Gurunanak College of Pharmacy

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NEWSLETTER

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DRUG JOURNEY – DISCOVERY TO DEVELOPMENT

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Overview

Numerous changes are now occurring in the pharmaceutical industry, not just in the way that the industry is perceived, but also in the rapid expansion of biomedical and scientific knowledge, which affects the way science is practiced in the industry.

Drug Discovery and development is the mission of pharmaceutical research companies to take the path from understanding a disease to bringing a safe and effective new treatment to patients. It is a challenging and expensive activity of the pharmaceutical industry. The success rate, the economic and time involve in this are staggering that every pharmaceutical industry or research institute cannot undertake drug discovery programme.

The research of new drug discovery involves:

• Validation of targets,

• Discovery of the right molecule (potential drug) to interact with the target chosen,

• Study of new compound in the lab and clinic for safety and efficacy and

• Gain approval and get the new drug into the hands of doctors and patients.

This whole process takes an average of 10-15 years, cost in range of 400-600 crores and approximately of 10,000 compounds that enter the research and development (R&D) pipeline, ultimately only one receives approval.

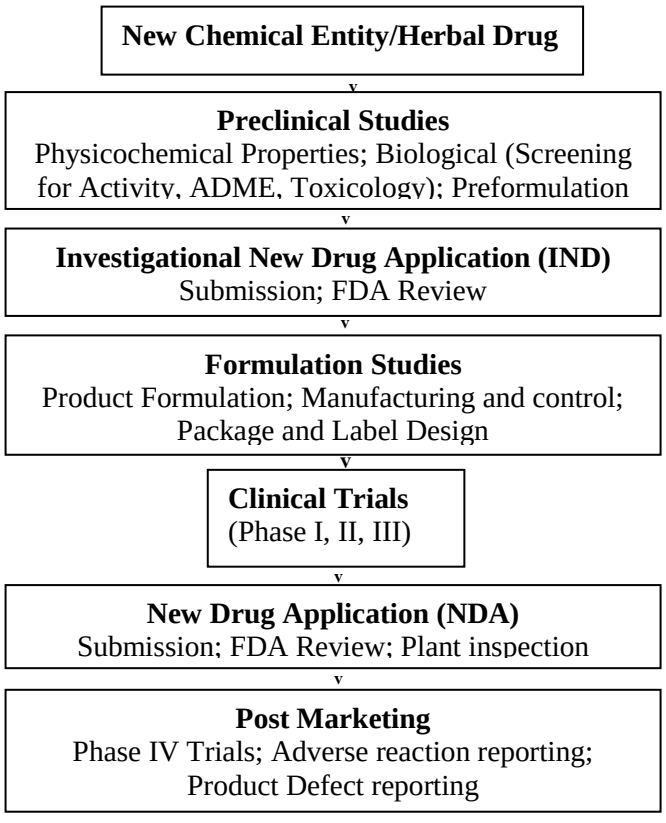

Figure: New Drug Discovery and Development Process.

The basic underpinning for the effort is the cumulative bodies of scientific and biomedical information generated worldwide in research institute, academic centres, universities and industry. The combine effect of chemist, biologist, pharmacologist, toxicologist, statistician, clinician, pharmacist and many other are involve the drug discovery and development process.

The Discovery Process

Pre-discovery

Before any potential new medicine can be discovered, scientists work to understand the disease to be treated as well as possible, and to unravel the underlying cause of the condition. This knowledge is the basis for treating the problem.

Target Identification and Validation- Once they have enough understanding of the underlying cause of a disease, pharmaceutical researchers select a "target" for a potential new medicine. A target is generally a single molecule, such as a gene or protein, which is involved in a particular disease. Target validation is crucial to help scientists avoid research paths that look promising, but ultimately lead to dead ends. Researchers demonstrate that a particular target is relevant to the disease being studied through complicated experiments in both living cells and in animal models of disease.

Drug Discovery

New Chemical Entity (NCE)

Scientists search for a molecule, which may act on their target to alter the disease course. If successful over years of testing, the molecule can ultimately become a new drug. NCE may be discovered from a variety of source-

Nature: plant material served as a reservoir of the potential new drugs. After isolation and structural identification of active constituent chemist may recreate them by total synthesis in laboratory or use as starting material for creation of different structure through molecular manipulation.

Synthesis and molecular modification: synthesis in laboratory or alteration of known and previously characterised organic compound for the purpose of enhancing its usefulness as a drug.

Serendipity: They may found quite by accident.

High-throughput Screening: Advances in robotics and computational power allow researchers to test hundreds of thousands of compounds against the target to identify any that might be promising. This resulted in a rapid and cost effective way of establishing the structure activity relationship for a series of compounds.

Biotechnology: genetically engineer and sub-microscopic DNA manipulation technique can create lead molecule.

Preclinical Testing

Early Safety Tests: NCE go through a series of tests to provide an early assessment of the safety of the lead compound. They test for Absorption, Distribution, Metabolism, Excretion (ADME) and Toxicological properties.

Lab and animal testing: With one or more optimized compounds in hand, researchers turn their attention to testing them extensively to determine if they should move on to testing in humans. Test done on animals often includes general screening test for pharmacological effects, blood test, histopathological examination of tissue and test of teratogenicity, mutagenicity and carcinogenicity.

The Development Process

Investigational New Drug (IND) Application and Safety

Before any clinical trial can begin, the researchers must file an Investigational New Drug application with the FDA. The application includes the results of the preclinical work, the candidate drug's chemical structure and how it is thought to work in the body, a listing of any side effects and manufacturing information. The IND also provides a detailed clinical trial plan that outlines how, where and by whom the studies will be performed. The FDA reviews the application to make sure people participating in the clinical trials will not be exposed to unreasonable risks.

Clinical Trials

Clinical trials are a means of developing new treatments and medications for diseases and conditions. There are strict rules for clinical trials, which are monitored by the National Institutes of Health and the U.S Food and Drug Administration. Clinical trials are often compare one drug against another to see which is more effective.

Phase I Clinical Trial: A phase I trial for a new drug is designed to determine the safety of the new drug, route and the correct dosage. These studies are usually conducted with small number (about 20 to 100) of healthy volunteers.

Phase II Clinical Trial: Phase II trial begins the process of determining the drug's effectiveness in treating a specific type of disease. Trials can involve about 100 to 500 patients with the target disease. If a drug in a phase II trial brings about a positive change in at least one-fifth of the patients, then it can be tested in a phase III trial. However, if the new drug has shown very positive effects in patients, the FDA also has the option of approving the drug for general use at this point.

Phase III Clinical Trial: A phase III trial involves the largest number of patients (about 1,000-5,000). Phase III trials are randomized. In some phase III trials blinded studies (single-blind study and double-blind study) are used to prevent biased study results. If a new drug successfully passes a phase III trial, the FDA will approve the drug for marketing to the general public.

New Drug Application (NDA) and Approval

Once all three phases of the clinical trials are complete, the company analyzes all of the data. If the findings demonstrate that the experimental drug is safe and effective, the company files a New Drug Application with the FDA requesting approval to market the drug. The NDA includes all of the information from the previous years of work, as well as the proposals for manufacturing and labelling of the new drug. Permission to market a drug product will be given by the FDA after confirming the drug's safety and effectiveness.

Ongoing Studies and Phase IV Trials

Research on a new drug's continues even after approval. As a much larger number of patients begin to use the drug, companies must continue to monitor it carefully and submit periodic reports, including cases of adverse events, to the FDA.

In addition, the FDA sometimes requires a company to conduct additional studies on an approved drug in Phase IV (Post-marketing surveillance) studies. These trials can be set up to evaluate long-term safety or how the new medicine affects a specific subgroup of patients.

Conclusion

The discovery and development of new drug is a long, complicated process. Each success is built on many, many prior failures. Researchers face great challenges in understanding and applying advances to the treatment of disease. Research-based pharmaceutical companies and institutes are committed to advancing science and bringing new molecules.

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Section II: Campus Report of past 6 months

It shall be constant endeavor of Gururnanak college of Pharmacy to meet the educational need of youth in the area of pharmaceutical sciences and provide learning opportunity along with inculcation of values of commitment and uprightness. This institution is doing well in accomplishing this task. As on today, we have 257 students-(201 -B. Pharm, 56 -M.Pharm) on our roll hailing from various parts of the state and country with different economic, religious and social background.

❖ ACADEMIC ACHIEVEMENTS

- Aditya Jamkhindikar and Chirag Vora secured admission for MS course in NIPER, Mohali.

- **University Result**

Achievement in the University examination held by RTM Nagpur University in April 2010 has been good-

Academic Year 2009-2010	% Result	Academic Topper
First B. Pharm.	64	Ms. Amruta Bajaj
Second B. Pharm.	50	Mr. Raghvendra Rai
Third B. Pharm.	66	Mr. Bharat Wadhwani
Final B. Pharm.	59	Ms. Jyotsna Sehgal
First M. Pharm. (Pharmaceutics)	100	Mr. Vinit Agnihotri

- **Prize Winner**

1. Sachin Namewar, Ravi Potdukhe, Vikram Chhabra, Madhura Denge (M. Pharm. I) - Winner up prize of Rs.5000 in Jignyasa 2010 held at GNCP, Nagpur.
2. Vineet Agnihotri (M. Pharm. II) - Consolation prize of Rs. 1000 in Jignyasa 2010 held at GNCP, Nagpur.

❖ NEW COURSE INTRODUCED

Master of Pharmacy in (1) **Pharmaceutical Chemistry** and (2) **Quality Assurance**: both the branches got intake of 18 seats.

❖ EVENTS ORGANIZED

- **Teacher's Day Celebration**

The teacher's day celebration was organized on 6 Sept. 2010 by M. Pharm. Students.

- **Fresher's Day Celebration**

To the new entrants of GNCP, Fresher's day party was given by seniors B. Pharm. and M. Pharm. Students. The party was held on 18th Sept. 2010.

- **Jignyasa-2010**

Jignyasa 2010, a technical paper presentation competition was conducted on 28th August (for B. Pharm students) and 25th September (for M. Pharm students). The theme for M. Pharm students was "Co-processed Excipients" and that for the B. Pharm students was "Pharmacy Education".

The competition aimed for developing demonstration skills in power point presentation. The students from colleges of Vidarbha region were participated and winners were awarded with prize of Rs.5000, Rs.3000 and Rs.1000 for winning, runner-up and consolation prize respectively.

- **Guest Lectures**

In order to develop a holistic personality of students, we greatly stress on developing skills and confidence of the students for pharmacy field. We have arranged guest lectures by eminent personalities.

1. 'Self motivation and planning' by Prof. S.P. Ghisad, Asst. Prof. Training and Placement, RTM Nagpur University, Nagpur on 18 Aug 2010.
2. 'Regulatory aspects in bioavailability and bioequivalence studies' by Mr. Ashish Dhoka, Research Asst., Bioavailability and Bioequivalence dept., Sun Pharma Ltd., Vadodara, on 27 Aug 2010.
3. 'Generic product development processes' by Mr. Prashant Deshpande, Plant Incharge, Cipla Ltd., Patalganga, on 26 Oct 2010.
4. 'Relevance of Clinical Research for Pharmacy Students' by Dr. Sushil Pande, Asst. Prof., Dept. of Dermatology and Head, Clinical Research and Pharmacovigilance, Lata Mangeshkar College and Hospital, Nagpur, on 3 Dec. 2010.

- **Alumni meet**

Alumni meet was held on 15th Aug 2010 in college premises. 28 alumni were attended the meet. The alumni of GNCP are placed in R&D and F&D section of pharma industries; educational organization and in the field of marketing. In meet alumni shared their work experiences with students and guide them for their carrier.

❖ NON ACADEMIC ACHIEVEMENTS BY THE STUDENTS

- **Poster Presentation**

- Abhijit M. Pawade, Pharmacy Education: current and future prospective, in Jignyasa 2010 -Technical paper presentation competition, held

at Gurunanak College of Pharmacy, Nagpur, on 28/08/2010.

- Aparna S. Awasthi and Heena Kausar Mohd. Sharif, Need of change in pharmacy education, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 28/08/2010.
- Girish R. Alaspure, Pharmacy Education and Pharmacy Status, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 28/08/2010.
- Biswajit Panda, Co-processed excipients: an overview of formulation aspects, physical characteristics and role as a pharmaceutical-aid, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Vineet Agnihotri and Mitali M. Bodhankar, The integrity of protein associated with enteric coated tablet excipient in formulation and its degradation in simulated intestinal, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Vikram Chhabra and Madhura Denge, Dynamics of validation of co-processed excipients, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Sachin Namewar and Ravi Potdukhe, Improving the tablet characteristics and dissolution profile of Ibuprofen by using a novel co-processed superdisintegrant, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Mahesh Wazade and Sunil Tripathi, Co-processed excipients as pharmaceutical aid (Di-Pac), in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Qureshi M.M. Akhtar and Bhendarkar K.R. Role of poloxamer and cyclodextrins in stabilization of ceftazidime in liquid state, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Tejas Chaudhari and Preetu Shendre, Spherical Composite Particles of Rice Starch and Microcrystalline Cellulose: A New Co-processed Excipient for Direct Compression, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Prateek Shende and Rohit Sinha, Co-processed excipients as a pharmaceutical aid, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.
- Bhushan S. Bhoyar, and Mrs. Mitali. M. Bodhankar, The excipients used in ocular dosage form and drug delivery systems, in Jignyasa 2010 -Technical paper presentation competition, held at Gurunanak College of Pharmacy, Nagpur, on 25/09/2010.

❖ EXTRACURRICULAR ACTIVITY

For the all round development of a student, it is essential that avenues for partaking in extracurricular activities be available. It is with this view, that extracurricular activities are conducted regularly to enable students to discover and hone their skills in fields that are not academic in nature.

- **Personality development tour to Chikhaldara:** 35 students of final year B. Pharm. participated in this tour that was held on 18th Oct. 2010. The main objective of this tour was to provide a feel of outside campus reality and to strengthen the personality area of students. The iternary of tour include visit to Salbardi, campaign in Chikhaldara, visit to tiger national forest (Simahdoh) and Kolkaj project, it also included rock climbing activity at Muktagiri and visit to irrigation project near Morshi.
- **Staff recreation tour to Korambi (Bhandara):** one day staff recreation tour was arranged to Korambi on 12th Nov 2010.
- **Student recreation tour to Goa:**
  Student recreation tour was conducted to Goa between 6th to 11th Dec. 2010. The group consist of B. Pharm and M. Pharm students (50) and staff member (7). They visited to different historic places of South and North Goa.
- **Industrial and Educational tour:**
  Students of B. Pharm and M. Pharm. visited **Glenmark Ltd. Goa** as part of Industrial tour on 8th Dec. 2010.
- **National Pharmacy Week:**
  Students were actively participated in various completions organized in view of National Pharmacy week from 22nd Nov. 2010 to 28th Nov. 2010.

▪ Girish Alaspure and Vishal Dharmari (B. Pharm Final) participated in **Elocution competition,**

held at Kamla Nehru College of Pharmacy, Butibori, Nagpur on 22 Nov 2010.

- Pooja Grover and Akshay Jha (B. Pharm II) participated in **Debate competition**, held at Sacchidanand College of Pharmacy, Nagpur.
- Vivek Mishra (B. Pharm III), Supriya Mishra and Ankit Sharma (B. Pharm II) participated in **Quiz competition,** held at Agnihotri College of Pharmacy, Wardha on 24 Nov. 2010.

➢ **NSS Activity: Blood Donation Camp**

A Blood donation camp in association with Govt. Medical College and Hospital, Nagpur was organized on 27th Nov. 2010. 51units of blood were collected from the staff and students.

➢ **Sports Activity:**

College Cricket team participated in RTM Nagpur University Inter Collegate Cricket Tournament 2010-11. In contest the team played against Santaji College, Wardha road, Nagpur. The member of team include Mr. G. A. Gurunani (Sport Incharge), Mr. P. D. Wanhkede (Team manager), Amit B. Singh (Captain), Dhammpal Waghmare, Pranay Thakre, Ravindra Bonde, Abhijit Dambhare, Bharat Wadhawani, Piyush Atre, Mohd Qureshi, Rahul Jawarkar, Avinash Chaware, Jaypal Upadhyay, Mitesh Patel, Akshay Jha, Swapnil Nandkar, Rahul Dugane, Mohd Opai.

❖ **RESEARCH AND DEVELOPMENT ACTIVITY OF THE FACULTY**

The institute is inspired by identifying future needs of human recourses to be felt by fast developing academics and scientific research at national and international level in the area of pharmaceutical sciences.

➢ **Ph. D. Ongoing:**

- Mrs. M.M. Bodhankar- UDPS, R.T.M. Nagpur University, Nagpur
- Mr. S.P. Padmane- UDPS, R.T.M. Nagpur University, Nagpur
- Mr. D.P. Dharkar-J.N.T. University, Hyderabad
- Mr. A.H. Deshpande- J.N.T. University, Hyderabad
- Mrs. B.A. Jacob- J.N.T. University, Hyderabad
- Mr. S. R. Yende- J.N.T. University, Hyderabad
- Mr. G.A. Gurunani- QIP, M. S. Uni. Vadodara.
- Mr. V. B. Pande – NIMS University, Jaipur

➢ **M. B. A. Ongoing:**

- Mr. S. S. Ramteke – IRMA, Anand, Gujarat.

➢ **Research Article Presented:**

1. Nidhi Sapkal and Vaishali Kilor, "Enhanced transdermal delivery of meloxicam through o/w nanoemulsion", in 3rd Summer school on Nanotechnology in advanced drug delivery, held at NIPER, Mohali, India, on 23-30 Aug. 2010.
2. Vaishali Kilor and Nidhi Sapkal, "Transdermal delivery of aceclofenac from eucalyptus oil based o/w nanoemulsion: Effect of using combination of surfactants", in 3rd Summer school on Nanotechnology in advanced drug delivery, held at NIPER, Mohali, India, on 23-30 Aug. 2010.
3. S. R. Walde, "Microbiological screening of some polyherbal tablet formulations", in APTICON-2010, Hyderabad on 2-3 Nov 2010.
4. S. P. Padmane, "Application of stability indicating assay method for the estimation of Doxofylline in bulk drug and tablet formulation", in APTICON-2010, Hyderabad on 2-3 Nov 2010.

➢ **Research Article Published:**

1. V. V. Kale. 'Oral sustained release *in situ* gel forming polymeric drug delivery system' Research Journal of Pharmacy and Technology, 3(3), July-Sept. 2010.
2. N. P. Sapkal, V. A. Kilor. Study of the Complexation Behaviour of Fexofenadine with β-Cyclodextrin. Indian Journal of Pharmaceutical Sciences, 72(3), 2010, 318-323. DOI:10.4103/0250-474X.70477.
3. V. V. Kale, T. M. Rasala, G. K. Lohiya, Optimization of compress Guar Gum based matrix system, influence of formula on change of drug release rate. International journal of Pharmaceutical Review and Research, 3(1), 2010.
4. T. M. Rasala, G. K. Lohiya, V. V. Kale. 'Comparative study of ionotropic gelation technique to entrap diltiazem HCL in mucoadhesive microperticulate system' Journal of Pharmacy Research, 3, July 2010.
5. T. M. Rasala, V. V. Kale. Formulation and evaluation of mucoadhesive microcapsule of diltiazem HCL and Diclofenac Sodium by orifice ionic gelation method. IJPIS Journal of Pharmaceutics and Cosmetology, 1 (1), 2010.
6. S. R. Yende. 'Antirheumatoid activity of aqueous extract of *Piper longum* on Freunds adjuvant-induced Arthritis in rats' International Journal of Pharmaceutical Science and Research, 1 (9 Suppl.), 2010, 129-133.
7. S. B. Waikar. Development and evaluation of floating tablets of Salbutamol Sulphate.

International Journal of Pharma Research and Development, 2(5) 2010, 1-7.

- **Seminar/Conference/Workshop/STT/SDP/QIP Attended:**

1. N.P. Sapkal- 3rd Summer school on Nanotechnology in advanced drug delivery, held at NIPER, Mohali, on 23-30 Aug. 2010.
2. V.A. Kilor- 3rd Summer school on Nanotechnology in advanced drug delivery, held at NIPER, Mohali, on 23-30 Aug. 2010.
3. S. R. Walde- APTICON-2010, Hyderabad on 2-3 Nov. 2010.
4. S. P. Padmane- APTICON-2010, Hyderabad on 2-3 Nov. 2010.
5. K.S. Moharir- AICTE sponsored Quality Improvement Program on Glimpses of current advances in the field of pharmaceutical Science, held at M. S. University, Vadodara on 7-12 June 2010.
6. A.H. Deshpande- Two day Workshop on Teaching skills in Physical Pharmacy, held at SVKM'S NMiMS, School of Pharmacy and Technology Management, Shirpur on 4-5 Dec. 2010.
7. K.B. Bhelkar- Two day Workshop on Teaching skills in Physical Pharmacy, held at SVKM'S NMiMS, School of Pharmacy and Technology Management, Shirpur on 4-5 Dec. 2010.

Section III: Photo Gallery

Fresher's Day Celebration

Jignyasa- 2010

Blood Donation Camp

Alumni Association

Guest Lecture by Prof. S. P. Ghisad

Guest Lecture by Dr. Sushil Pande

Chikhaldara tour

Staff's Korambi Tour

Industrial Tour

Goa tour

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