NIRMA UNIVERSITY
INSTITUTE OF PHARMACY

Address for correspondence
The Organizing Secretary – NIPiCON 2014
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NIPiCON

NIRMA UNIVERSITY
INSTITUTE OF PHARMACY

NIPiCON-2014

2nd Nirma Institute of Pharmacy International Conference

January 23-25, 2014

"Fostering Innovation in Drug Discovery & Development"

Organized by
Institute of Pharmacy, Nirma University
S. G. Highway, Ahmedabad - 382481, Gujarat, INDIA
Phone : +91-2717-241900-04 • Fax : +91-2717-241916
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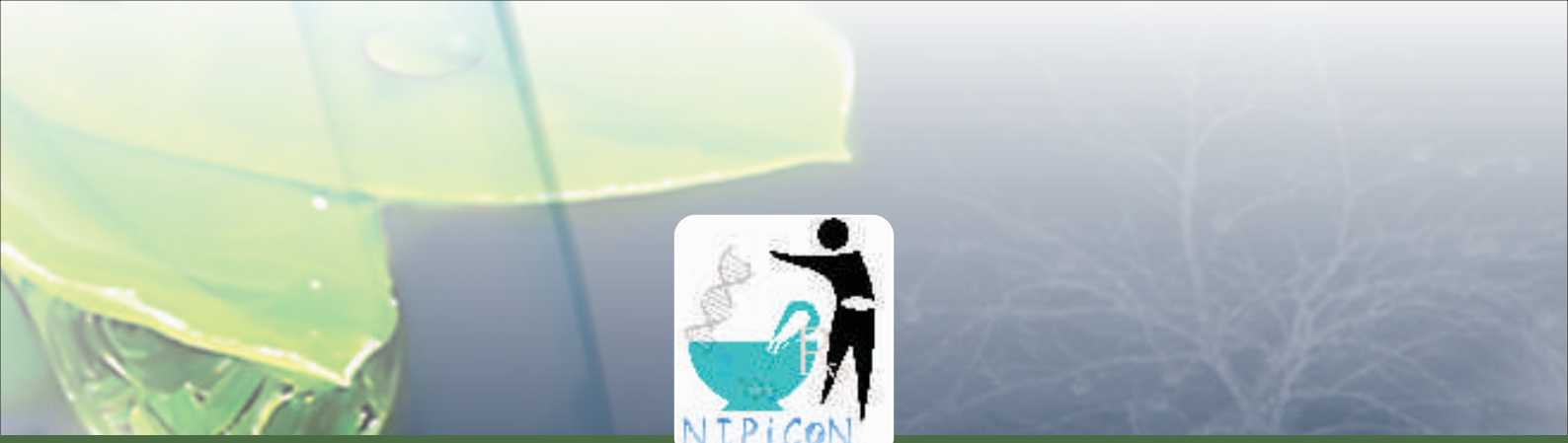

NIPiCON-2014

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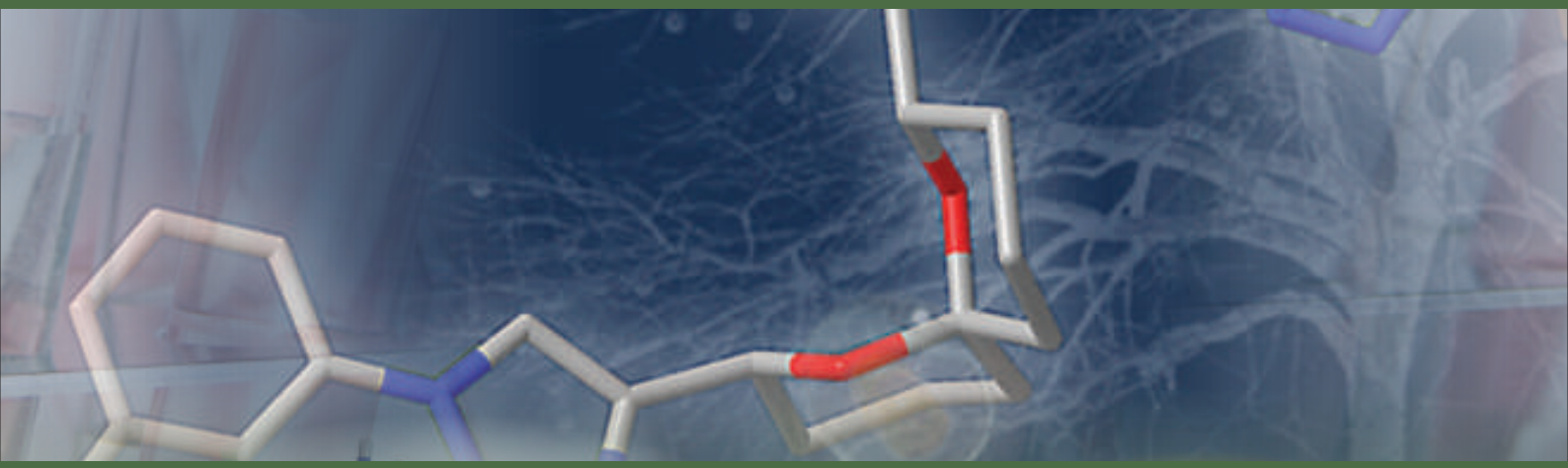

Souvenir

NIRMA UNIVERSITY
INSTITUTE OF PHARMACY

Organized by:

Institute of Pharmacy, Nirma University
S. G. Highway, Ahmedabad - 382481, Gujarat, INDIA
Phone : +91-2717-241900-04, Extension : 716 • Fax : +91-2717-241916
Email : convener@nipicon.org, os@nipicon.org
Website : http://www.nipicon.org

Shri Narendra Modi
Hon'ble Chief Minister
Gujarat State

Dt: 11-12-2013

MESSAGE

Innovation in the healthcare sector is more important than in many other sectors of the economy, as it stands to provide safe, effective and value creating products. The pharmaceutical sector, a cornerstone of the healthcare industry is undergoing a dramatic change due to diminishing output of the new medicines from research and development, constraints related to drug pricing and current regulatory environment. Indian Pharmaceutical Industries are in urgent need for finding improved ways to increase the output of new drugs through innovation and cultivating a holistic approach towards management of comprehensive healthcare to facilitate better healthcare services to the society.

GUJARAT is a front line entrepreneurial state known for being a "**Pharma Innovation Hub**" with exuberant and successful approaches for new drug development by leading pharmaceutical industries in the state. I am pleased to welcome all the delegates and participants to the vivacious land of Gujarat at Nirma University for **2nd NIRMA INSTITUTE OF PHARMACY INTERNATIONAL CONFERENCE NIPiCON**-2014 with the pioneering theme of "**Fostering Innovation in Drug Discovery & Development**" held at Institute of Pharmacy, from January 23-25,2014.

I am sure that NIPiCON-2014 will lead to the opportunities to all the stakeholder of Pharmaceutical industry, academicians as well as researchers for fruitful deliberations and future recommendations through their experience on conducive land of GUJARAT for charting a road map to ongoing drug discovery efforts for curing various life threatening diseases in the country.

I convey my best wishes to organizers for the grand success of this international conference.

(Narendra Modi)

To,
Prof. Tejal Mehta,
Organizing Secretary, NIPiCON-2014,
Institute of Pharmacy,
Nirma University,
Sarkhej-Gandhinagar Highway,
Ahmedabad-382481.

Narendra Modi
Chief Minister, Gujarat State

Shri Nitin Patel
Hon'ble Minister
Finance, Health,
Medical Education,
Family Welfare, Transport,
Govt. of Gujarat

NITIN PATEL

सत्यमेव जयते

No. : Finance/H.F.W./Trans/ 57/ 103/13

Minister
Finance, Heath, Medical Education,
Family Welfare, Transport,
Government of Gujarat,
Swarnim Sankul-1, 2nd Floor,
Sardar Patel Bhavan, Sachivalaya,
Gandhinagar-382 010.

2 DEC 2013

MESSAGE

I am very happy to know about the organization of 2nd NIRMA INSTITUTE OF PHARMACY INTERNATIONAL CONFERENCE NIPICON-2014 with the theme of "Fostering Innovation in Drug Discovery & Development" from January 23-25, 2014.

In recent years there has been a greater emphasis placed on prevention of illness and an encouragement of health promotion because of increasing consciousness of the demands that ill-health places on national resources in developing countries. General public health is increasingly being affected by stagnancy in the innovative approach for the development of a new drug. Innovations in the development and delivery of the drugs for the treatment of many incurable diseases are demand of the present day and, I am hopeful for this conference as an oasis amidst the desert to foster innovation in drug discovery and development.

I would like to convey my warm compliments to the Institute of Pharmacy for organizing such a conference, that will act as a catalyst in the field of Research and development of drugs and anticipating its grand success.

N Patel

(Nitin Patel)

To,
Prof. Tejal Mehta
Organizing Secretary, NIPICON-2014,
Department of Pharmacognosy, Institute of Pharmacy,
Nirma University, Ahmedabad- 382481

Resi. : Minister's Bunglows No. 20, Sector-20, Gandhinagar-382020
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Fax : 079-23257616
Vidhansabha : 079-23253194/23251058.

Shri Bhupendrasinh Chudasama
Hon'ble Minister
Education (Primary, Secondary and adult), Higher and Technical Educaton, Law and Justice, Food, Civil Supplies and Consumer Affairs, Panchayats, Rural Housing, Rural Development, Govt. of Gujarat

BHUPENDRASINH CHUDASAMA

No.Edu(P&S).H&T.Law.&Jus.F&CS.Pan/ /2013

Minister,
Education (Primary, secondary and adult), Higher and Technical Education, Law and Justice, Food, Civil Supplies and Consumer affairs, Panchayats, Rural Housing, Rural Development
Government of Gujarat,
Swarnim Sankul-1, 2nd Floor,
New Sachivalaya, Gandhinagar-382010

E-mail: min-education@gujarat.gov.in
Date: 18 /12 / 2013

MESSAGE

I am happy to observe that Institute of Pharmacy, Nirma University is organizing NIRMA INSTITUTE OF PHARMACY INTERNATIONAL CONFERENCE NIPiCON-2014 with the theme of ***""Fostering Innovation in Drug Discovery & Development""*** from January 23-25, 2014.

Innovation is an essential feature for continued growth and progress of any scientific discovery in the world. Over the past two decades, the pharmaceutical industry has produced some remarkable medicines to treat several conditions, ranging from infections, metabolic disorders to cardiovascular diseases (CVD), resulting in reduced mortality rates in the country. The pharmaceutical industry needs to manage its resourcefulness to ensure that new and innovative products should constantly emerge from R&D operations. One common thread to these efforts is related to fostering newness by organizing conferences like NIPiCON-2014 addressing emerging trends of drug discovery and development process.

I offer my heartfelt congratulations and best wishes to Institute of Pharmacy for conducting such event and I wish for the grand success of this international conference.

(Bhupendrasinh Chudasama)

To,
Dr. Niyati Acharya
Assistant Professor
Department of Pharmacognosy
Institute of Pharmacy
Nirma University
Ahmedabad- 382481

Office Phone : 079-23250116 to 23250119, 23238076, 23243389 Fax: 23250120
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E-mail : min-education@gujarat.gov.in

Prof. B. Suresh
President
Pharmacy Council of India

3830

PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

Prof. B. Suresh M.Pharm., Ph.D., D.Sc.
President

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December 12, 2013

MESSAGE

It is indeed a matter of pleasure that Nirma University Institute of Pharmacy, is organizing 2nd 'Nirma Institute of Pharmacy International Conference NIPiCON-2014' on January 23-25, 2014 at the Institute of Pharmacy, Nirma University.

I am sure the conference will strive to strengthen the current international and national scenario of drug discovery and development and facilitate global exploration on the recent advances in emerging healthcare related problems and discovery of new medicines through innovative approaches, benefitting the pharmaceutical industry.

On the occasion, I convey my best wishes and greetings and wish the conference a success.

With best wishes.

Dr. B. Suresh
President

Prof. A. N. Rai
Director
National Assessment and
Accreditation Council

राष्ट्रीय मूल्यांकन एवं प्रत्यायन परिषद
विश्वविद्यालय अनुदान आयोग का स्वायत्त संस्थान
NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL
An Autonomous Institution of the University Grants Commission

प्रो. ए. एन. राय
निदेशक
Prof. A.N. Rai
Ph.D. (DUNDEE)
Director

December 18, 2013

MESSAGE

I am glad to know that 'Nirma Institute of Pharmacy' is organizing International Conference on the theme "Fostering innovation in drug discovery & development" from 23 – 25, January 2014.

The theme of the conference is highly appropriate and contextual. I hope it will provide an opportunity for discussions and knowledge dissemination.

I send warm greetings on the occasion and extend my best wishes to the institution.

(A. N. Rai)

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ई-मेल : e-mail: director.naac@gmail.com वेबसाइट Website : www.naac.gov.in

Dr. V. M. Katoch
Director General
Indian Council of
Medical Research

डॉ विश्व मोहन कटोच
सचिव, भारत सरकार
(स्वास्थ्य अनुसंधान विभाग)
महानिदेशक, आई सी एम आर
Dr. Vishwa Mohan Katoch
Secretary to the Government of India
(Department of Health Research)
Ministry of Health & Family Welfare &
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
(स्वास्थ्य अनुसंधान विभाग)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029 (भारत)
Indian Council of Medical Research
(Department of Health Research)
Ministry of Health & Family Welfare
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029 (INDIA)

Message

I am pleased to know that Institute of Pharmacy, Nirma University is organizing 2nd *NIRMA Institute of Pharmacy International Conference NIPiCON-2014* with the theme of "Fostering innovation in drug discovery & development" in association with GUJCOST, Gandhinagar from 23-25 January 2014 at Ahmedabad. The theme of the conference is very appropriate and need of the hour.

The pharmaceutical sciences encompass a wide range of scientific disciplines that are critical to the discovery and development of new drugs and therapies. The objectives of the conference are very relevant and this event will provide an opportunity to pharmaceutical scientists and young researchers from various organizations to put forth their innovative ideas for discovering and developing new drugs.

I am sure, discussions among senior scientists during the conference will result in fruitful recommendations for implementation by concerned agencies.

I wish, the whole program a great success.

(V. M. Katoch)

Tele. : (Off.) +91-11-26588204, 26589620; Fax (Off.) : +91-11-26588662, E-mail : secydhr@icmr.org.in; dg@icmr.org.in

Dr. Karsanbhai K. Patel
President
Nirma University

Dr. Karsanbhai K. Patel
President

NIRMA UNIVERSITY

WELCOME MESSAGE FOR NIPiCON 2014

I am pleased to know that Institute of Pharmacy, Nirma University is organizing the 2nd NIRMA INSTITUTE OF PHARMACY INTERNATIONAL CONFERENCE NIPiCON-2014 with the theme of ***"Fostering Innovation in Drug Discovery & Development"*** during January 23-25, 2014.

The motive of the conference goes well with the present the pharmaceutical scenario. With the growing disease condition of various diseases, pharmaceutical organizations are facing great challenge in meeting the apt drugs to cure life threatening diseases. Thus, there is a desperate need to develop new and innovative approaches for safe and efficacious drug development. The theme of present conference addresses the burning issues pertaining to innovation, faced by the pharmaceutical research industry as well as the healthcare sector in India and across the globe. Pharmaceutical companies must find a better way through innovation in drug development, for the benefit of patients and to increase their output of truly new drugs.

I heartily congratulate Institute of Pharmacy for organizing such event that addresses the factors of innovation and drug development. It will certainly help the participants understand drug discovery process and significance of innovational research.

I heartily welcome all the invitees, delegates and researchers to the vibrant campus of Nirma University and wish the grand success to the international conference.

Dr. Karshanbhai K Patel
President
Nirma University

Nirma University of Science and Technology
Sarkhej-Gandhinagar Highway, Ahmedabad 382 481, INDIA, Ph.: +91-02717-241511/12/13/14/15 Fax: +91-02717-241917, Website: www.nirmauni.ac.in

Shri Ambubhai M. Patel
Vice-President
Nirma University

Ambubhai M. Patel
Vice President

NIRMA UNIVERSITY

WELCOME MESSAGE FOR NIPSCON 2014

I am pleased to welcome all invited guests and participants at Nirma University for the 2nd NIRMA INSTITUTE OF PHARMACY INTERNATIONAL CONFERENCE NIPsCON-2014 with the theme of ***"Fostering Innovation in Drug Discovery & Development"*** during January 23-25, 2014.

The Indian Pharmaceutical industry is one of the most developed industries and it is the third largest in the world. There is immense scope for innovation driven drug discovery and development in India due to availability of skilled and scientific work force, comparatively low production cost and less research and development expenses with strong network of national laboratories. Government is also embarking a public-private partnership model to harness India's innovation capability and main goal is to catapult India into one of the top five pharmaceutical innovation hubs by 2020.

In backdrop of above, the organization of such a conference will serve the purpose of nurturing innovations in the field of drug discovery and help in exchange of research ideas amongst the budding scientists from academia and industries.

I extend my warm compliments to Institute of Pharmacy for organizing such conference that encourages drug discovery. I wish the grand success of this international conference.

Shri Ambubhai Patel
Vice President

Nirma University of Science and Technology
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Dr. Anup K. Singh
Director General
Nirma University

Dr. Anup K. Singh
Director General

NIRMA UNIVERSITY

WELCOME MESSASGE FOR NIPiCON 2014

It gives me immense pleasure to say that Institute of Pharmacy, Nirma University is organizing 2nd NIRMA INSTITUTE OF PHARMACY INTERNATIONAL CONFERENCE NIPiCON-2014 with the theme of ***"Fostering Innovation in Drug Discovery & Development"*** during January 23-25, 2014.

The speed with which the diseases occur nowadays and their resistance towards the conventional medicines leaves the health care researchers to search for new drug candidates with more potency and minimum side effects to treat the patients. Discovery of new drug and its development right from the grass root level to its dispensing becomes increasingly important for the research and development in the pharmaceutical industries. There is a need of scientific research to enhance drug development efforts and to bring safer, efficacious and cost effective medicine to the market.

Drug innovation will require a plethora of specialized skills with the inherent expertise from all the segments of drug discovery and development to the fullest, resulting in optimum utilization of funds and skill set available. Further in support of this fact, many academic institutes and research centers have been working on the unconventional and inventive research for the development of novel chemical entities and at Nirma University also, the researchers and faculties from Institute of Pharmacy have been working on discovery of bioactives from various natural sources, formulation development for target delivery and synthesis of novel molecules in a search for suitable chemical entities for the treatment of wide range of diseases.

I appreciate the efforts of Institute of Pharmacy for taking lead in fostering innovations in drug discovery by organizing such kind of international conference to offer common platform for the researchers from various parts of the country. I wish from the bottom of my heart that this conference will serve as a medium to bring together eminent personalities across the globe to share their experience in the field of drug discovery and innovation.

I welcome all the dignitaries, delegates and participants at Nirma University for the conference and wish Institute of Pharmacy to have a grand and successful event.

Dr. Anup K. Singh
Director General

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Website: www.nirmauni.ac.in

From the Desk of Organizers

On behalf of the Organizing Committee, we are delighted to invite all the delegates, invitees, researchers and students to participate in the 2nd Nirma Institute of International Conference (NIPiCON-2014) on "Fostering Innovation in Drug Discovery & Development" held during January 23-25, 2014.

Pharmaceutical research involves a lot of challenges as the path of understanding a disease to its treatment is long, difficult and expensive. Discovering safe and effective drug with cost effectiveness and industrially applicability is highly promising as the process requires 10-15 years and has regulatory issues. New innovations in technologies, genomics, proteomics, computational chemistry , medical devices have opened various avenues for treatment of various diseases and disorders. In view of this, the 2nd International Conference, NIPiCON 2014 is organized on the theme of "Fostering Innovation in Drug Discovery & Development" focusing on effective strategies to be used for successful drug discovery and its regulatory approval. A number of exciting endeavors will be held in this conference which will provide a unique opportunity for academicians, researchers and scientists to converge so as to discuss the important role of interdisciplinary research through innovations and collaborations. The scientific program will focus on lectures delivered by distinguished speakers, session lectures by young scientists as well as poster sessions from all over India.

The organizing committee, under the valuable guidance of our management of Nirma University and National and International Advisors, have been very active and arrangements are well under way to ensure that NIPiCON-2014 is a resounding success. We are well connected with ICT tools for continuous interactions and critical suggestions. We acknowledge financial support received from Department of Science & Technology (DST), Gujarat Council on Science and Technology (GUJCOST) and Indian Council of Medical Research (ICMR) as wells advertisers of various companies.

It is our humble and sincere request to you all to come forward with your contributions by way of your presence. On behalf of the Local Organizing Committee, we look forward to welcome you to Nirma University, Ahmedabad for participating in conference and wish you all memorable time in this conference. Also we are looking forward for your dynamic support and valuable cooperation to make this conference a grand success.

(Dr. Tejal Mehta)
Organizing Secretary, NIPICON 2014
Institute of Pharmacy, Nirma University

(Dr. Manjunath Ghate)
Convener, NIPiCON 2014
Director, IP, NU

CONTENTS

ABOUT NIRMA UNIVERSITY

Padma Shri Dr. Karsanbhai K. Patel, the founder of Nirma Group of Industries and Internationally famous entrepreneur crystallized his long cherished dream of providing world-class facilities for professional education in Gujarat in 1994. He established Nirma Education and Research Foundation (NERF), which in turn, established, in a 125 acre campus, six leading institutions within a short span: Institute of Technology in 1995, Institute of Management in 1996, Institute of Diploma studies in 1997, Institute of Pharmacy in 2003, Institute of Science in 2004 and Institute of Law in 2007. The establishment of the Nirma University in April 2003 was a natural consequence of the very high standards achieved by the Institutes.

Nirma University was established at the initiative of NERF in 2003 as a statutory university under the Gujarat State Act and is recognized by University Grants Commission (UGC) under section 2(f) of the UGC Act. Padma Shri Dr. Karsanbhai K. Patel, Chairman, Nirma Group of Companies and Chairman NERF, is the President of the University. Shri Ambubhai M. Patel is the Vice-President and Dr. Anup K. Singh is the Director General of the University.

Nirma University consists of Faculty of Technology and Engineering, Faculty of Management, Faculty of Pharmacy, Faculty of Doctoral Studies & Research, Faculty of Science and Faculty of Law. The diploma, graduate, postgraduate and doctoral level programmes offered by these faculties are rated high by industries, business magazines and by the students.

Innovation, excellence and quality are the dynamic attributes on the campus and that has translated the vision of these institutions into a reality over a short period of time. The campus vibrates currently with not only outstanding curricular activities but also with innumerable co-curricular and extra-curricular activities like symposia, international conferences, student competitions, short term industry relevant programmes, sports and cultural activities.

ABOUT INSTITUTE OF PHARMACY

OUR VISION

Shaping a better future for mankind by developing effective and socially responsible individuals and organizations.

OUR MISSION

Institute of Pharmacy emphasizes on all round development of its students. It aims at not only producing good professionals, but also good and worthy citizens of a great country aiding in its overall progress and development.

It endeavors to treat every student as an individual, to recognize their potential and to ensure that they receive the best preparation and training for achieving their career ambitions and life goals.

OUR OBJECTIVES

Institute of Pharmacy was established in the year 2003 with an insight to promote excellence in pharmaceutical education and to groom young scientists to meet the diversified challenges in the area of pharmaceutical industries, education, research and development and marketing with supreme professional standards.

Institute of Pharmacy is a model centre of excellence in pharmacy, conducting various graduate, post graduate, doctoral and research programs in pharmaceutical sciences. The Institute is poised to face global challenges of the pharmaceutical industry and education with the changed perspectives.

Our goal is to impart continuing education and to develop a national center catering to the needs of pharmaceutical industries for raising the level of pharmaceutical education and research by training future teachers, research scientists and managers for the industry and academia.

The major objectives of the Institute are to promote National/International collaborative research in the thrust areas of medicine and human healthcare with excellent industry academy interactions to meet the global challenges and to advance the curriculum and research by undertaking various research projects from governmental bodies and research centers to meet the set national objectives in pharmaceutical education and technology. Institute also aims to be established as a state of the art research institute and center for excellence in pharmaceutical sciences.

PROGRAMMES OFFERED BY THE INSTITUTE INCLUDE:

1. B.Pharm (Eight semester programme)*
2. M.Pharm (Four semester programme)* with specialization in:
    - Pharmaceutical Technology & Bio-pharmaceutics
    - Pharmaceutical Analysis
    - Pharmacology
    - Medicinal Chemistry
    - Phytopharmaceuticals and Natural Products
    - Drug Discovery
    - Clinical Pharmacy
    - Regulatory Affairs & Quality Assurance
3. Ph.D in Pharmaceutical Sciences (Full time & External)**

**With Industrial Training, **With course work*

THE CAMPUS

The Institute is situated on the Nirma University campus and has facilities like canteen, bank, student store, play ground, indoor games and gymnasium. The campus provides an ambiance that motivates students to grow.

The Institute building has modern amenities, with enough space and replenished with modernity and grandeur. The postgraduate laboratories are independently developed for M.Pharm and Ph.D students. Apart from this, the campus has sports facilities and the overall ambiance is distinguishable by serenity, which is conducive for intellectual pursuits.

MAJOR FACILITIES AVAILABLE AT THE INSTITUTE:

CLASS ROOMS: The classrooms are spacious, ventilated and equipped with multimedia and audiovisual equipment to facilitate effective learning. The classrooms are designed to provide maximum interaction between the faculty and students.

LEARNING RESOURCES CENTRE (LIBRARY): The Library at Institute of Pharmacy plays a vital role in the collection, development and dissemination of scientific information and includes a wide range of volumes of different branches of Pharmaceutical Sciences and allied subjects and also provides extensive access to leading Indian and international research journals. Currently it houses more than 8080 volumes of books selectively chosen for reading and reference, 327 CDs, 1420 Bound Volumes, 459 Project Reports (B. Pharm), 274 Research Project Reports (M. Pharm), 25 PhD Theses and subscribes about 37 printed national, 21 international periodicals, 19 magazines and 11 newspapers. Library is also providing Web access to SciFinder Single user access and 116 e-journals: Bentham Science Publisher (23), Science Direct – Pharmacology, Toxicology and Pharmaceutical Sciences (92).

COMPUTER CENTRE: The central computer facilities consist of 20 servers and more than 1100 systems, which are interconnected by fibre optic cables and 4 Mbps, leased line internet connectivity. Computing facilities for students include a laboratory equipped with 24 computers for U.G. and 10 for P.G. lab and Local Area Network. The network also connects the faculty and staff for information sharing and communication. The students have an easy access to the internet with Wi-Fi facility. The faculty members are also provided computer and internet facilities.

SOPHISTICATED INSTRUMENT LABORATORY: The Institute houses modern analytical instruments like FT-IR, Fluorescence Spectrophotometer, UV-Spectrophotometer, HPLC, Supercritical Fluid Chromatography and Extraction, HPTLC, MPLC and RAMAN Spectrophotometer which provide analysis comprising elemental composition, chromatography, diffraction, particle/material characteristics including various spectroscopes. The laboratory provides analytical support and intellectual input to both in-house and externally funded R & D projects.

DRUG DISCOVERY LABORATORY: Our Institute has a separate Drug Discovery Laboratory equipped with necessary computational facilities. It possesses seven workstations (computers) with latest configurations. It also possesses molecular modeling software like Sybyl X1.3 and Gold Suite 5.1. Students are trained on these soft wares for docking, pharmacophore modeling and QSAR studies etc.

MACHINE ROOM: A centralized machine room is equipped with Rotary tablet machine, Fluidized bed drier cum coater, Digital tensiometer, Texture analyzer, Mini Spray Dryer, Freeze dryer, Automated dissolution apparatus and Extruder-spheronizer etc. The laboratory provides facilities to carryout extensive research and consultancy for Pharmaceutical Industries.

NIRMA HERBAL WEALTH: A medicinal plants garden covering a total area of 2000 sq. meters has been developed at the university campus. More than 170 Genus of various medicinal plants

have already been planted. The plants garden provides a strong impetus for herbal drug research and for the training of our P.G. & U.G. students

ANIMAL HOUSE: The two storey conventional animal house has been registered by CPCSEA, Government of India. It is envisaged to provide pre clinical testing in conformity with national and international regulatory guidelines (Schedule Y, GLP and OECD). The animal house facilitates the availability of healthy and homogeneous animals for U.G. and P.G. studies and for research/outsourced testing. Incinerator is also available at animal house.

RESEARCH LABORATORY: A fully dedicated research laboratory helps the faculty members to undertake sponsored research projects as well as to carry out doctoral research work in various areas.

ACHIEVEMENTS

A team of highly qualified and dedicated faculties is continuously skilled in latest methods of educational technology and in their respective fields of specialization. Faculty members are actively involved in research, consultancy and financially funded and sponsored projects.

Total 13 recognized Ph. D guides with more than 85 research scholars are actively working in the diversified thrust areas of pharmaceutical sciences. Apart from presenting and publishing their work in reputed journals and conferences, faculty members and students have won laurels for the institute by publication of books, patenting their research work and by receiving many prestigious awards.

The Institute has received research projects worth more than around 100 lakhs Rupees from GMDC (Ahmedabad), GUJCOST (Gandhinagar) and various Pharmaceutical Industries. Many full time PhD research scholars have received the prestigious DST INSPIRE (Innovation in Science Pursuit for Inspired Research) fellowship from the DST and CSIR Government of India and from Confederation of Indian Industries (CII).

Many M.Pharm students and research guides from the department of Medicinal Chemistry, Pharmaceutical Technology & Bio-pharmaceutics and Pharmaceutical Analysis have received national recognition for "R. V. Patel Competition for Best Thesis at Masters Programme" supported by DST, Government of India and Troikaa Pharmaceuticals Ltd., Ahmedabad. Faculties have been awarded with P. D. Shethi awards and APTI awards for publishing the best research papers and for their contribution in innovative pharmaceutical research by solving web based challenges floated by the Innocentive. Inc. USA. Various faculties have also been awarded with N. S. Dhalla Young Scientist Award for Basic Sciences and awards from Association of Pharmaceutical Teachers of India for their presentations during symposiums and conferences.

The graduate students have been awarded for securing the highest grade in B.Pharm Examination and many students perform well to achieve All India rank in GPAT and secured admissions at reputed institutes like IITs, NIPER and other PG centres of India and also abroad. The post graduate

students have been placed at reputed academic institutions and industries of India.

Different departments have received support from government organizations like ICMR, DST, AICTE, ISTE, GUJCOST and CSIR in organizing various workshops, conferences and symposia of national and international level on recent advances in pharmaceutical sciences.

Memorandum of Understanding (MOU) has been signed between Institute of Pharmacy, Nirma University And University of Plovdiv, Bulgaria and with Ayurlab Herbals Pvt. Ltd, Vadodara For Academic Research Collaboration.

RESEARCH COLLABORATION WITH RESEARCH INSTITUTES/ UNIVERSITY:

- Plovdiv University, Bulgaria
- B. V. Patel PERD centre, Ahmedabad
- Cadila Pharmaceuticals Clinical Research and Pharmacology Centre, Dholka
- Intas Pharmaceuticals Ltd., Ahmedabad
- Piramal Pharmaceutical Development Services Ltd., Ahmedabad
- Green Chem Ltd., Bangalore
- Ayurlab Herbals, Vadodara

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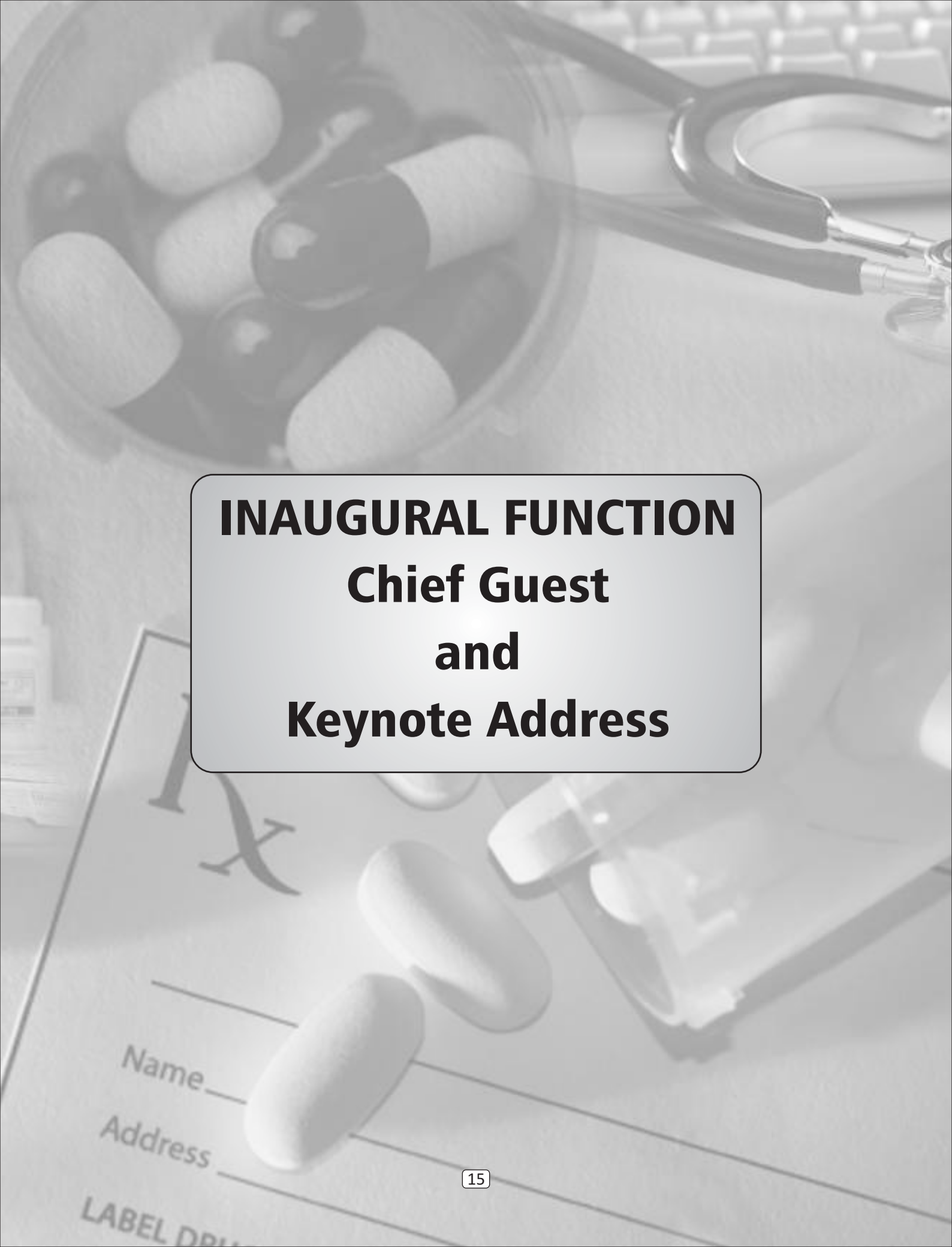
SCIENTIFIC SCHEDULE AT A GLANCE

(Venue for Scientific Sessions: Auditorium, Institute of Management)

DAY 1: JANUARY 23, 2014	
9.00 to 10.30	Registration & Breakfast
10.30 to 11.30	Inauguration
11.30 to 12.00	**TEA BREAK** Venue: Lawn, Institute of Management
12.00 to 13.00	**Key Note Address: Current Issues of Clinical Trials in India** *Dr. Y. K. Gupta* *AIIMS, New Delhi, India*
13.00 to 13.45	**Innovation in Drug Discovery** *Dr. C. L. Kaul* *Founder Director, NIPER, SAS Nagar, Mohali, India*
13.45 to 15.00	**LUNCH BREAK** Venue: Lawn, Institute of Management
15.00 to 15. 45	**Early Drug Discovery To Market Place : The Ups and Downs!!** *Dr. S. Chandrasekhar* *Chief Scientist & Head, Division of Natural Products Chemistry,* *CSIR-Indian Institute of Chemical Technology, Hyderabad, India*
15.45 to 16.30	**Reverse Pharmacology: A Trans-Discipline for Drug Discovery and Development** *Prof. Ashok D. B. Vaidya* *Research Director, ICMR Advanced Centre of Reverse Pharmacology,* *Kasturba Health Society, Mumbai, India*
16.30 to 17.00	**TEA BREAK** Venue: Lawn, Institute of Management
17.00 to 17.45	**Quest For a Novel Tuberculosis Vaccine: A Global Endeavor** *Dr. U. D. Gupta* *Scientist F/Deputy Director (Senior Grade)* *National JALMA Institute for Leprosy & Other Mycobacterial Diseases,* *Tajganj, Agra, India*
17.45 to 19.00	**CULTURAL PROGRAMME**
19.00 onwards	**GALA DINNER** Venue: Lawn, Institute of Management

DAY 2: JANUARY 24, 2014		
8.30 to 9.30	**BREAKFAST** Venue: Lawn, Institute of Management	
9.30 to 10.15	**Pulmonary Targeting Using Orally Administered Nanocarriers- A Revolutionary Approach in Tuberculosis Therapy** *Prof. Padma Devarajan* *Professor & Head, Department of Pharmaceutical Sciences, UICT, Mumbai, India*	
10.15 to 11.00	**Application of Quality by Design (QbD) Principles: Case Studies with Polymeric Excipients used in Development of Oral Controlled Release Formulations** *Dr. Sandip Tiwari* *Technical Director, South Asia, Colorcon Asia Pvt. Ltd., Goa, India*	
11.00 to 11.15	**TEA BREAK** Venue: Lawn, Institute of Management	
11.15 to 12.00	**Challenges of Microwave as Transdermal Permeation Enhancer** *Prof. Wong Tin Wui* *Associate Professor, School of Pharmaceutics, Faculty of Pharmacy, Universiti Teknologi MARA (UiTM), Malaysia*	
12.00 to 12.45	**Polysaccharide-Derived Non-Viral Vectors For Efficient Delivery of Biomolecules In-Vitro and In-Vivo** *Dr. K. C. Gupta* *Director, CSIR-Indian Institute of Toxicology Research, Lucknow, India*	
12.45 to 14.00	**LUNCH BREAK** Venue: Lawn, Institute of Management	
14.00 to 14.45	**Pharmaceutical Approach in Innovation and Development of Herbal Products** *Dr. Rajendran R.* *CEO and Founder, Green Chem, Bangalore, India*	
14.45 to 15.30	**Fostering Innovation in Drug Development** *Dr. Nikolaos G. Kostopoulos* *M.D. (Ath), M.F.Hom., Chr. Lada-Kifisia, Athens*	
	Session Lectures Venue: Auditorium, Institute of Management	***Session Lectures Venue: Seminar Hall, Institute of Pharmacy***
15.30 to 15.50	***Let's Foster Innovations in Nanotechnology For Better Management of Cancer*** *Dr. Munira M Momin* *Oriental College of Pharmacy, Sanpada (W), Navi Mumbai, India*	***Developing Clean-Green Technologies For Botanicals: Accelerating Drug Discovery From Medicinal Plants*** *Dr. Vivekananda Mandal* *Department of Pharmacy, Guru Ghasidas University (Central University) Bilaspur (C.G), India*

15.50 to 16.10	***Competitive Intelligence and Commercial Viability Analysis – Emerging Pillars of Drug Discovery in India*** *Dr. Varun Gupta* *Business Development, NCE Research, Piramal Life Sciences, Mumbai, India*	**Green Chemistry: An Approach Towards Drug Discovery** *Dr. Prateek Kumar Jain* *ADINA Institute of Pharmaceutical Sciences, Sagar (M.P.), India*
16.10 to 16.30	***QbD and Drug Delivery Systems*** *Dr. Rajesh.K.S.* *Parul Institute of Pharmacy, Vadodara, Gujarat, India*	***Incurred Sample Reanalysis (ISR): A Reconfirmation of the Bioanalytical Method*** *Mr. Abhay R. Shirode* *Bharati Vidyapeeth's College of Pharmacy, Navi Mumbai, India*
16.30 to 18.30	**POSTER PRESENTATION** Venue: Institute of Pharmacy Tracks: Pharmaceutical Technology, Biotechnology & Drug Delivery Pharmacognosy, Phytochemistry & Herbal Technology	
DAY 3: JANUARY 25, 2014		
8.30 to 9.15	**BREAKFAST** Venue: Lawn, Institute of Management	
9.15 to 10.00	**Drugs Vs Diet in Treating Metabolic Disorders** *Dr. Sukhinder Kaur Cheema* *Professor, Department of Biochemistry, Memorial University, St. John's NL, Canada*	
10.00 to 11.00	**Pharmaceuticals in The Environment** *Dr. Saranjit Singh* *Professor and Head, Department of Pharmaceutical Analysis, NIPER, S.A.S. Nagar, Panjab, India*	
11.00 to 13.00	**POSTER PRESENTATION** Venue: Institute of Pharmacy Tracks: Drug Discovery & Medicinal Chemistry Pharmaceutical Analysis, Quality Assurance & Regulatory Affairs Pharmacology, Clinical Pharmacy & Pharmacy Practice	
13.00 to 14.00	**LUNCH BREAK** Venue: Lawn, Institute of Management	
14.00 to 14.45	**Exploring Nanotechnology Through Drug Delivery For Healthcare** Dr. N. Udupa Professor and Principal, Manipal College of Pharmaceutical Sciences, Manipal, Karnataka, India	
14.45 to 15.45	**VALEDICTORY FUNCTION**	



INAUGURAL FUNCTION
Chief Guest
and
Keynote Address

CHIEF GUEST - INAUGURAL FUNCTION

Dr. Sourav Pal
Director, National Chemical Laboratory
Pune

Dr. Sourav Pal, is currently working as Director, CSIR-National Chemical Laboratory, Pune since 1st December, 2010. Dr. Pal is a distinguished theoretical chemist and has been working at National Chemical Laboratory since last 30 years. He has contributed to diverse areas of theoretical chemistry including the challenging aspects of methodological and conceptual developments. He has contributed significantly to the many-body theory of molecular electronic structure and properties using coupled-cluster methods and is well recognized in India and abroad. He has also contributed significantly to the area of chemical reactivity and density functional theory response. In recent years, he has contributed to the catalytic and hydrogen storage materials using computational material science. Specifically, he has been looking into the beta zeolites as catalytic systems and doped magnesium hydrides and metal-decorated metal-organic frameworks as solid state materials for hydrogen storage. In addition to his scientific contribution, Dr. Pal has been associated with several important management positions at NCL for last several years and currently as a Director, has important job of shaping the vision of the laboratory and transforming NCL into an innovation-centric organization in chemical and allied sector.

Dr Sourav Pal obtained his integrated masters degree in Chemistry from Indian Institute of Technology (IIT) Kanpur in 1977. He received his Ph.D. degree from Calcutta University and joined NCL in 1982. He was a post-doctoral fellow at the University of Florida, Gainesville, USA (1986-87) and has been Alexander von Humboldt Fellow at the University of Heidelberg, Germany (1987). He was a visiting Professor at the University of Arizona, Tucson, USA (1995) and the Institute for Molecular Sciences, Okazaki, Japan (1997). He is currently also an adjunct Professor at Indian Institute of Science Education and Research (IISER) Pune.

Dr. Pal has been recognised by several awards and honours for his contribution to science and technology including the prestigious Shanti Swarup Bhatnagar Award in Chemical Sciences in 2000. He is a recipient of the Prof. R. P. Mitra Memorial Lecture Award, Delhi University, 2010, INSA Dr Jagdish Shankar Memorial lecture Award, 2006, Chemical Research Society of India (CRSI) Silver Medal, 2009, as well as INSA and CSIR Young Scientist Awards in 1987 and 1989, respectively amongst others. He is a Fellow of The Indian National Science Academy (2003), Indian Academy of Sciences (1996) and National Academy of Sciences (1998). He is also a Fellow of the Royal Society of Chemistry (2011), the Maharashtra Academy of Sciences (1994), J.C. Bose National Fellow of Department of Science and Technology from 2008, Dai-ichi Karkaria Endowment fellow of ICT, Mumbai, 2004-05 and Fellow of West Bengal Academy of Science & Technology (WAST) (2011).

Dr. Pal serves on the editorial boards of several international and national journals in chemistry and has guided over 20 Ph.D. thesis. He has published about 190 papers in International peer reviewed journals. He has authored a book titled “Mathematics in Chemistry” and contributed to chapters in several books. He has been invited to deliver plenary / keynote / highlighted lectures in several institutions and international conferences of repute over the years.

KEYNOTE ADDRESS

Current Issues of Clinical Trials in India

Dr. Y. K. Gupta
Professor and Head,
Department of Pharmacology,
All India Institute of Medical Sciences (AIIMS), India

BIO-DATA

Dr. Y. K. Gupta, M.B.B.S (1974), M.D (Pharmacology, 1979) from King George's Medical College, Lucknow is Professor and Head, Department of Pharmacology and Spokesperson, All India Institute of Medical Sciences (AIIMS), New Delhi. He earlier served as Sub Dean, A.I.I.M.S (1996 – 2001) and Director, Indian Institute of Toxicology Research (IITR, CSIR), Lucknow from 2003 to 2005. Dr. Gupta is incharge of National Poison Information Centre and is also National Scientific Coordinator of Pharmacovigilance Program of India (PvPI). He has been honored with Fellowships of National Academy of Medical Sciences (FAMS), Indian Pharmacological Society (FIPS), National Academy of Science (FNASc), Indian Academy of Neurosciences (FIAN) and Society of Toxicology (India) (FST). He has more than 180 publications in International and National journals and several chapters in books to his credit. Dr. Gupta is recipient of several awards including Young Scientist Medal from Indian National Science Academy, Shakuntala Amirchand Prize, Chandrakanta Dandiya Prize, G. Achari Oration Award, Major General S. L. Bhatia Oration Award, AEB Honors Award, C. L. Malhotra Prize etc. Dr. Gupta is currently President of Society of Toxicology, India and Dean Indian Society for Rational Pharmacotherapeutics, and was President of the Indian Pharmacological Society (2005-2006). He is the Editor of the Indian Journal of Physiology and Pharmacology (Pharmacology Section) and member editorial board of several International and Indian journals. He is the Chairman of National Committee of IUPS-IUPHAR of Indian National Science Academy (INSA), Member of IUPHAR–IOSP committee and member of Advisory Committee on Safety of Medicinal Products (ACSoMP) of WHO, Chairman of Equivalence Committee and member Ethics Committee of Medical Council of India. He has been member of Project Advisory Committee / Research Council / Scientific Advisory Committee and Task force of CSIR, ICMR, DST and DBT and Chairman, SAC of National Institute of Occupational Health (NIOH-ICMR). He is Chairman of national GLP technical committee of DST, member of the Scientific Body of Indian Pharmacopoeia (IP) and Chairman of Expert Committee on Clinical Medicine and Pharmacology of IP. He was the Chairman of National Essential Medicine List Committee 2011 of Ministry of Health & Family Welfare, Government of India and also the Chairman of the working group of High Powered Inter-Ministerial Coordination Committee to look into the matters of implementation Government commitment to provide quality medicine at affordable prices.

ABSTRACT

Clinical research including clinical trials has grown exponentially over the past decade in India. This is because of unique advantages that the country offers in terms of cost advantage, large treatment naïve patient population, well qualified doctors conversant in English, to name a few. India was the second most preferred country to conduct clinical trials outside of USA in 2009 with an average

annual increase of 30%. However, more recent years have witnessed a flattening and then a sharp decline in number of trials in India (529 in 2010; 253 in 2012).

The number of drugs entering the Indian markets had been gradually reducing even before the current slump in clinical research activity (270 in 2008;140 in 2011; 43 in 2012). Clearly, the fruits of labour never accrued to our population. This necessitates a relook on the strategy so as to optimize clinical research in Indian context. Some of the important issues regarding clinical research can be broadly classified into capacity building issues and those concerning the ethicoregulatory environment in India.

To begin with, there are scant training resources to train adequate number of researchers so as to carry out research activities as per the International Standards. There is a need to build dynamic training modules and platforms which confirm to International Regulations and best practices while addressing peculiar national needs. The training infrastructure needs to be flexible enough to accommodate ever changing regulatory landscape. We have a thriving knowledge base of traditional medicine systems which cater to a large segment of population are regulated by a separate Department of AYUSH. To this end there is a requirement of involving traditional medicine practitioners in research training. In spite of a lot of resources being deployed in research involving herbal medicines, there are few examples of translational success and any worthwhile medical breakthrough.

Of late, a lot of negative perception has gained ground about the scientific and ethical standards of clinical research in India. It is perceived that Indian patients being poor and less informed are vulnerable to exploitation by unscrupulous researchers. That the clinical research activity is mostly industry sponsored, deepens the suspicion. While a more informed debate and perception management is the need of the hour, there is need to address these issues and fill the gaps if any. The confidence building amongst all stake holders has now assumed paramount importance.

Govt. of India has taken a lot of steps to ensure participant safety. A lot of emphasis is being put on informed consent process which now involves video recording to ensure transparency although many issues about logistics and confidentiality have to be addressed.

Institutional ethics committees (IECs) have been empowered and made more accountable. Now they are required to actively monitor and participate in reporting of SAEs. However training of over 600 IECs need to be undertaken by a competent body so as to empower them about their roles and responsibilities such as arriving at recommendation about the quantum of compensation in cases of clinical trial related injuries.

Similarly, it is now mandatory to register all clinical trials with the Clinical Trials Registry India (CTRI) before commencing any trial procedure. This is a welcome step aimed at putting trial related information in the public domain. However, there is a case for broadening the ambit of CTRI by capturing the subsequent trial results (positive, negative or inconclusive termination) too in the national database. This step shall go a long way in ensuring optimum publicity of trial results thereby mitigating publication bias.

Fresh guidelines have also been issued for provision of compensation for trial related injuries or deaths. While this has been done to ensure patient safety and instill confidence in environment, it has led to some fresh issues leading to apprehension amongst the sponsors. Some important contentious issues are the provision of compensation when injury takes place due to non response to the investigational drug (the efficacy of which is yet to be established through the very trial),

provision of compensation for death in terminally ill patients (who were not expected to survive even if they were not to participate in trial), or in cases where injury is purported to have taken place due to use of placebo (some patients need to be assigned placebo group so that true effects of investigational drug are assessed).

While the issue of compensation is clearly partially addressed, it is hoped that necessary clarifications and additional guidelines are on anvil and there shall be more clarity on this subject as it evolves.

Other recent changes in regulatory framework will require substantial logistic backup besides the need of imparting quick intensive training to various stake holders such as members of IECs, prospective investigators and regulators themselves.

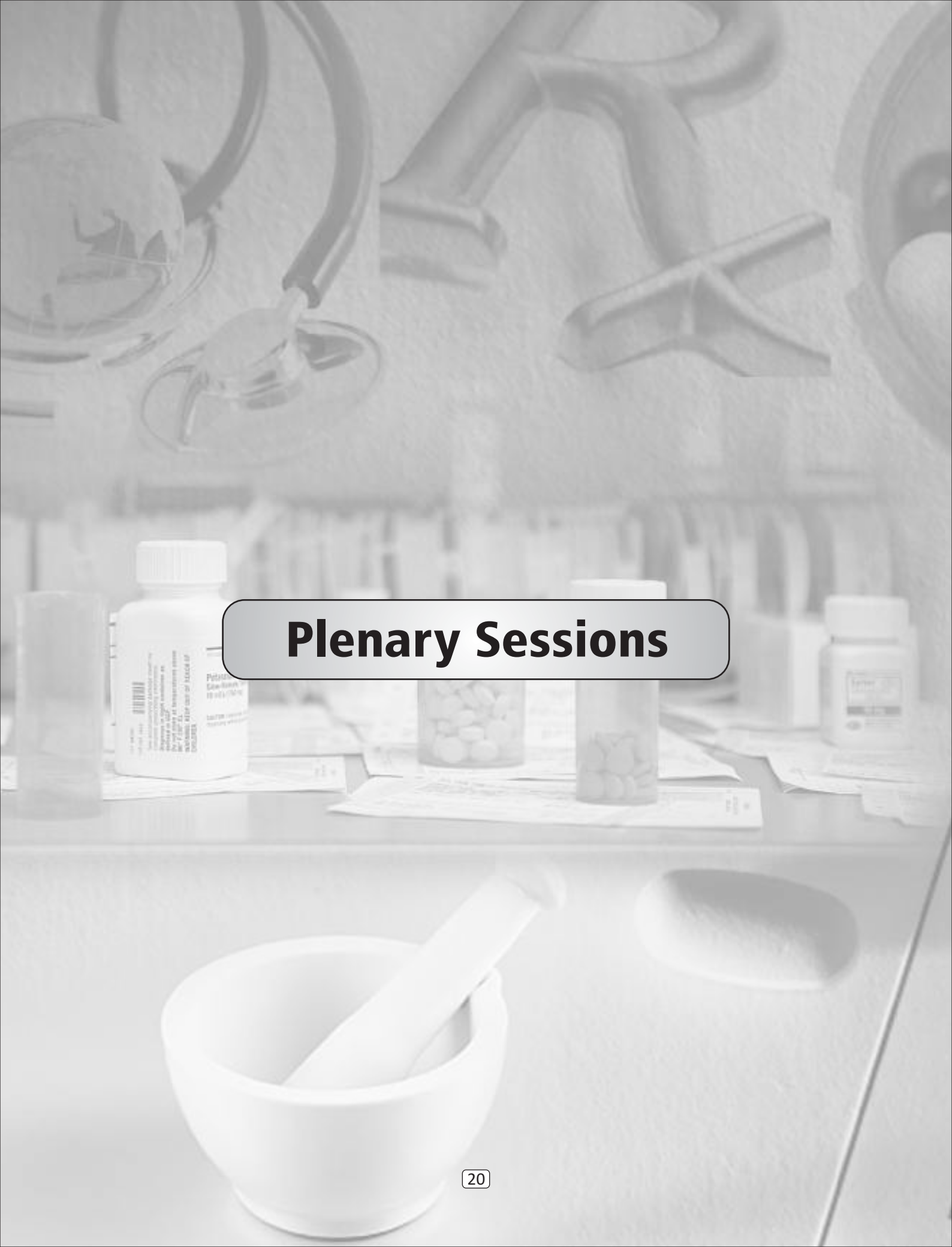
This spate of well intended regulatory overhaul has also made pharma companies apprehensive and skeptical about doing trials in India. Once the grey areas and contentious issues are addressed, it is envisaged that clinical research in our country will quickly scale up in a much safer, regulated and enabling environment.

Besides the regulatory action, patient, the most important stake holder, needs to be sensitized too. There is a need to generate informed and balanced debate in electronic and print media highlighting the 'pluses', acknowledging the 'minuses' and clarifying the grey areas. The entire spectrum of clinical research needs to be made transparent with seamless knowledge sharing and information exchange. IECs must enforce the publication of all the studies, even negative ones. Regulators also need to act more as facilitators of research and not merely as law enforcers.

While the arena of clinical trials is under close watch, other types of clinical research such as observational studies, population based studies, outcomes research etc. also deserve equal emphasis. We need to formulate standardized protocols and SOPs for these activities and train adequate manpower. In the country of our size and magnitude, this is where the clues and leads are likely to emerge from.

Another important issue is to align the clinical research activity in our country as per our national health needs. Research in India specific problems (such as Japanese Encephalitis (JE), Dengue, malaria, Multi Drug Resistant TB) should be incentivized by way of faster approvals, liberal funding and extended marketing rights. It is good to have a vaccine against HPV but one against JE may be needed more and sooner.

Clinical research is essential not only for developing medicines for emerging health concerns (such as Extensively Drug Resistant (XDR) TB, antibiotic resistant pathogens, H1N1, Ebola virus, etc) but also for finding safer and better medicines for entrenched Diseases such as HIV, Malaria, Diabetes, Hypertension etc. India, with its large patient population, unmet health needs and limited resources, needs to make newer and better treatment options available to its population in a quick, economical and dependable manner. For this, India must take proactive part in clinical research and assume leadership role globally. We must ensure that clinical research in our country is carried out as per global scientific standard, is moored in sound ethical foundations befitting a liberal democracy but is optimally oriented towards addressing national medical and health needs.



Plenary Sessions

Innovation in Drug Discovery

Dr. C. L. Kaul
Ex-Director,
National Institute of Pharmaceutical Education and Research (NIPER),
Mohali, India

BIO-DATA

Dr. C. L. Kaul has recently retired as a Founder Director of NIPER, Chandigarh. In building of this institution of National Importance, Dr. Kaul used his rich experience of working with research institutions within the country and abroad through his associations with industry and educational bodies. Dr. Kaul is a pharmacy graduate from Gujarat University and had his Post Graduate education at the University of London and Glasgow, UK. Apart from carrying out and directing research at the Boots Pharmaceuticals and Ciba-Geigy, he had worked at several research centers across the UK and Switzerland. His research work spanning over more than 4 decades had centred around development and preclinical studies of new drugs, stability studies, bioavailability, pharmaceutical formulations and quality control. His research work has been published in both National and International peered review Journals (More than 150 publications). His main areas of interest are Hypertension, Diabetes, Autonomic Pharmacology and Tropical Diseases. He is associated with number of Universities and Pharmacy institutions as a visiting professor and is on the Governing and the Management Boards of some of the pharmacy schools. Dr. Kaul is a member of several scientific organisations and Editor of Indian Journal of Pharmaceuticals Sciences, President of Indian Pharmaceutical Association. He is a fellow of National Academy of Sciences, Punjab Academy of Sciences and IPA. He was also awarded Eminent Pharmacist Award by the IPA in 2003.

ABSTRACT

Amongst the various operations of the pharmaceutical industry, the drug discovery offers the greatest challenge. Today, pharmaceutical industry is facing intense pressure including scientific, regulatory and payer related concerns that affect the R&D productivity. In the past two decades the R&D productivity has gone down in terms of new entities approved by regulatory authorities, even some entities which have been approved are not commercialized because of various reasons. Industry profitability and growth prospects are under pressure as healthcare budgets are being reduced. Increase usage of generic drugs in the United States (around 70% of the prescriptions) is keeping the cost down. Expiry of patterns (2010-2014) put around $209 billion in annual drug sales at risk resulting in 113 billion dollars being lost to generic substitution. The increased R&D expenditure is vastly due to expanded research opportunities created by advance in basic sciences, increase in drug targets, investments in new technology, development of new research capabilities which will pay off in due course and increase regulatory requirements. With the world population

aging and the number of patients with Cancer, Diabetes, Alzhemiers and other diseases increasing, there is an urgent need of new innovative drugs to cure, prevent and slow the progression of the disease. Some of the approaches used by the industry to resolve some of the innovative issues is to look as to how one can intervene to treat diseases earlier or prevent disease progression. How can genome mining be done more effectively to find more human validated disease targets and increase our understanding of multiple cell signaling pathways. Some other approach which has been initiated is trying to develop multi specific therapeutic to boost efficacy by combining more than one mechanism of action in one molecule. One important intervention in the drug discovery is clinical development which is the most expensive stage in the drug development process. It has been suggested that we should move away from the conventional approach based on different phases, towards integrative view where one uses adaptive design, tools to increase flexibility and maximize use of accumulated knowledge which could result in achieving the desired goal. Increased usage of micro-dosing is also playing a very useful role in the R&D productivity. Crowd sourcing is also emerging as an open innovative approach to promote collaboration and harness the complementary expertise of academic and industrial partners. Advances in network pharmacology is the next paradigm in drug discovery which is again being investigated. Development of fully humanized monoclonal antibodies is a source of future innovation and rapidly growing category of therapeutic agents. As to which of these strategies would yield the desired results need to be seen. Science and the long term approach would be the foundation and the way forward to support innovations. While following these strategies it is important to get the right attrition at proper times and look for low risk and high pay off drugs.

Early Drug Discovery to Market Place : The Ups and Downs!!

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BIODATA

Dr. S. Chandrasekhar is Chief Scientist and Head of the Division of Natural Products Chemistry at CSIR-Indian Institute of Chemical Technology, Hyderabad. Dr. Srivari obtained his Bachelors, Masters and Ph. D. degree from Osmania University while the work for Ph. D. was carried out in IICT on total synthesis of Cyclosporin. Dr. S. Chandrasekhar has made significant contributions in diverse areas of organic chemistry especially in chiral chemistry and total synthesis of biologically active natural products (marine natural products with architectural complexity). The development of PEG as a novel solvent medium created a totally different platform for practitioners of Green chemistry. Development of new methodologies for C-C bond formation reactions involving organo-catalysis and organo-metallic reagents is highly cited. Process development and drug discovery in collaboration with pharmaceutical industry have resulted in development of economically viable processes and lead compounds. He has 231 publications and two patents with over 3900 citations. 36 students have already obtained their Ph.D. award under his able guidance and 21 students are currently pursuing their research work with Dr. S. Chandrasekhar. He is a recipient of the Natioanl Academy of Sciences-Reliance platinum jubilee award in physical sciences for work on innovations in applied research with fundamental approach. He has been awarded the Ranbaxy Research award in Pharmaceutical sciences-2009 for his contributions to total synthesis of natural products and medicinal chemistry. He is a fellow of the Indian Academy of Sciences and National Academy of Sciences. He was Alexander von Humbodlt Fellow at Goettingen and post-doctoral fellow at University of Texas.

ABSTRACT

The diseases and their cure have been part of human evolution. As mankind conquers one disease, a new one is discovered and the challenge to overcome this new problem is on. The pioneering contributions from drug discovery scientist have been successful in the form of a great increase in the average life expectancy of the human race and quality of life. There are tremendous challenges in drug discovery as this is multidisciplinary effort and also the disease manifestation is a very complex process and several biological pathways are engaged. The cardiac disorders, CNS related diseases, cancer and infectious diseases occupy top of the list of diseases affecting human beings. The present lecture will address the challenges posed in early drug discovery, preclinical and clinical trials and finally the challenges to take a molecule to the market place. Some case studies from our own research group targeting the CNS, Cancer and infectious disorders will also be discussed.

Reverse Pharmacology: A Trans-Discipline for Drug Discovery and Development

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BIODATA

Prof. Ashok D. B. Vaidya is a Research Director at ICMR Advanced Centre of Reverse Pharmacology, Kasturba Health Society, Mumbai, Adjunct Professor at Gujarat Cancer Research Institute: Saurashtra University, Drexel University, Philadelphia, Director of Clinical Pharmacology, BSES Hospital & Global Research Centre, Mumbai and Chairman of American College of Clinical Pharmacology (South Asia Chapter), American Association of Pharmaceutical Scientists (West India Group). Dr. Ashok Vaidya had his medical education at Seth G.S. Medical College & KEM Hospital (KEMH), Mumbai. With a long family tradition of medicine and Ayurveda, Dr. Vaidya has inherited all the archives of his ancestor- Aryavaidya Mayaram a renowned Ayurvedic scholar and author. He has applied Reverse Pharmacology (RP) to the heritage and over the two decades, he has gained the complex expertise of drug discovery and development. He started his research career as a Resident Microbiologist and Typhoid Officer at the Haffkine Institute, in 1961. Later, as the first research fellow at KEMH, he pioneered the first Clinical Pharmacology Unit in India. He was the Merck International Fellow in Clinical Pharmacology, at the Yale Medical School, for advanced clinical and research training and conducted first trials with brocresine, p-CPA and L-dopa. At the CIBA, and KEMH, he carried out first of its kind in India, Phase I, II and III trials of around 10 new drug molecules with the largest post-marketing surveillance with Voveran, Lopresor and Aubril. He was the Regional Medical Director (South Asia) for CIBA-GEIGY, now Novartis. The clinical research on natural products, at Podar Ayurvedic Hospital, led to new leads from the Ayurvedic plants for the treatment of various diseases. Later, at SPARC, he strengthened the new discipline of Reverse Pharmacology and he was awarded the ICMR's Advanced Centre of Reverse Pharmacology in Traditional Medicine at Kasturba Health Society. The research in RP has contributed new modalities in diabetes, hepatitis, arthritis, menorrhagia, burns & wound-healing, malaria, urticaria, and cancer. He was the first to point out Prakriti Genomics and guided the CSIR-NMITLI R&D on diabetes mellitus. He trained many researcher at several national and international conferences, seminars and workshops and guided several pharmaceutical R&Ds in new drug discovery and development. Dr. Vaidya is recipient of several honours and awards viz. Lifetime Achievement Award and Sir Ram Nath Chopra Award by IPS, Haffkine Oration, Unilever Lifetime achievement Award, Nutra Summit Lifetime Achievement Award, Prof. U. K. Sheth Oration Award in Clinical Pharmacology, Dr. K. N. Udupa Award for excellence in Ayurvedic research, Prof. O.D. Gulati Oration in Pharmacology, Dr. Hussein Zaheer Oration–IICT, Shri B. V. Patel Memorial Award, Dr. S. L. Bhatia Oration, Rotary Distinguished Service Award, Bhrigu Award, Arya Vaidyan P. V. Rama Varrier Memorial Excellence Award in Ayurveda, Vd Shankar Daji Pade Oration, Distinguished CIPLA Fellow, Institute for Chemical Technology, Dr P. N. Avasthi Oration and Prof. Derasari Award for Research in Pharmaceutical Sciences. He was the President of the Indian Society of Clinical Pharmacology and of the Association of Medical Advisors to the Pharmaceutical Industry. He has been on the editorial boards of several journals. Currently he is the Chief Editor of the Journal of Obesity and Metabolic

Research. He has been a consultant and expert to WHO, CSIR, ICMR, DBT, AYUSH, several industries and research institutes and provided expert inputs to the 11th and 12th five-year plans of India. He has more than 250 research publications to his credit.

ABSTRACT

Reverse Pharmacolgy (RP) has been systematically developed over the last three decades as a novel approach to new drug discovery and development, by our group. The maturation of the approach into a trans-discipline has been a result of both national and international active interest in a cost-effective, safe and fast-track alternative to the conventional R&D carried out by the pharmaceutical industry. However this shift in the ruling paradigm of drug discovery has only a few takers. As a consequence, the resources needed for the trans-discipline, in terms of personnel, infrastructure and funds are hard to come by. Despite that the ICMR, in its wisdom, granted 'the first in the world' Advanced Centre of RP at the KHS. The Maharashtra University of Health Sciences has established the first post-masters' Diploma course in RP. We hope that other universities will also follow up on the initiative. CSIR-NMITLI programme adopted the RP approach for Ayurveda-inspired new drug discovery.

The definition of RP: It is the science of integrating well-documented clinical/experiential/historical drug hits, into leads by trans-disciplinary exploratory studies and further developing the leads into drug candidates by experimental and clinical research. The scope of RP is immense and covers the understanding of the mechanism of action at multiple levels of human biology and to optimize the quality, safety, efficacy and acceptability of the drug leads, with relevant science from the bedside to the bench. The very nature of work requires expertise from diverse disciplines: Clinical medicine (specialists and astute observers), clinical/experimental pharmacology, pharmacy, phytochemistry, ethnobotany, systems biology, laboratory medicine, molecular pharmacology, toxicology and epidemiology/statistics. It is only through a R&D network that so many disciplines can be engaged in RP. It would be counterproductive to have all such top experts under one roof. But the work of steering, managing and monitoring of the inter-institutional R&D network is no mean task. We have learnt a great deal on these aspects during the CSIR-NMITLI programmes. There is an urgent need to revitalize that chain. Recently, a National Task Force for Phyto-Pharmaceuticals has been initiated for the very purpose.

There are innumerable success stories of drug discoveries at the bedside. However, all along, this was considered to occur only by a chance. A systematic path was not evolved to develop bedside hits. Ayurvedic Pharmacoepidemiology, Observational Therapeutics. Reverse Pharmacolgy and Systems Biology have identified the path and its milestones. As a consequence, several leads and drug candidates have emerged: *Mucuna pruriens* for Parkinson's disease, *Tinospora cordifolia* for cancer chemotherapy side effects, *Enicostemma littorale* for diabetes, *Semicarpus anacardium* + T. cordifolia for osteoarthritis, *Curcuma longa* for neuro-plasticity, *Saraca indica* for menorrhagia, Panchvalkal for burns/wounds, *Picrorhiza kurroa* for viral hepatitis, *Phyllanthus amarus* for HIV infection, and Dolichos biflorus for the kidney stones. Even with the chemical drugs the bedside hits have given some new uses of the old drugs or unsuspected uses of the new drugs. Piperazine, metronidazole, aldomet, thalidomide and iproniazid are some such examples.

A plea is made that the Pharmacy colleges must initiate basic courses in understanding RP both at the undergraduate and postgraduate levels. Theses in RP should also be encouraged.

Quest for a Novel Tuberculosis Vaccine: A Global Endeavor

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BIODATA

Dr. Umesh Datta Gupta is Scientist F/Deputy Director (Senior Grade) at National Jalma Institute for Leprosy & Other Mycobacterial Diseases, Tajganj, Agra. He is from the science background with Specialization in Experimental Leprosy & Experimental Tuberculosis. Sir has total 31 years of teaching and research experience of working in large animals as well as Small laboratory Animals. Earlier he was an Assistant Professor in GBPUA&T, Pantnagar from 1985 to 1993; Joined ICMR in Dec. 1993 as SRO. He has attended more than 75 National and International Conferences and published more than 60 papers in National and International Journals. He is a recipient of ICMR Senior International Fellowship in 2006, ICMR JALMA ORATION award-2008 for research in Mycobacteria, BEP (USA). Sir has received travel grant for attending International Conferences on Infectious Diseases-Miyami (USA) and also won Bill & Melinda Gates Foundation Global Health Travel Award for attending Key Stone Symposium on Tuberculosis (2012) and (2014). He visited countries like Brazil, Netherland, USA, Switzerland, Uganda, Taiwan, Belgium and Nepal for attending International Conferences and delivering lectures.

ABSTRACT

The success of Mycobacterium tuberculosis as a human pathogen relies immensely on its ability to subvert the host immune responses and persist in a dormant state. *M. bovis Bacille Calmette-Guerin* (BCG) is currently the only tuberculosis (TB) vaccine approved for human use. It has been used to vaccinate more than 4 billion individuals worldwide and still continues to be a part of the childhood immunization program in most of the countries due to its ability to impart effective protection against TB in children. However, the protective immunity generated by BCG wanes off with age and its efficacy against the disease has been less than satisfactory in adults and older individuals. Besides, the inability of BCG to provide sterilizing immunity at the time of primary infection leads to an enormous reservoir of asymptomatically infected individuals worldwide (2 billion). These latently infected individuals have a persistent risk of developing clinical disease due to endogenous reactivation if the immune system is compromised due to several reasons such as HIV infection, malnourishment etc. Latency-associated antigens are expressed by M. tuberculosis while adapting to long-term persistence; however, BCG being an attenuated strain does not persist long enough to express these antigens. Thus, despite sharing a vast repertoire of antigens with M. tuberculosis, BCG fails to elicit an efficient response against these latency antigens. Hence, the latency-associated antigens are attractive targets for developing booster vaccines to enhance the protective efficacy of BCG. During last 10 years, there has been extensive work for the development of potential tuberculosis vaccine candidates using the mice and guinea pig models. Though till date several promising candidates have been identified and many of these have already found their way into clinical trials or pre-clinical development. These recent advances in the clinical testing of new TB vaccines are very exciting and promising. However, there is a need to continue the search for additional vaccine candidates or vaccination strategies.

Pulmonary Targeting using Orally Administered Nanocarriers- A Revolutionary Approach in Tuberculosis Therapy

Prof. Padma V. Devarajan

Professor and Head, Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, Mumbai, India

BIO-DATA

Prof. Padma V. Devarajan is Professor in Pharmacy and Head, Department of Pharmaceutical Sciences and Technology at the ICT, Mumbai, India. With over twenty five years of experience in teaching and research, she has supervised over 75 students for the Masters and PhD degree. Her research interests include colloidal carriers for targeted delivery in cancer and infectious diseases, bioenhancement strategies, and mucosal DDS as alternative to parenteral administration. She has over 200 presentations and publications in national/international conferences/cited journals and five book chapters in the area of drug delivery. She is currently editor for a book on "Targetted Drug Delivery" to be published by Springer. She was invited to present at the Ehrlich II conference to Germany. She has filed over 25 patents international/ national, has 7 patents granted and 4 patents licensed. Her research is funded through a number of grants from the Government of India. She was invited by the Government of India, for support under the New Millenium Indian Technology Leadership Initiative. She also has a number of sponsored projects from the industry including companies from Japan, Germany and USA and is a consultant to the Pharma industry national and international. She was Board Member, Member on the Board of Scientific Advisors and Chair of the Young Scientist Mentor Protégé Committee of the Controlled Release Society Inc., USA. She is ex Secretary, treasurer and Patron Member of the CRS Indian Chapter and Member of the Advisory Committee of the DIA, India. Prof. Devarajan is a nominated Fellow of the Maharashtra Academy of Sciences, a recipient of the American Association of Indian Pharmaceutical Scientists (AAiPS) Distinguished Educator and Researcher Award 2011, the VASVIK award for Industrial Research to Women in 2011 and the Association of Pharmaceutical Teachers of India (APTI), C.J. Shishoo Award for Research in Pharmaceutical Sciences in 2013.

ABSTRACT

TB causes substantial mortality and morbidity leading to approximately 14.6 million chronic active cases, 8.9 million new cases and 1.6 million deaths, with new infections occurring at a rate of one per second according to the latest WHO report. Limitations of conventional therapy including long term treatment, life threatening side effects, and emergence of resistant strains pose significant challenges in the treatment of tuberculosis. Pulmonary tuberculosis is the most prevalent tuberculosis and specifically important as it can be contagious. One of the major challenges in tuberculosis therapy is achieving high drug concentration in the lungs and more specifically in the alveolar macrophages the site of infection. A direct strategy to tackle pulmonary tuberculosis is pulmonary delivery of anti-tubercular drugs. Direct pulmonary deposition of micro/nanoparticles through inhalation/nebulization has been evaluated by various research groups to deliver high concentration of anti tubercular drugs to the lungs. Although promising, the dose that can be delivered by this route poses serious constraints. Variable deposition of inhaled nanoparticles in the lungs, resulting in suboptimal drug concentrations in certain lung regions is another limiting issue. Oral drug administration with high bioavailability and sustained release, coupled with enhanced pulmonary uptake presents an ideal drug delivery strategy for the treatment of tuberculosis. Targetting to the lungs following oral administration is an attractive, although difficulty strategy. The present study discusses the discovery of a new ligand for pulmonary targeting following oral administration. High drug concentrations of anti tubercular drugs, significantly greater than concentrations following conventional oral administration, and many fold higher than the MIC and was achieved. A hypothesis to explain the high lung uptake with Gantrez would be presented.

Application of Quality by Design (QbD) Principles: Case Studies with Polymeric Excipients used in Development of Oral Controlled Release Formulations

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BIO-DATA

Dr. Sandip B. Tiwari is currently Technical Director-South Asia, Colorcon Asia Pvt. Ltd, Goa, India. He earned his PhD in Pharmaceutical Sciences from College of Pharmaceutical Sciences, Manipal, Karnataka, India. He is responsible for leading the Formulation Center of Excellence, FCE (product development laboratory) in Goa. Prior to his relocation to India in July 2011, Dr. Sandip was a Senior Manager, Product Development at Colorcon Inc., Harleysville, PA, USA for over 5 years, where he was responsible for the development of the extended release matrix system portfolio including design and development of osmotic drug delivery technology platform, implementation of Quality by Design (QbD) initiatives for extended release hydrophilic matrix systems and developing strategies for modulation of drug release profiles from hydrophilic matrices. Dr. Tiwari was also a post-doctoral fellow at Northeastern University, Boston, MA, USA where he investigated the application of nanotechnology in drug delivery and diagnostics. While in India, Dr. Tiwari worked at the Zydus Research Center, Ahmedabad, India, as an Associate Research Scientist and then as a Senior Scientist and Head of the Department of Novel Drug Delivery Systems. He led a team that developed the formulation for NCE for "first dose" in humans that subsequently completed Phase III trials and approved for commercialization in India under the name of Lipaglyn™ : the world's first drug for treating diabetic dyslipidemia (Saroglitazar). He has over 15 years' experience in the pharmaceutical field and has participated in various stages of drug development during his career. He has written six book chapters/ monographs and contributed more than 100 research publications and conference presentations in the areas of controlled release technology, non-invasive drug delivery, and nanotechnology. He has spoken at many national and international conferences as an invited speaker.

ABSTRACT

In contrast to the traditional regulatory system of Quality by Testing (QbT), Quality by Design (QbD) is a systemic approach to pharmaceutical development that begins with predefined objectives and emphasizes product and process understanding and control. It means designing and developing formulations and manufacturing processes to ensure predefined product quality. Pharmaceutical excipients are commonly used in the design of wide array of dosage forms. Controlling the quality and consistency of the excipients is critical to the performance of the dosage forms. QbD drives pharmaceutical companies to have a thorough understanding of the functional effects that excipients may have on their product. A combination of the understanding of raw material properties, their inherent variability and process control will lead to successful QbD implementation for pharmaceutical dosage forms. Ideally, formulators should build robust formulations which can accommodate the variability potentially found in pharmaceutical excipients rather than simply try to tighten specifications that could be difficult to meet routinely. This presentation will review various functional aspects of commonly used excipients that relate to QbD and discuss examples with case studies. It is imperative to improve communication between excipient supplier and user concerning excipients process capability in order for QbD to be successful. Some of the frequently asked questions on QbD studies with specific reference to excipients will also be discussed.

Challenges of Microwave as Transdermal Permeation Enhancer

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BIODATA

Dr. Wong Tin Wui is an associate professor at School of Pharmaceutics, Faculty of Pharmacy, Universiti Teknologi MARA (UiTM), Malaysia. He is the founder and Chairman of PharmaTech, a biennial international conference and exhibition event focusing on pharmaceutical, nutraceutical and cosmeceutical technology, as well as, non-destructive Biomedical and Pharmaceutical Research Centre UiTM. He serves as editor for 5 international journals, reviewer for 40 international journals, advisory board member for several international conferences, nanotechnology expert panel for Academy of Sciences Malaysia, steering committee for National Nanotechnology Directorate, Ministry of Science, Technology and Innovation Malaysia. His research areas are primarily focused on particle/scaffold design for oral, transdermal and pulmonary drug delivery, development of novel non-destructive pharmaceutical and biomedical analysers, as well as, design of pharmaceutical processors for innovative dosage form manufacture.

ABSTRACT

Transdermal drug delivery provides a controlled continuous delivery of drug molecules from the surface of skin, through its layers, and into the systemic circulation. It bypasses enzymatic digestion in gastrointestinal tract and hepatic portal system which can lead to excessive drug degradation and therapeutic ineffectiveness. Nevertheless, the skin permeation propensity of most drugs is practically low due to the impermeable nature of epidermis. A wide range of approaches has been invented to enhance the skin permeability to drugs. The current advances include microneedles, iontophoresis, ultrasound, photomechanical waves, electroporation and pressurized air techniques. Starting from the year of 2008, non-destructive Biomedical and Pharmaceutical Research Centre investigates microwave of specific characteristics for its potential as transdermal permeation enhancer. The microwave is found to be able to exert spacing of lipid architecture of stratum corneum into structureless domains and promote transdermal drug delivery. The treatment of skin by microwave allows chemical penetration enhancer such as oleic acid to permeate stratum corneum, accumulate in dermis at a greater ease, and synergistically inducing lipid/keratin fluidization at hydrophobic C-H and hydrophilic O-H, N-H, C-O, C=O, C-N regimes of skin, thereby enhancing further drug permeation. The usefulness of microwave as transdermal permeation enhancer is challenged by its dosage form-dependent performances, where solid matrix outweighs wet samples. Recent findings indicate that macromolecules from wet samples can act as a binder to the intercellular spaces created by microwave, thereby leading to reduced drug permeation. Microwave is reckoned to be the next generation technology in transdermal delivery. More research and development works are required to examine its worth in drug delivery, side effects and reversibility of biomedical consequences.

Polysaccharide-Derived Non-Viral Vectors for Efficient Delivery of Biomolecules *in-Vitro* and *in-Vivo*

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BIO-DATA

Dr. Kailash C. Gupta is a Director, CSIR-Indian Institute of Toxicology Research, Lucknow. He completed his Ph.D. (1978) from University of Jodhpur. His research experience is 37 years. He has authored 97 research publications and 12 Reviews/books/book chapters of various reputed publication houses. He has total 17 patents in his credit. Dr. Gupta has successfully transferred 2 technologies to M/s. Argosy Overseas (P) Ltd., Lucknow. His area of interest includes Nanobiotechnology, Bioorganic Chemistry (Nucleic acid chemistry). He has received around 14 research projects from different government agencies like DBT, CSIR, DST etc.

ABSTRACT

Development of efficient and safe non-viral vectors is one of the essential requirements for the success of efficient drug and gene delivery. We have evaluated the gene transfer capability of polysaccharide (chitosan)-PEI conjugates (CP) prepared by conjugating low molecular weight branched polyethylenimine (LMWP) with depolymerized chitosans (7 and 10 kDa) via their terminal aldehyde/keto groups. The CP conjugates interacted efficiently with nucleic acids and also showed higher cellular uptake. These conjugates on complexation with DNA yielded nanoparticles in the size range of 100-130 nm (in case of C7P) and 115-160 nm (in case of C10P), which exhibited significantly higher transfection efficiency (~ 2–42 folds) in vitro compared to chitosans (high and low mol. wt.) and the commercially available transfection reagents retaining cell viability almost comparable to the native chitosan. Of the two CP conjugates, chitosan 7 kDa-LMWP (C7P) displayed higher gene transfer ability in the presence and absence of serum. Luciferase reporter gene analysis in male Balb/c mice receiving intravenous administration of C7P3/DNA polyplex showed the maximum expression in their spleen. Further, tuftsin, a known macrophage targeting molecule, was tethered to C7P3 and the resulting complex exhibited significantly higher gene expression in cultured mouse peritoneal macrophages as compared to unmodified C7P3/DNA complex without any cytotoxicity demonstrating the suitability of the conjugate for targeted applications. For nanoparticulate based drug delivery, we have developed Doxorubicin (DOX) loaded targeted nanoparticles for targeted drug delivery in tumor tissue. DOX is a well-known anticancer drug used for the treatment of a wide variety of cancers. However, undesired toxicity of DOX limits its uses. To address the issue of minimizing toxicity of DOX by making it targeted towards cancer cells, DOX was entrapped in self-assembled 6-O-(3-hexadecyloxy-2-hydroxypropyl)-

hyaluronic acid (HDHA) nanoparticles. The anticancer efficacy of DOX loaded HDHA-NPs was evaluated by measuring the changes in tumor volumes, tumor weights, and mean survival rate of Swiss albino mice grafted with Ehrlich's ascites carcinoma cells. For this, the animals were given HDHA-DOX-NPs intravenously and a green tea polyphenol, Epigallocatechin-3-gallate (EGCG) orally through gavage. The targeted NP dose with EGCG significantly increased mean survival time of the animals and enhanced the therapeutic efficacy of the drug compared to the non-targeted NPs and free DOX. Further, we showed that these NPs (HDD and HDHA) were more active in the presence of EGCG than DOX alone in inducing apoptosis in EAC cells as evident by an increase in sub-G1 cells (percent), Annexin V positive cells and chromatin condensation along with the reduction in mitochondrial membrane potential (MMP). The study demonstrated that HDHA-DOX NPs along with EGCG significantly inhibit the growth of carcinoma cells with 38-fold dose advantage compared to DOX alone and thus opens a new dimension in cancer chemotherapy.

Pharmaceutical Approach in Innovation and Development of Herbal Products

Dr. Rajendran R.
CEO and Founder,
Green Chem, Bangalore

BIO-DATA

Dr. Rajendran R. is the CEO and Founder of Green Chem which is 100% Export oriented Unit in Bangalore with USFDA and Australian TGA standards. Dr. Rajendran did his post graduation in Bio Chemistry in 1974 from Madras University. He has over 38 years of experience in Pharmaceuticals and Natural Products. Before Green Chem, he started his career from Kothari Phytochemicals, Madurai. Then he joined CIPLA, Bangalore as Head of Technical Function and spent 17 prosperous years. In 1994, he promoted and worked as President and COO of the herbal manufacturing company for Sabinsa Corporation, USA as Sami Chemicals. He was credited with various accolades for his contribution in the herbal Industry and received due recognition in the form of an award for Quality Products from the President of India in 1994. During 1997, he started his own companies GREEN CHEM in Bangalore and Natsyn Catalysts in Tamil Nadu for Herbal ingredients and Phyto Reference standards. Another big manufacturing unit is being set up near Coimbatore for Formulations of Herbal products under his leadership. He has filed 45 patents from which 22 are already granted. He received a NATIONAL AWARD for Herbal Patents from Government of India 4 times in a row for the last 4 years. He received the BEST EXPORT EXCELLENCE AWARD – GOLD category for 2012 from FKCCI, Bangalore and Best Export Award 2013 from Chemexcil, Mumbai. Green Chem was awarded a project by Indian Ayurvedic Pharmacopeia for developing monographs for Herbal extracts, an AYUSH project from Indian Government. He has been invited to sign MOU with Department of Science & Technology, South Africa and Pretoria University for developing monographs for South African Herbs. He has introduced an antiobesity product, Slimaluma in USA and many other countries market which has been patented in many countries for Process, Product and applications. This is sold in India as SLIMTONE by Zydus Cadilla. He has sponsored research in more than 45 colleges and Institutions in India and abroad.

ABSTRACT

Growth of Herbal products industry is amazing, but achieving consistent quality is a big challenge. Quality and safety need to be incorporated during development stage itself. To develop competent products, innovation and pharmaceutical approach are needed. There are no stringent quality standards available for Herbal products unlike pharmacopeial monographs.

Ayurveda recommends use of crude herbs, powders, tinctures, churnas, crude extracts etc., These are all not standardized for actives. Quality of herbs can vary a lot due to many factors. This means the health benefits are not assured. Therefore a standardization is needed to get consistent quality. In addition to quality consistency, innovation is also needed to overcome competition. Innovation

can be done in new product identification, Herb selection, extraction methods, testing methods, packaging, Formulations,marketing concepts etc., Each herb and each extract should be studied in depth to specify quality standards, covering impurities relating to physical, chemical, biological in addition to purity parameters, similar to Pharmacopeial products. This should cover the dosage, expiry dating, compatibility parameters in multiple ingredients formula as well. Concept of delivering herbal ingredients with Pharmaceutical Quality by adapting innovative technology is the key for consumer safety. This assures quality consistency in herbal ingredients where pharmacopeial standards are not available. In India AYUSH has taken a serious step to develop herbal monographs. GREEN CHEM is part of this program. Now, the testing of products includes herb identification (botany, chemistry), physiochemical parameters, organoleptic properties, assay of active phyto-compounds, heavy metals, residual solvents, residual pesticides, organic volatiles, microbial tests, stability monitoring, impurity profiling, compatibility with other combinations, expiration dating etc. The bioactivity and safety of the product are confirmed by pre clinical studies. Suitability for human consumption is ensured by double blind, randomised, placebo controlled study as per requirement. Mechanism of action of the product is established to know more about the product. Herbal Products are ensured non toxic by conducting various toxicity studies. Toxicity study should be carried out elaborately covering acute oral toxicity, mutagenicity and sub-chronic toxicity and teratogenicity. Efficacy confirmation and dosage levels should be established. Complimentary medicines are the new innovative approach, being attempted to get the benefits of Natural and synthetic products in supplements industry . Using synthetic drugs to reduce the sugar levels to normal level and then taking herbal extracts to maintain the sugar levels is the new approach. Herbs can give lot of variety and flexibility in usage. Gymnema herb is an anti diabetic herb. The mechanism of working is unique! This is to be taken before a meal so that the Gymnemic acids present in Gymnema, obtunds sugar identifying receptors temporarily when the sugar is passing thro the alimentary canal. Therefore entry of sugar into blood stream is limited. Taking Gymnema before meal and taking other herbal extracts after the meal can regulate sugar levels. Green Chem is promoting this concept with DiaBef and DiaAft for sugar control. Herbal extracts can work better at a different platform as compared to drugs. Synthetic Drugs can help in controlling the disease and thereafter herbal extracts can take over to maintain the effect. The inter phase has to be gradual to avoid imbalance due to sudden abrupt change over. By this way long use of synthetic drugs can be minimized with lesser side effects. Few countries like Philippines allow combined formulation of synthetic pharma products with standardized herbal products. Regulatory bodies should consider careful handling of this issue. Another area of innovation is the use of multiple herbal extracts to exploit synergy in areas like anti-ischemia, female libido enhancing, male libido enhancing, anti-obesity and hair growth. Green Chem is developing an all in one life style management package to manage sugar, fat, joint health, libido, Ischemia and other ageing problems. Innovation and patent protection are essential for safeguarding business stability. Innovation means newness and that should be properly validated for human safety. The scope for developing innovative herbal ingredients using pharma approach is very big. It is important to establish the safety and efficacy first and then market it.

Fostering Innovation in Drug Development

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Holistic Health Centre, Athens, Greece

BIO-DATA

Dr. Nikolaos Kostopoulos qualified at Athens Medical University, Greece. He worked in the Renal Unit of the Naval Hospital in Athens, in the Intensive Care Unit of the Hospital of Chest Diseases in Athens and in the Respiratory Unit of the Manchester Royal Infirmary in England. He is a member of the Faculty of Homeopathy in England and of the Hellenic Homeopathic Association in Greece. He is a member of the editorial review board of the JAIM(Journal of Ayurveda and Integrative Medicine). Vaidya Asvin Barot introduced him to Ayurveda. Dr. Kostopoulos practiced in private practice in England for ten years, combining Ayurveda and modern medicine. Since 1999 he has been running the Holistic Health Centre in Athens, Greece. He is also involved in ongoing research in the field of psychosomatic disease and stress management through Ayurveda. He participates in international conferences and has given lectures in the UK, Ireland, Germany, France, Switzerland, Japan and India, promoting a modern, scientific approach to Ayurveda.

ABSTRACT

We live in an era where civilization faces new health challenges compared to 50 years ago. An aging population suffering from degenerative diseases, the re-emergence of infectious diseases and their resistance to antibiotics, the stress epidemic and the increase of mental diseases are the new problems that the scientific world is called upon to meet and try to solve. These diseases are not limited to a few countries only and the barriers between the East and West do not exist any more. Globalization of economy and globalization of diseases co-exist. India faces epidemics of diabetes and cardiovascular diseases and starts following the West in stress related disorders. The West, despite its material wealth, suffers from depression, stress and lifestyle diseases at an ever increasing rate. Chemical drugs are like double-edged swords, with an efficacy that decreases and side effects that increase when used for a long period of time or in multiple combinations. There is, therefore, a need to rediscover nature and to develop new ways to confront the emerging health challenges. Pharmacognosists, pharmacologists, clinicians and physicians from the modern and traditional systems of medicine should join forces for the benefit of future generations in the East and West. I will be presenting our experience in the practice of Holistic medicine in England and Greece during the last 25 years, combining Ayurveda and Modern medicine both in a clinical and research set-up.

Drugs Vs. Diet in Treating Metabolic Disorders

Dr. Sukhinder K Cheema
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Department of Biochemistry, Memorial University,
St. John's, NL, Canada

BIODATA

Dr. Sukhinder K Cheema is a Professor and Deputy Head of Graduate Studies at Department of Biochemistry, Memorial University, Canada. Dr. Cheema's research focuses on investigating the molecular mechanisms by which nutrients and dietary fats regulate metabolic pathways, under normal and pathological conditions. She has published over 60 papers in high impact international peer-reviewed journals, and has presented over 100 papers nationally and internationally. Dr. Cheema's research findings on developmental origins of health and disease have attracted editorial focuses. Her latest publication in PLoS One has revealed for the first time that maternal omega-3 polyunsaturated fatty acids induce changes in novel bioactive lipids that are likely responsible for eliciting beneficial health effects, and may be used as a novel biomarker in cardiovascular disease. She has been invited internationally to present her research findings. She was awarded the Japanese Society for the Promotion of Science Scholar award to initiate a collaborative study in Japan on the health benefits of flaxseed oil in metabolic syndrome and other metabolic disorders. Her recent research has focused on studying the importance of maternal dietary fats in fetal programming and nutrient-gene interaction to regulate metabolic pathways involved in cardiovascular disease - she is one of the leading scientists in Canada in this area.

ABSTRACT

The incidences of diabetes and obesity are increasing dramatically to epidemic proportions in virtually all societies of the world, and it comes with the major pathological consequences such as cardiovascular complications. According to the World Health Organization, 30% of global deaths in 2008 were caused by CVD, and it is estimated that by 2030, more than 23 million people will die annually from CVD. Unfortunately, India will be the leading country of the world to have the highest rate of CVD, diabetes and obesity by 2030. Genetics, as well as diet and life style are the predominant factors predisposing the population to increased risk of metabolic diseases. Conventional drugs are available in the market to fight against diabetes, obesity and CVD; however these drugs cause several side effects. Diet and lifestyle modifications are thus recommended, and are preferred means to prevent the onset of metabolic disorders and to treat diabetes, obesity and CVD. Functional foods and nutraceuticals with added health benefits are becoming highly popular as these are considered less toxic compared to drugs. The bioactive compounds in functional foods and nutraceuticals have the ability to alter the expression of genes leading to several metabolic changes, thereby eliciting health benefits. The mechanisms by which bioactive compounds in functional foods and nutraceuticals elicit health benefits in metabolic disorders are similar to those of the drugs; the question arises as to whether drugs are better than diet and under what conditions. The focus of this presentation will be to compare the mechanisms by which diet and drugs regulate metabolic pathways to prevent metabolic disorders, to discuss the challenges of using drugs vs. diet, and finally to adopt new strategies in the treatment of metabolic disorders associated with diabetes, obesity and CVD.

Pharmaceuticals in the Environment

Dr. Saranjit Singh
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Department of Pharmaceutical Analysis,
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BIODATA

Dr Saranjit Singh is Professor and Head of the Department of Pharmaceutical Analysis at the National Institute of Pharmaceutical Education and Research (NIPER) at S.A.S. Nagar, Panjab. He acted as Dean of the institute from 2008-2011. He is Member, Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations, World Health Organization, Geneva. He specializes in drug stability testing and drug impurity/degradation profiling. He is in education and research for the last 32 years and has delivered 362 invited lectures in India and abroad. He has spoken at the forums of AAPS, USP, IPA, IDMA, etc. He has published 176 research papers, general articles and book chapters. He is a member, Editorial Advisory Board of Journal of Pharmaceutical and Biomedical Analysis (Netherlands). He is reviewer to most of the journals in the area of pharmaceutical analysis. Dr Singh is recipient of Professor M.L. Khorana Memorial Lecture Award (2005), and IDMA-APA Eminent Analyst (2008) and Outstanding Analyst (2002) Awards.

ABSTRACT

The presence of pharmaceuticals in the environment is a matter of concern. The source of contamination may be the discharge from pharmaceutical industry; hospital affluent; regulatory disposal of counterfeits; industry and household disposal of expired medicines, etc. In India, the rampant use of drugs and hormones for increasing yields of food and even use of drugs for abuse can also be considered as additional factors in loading of the environment with toxic and potent pharmaceuticals. Residues of un-metabolized drugs are excreted in urine and faeces, and topically applied medications are washed from skin during bathing. In future, there is likelihood of increase in loading of environment with pharmaceuticals with enhancement in number of patients and hospitals and with increase in number of companies and improvement of general affordability of patients to buy medicines. Although there are no known short term effects on humans, long term effects are not ruled out. Therefore, regulatory bodies world-wide are striving hard to attend to this issue, though in India and other developing countries no stringent regulations have been implemented yet. In recent years, reliable protocols have been established for residue analysis of these pollutants down to ng/L levels. The presentation will cover all these aspects to sensitize on the issue and propose the same as a newer research area for pharmaceutical scientists.

Exploring Nanotechnology through Drug Delivery for Healthcare

Dr. N. Udupa
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Director - Research (Health Sciences), Manipal University,
Manipal, Karnataka, India

BIO-DATA

Dr. Nayanabhirama Udupa is presently serving as Professor at MCOPS and as Director of Research (Health Sciences) at Manipal University, Karnataka, India. Prof. Udupa obtained his B.Pharm, M.Pharm from BHU,Varanasi. After serving in pharma industry for 8 years, he then returned to his alma-matter and received Ph.D. in 1987. He has total 36 years of teaching & professional experience. Dr. Udupa has guided more than 80 M.Pharm and 32 Ph.D. scholars. His research area includes novel and targeted drug delivery systems. He has published more than 450 research/review publications in various reputed national and international journals. There are also 7 patents in his credit. He also authored 8 text books and contributed more than 20 chapters in various text books. He has visited, delivered and/or presented his research work around the globe. Dr. Udupa is an editorial board member of Pharmag, Indian Journal of Hospital Pharmacy and several other journals. Dr. Udupa has been honored with Dr. P.C. Dandiya Endowment Trust Research award in Pharmaceutical Sciences in 1997, The Principal of the Year Award-2001, IPA Fellowship Award 2009, Prof C J Shishoo Award given by APTI in 2012, Acharya P C Ray Gold Medal Award by IPA, Bengal Branch and Schroff Memorial National Award by Indian Hospital Pharmacists' Association (IHPA), 2012. Dr. Udupa has successfully handled more than 50 major research projects granted from various government agencies, industries and reputed foreign universities. Many of his projects were successfully transferred into pharmaceutical industries and are marketed widely. The 62nd IPC at Manipal in Dec 2010 was organized under the leadership of Dr. Udupa. Presently he is also serving as a scientific convener of Indian Pharmaceutical Congress Association from year 2010-2012. Dr. Udupa was instrumental in setting up the Bioavailability and Bioequivalence center, Manipal Acunova, approved by DCGI.

ABSTRACT

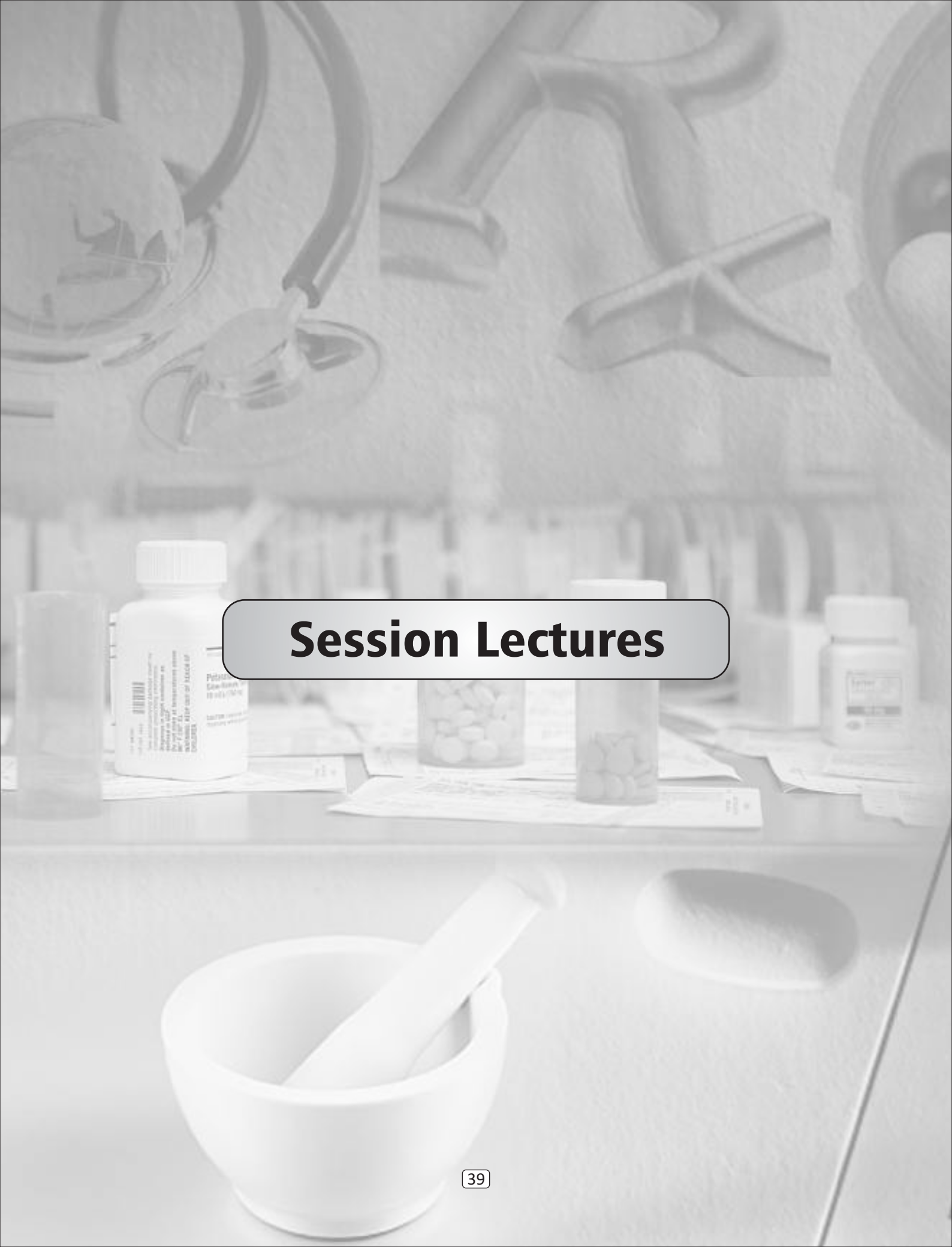
Modern science has contributed to expand the horizons of nanotechnologies in various fields metamorphosing it from a tiny part of science to a separate discipline. Applications of nanotechnology in diagnosis and therapy are wide including development of various nanoparticle dosage forms and drug delivery systems, tissue engineering, DNA nanostructures for drug and gene delivery, nano-diagnostics and so on. Nanotechnology is revolutionizing biomedical sciences because of its impact or influence in various fields like drug targeting, controlled drug delivery, drug screening technologies, nanomedicine, bio-nanosensors, biodetection of pathogens, nano-diagnostics, biomedical nano devices, tissue engineering, lab-on-chip technology, advanced medical imaging etc.

Nanotechnology based drug delivery systems have wider technological platform for various potential applications in biomedical and healthcare areas. Nanoparticles are the particles in a colloidal range (10-1000 nm), containing drugs in encapsulated or entrapped form. Depending on the method of preparation, types of materials used in the construction of nanostructures and the area of application, nanopharmaceuticals can be categorized into polymeric nanoparticles, nanospheres, nanocapsules, nanoemulsions, micelles, solid lipid nanoparticles, magnetics nanoparticles, carbon nanotubes, etc. Presently, the development of therapeutically effective nanotechnology based drug delivery systems, that have capacity to specifically target the drug to the preferred site of action, is a big challenge.

Preparation of nanoparticles involves two approaches i.e., top down or bottom up. In top down, the heavier particles are broken into lighter particles in nanorange, while in bottom up approach, ionic or atomic stage agglomerates are formed in nanorange. Choice of preparation method should be easily scalable, reproducible and number of unit operations should be minimum and economic. Polymers, metals, lipids, magnets are some of precursors used for the preparation of nanoproducts. In synthesis of metallic nanoparticles, use of low toxic precursors in water or more environmental friendly solvents, number of reagents involved in the synthesis, number of synthetic steps involved in synthesis to minimize the quantities of generated by products should be considered. Depending on the type of precursor, application, type of active ingredient, which is to be encapsulated, and structure of nanoparticles, the method of preparation will vary.

Biodegradable (natural or synthetic origin) polymers are preferred for pharmaceutical applications as these are biocompatible. Emulsion technique and cross-linking method are widely used methods for the polymeric nanoparticles. Cross-linking involves the strengthening of the bonds between the aggregated particles, which can be achieved by physical or chemical methods. Among lipid-based nanoproducts, heating is the common unit operation to form lipid matrix in which active ingredient is encapsulated to form solid lipid nanoparticles and hydration of the lipid is an essential step to form liposomes.

The smaller the particle, higher is its reactivity in the cellular environment resulting in enhanced intrinsic toxicity. The respiratory system, blood, CNS, GIT and skin are the common sites targeted by NPs. Evaluation of toxicity is challenging as several factors can lead to toxicity. Appropriately validated analytical methods and carefully designed experiments are required to elucidate the mechanisms of toxicity.



Session Lectures

Let's Foster Innovations in Nanotechnology for Better Management of Cancer

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BIO-DATA

Dr. Munira Momin is currently working as a Professor and Head, Pharmaceutics Dept at Oriental College of Pharmacy, Sanapda, Navi Mumbai. She studied in L. M. college of Pharmacy, Ahmedabad and obtained her B. Pharm and M. Pharm (Pharmaceutics) with first class from Gujarat University, Ahmedabad. Dr. Munira has received a gold medal (Pharmaceutics and Pharm. Sciences) in B. Pharm. for standing first in the Gujarat University. She is a recipient of Prof M. L. Khurana Memorial Award for Best Research Paper published during the Year 2008 in Pharmaceutics and Bio-Pharmaceutics. Dr. Munira took up teaching as her profession and served for eight years as lecturer and then joined as Associate Professor and Head of the Department of Pharmaceutics at L. J. Institute of Pharmacy in June, 2005. She is a recipient of best teacher award for the year 2012 conferred upon her by Swarnim Vision organized National Symposium 2013 supported by DST-India, IPA-Gujarat branch, Gujarat Government, FIP, Gujarat Innovation Society. Dr. Munira has published 29 research papers in national and international journals. She has one patent based on nanotechnology to her credit. Dr. Munira is the author of total four books in the field of Pharmaceutical Engineering, Dosage Form Design and Pharmaceutical Technology.

ABSTRACT

Fostering innovations, collaboration among inter-disciplinary researchers and to resolve some of the major challenges in the application of nanotechnology to cancer is the need of the hour. National Cancer Institute (NCI), USA has set the goal of eliminating death and suffering from cancer by 2015 and to meet this goal, NCI is engaged in efforts to harness the power of nanotechnology to radically change the way cancer is being diagnosed and treated. My speech on "Let's Foster innovations in Nanotechnology for better management of cancer" will mainly emphasize the role of nanotechnology, phyto-constituents for chemoprevention and the major challenges NCI is focusing on. The nano-devices which are smaller than human cells and similar to the size of enzymes, haemoglobin etc. This gives a way for nano-devices to go in and out of cells and interact with cell components without altering their biochemical properties. The non-invasive behaviour of these devices leads to an opportunity for basic research and clinical aspects of the disease. Nanoscale devices serve as customizable and targeted drug delivery vehicles capable of ferrying large doses of chemotherapeutic agents or therapeutic genes into malignant cells while sparing healthy cells, which would greatly reduce or eliminate the often unpalatable side effects that accompany many current cancer therapies.

The Asian continent is rich in plant based molecules which have been used since times immemorial. The amalgamation of nanotechnology and phytoconstituents have opened up a very promising area for in-depth research for an answer to cure cancer and its management. β-carotene, curcumin, epigallocatechin gallate, genistein, resveratrol, gingerol, green tea extract (GTE), pomegranate extract etc. have been studied extensively. Conventional natural products used with entities in nanometer sizes enable us to solve many of the inherent problems (stability, solubility and toxicity) associated with natural products and also provide a platform for targeted delivery to tumor sites.

Combinatorial effect of phyto-constituents is proposed to show better results than individual therapy. Our proof-of-principle study demonstrated the usefulness of nanoparticulate technology to enhance the therapeutic effectiveness of natural agents, curcumin and resveratrol (NanoResCu™).

In conclusion, we can say that nanotechnology combined with multifunctional nanocarriers with tumor-specific ability carrying one or multiple natural products has the potential to be within reach to treat cancer in the near future. It is the new generation who needs to foster inventions and come up with an answer to complete cancer management/treatment to reduce the cancer mortality.

Competitive Intelligence and Commercial Viability Analysis – Emerging Pillars of Drug Discovery in India

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BIODATA

Dr. Varun Gupta is a part of the Business Development group at Piramal Life Sciences, NCE Research located in Mumbai. With close to 8 years of combined experience in Financial services and Healthcare sector, he is responsible for commercial assessment of the pipeline molecules, portfolio valuation and competitive intelligence. He also facilitates the scientific and commercial evaluation of in-licensing opportunities.

ABSTRACT

Drug discovery has traditionally been a long, expensive and risky process. Globally, challenges of increasing R&D costs, depleting pipeline and patent cliffs of blockbuster drugs are hitting drug discovery companies hard. More specifically in India, environmental factors, including intricacies in conducting clinical trials, compensation issues and patent uncertainties pose additional challenges. Thus, for modern day drug discovery to be commercially viable, there is an emerging need for pharmaceutical companies and drug discovery laboratories to continuously evaluate the "Economic Merit" of the investigational drug to help make sound investment decisions. Commercial Viability Analysis is a tool to help R&D managers make investment decisions. Using the forecasting techniques for estimating scenario based (worst case and best case) drug revenue and developmental expenses through the preclinical, clinical, commercialization and post launch stages helps derive the "Economic Value of the drug". Factoring in the uncertainties associated with drug development refines it even further to reflect risk adjusted economic value, also called expected Net Present Value (eNPV) of the drug. Replicating the same for all pipeline drugs provides a portfolio level insight to the stakeholders for decision making. Continuous portfolio optimization and rational Go/No-Go decisions need to be taken to actively manage the risk associated with new drug research and development efforts. As a result, commercial viability analysis is becoming an indispensible part of Indian drug discovery and is likely to help increase probability of commercial success and at the same time reduce the economic burden associated with drug development.

QbD and Drug Delivery Systems

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BIO-DATA

Dr. Rajesh is the principal of Parul Institute of Pharmacy and Director (academics) of Parul campus, Vadodara since December, 2010. Sir has completed his M.Pharm (Pharmaceutics) from Karnataka University, Dharwad in 1992 and Ph.D. from Jadavpur University in 2004. He has 20 years of experience and has guided 31 students in M.Pharm (Pharmaceutics) and 8 are currently doing their projects. Sir is a recognized Ph.D. Guide at JNTU, Hyderabad; GTU, Ahmedabad; R. K. University, Rajkot; Vinayaka Mission Research Foundation, deemed University, Salem. He has 8 patents in his credit and has published 70 research and review articles in various reputed journals. He has also authored two Pharmaceutics books and wtitten two chapters in a book named "Vesicular and Particulate Drug Delivery Systems" of Career Publication, Nasik, India. He has received several research grants from GUJCOST and AICTE. He was awarded gold medal by Vasavi Union for acheivement in Ph.D. in February, 2005 and recently awarded with Certificate of Excellence by Research Wing for Excellene in Professional Education and Industry for Faculty Branding Awards - 2013. Sir has submitted the resistin modelled using *in silico* methods to protein data bank named 1lv6.

ABSTRACT

QbD (Quality by Design) is a regulatory requirement for developing dosage forms from January, 2013. The art of designing by building quality into it is typical for every dosage forms. Many industries have started this science in their facilities coupled with DoE to see results which are faster and better. As the saying goes, quality has to be built in, rational understanding of the dosage form and all its associated paraphernalia viz excipients, process, equipment etc. is critical to the system. After the roadmap for QbD was released by the USFDA, several companies followed suit and implemented the same in its various activities. Areas like method development and analytical procedures also started seeing this unique concept implemented with marvelous results. Implementing controls and minimizing errors within the design space was the result of understanding the entire process. Robust products with minimum errors and ethical products are rolled out throughout the world because of the technology. Developing a real product always differ from the examples and hypothesis. PAT and other allied parameters make the development of the product with lesser runs and also more robust. USFDA strongly recommends implementing QbD approach for ANDA applications making the science become more applicable. A demonstration of process understanding through the identification of critical process parameters leads to develop a control strategy giving the product little or no room for rejection. Irrespective of the type of dosage form, the approach builds quality. A long list of papers published proves the point of acceptance and variability. Several researchers and industries have proven that a product which is a result of QbD has little / no errors. An attempt to explain along with relevant case studies is made here in short to make the concept clear.

Developing Clean-Green Technologies For Botanicals: Accelerating Drug Discovery From Medicinal Plants

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BIO-DATA

Dr. Vivekananda Mandal is currently working as Assistant Professor at Institute of Pharmacy, Guru Ghasidas Central University, Bilaspur. Dr. Mandal did his M.Pharm in Pharmacognosy (Gold Medalist) from IIT, BHU-Varanasi and Ph.D (Pharmacy) from Jadavpur University, Kolkata. Dr. Mandal has more than 25 international publications in several high impact factor journals. Dr. Mandal works in the field of extraction of botanicals coupled with innovations in separation and purification science of natural products through a green chemistry approach. He holds 03 Indian patents, 04 book chapters in this regard and has also presented several invited talks at various national and international conferences. Dr. Mandal is also the Associate Editor of Pharmacognosy Magazine which has an impact factor of more than 1 and also is indexed in Pubmed and Scopus. Dr. Mandal also serves as a scientific advisor for industries.

ABSTRACT

Natural products have been long regarded as mainstay of drug discovery programmes. One of the basic objectives of medicinal plant research has been isolation of bioactive compounds which can compete against synthetic drugs with added advantage of minimal side effects and better therapeutic management. Whichever route we adapt to achieve this objective, extraction of botanicals forms the very basic first step in extraction of botanicals. However, in Indian scenario no significant improvement has taken place for this vital step. Most of the focus is diverted towards the more interesting steps to follow after extraction such as isolation, chromatographic separation and bioassay studies. But we fail to understand that a poorly prepared extract from an injudiciously selected extraction step can spoil the world's most powerfull chromatographic system and thus jeopardize the entire objective of drug discovery from medicinal plants. After the 2009 Copenhagen summit on world climate change a lot of thought process has been initiated on increasing carbon foot print on earth. Henceforth, it is high time to turn towards cleaner, greener alternatives for accelerating drug discovery process from natural products. This however is not definitely possible with conventional methods like Soxhlet, maceration and percolation. In a recent research venture by my team an effective microwave assisted extraction (MAE) was developed for the rapid large scale extraction of potent bioactive compound oleanolic acid. Under optimum conditions, 8 min of MAE produced a maximum yield of 7.6 % w/w of oleanolic acid which was found to be 22.6%, 300% and 230.4% more effective than heat reflux extraction, maceration and stirring extraction respectively. From the results of scanning electron microscopy a new synergistic phenomenon of heat transfer and mass transfer was proposed to explain the phenomenon of increased yield. With regard to environmental impact, the carbon load of the process was 27 times lesser than the conventional methods. The green aspect of the total procedure becomes a key feature since research concerning new alternatives and new solvents in chemistry are at the moment, for earth and environment protection, a key challenge that we cannot disregard.

Green Chemistry: An Approach towards Drug Discovery

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BIO-DATA

Dr. Prateek Kumar Jain is Associate Professor and Head at ADINA Institute of Pharmaceutical Sciences, Sagar, M.P. Sir has completed his Ph.D. In Pharmaceutical Chemistry in 2009 from H.S. Gour University Sagar. He has published around 40 research and review articles in various reputed journals,. He has delivered many invited sessions at various scientific platforms in India as well as abroad. He has guided 24 M.Pharm. Students and currently 4 students are doing Ph.D under his guidance. He has received research project grants from various Gov. Agencies like M. P. Council of Science and Technology, DST, AICTE etc. He won Out Standing Oral Presentation Award in "2nd International Conference on Natural Products for Health and Beauty (NATPRO)" held at Naresuan University at Phayao, Thailand (2008) and SFRR ASIA Young Investigator Award in 7th COSTAM/SFRR (Malaysia/Asia) International Workshop 2009 held at Meritus Pelangi Beach Resort, Langkawi, Malaysia.

ABSTRACT

Chemistry is undeniably a very prominent part of our daily life. Green chemistry is defined as invention, design, development and application of chemical products and process to reduce or eliminate the use and generation of hazardous substance to human health as well as environment. The green chemistry provides an enormous number of opportunities to those who practice chemistry, drug design and discovery in education, research and industry. Some of the challenges for chemists include the discovery and development of new synthetic pathways using alternative feedstocks or more selective chemistry, identifying alternative reaction conditions, solvents for improved selectivity, energy minimization, designing less toxic and inherently safer chemicals. Chemical development also bring new environmental problems and harmful unexpected side effects, which result in the need for 'greener' chemical products and monograph with safe green laboratory experiments.

Incurred Sample Reanalysis (ISR): A Reconfirmation of The Bioanalytical Method

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BIO-DATA

Mr. Abhay R. Shirode is an Assistant Professor and I/c of Sophisticated Analytical Facility at Department of Pharmceutical and Analytical Chemistry, Bharati Vidyapeeth's College of Pharmacy, Navi Mumbai. He completed his M.Pharm. in Quality Assurance from University of Mumbai and currently pursuing Ph. D. in Pharmaceutics. He has 1 year of Industrial and 7 years of Academic experience. His current research focus is on Bioanlytical HPLC and HPTLC method development and validation for simultaneous estimation of drugs from human plasma. He has published 11 research and review articles in various reputed journals. Before this, he has delivered a lecture at Entrepreneurship Development programme on Absorbent cotton Technology, organised by ZTM-BPD Unit of Central Institute for Research on Cotton Technology(CIRCOT), Mumbai.

ABSTRACT

The key parameters for Bioanalytical method validation (BMV) are accuracy, precision, specificity, matrix effect, stability. Incurred Sample Reanalysis (ISR) is an evaluation where a selected number of study samples are re-analysed and the results are compared with origional analysis. In ISR, accuracy of incurred samples is evaluated by reanalysis of study samples in separate runs at different days.

ISR came into the consideration as there were certain observations by the USFDA, that the reproducibility of QC samples was excellent, but reproducibility of re-assayed incurred samples was poor. This may be in part due to inefficient bioanalytical method. During the 3rd American Association of Pharmaceutical Scientists (AAPS)/Food and Drug Administration (FDA) Bioanalytical Workshop, it was suggested that the reproducibility in the analysis of incurred samples be evaluated in addition to the usual prestudy validation activities performed. According to Draft US-FDA guideline for BMV (September 2013), ISR is a necessary component of BMV.

ISR is indented to verify the reliability of the reported subject sample analyte concentrations. The whole logic behind conducting ISR is to provide a challenge to the developed bioanalytical method. The major concern for reanalysis of study samples is attributed to the instability of analyte and/or its labile metabolite(s) and matrix components in biological samples. ISR is required, because the use of calibration standards and QC samples during validation may not absolutely represent the actual study samples as there are inherent difference between QC and the study samples like differences in protein binding, back-conversion of metabolites during storage, sample inhomogeneity or co-medications may affect the accurate quantification. Therefore it is recommended to evaluate accuracy of incurred samples by reanalysis of study samples in separate runs at different days.

It may be advantageous to incorporate ISR during method development/validation stage, by conducting a pilot study. ISR is expected for all human in vivo BE studies and all pivotal PK studies. For nonclinical safety studies ISR should be conducted for each species/method. ISR should be done at least, in the toxicokinetic studies once per species, all pivotal bioequivalence trials, first clinical trial in subjects, first patient trial.

As per the recommendations made by the European Medicines Agency (EMA) in "the guideline on bioanalytical method validation" (EMEA/CHMP/EWP/192217/2009): 10% of the samples should be reanalysed, if the number of samples is less than 1000. If the number of samples is above 1000, 5% should be reanalysed. Furthermore, it is advised to obtain samples around maximal concentration cmax and in the elimination phase. The concentration obtained for the initial analysis and the concentration obtained by reanalysis should be within 20% of their mean for at least 67% of the repeats. Large differences between results may indicate analytical issues and should be investigated.

According to Draft US-FDA guideline, September 2013 for Bioanalytical method validation, 7 % of study samples should be reanalysed for ISR. While selecting the points for ISR adequate coverage of PK profile is essential. It should include points around Cmax and the elimination phase. 67 % of the reanalysis results should be within 20 % of the original value.

If incurred sample reanalysis failure is observed then place study on hold, investigation should be initiated. Investigation includes checking of documentation and written plan and additional experiments.

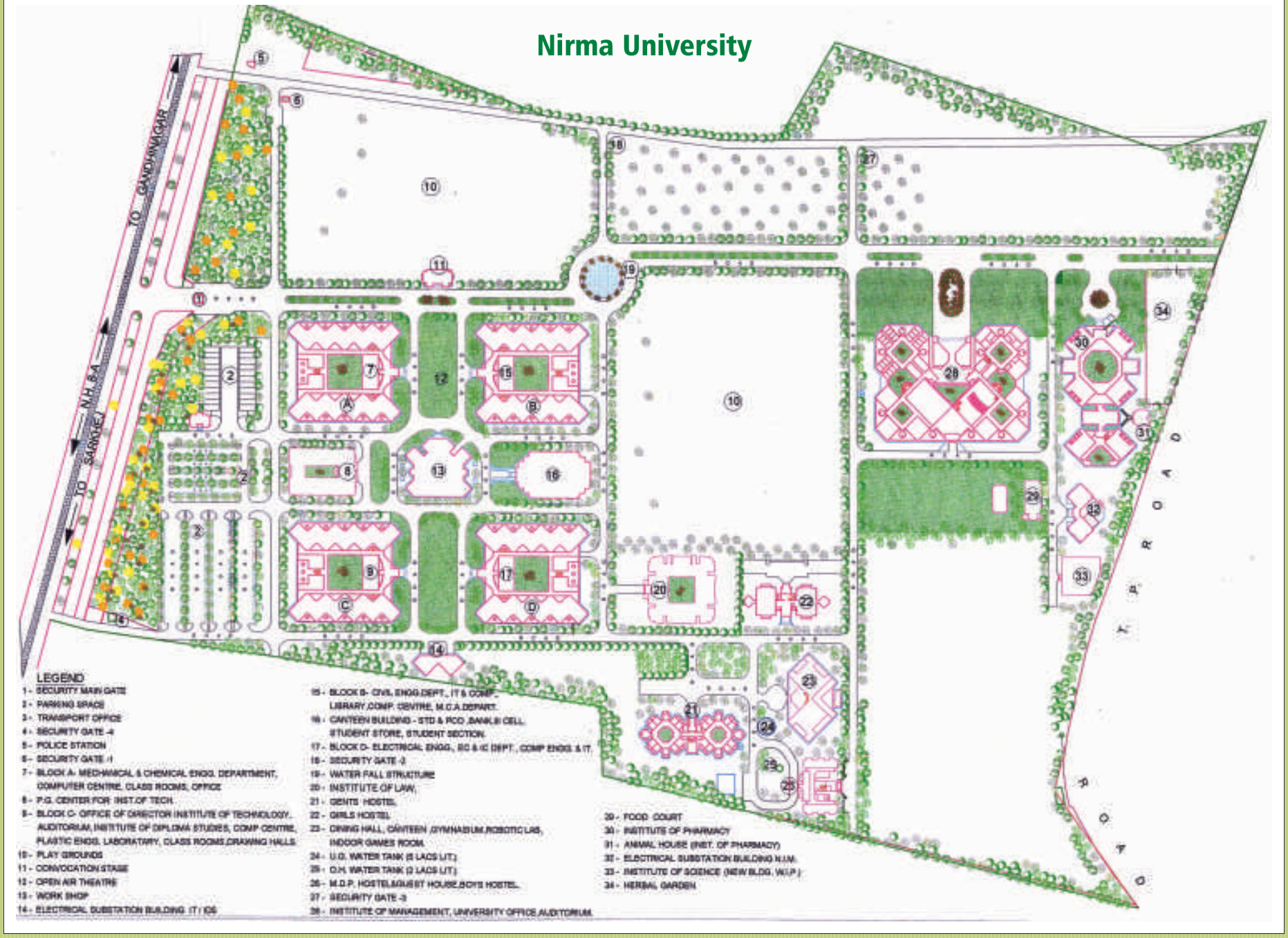
Possible reasons for ISR failure include- sample stability issues (metabolite converts to parent or vice versa during storage), assay stability issues (metabolite converts to parent or vice versa during sample extraction or instrument analysis , sample non-homogeneity (poor sample mixing , small sample volume), matrix effects (ionization /extraction differences), variable recovery, personal error.

ISR is performed by reanalysis of selected portion of the study samples, it determines the reproducibility of original bioanalytical results, and hence it is considered to be a reconfirmation of the bioanalytical method.

About Ahmedabad

Ahmedabad, one of the liveliest cities in India and one of the major industrial centers in India, had often been called the 'Manchester of the East'. Ahmedabad is the largest city in Gujarat with a population of about 5 million. The city has developed itself into a leading industrial centre and has become economic capital of Gujarat. Ahmedabad offers something to celebrate all year round that ranges from celebrations of 'Deepawali', 'Navratri' and 'Kite Festival'. The city has many places to visit, like Science City, Akshardham Temple, Gandhi Ashram, Adalaj Vav (step well) etc. The weather of Ahmedabad is very pleasant during the month of January.

Nirma University



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Our Production Unit Of 50000 Sq Ft Is Built On A Land Area Of 36000 Sq Ft. Area, 20 Km Away From Ahmedabad Gujarat India.

Our Manufacturing Facility Consists Of Well-designed Dust Free Hygienic Plant, State Of The Art Infrastructure And Machinery & Eco Friendly Work Environment.

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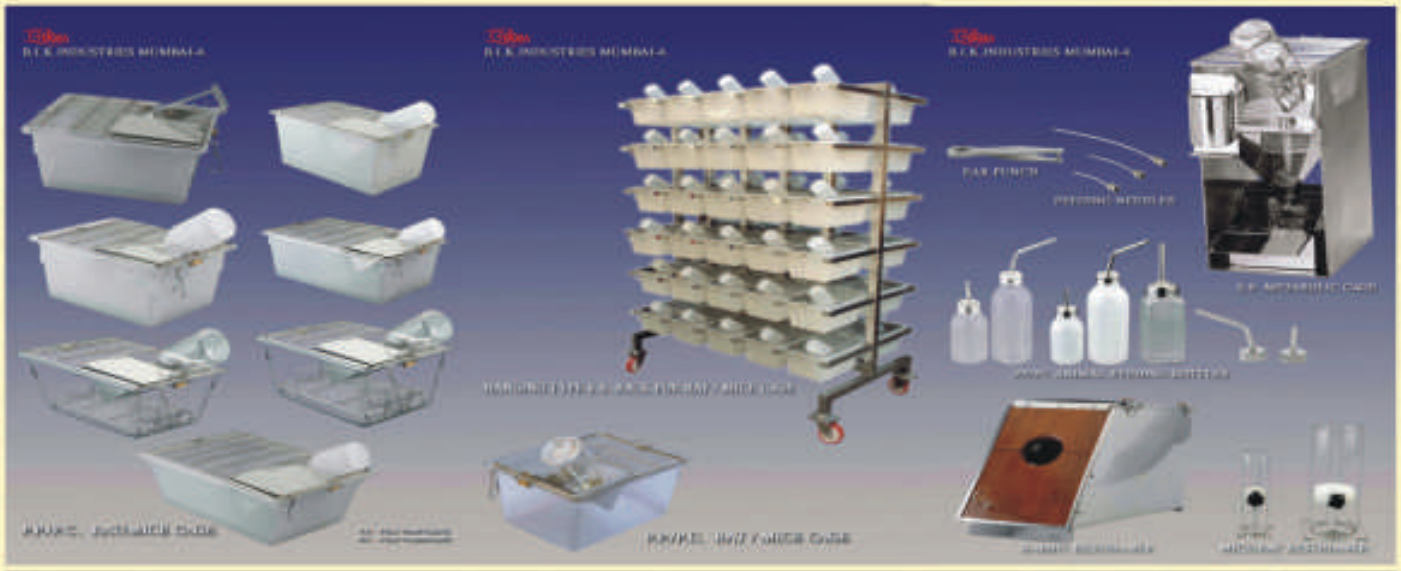

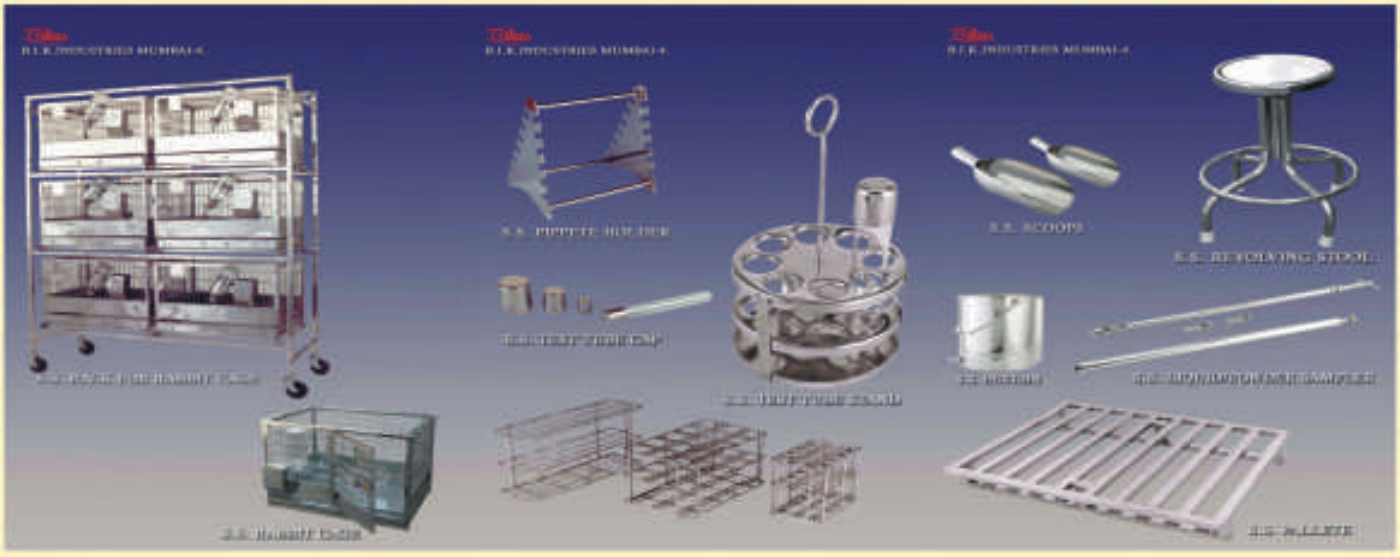

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બાગાયતી ખેતી અપનાવો..

વધુ ઉત્પાદન, મુલ્યવર્ધન , પોષણક્ષમ આહાર, વધુ આવક

ફળ, શાકભાજી, મસાલા, ફૂલ અને સુગંધીત પાકોના ઉત્પાદન વધારવા ઉચ્ચ ટેકનોલોજીના ઉપયોગ, કલમો અને ધરૂ ઉછેર તથા મૂલ્યવર્ધન-સંગ્રહ- બજાર વ્યવસ્થા માટે માળખાકીય સુવિધાઓ ઊભી કરવા વ્યક્તિગત તેમજ ખાનગી ક્ષેત્રોને ૪૦% થી ૭૫ % સુધી તેમજ જાહેર ક્ષેત્રોને ૧૦૦% સુધી આર્થિક સહાય. અનુસુચિત જાતિ, જનજાતિ તથા દેવીપૂજક ખેડૂતો માટે ખાસ સહાય.

- ફળ નર્સરી, શાકભાજી અને ફૂલ માટે પ્લગ નર્સરી, ટીસ્યુકલ્ચર લેબોરેટરીની સ્થાપના
- નવા ફળ,ફૂલ, શાકભાજી, સુગંધીત પાકો તથા મસાલા પાકોના કલ્સ્ટરમાં વાવેતર તથા જુનીવાડીના નવિનીકરણ
- સેન્દ્રીય તથા નિકાસલક્ષી બાગાયતી ખેતી અપનાવવા
- બાગાયતી પાકો માટે ગ્રીનહાઉસ અને નેટહાઉસની સ્થાપના, ટ્રેલીઝ/ મંડપ પધ્ધિતથી શાકભાજીની ખેતી મલ્ચીંગ, બર્ડનેટનો ઉપયોગ
- બાગાયતી પાકોમાં યાંત્રિકીકરણ, સંકલિત ખાતર - જીવાત નિયંત્રણ વ્યવસ્થા
- પ્લાન્ટ હેલ્થ કલીનીક, લીફ ટીસ્યુ એનાલીસીસ, બાયોકન્ટ્રોલ લેબની સ્થાપના
- જળ સંગ્રહ મારફત બાગાયતી વાડી
- મધમાખી ઉછેર મારફત પોલીનેશન વધારવા
- ખેડૂત તથા યુવાનોને સ્વરોજગારલક્ષી તાલીમો
- બાગાયતી પાકોના ગ્રેડીંગ-શોર્ટીંગ, પ્રોસેસીંગ એકમો તથા રાઇપનીંગ ચેમ્બર
- પ્રિ-કુલીંગ એકમ, કોલ્ડસ્ટોરેજ, રીફરવાન તથા પેકહાઉસની સ્થાપના
- બાગાયતી પાકોના ગ્રામ્ય તથા જથ્થાબંધ બજાર વ્યવસ્થા ઊભી કરવા

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- નાયબ બાગાયત નિયામકશ્રીની કચેરી, જીલ્લા કૃષિ વિસ્તરણ તંત્ર, એ.ટી.વી.ટી. ખાતે
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