘Dose’
‘Time’
‘People’

COMPANION DIAGNOSTICS

NEXT GENERATION



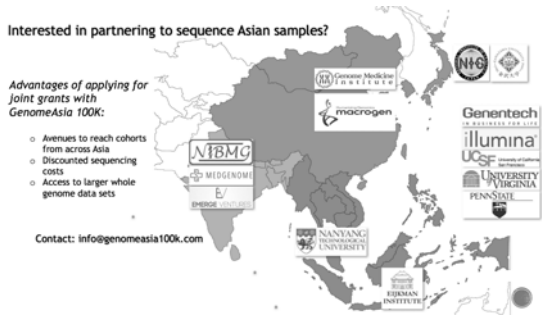


Precision medicine: Market Potential

Global Precision Medicine Market Research Report – Forecast to 2022
ID: MRFR/HC/0420-CRR | March, 2017 | Region: Global | 313 pages | Cooked Research Reports

- **USD 88.64 Billion by 2022**

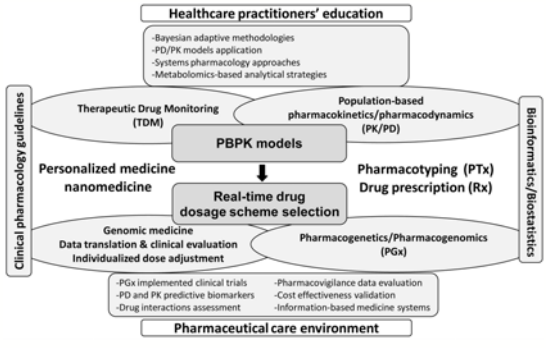
Globally North America is the largest market for global precision medicine. Europe is the second-largest market for global precision medicine. The near future market for precision medicine will be dominated by the developed regions with developing regions providing a supporting role only. However the developing regions market particularly Asia Pacific will be the fastest growing and is likely to be the key to the future.



Opportunities & Challenges in India

- Population
- Cost-sensitive environment,
- Companion Diagnostics Facilities
- Skilled manpower and resources
- Adequate regulatory support
- Targeted efforts/support from Government and others

Emerging Role of Pharmacist in Precision Medicine



Precision in Community Pharmacy

Know which medications are right for you ?

- Amina Abubakar, PharmD, Owner, Rx Clinic Pharmacy in North Carolina, USA
- Pharmacist-driven Pharmacogenetics - Medication Therapy Management (MTM) Program
- Genetic variations and how that affect Pharmacokinetics of drugs
- ~160 prescription medications label now include info from FDA "for people with certain genetic variations

Innovations

Pharmacists' role in pharmacogenomics increasing in an age of precision medicine

Amina Abubakar (left), PharmD, and Olivia Bentley (middle), PharmD, of Rx Clinic Pharmacy in Charlotte, NC, co-developed a pharmacist-driven pharmacogenetics and medication therapy management (MTM) program in their community pharmacy.

LOREN BONNER

Health care is inching closer to a reality in which patients are prescribed medications that work most effectively for them based on their DNA. The White House has been pulling resources together to make this happen since President Barack Obama announced the "Precision Medicine Initiative" during his State of the Union address in 2015.

"I want the country that eliminated polio and mapped the human genome to lead a new era of medicine—one that delivers the right treatment at the right time," Obama said during his address.

Precision medicine typically refers to using genomics to tailor treatments for an individual.

Optimizing drug therapy

Pharmacogenetics (PGx) is an important part of precision medicine. PGx analyzes gene-to-drug interactions and provides information about how an individual's genes affect both the body's response to medications as well as the rate at which medication is metabolized and removed from the body. As experts in medication and the effects they have on the body, pharmacists are poised to become the point person for the safe and ethical use of this tool to optimize drug therapy.

"Precision medicine is so big and so complex, but if we focus on just the pharmacogenetics side of it and the medication piece, precision medicine will catch on quicker than trying to find out the disease risk and all the other variables," Amina Abubakar, PharmD, owner of Rx Clinic Pharmacy in North Carolina, told *Pharmacy Today*.

More than 160 prescription medi cation labels now include informa tion from FDA for people with certain genetic variations.

But making the connection between pharmacists and pharmacogenetic testing is not immediately intuitive for many outside the profession. Abubakar has successfully implemented a pharmacogenetic testing program at Rx Clinic Pharmacy, and she was one of the only two pharmacists at a recent FDA hearing on returning genetic test results to patients.

Doctors at the hearing said they wished they had clinical professionals on their team to help with pharmacogenetic testing; genetic counselors said patients normally wait 9 months for an appointment.

"I had to explain that pharmacists already have the pharmacokinetics and dynamic information and pharmacists are also accessible," said Abubakar.

Abubakar, APhA representatives and others were later invited to the White House to discuss pharmacogenetic testing and how it fits with Obama's initiative on precision medicine.

How the program works

Abubakar and her colleague, Olivia Santoso Bentley, PharmD, co-developed a pharmacist-driven pharmacogenetics and medication therapy management (MTM) program at Rx Clinic Pharmacy. They work with a lab called MD Labs that outlines clear instructions for patients to interact with their pharmacist during each point of the process.

"MD Labs agreed with the vision we had for this to be an important screening tool at the community level—not to have to wait until patients have some acute condition and need it right away," Bentley, who is director of clinical services at Rx Clinic Pharmacy, told *Today*.

Pharmacogenetic tests can pick up on the genetic variations that can affect how fast or how slow an individual metabolizes a medication.

PHOTOS BY JEFF GLANTZ/DCA

Precision Pharmacist by 2030

- Expert in Pharmacogenetics / genomics
- Competent Medication Manager
- Patient-centric profession

Educate & Train our Pharmacist to Embrace Science & Technology Advancements

FUTURE OF PHARMACEUTICALS THROUGH INNOVATION AND PATENTING

by

Dr. Gopakumar G. Nair
Gopakumar Nair Associates & Past President & Chairman – IPR Committee, IDMA, Mumbai

INNOVATION is the Key

Constitution of India –

Fundamental Duties include

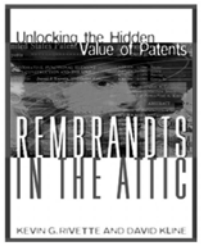
It shall be the duty of every citizen of India

To develop the SCIENTIFIC TEMPER,

humanism and the SPIRIT OF INQUIRY...

Need for Invention Mining

Unlock Hidden Value Of The Patents



"survival of the fittest will mean mastering the secrets of intellectual property and, like modern-day alchemists, using these to turn knowledge into gold."

INNOVATION is the

Platform and the Bridge

Industry with Academia

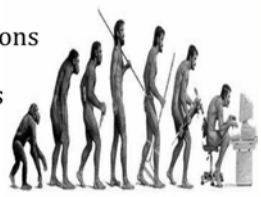
Need to make Strides in Innovation
Skilling & Networking

Name of Molecule	Company marketing the drug	Invented by
Trastuzumab	Roche	Genetech & University of California, Los Angeles (UCLA).
Atorvastatin	Pfizer/ Astellas pharma	Bruce Roth of Parke-Davis Warner-Lambert Company (Acquired by Pfizer)
Adalimumab	Abbott Laboratories.	BASF /Cambridge Antibody Technology
Sorafenib	Bayer	Onyx
Enzalutamide	Medivation / Astellas	University of California
Trabectedin	Zeltia and Johnson and Johnson	University of Illinois
Rituximab	Biogen Idec ,Genentech and Roche	IDEC / Biogen Idec Pharmaceuticals
Infliximab	Janssen Biotech.	New York University School of Medicine, Centocor.

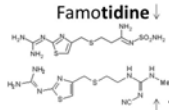
Innovations Evolution

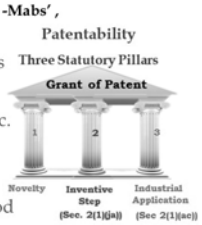
Sources

- Incremental Innovations
- Need-based Solutions
- Intensive Research
- Disruptive Inventions
- Serendipity



- NCE/NME
- API
- Product Patent
- Process Patent
- 'Me too' derivatives – Imati**nib**, Erloti**nib**
  - **'virs', - 'tabines, - 'rtans', –'gliptins' , -Mabs' ,**
- Formulations – PNIS / FTO, ANDAs
- Dosage Forms – Tablet, Capsule, etc
- Release Profile – Controlled, Slow etc.
- NDDS – ex. Transdermal Patches, Transmucosal Drug Delivery.
- New Use – Aspirin (analgesic & blood thinner)





RESEARCH in Pharma

- MSMEs
  - continue with low innovation- generics.
- Larger Units
  - NDDS, Combinations, Processes.
- Top 20 Companies
  - NCE Research(Drug Discovery)
  - Biosimilars
  - Vaccines

Dr. Reddys, Cadila, Glenmark, Sunpharma, Aurobindo, Lupin, Biocon, Cipla, Wockhardt, Torrent, Jubilant Life, etc.

Strategies for Larger Indian Pharma

- Super Generics & Value added Generics.
- Sec.505 (b)(2)/ Para IV challenge/ Orphan drugs.
- Ranbaxy
  - Canadian Co. – Cipher: Absorica.
- Cipla
  - Swedish firm – Meda: Dymista.
- Lupin
  - Japan's – Fujisawa: Suprax.

Source: BusinessWorld, Jan, 2014.

Indian: Case Laws

- **Vardenafil**: MNC vs Indian Generic
  - Website & Drug Approval
- **Sitagliptin:** MNC/Indian Licensee vs. Indian Generic
- **Linezolid:** Indian MSME vs. Other Indian Comp
- **Decapeptide:** Indian Comp vs. Indian Comp
- **Diclofenac:** Indian MSME vs. Other Indian Comp
- **Enzalutamide:** against Govt / IPO
- **ORS:** Indian MSME vs. Other Indian Comp
- **Trastuzumab:** against DCGI / CDSCO

Cipla to market Novartis, and J&J's products, while Alkem partners Dong A of South Korea

By *DIVYA RAJAGOPAL*, ET Bureau | Feb 08, 2018, 12.06 PM IST

0 Comments

MUMBAI: India's third-largest drug maker Cipla BSE 6.33 % and Mumbai-based Alkem Pharma are both foraying into the antidiabetic drug market in the country through partnerships with multinationals for the highly fought over gliptin class of oral agents.

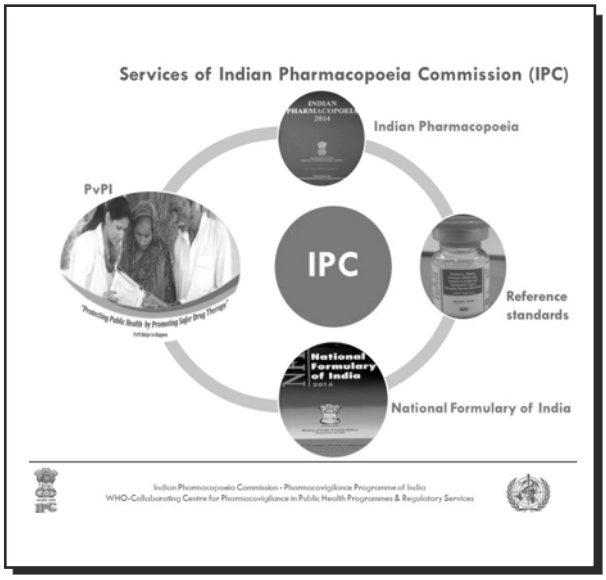
Cipla has tied up with Swiss drug maker Novartis BSE 0.28 % and US firm Johnson and Johnson to market their anti-diabetic drug Vildagliptin and Canagliflozin, respectively. Alkem BSE 0.81 % has teamed up with South Korean drug maker Dong A to launch the latter's Evogliptin.

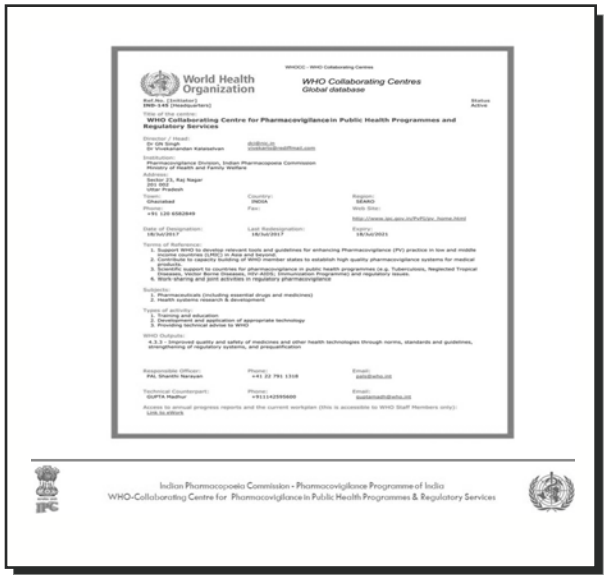
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cipla-to-market-novartis-and-js-products-while-alkem-partners-dong-a-of-south-korea/articleshow/62832037.cms

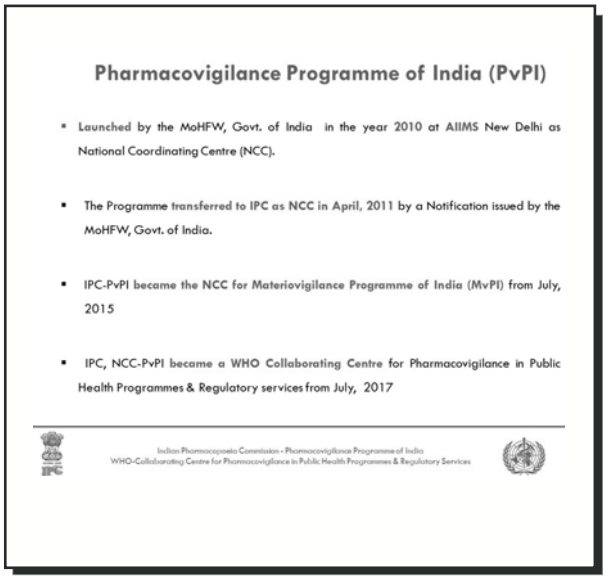
PHARMA VISION 2030: PHARMACOVIGILANCE

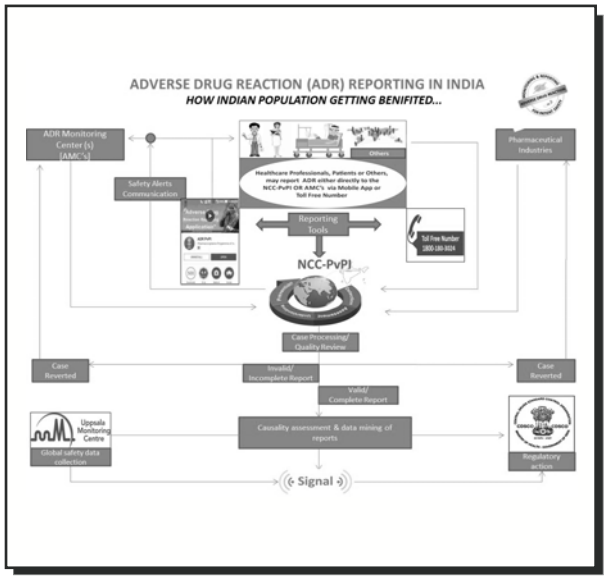
by

Dr. V. Kalaiselvan
Principle Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad









Pharmacovigilance in Drugs & Cosmetics Act 1940 and Rules 1945

- **Schedule Y**- Post Marketing surveillance/PSURs
- **Schedule M –** adverse events reporting- para 28.2

REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
PUBLISHED BY AUTHORITY

No. 154] NEW DELHI, TUESDAY, MARCH 8, 2016/ PHALGUNA 18, 1937

2. In the Drugs and Cosmetics Rules, 1945, in Schedule Y,-

(A) for paragraph "(2) **Post Marketing Surveillance**" and clause (i) relating thereto, as published in Part II, Section 3, Sub-section (i) of the Gazette of India, Notification G.S.R. 32 (E) dated 20th January, 2005, at page 63, the following shall be substituted, namely:-

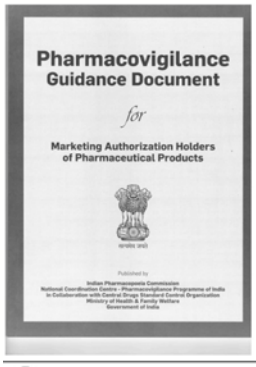
"4. **Post Marketing Surveillance.-**

(i) The applicant shall have a pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drug manufactured or marketed by the applicant in the country.

(ia) The system shall be managed by qualified and trained personnel and the officer in-charge of collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.

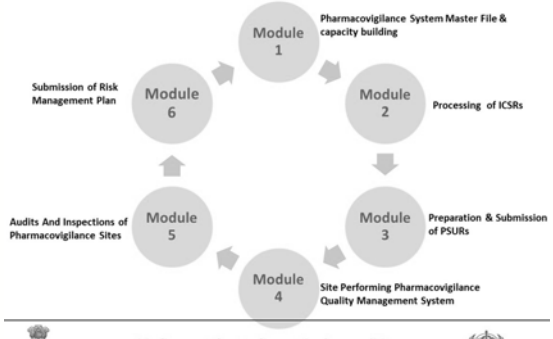
(ib) Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.

Indian Pharmacopoeia Commission-Pharmacovigilance Programme of India



- Effective from January 2018
- Applicable to PvPI, CDSCO and State(s)/UT(s) Drugs Control department
- Ensures compliance of good Pharmacovigilance practices

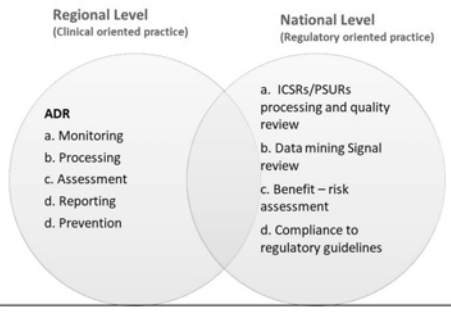
Modules in the Guideline



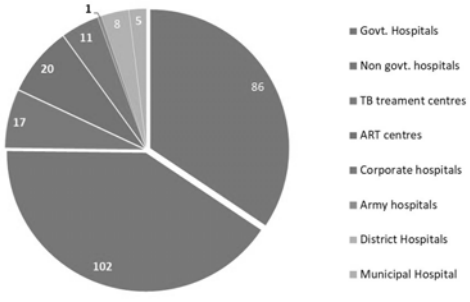
State(s) Drugs Controller Meeting to Promote Good PV Practices

- Held on 2nd February 2018
- 28 states were represented
- Appraised about the PV guidelines for industries
- Discussed about joint PV inspection

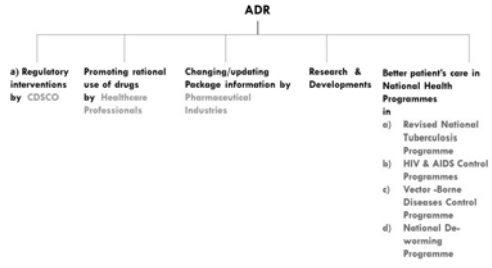
Pharmacists Role in PvPI



ADRs Monitoring Centers (AMCs): 250



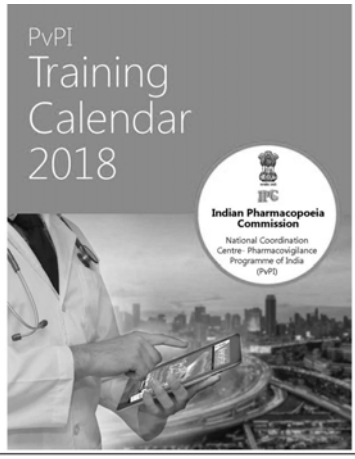
Utilisation of ADR data



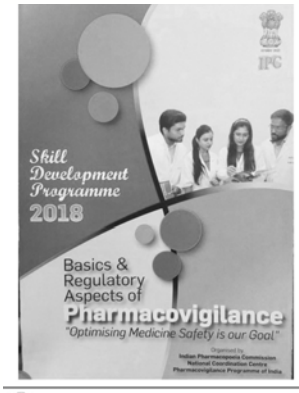
WHO National Regulatory Authority Assessment - India

	Regulatory system (vaccines assessment)	2001	2004	2007	2009	2012	2017
Regulatory functions	MAH & licensing			No		Yes	
	PMS & AEFI (Pharmacovigilance)			No		Yes	Secured highest standards (maturity level 4)
	NRA Lot release			Yes		Yes	
	Laboratory access			No		Yes	
	Regulatory inspections			No		Yes	
	Authorisation/approval Of clinical trials			Yes		Yes	
Result				Fail		Pass	

National Coordination Centre-Pharmacovigilance Programme of India



Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services



- Medical, Pharmacy and other professionals students can attend
- Training scheduled in the month of January, March, May, July,
- September, November
- Provides adequate knowledge and skills

Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services

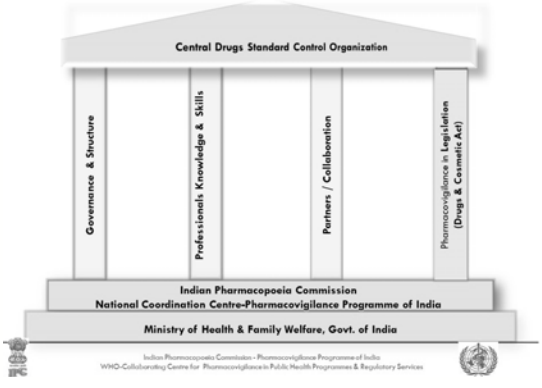
- Pharmaceutical industries can participate
- Provides adequate knowledge and skills to ensure the compliance of good pharmacovigilance practices

Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services

Current status & Future Plan of PvPI

S.No	Indicator	Status 2017	Action Plan 2030	Stakeholder(s)
1	ADRs Monitoring Centers	250	All district and medical /pharmacy institutions	a. Medical/pharmacy institutions b. Public/private hospitals
2	Skilled Professionals	10484	More than 1 lakh	a. Medical & paramedical b. Regulators c. Industries
3	Safety information and recommendations	100	More than 1000	a. CDSCO b. Healthcare providers c. Industries
4	Pharma Industries reporting	92	All Pharmaceutical manufacturers to report	a. Industries
5	PV Audit & Inspection	---	5000	a. Industries b. Regulators

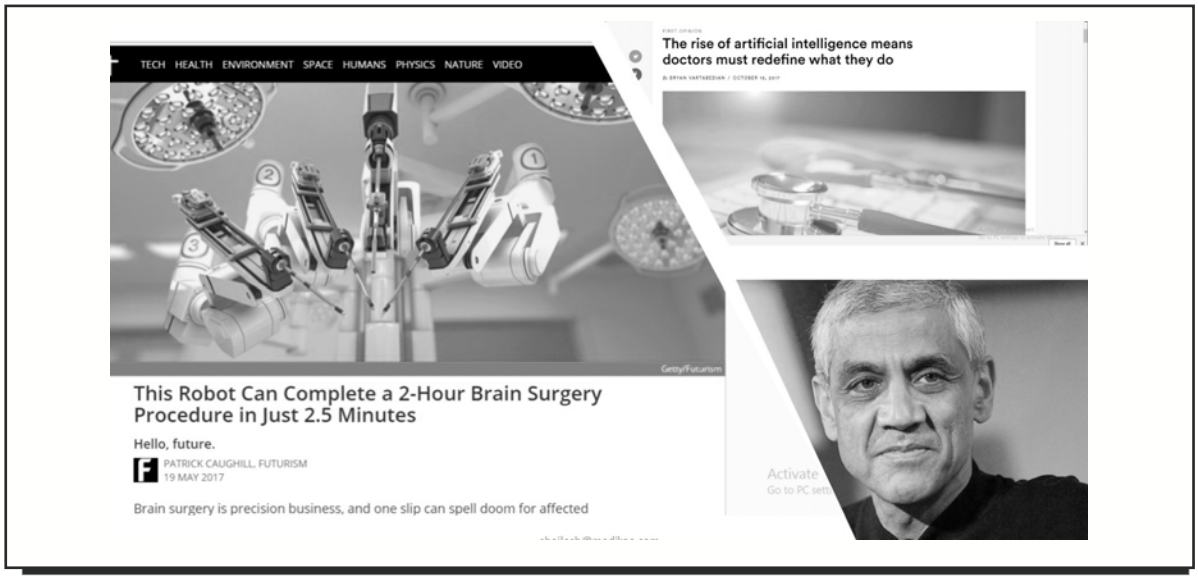
Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India
WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services



DIGITAL HEALTHCARE, NEW AGE PHARMACIES & PATIENT CENTRICITY

by

Shri. Shailesh Patel
Director- Medikoe Healthcare, Mumbai



Healthcare –Trapped in a Time Warp

- **Doctors & Care Delivery**

Predictable & a set of Protocols

- **Medicines**

One set fits all

- **Nutrition**

Thrive on fads, trends and Fear of Being Missed Out (FOMO)

- **Supply Chain**

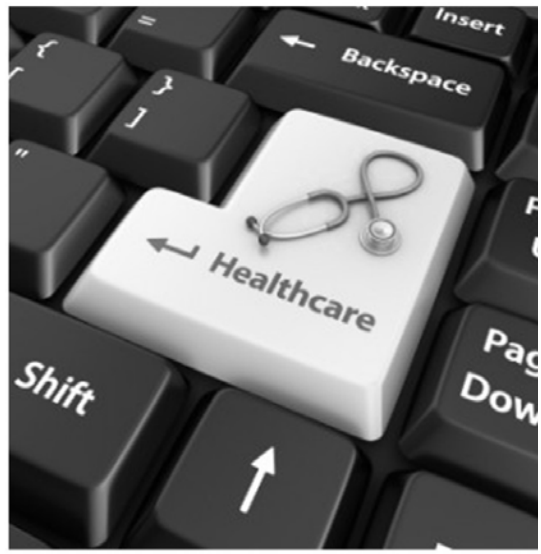
Order Based & Not Responsive

- **Diagnostic**

Stand Alone Data with No Patient Controls for Access

The PARADIGM is Shifting…Towards Patient Centricity

- More empowered, active, participatory e-patient.
- Access to their data – on-demand, at-will.
- More collaborative and participatory relationship with the health care providers
- For doctors, a change from being the source of expertise & to helping *interpret* data / information
- Help to coordinate the patient's interaction with the whole healthcare delivery ecosystem.

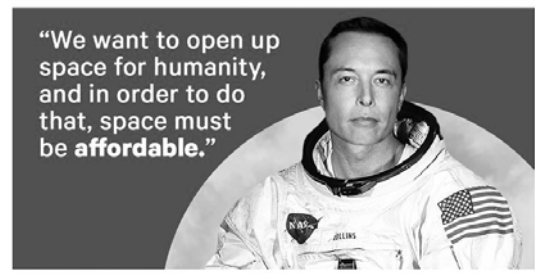


14 NOVEMBER, 2017

Otsuka and Proteus® Announce the First U.S. FDA Approval of a Digital Medicine System: Abilify MyCite® (aripiprazole tablets with sensor)

ACTIVE Medicines...

Digital Inhalers- Predictable Outcomes
Wound care – monitors healing, delivers antibiotics when required
3 D Casts
Customized & Evidence based Medicines & Nutrition Care based on Genomics
An augmented FAMILY PHYSICIAN with Tele-medicine set up
Risk Analysis and Reports based on AI



Regulations, Laws, Technology & Innovation

shailesh@medikoe.com

Lessons for HEALTHCARE & PHARMA from AMAZON

- 97% plus PIN Codes covered
- Understood that INDIA is like a Cluster 29 countries (states), different in culture, language, preferences, buying behavior and economic status.

It's a lesson in SUPPLY CHAIN

Customization

Reach – ACCESS

Quality

TRUST

Regulators are not able to catch up with Technology & Speed of Innovation

- In a Council on Foreign Relations meeting in 2014, Joel Garreau, a Future Tense fellow at the New America Foundation, gave a speech in which he captures the feeling succinctly:
- *"… if we're waiting for the House Judiciary to solve our problems, we're toast… they're talking about spending 5-10 years to regulate technologies that are already 5-10 years old. I see nothing good coming from that … I think that [kind of system of regulation] is doomed."*

…so what's the ANSWER

Self Regulation & Governance from the GROUND UP…

IIPA- Indian Internet Pharmacy Association

Other examples of successful self regulation :

Microfinance companies; SEBI (Sub Groups); Broadcasting Companies

The Future Clinics & Medical Stores

CLINICS :

- Revolve like AUTO PILOT
- Largely self driven
- Blockchain based PHR
- PHR Triggered Diagnostics
- Use AUGMENTED REALITY

Medical STORES:

- Personalized care
- Counselling Kiosks
- Save costs building trust
- Connected to care givers

The future is in DESIGNING your Own Health

- From PRACTICE of Medicine to the SCIENCE of MEDICINE
- One SIZE-FITS-ALL approach to Customized & Personalized & PRECISION Care
- With Tech-AI-Data: You can avoid the following :

"three doctors to look at the same problem, you'll get three different diagnoses and three different treatment plans"

" No Force on Earth can Stop an idea whose Time has come"

VICTOR HUGO

The Great French Writer

Time has come to ....

...connect the DOTS

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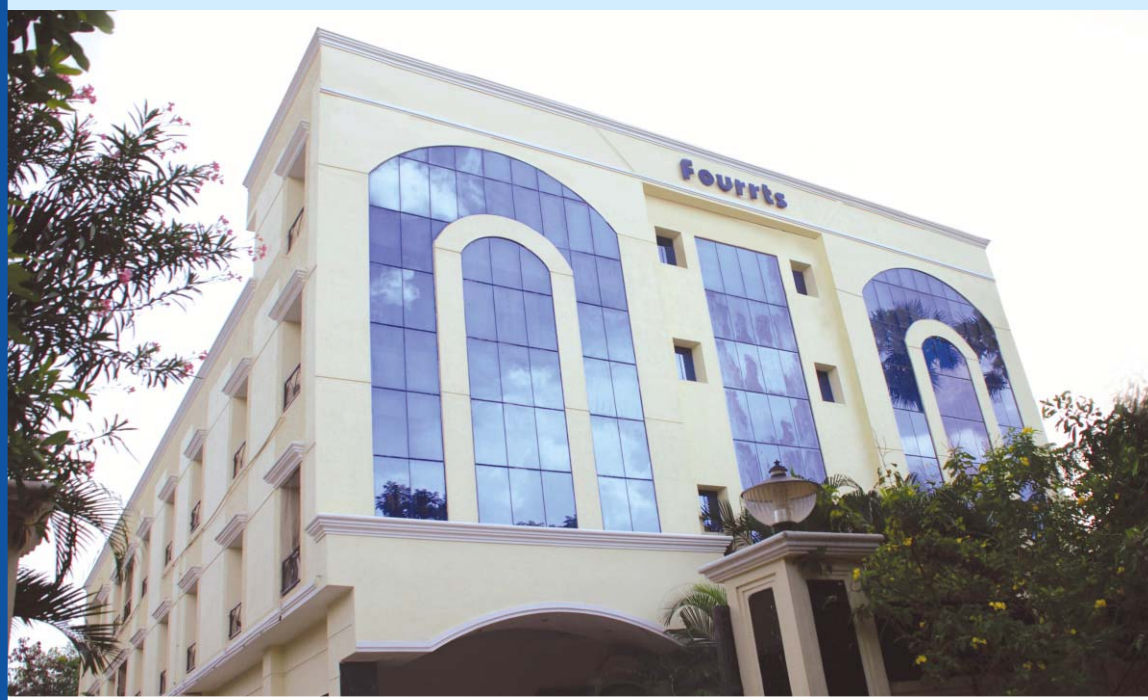
(India) Laboratories Pvt. Limited

Manufacturers and Exporters of
Quality Pharmaceutical Formulations
as per cGMP Standards

'7' Time Quality Excellence Award Winner

ISO 9001 BUREAU VERITAS Certification



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