HKCP ALUMNI BULLETIN

Issue – IV, December- 2011

From the Editors Desk:

Dear Alumni,

Its immense pleasure publishing the fourth issue of alumni bulletin .We have arranged Alumni meet on 11 thDecember 2011 (Sunday) . Please participate in the meet and convey this invitation to your batchmates . The programme will start at 9.30 AM onwards. It will be graced by eminent guest of honour followed by entertainment programme.

The Campus News section we have introduced new Faculties, Industrial visit by students and various events celebrated in the Institute.

In the Research Updates in Pharmacy section we have introduced about research work which won the Nobel prize of medicine in 2011 for the research work on autoimmune disease- Lupus Erythromatus.

In 'Success Secret Series' the present issue carries an article on professional aspects of pharmacy- Good manufacturing practice(GMP) by expertise faculty in GMP audits , Mrs Sunita Ogale. As the GMP is the back bone of every well performed Pharma Manufacturing company there is need to understand the essential skills required in GMP where every person is equally responsible.This article will help career aspirants in improving their skills.

As I take the opportunity to present issues in pharmacy profession, In the superfast life style the nutrition is always overlooked in all the stages of life. The recent incident about food poisoning at the Indian Institute of technology B campus is quite shocking but the reality is that most of us can fall victim to such poisoning since almost 70 % of Mumbaikars eat out at least once a day. Studies show that more than 80% of food borne illnesses come from attendants who prepare and handle the food. Health becomes a priority, the hygienic food is always essential to maintain a good health.

As ever we always work towards giving you more and more of news about college, do send us your views and suggestions.

Sushruta Mulay.

scientific.cell@hkcollege.ac.in, sushruta.mulay@hkcollege.ac.in

Campus News:

- Anti Ragging committee was set up to curb the menace of ragging.
- Teachers day was celebrated on 5 th September 2011.
- Four research projects received grants from UGC.

- **Scientific Day was celebrated on 8th October 2011**.
  Chief Guest - Dr Tipnis –Ex Principal Bombay College of Pharmacy, Mumbai.
  Guest of Honour – Dr Supriya Mahajan - Professor SNDT ,Mumbai.
  Lecture: In silico method of analysis and Cox II inhibitors as anticancer drugs.

  Students activities - Poster Presentation, Oral presentation, Model making Quiz, essay writing competition and debate.

- **Department of pharmaceutics had arranged Field Visit to Korten pharmaceuticals, Palghar Thane. a parenteral manufacturing company, on 29-09-2011 for students of Semester I, III, VandVII** to learn about practical approach in pharmaceutics such as chemical and microbiological evaluation of parenterals, various methods of sterilization, ampoule washing units, Ampoule filling and sealing processes , packaging section. It was guided by faculties Dr Sonali Kapse, Dr Rajeshri Dhurke, Mrs Jaya Agnihotri and Mr Mohammad Wais.

Scientific day

Industrial visit

Publications:

The following articles have been published from the research guidance cell of Institute, which are available in respective journals as well as online:

- **Dr. Anubha Khale-Principal and H.O.D.-Pharmaceutics "Composition and characterization of metered dose inhalers (MDI)"**-Research Journal of Pharmacy and Technology, vol 4, issue 5, 704 -709 May 2011.

  The review article is about various excipients required in formulation of and different evaluation tests required on MDI.

- **Dr. Anubha Khale- "Liposomal Nebulising solution of salbutamol sulphate-A Characterisation study ."**, Research Journal of Pharmacy and Technology – vol 4/issue 9, Sep 2011.

  The research article is based on formulation aspects of salbutamol sulphate-phosphatidylcholine loaded liposomes in pulmonary sustained drug delivery by nebulising solution.

- **Mrs. Priyanka Goswami Shah: Faculty-Dept of Pharmacognosy "Medicinal plants in obesity-A Review"-** International Journal of Pharmaceutical Sciences Review and Research, issue November 2011vol 11 page 117 to 123.

  The review article tells about various medicinal plants effective in obesity management.

- **Mrs Sushruta Mulay: Scientific officer "Overcoming interferences in Endotoxin testing"**- Indian Pharmacist Aug 2011.

  The review article tells about interferences in endotoxin testing and some important methods to overcome these interferences .

Introduction of New faculties:

Niteen Narkhede

Waseem Razaq Ahmed

Mr. Shrikant Boharupi

❖ **Mr Niteen Narkhede-Application Scientist:**

- Pursued M pharm in Pharmaceutical Chemistry from Manipal College of pharmaceutical sciences, Manipal university, Manipal.
- Worked in Piramal Life Sciences Ltd. Mumbai, as a Research Associate in natural product chemistry department.
- Expert in structural interpretation of spectras like MS-LCMS, NMR and FTIR.
- Expert in handling of HPLC, Flash chromatography and LCMS.

❖ **Mr Waseem Razaq Ahmad**

- Pursued M.Pharm. Pharmacology from Rajiv Gandhi university, Bangalore.
  - Research interests- Research expertise in pharmacological evaluation for antidiabetic property of herbal preparation.
  - Published research papers– Antidiabetic property of Iris Ensata Thumb root in international journal of advances in pharmacology and toxicology.

  Research paper analgesic and anti-inflammatory property of prosopis cineraria seeds in international Journal of green pharmacy.

- Teaching experience: As assistant professor in pharmacology from Osmania University, Hyderabad.

❖ **Mr Shrikant Boharupi**

- Pursued M.Pharm. Pharmaceutical chemistry from Amaravati university.
- Excelllent teaching experience at BMCDP College Nagpur.
- Hands on research experience in simultaneous estimation of drugs in their compound pharmaceutical dosage forms.

Success Secrets Series:

Implementing GMP has become an industry requirement and in many countries it has become a regulatory Requirement. Regulatory agencies are legally entitled to conduct unannounced inspections if they believe there are suitable grounds for doing so. These regulatory agencies include many national & international organizations. Training, therefore, is important so your organization can comply with industry and government good manufacturing practices, specifications, and regulations.

Good Manufacturing Practice (GMP) is a term that is recognized worldwide for the control and management of manufacturing, testing and overall quality control of food and pharmaceutical products.

The Advent of GMPs

It is a truism that it takes a disaster to happen for people, and especially regulators, to wake up and review the accepted way of doing things. So, too, with the question of drug safety and drug quality.

It was the "Elixir of Sulfanilamide" disaster in 1937 in the United States that alerted US authorities to the concept that a drug needed to be proven to be safe. In this situation, Sulfanilamide, the first of a new generation of "wonder drugs" and a popular and effective treatment for diseases such as strep throat and gonorrhea, was formulated into an Elixir of Sulfanilamide and marketed for use in children. But the liquid formulation contained a poison, the same chemical used in antifreeze (polyethylene glycol), and it killed 107 people, most of them children. Following the scandal caused by this tragedy, American law was changed to require drugs to be proven to be "safe". The need for drugs to be proven to be "effective" would, remarkably, have to wait for another 50 years.

It was the issuance of contaminated intravenous fluids in the United Kingdom in 1972 that killed 6 people that provided the British Department of Health with the powers to perform mandatory GMP inspections of pharmaceutical manufacturers.

It was the Haitian disaster of 1997, where 87 children died following ingestion of anti-fever medication contaminated with polyethylene glycol, rather than being what the pharmaceutical manufacturer thought it was (glycerol), but never tested, that any real concern was given to the source, origin and the quality of active pharmaceutical ingredients (APIs) and pharmaceutical excipients. In this case, the material had been bought by a Haitian company, Pharval, from a German supplier and they rely on the accompanying certificate of analysis.

The Haitian government asked the US FDA to assist their investigation by tracing the faulty material back to its source. It was found that the excipient had indeed been purchased from a German company, but what the Haitians did not know was that the material had in turn previously been purchased from a source in Holland that had purchased the material from a source in Germany that had purchased the material from a source in China. The material was accompanied by a certificate of analysis attesting to its nature and its quality and stating that the material was Glycerol USP grade. When the US FDA tried to track the material to its original Chinese source the Chinese government refused to cooperate with the investigation, and the FDA was unable to find out who exactly was either the manufacturer or the testing laboratory of the material. Indeed the investigation never revealed where the adulteration and fraud had occurred.

In the wake of the Haitian incident, and the lack of clear GMP guidelines for API manufacture, the International Conference of Harmonization (ICH) – a group consisting of the European Union, Japan and the United States – enacted an international set of GMPs governing the manufacture, testing, and distribution of Active Pharmaceutical Ingredients (APIs) – the ICH-Q7A guidelines), which have since been adopted as law in the United States, the European Union, Japan, and many other countries.

"**Good manufacturing practice**" or "**GMP**" are practices and the systems required to be adapted in pharmaceutical manufacturing, quality control, quality system covering the manufacture and testing of pharmaceuticals or drugs including active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs are guidance that outline the aspects of production and testing that can impact the quality of a product. Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation. Basic concepts of all of these guidelines remain more or less similar to the ultimate goals of safeguarding the health of the patient as well as producing good quality medicine, medical devices or active pharmaceutical products. In the U.S. a drug may be deemed adulterated if it passes all of the specifications tests but is found to be manufactured in a condition which violates current good manufacturing guidelines. Therefore, complying with GMP is a mandatory aspect in pharmaceutical manufacturing.

Basic principles of all guidelines: ---

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language.
  (Good Documentation Practices)
- Operators are trained to carry out and document procedures.
- Records are made, manually or by instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
- The distribution of the drugs minimizes any risk to their quality.
- A system is available for recalling any batch of drug from sale or supply.
- Complaints about marketed drugs are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective drugs and to prevent recurrence.

GMPs are intended to assure that:

- Raw materials used in the manufacture of drugs are of known, and of possibly standardized, quality and are free from contamination;
- The manufacturing process has been proven to produce a pharmaceutical product meeting its quality attributes;
- Adequate quality control testing measures have been employed to assure that the product meets its quality specifications at time of release to market, and at the end of its shelf life.
- Poor quality products can damage health.
- GMP helps boost export opportunities.

GMP addresses issues including documentation, record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation,and complaint handling. Most GMP requirements are very general and openended,allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but

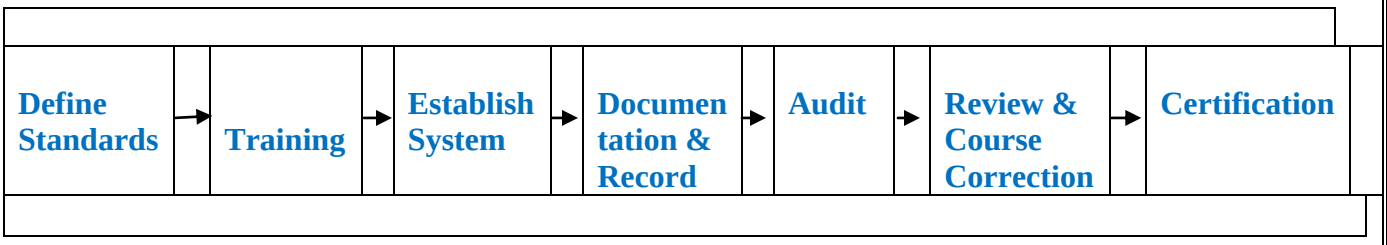
also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

An important part of GMP, **"documentation"** of every aspect of the process,activities, and operations involved with manufacture. If the documentation showing how the product was made and tested is not correct and in order, then the product does not meet the required specification and is considered contaminated (*adulterated* in the US).Additionally, GMP requires that all manufacturing and testing equipment has been qualified as suitable for use, and that all operational methodologies and procedures, such as manufacturing, cleaning, and analytical testing, utilized in thedrug or food manufacturing process have been validated to demonstrate that theycan perform their purported functions.The quality approach of GMP ensures manufacturing, enabling companies to minimize or eliminate instances of contamination, mixups, and errors. This in turn, protects the consumer from purchasing a product, which is not effective oreven dangerous. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

It is believed that GMP is a good business tool, which will help to refine both compliance and performance of the Company. GMP requirements are largely common sense practices, which will help companies better itself as it moves toward a quality approach using continuous improvement.

GMP is also sometimes referred to as **"cGMP".** The "current," methodologies of manufacture, testing, design and control. The Manufacturers must employ technologies and systems, which are up-to-date. Systems and equipment used to prevent contamination, mixups, and errors are adequate by today's standards.
Thus, Good Manufacturing Practices –GMP, when certified of an organization, is an authorisation and certification of Companies product & process that quality standards are adequate, up to date and controlled for the intended use by the consumer.

Steps for GMP Implementation and Certification:



Enforcement of GMP :--

GMPs are enforced in the United States by the US FDA, under Section 501(B) of the 1938 Food, Drug, and Cosmetic Act (21USC351). The regulations use the phrase "current good manufacturing practices" (cGMP) to describe these guidelines.

The World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over one hundred countries worldwide, primarily in the developing world.

Within the European Union, GMP inspections are performed by National Regulatory Agencies (e.g., GMP inspections are performed in the United Kingdom by the Medicines and Healthcare products Regulatory Agency (MHRA)); in the Republic of Korea (South Korea) by the Korea Food & Drug Administration (KFDA); in Australia by the Therapeutical Goods Administration (TGA); in South Africa by the Medicines Control Council (MCC); in Brazil by the Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency Brazil) (ANVISA); in India GMP inspections are carried out by state FDA and these FDA report to Central Drugs Standard Control Organization and Pakistan by the Ministry of Health;Nigeri has NAFDAC and by similar national organisations worldwide. Each of the inspectorates carry out routine GMP inspections to ensure that drug products are produced safely and correctly; additionally, many countries perform pre-approval inspections (PAI) for GMP compliance prior to the approval of a new drug for marketing.

Regulatory agencies (including the FDA in the U.S. and regulatory agencies in many European nations) are authorized to conduct unannounced inspections, though some are scheduled. FDA routine domestic inspections are usually unannounced, but must be conducted according to 704(A) of the FD&C Act (21USC374), which requires that they are performed at a "reasonable time". Courts have held that any time the firm is open for business is a reasonable time for an inspection.

Good manufacturing practices help boost pharmaceutical export opportunities

Most countries will accept the import and sale of medicines only if they have been manufactured according to internationally recognized GMP. For this reason, governments seeking to promote their country’s export of pharmaceuticals can do so by making GMP mandatory for all pharmaceutical production and by training their inspectors in GMP requirements.

Can manufacturers afford to implement good manufacturing practices?

Making poor-quality products does not save money. In the long run, it is more expensive finding mistakes after they have been made than preventing them in the first place. GMP are designed to ensure that mistakes do not occur.

Implementation of GMP is an investment in good-quality medicines, and will improve the health of both the individual patient and the community, as well as benefiting the pharmaceutical industry and health professionals.

Making and distributing poor-quality medicines leads to loss of credibility for everyone, including public and private health care services and pharmaceutical manufacturers.

Mrs Sunita Ogale- faculty, Dept of Pharmacology, HKCP.

Research updates

The Lupus Foundation of America (LFA) congratulates Bruce A. Beutle, Jules A. Hoffmann, and Ralph M. Steinman for receiving the 2011 Nobel Prize in Medicine for their revolutionary discoveries of the immune system that have contributed to key advances in the understanding of and treatments for autoimmune diseases, such as lupus.

"We would not have achieved the historic progress we have seen in lupus or other autoimmune diseases without this important work that has been honored by the Nobel Committee," said David R. Karp, M.D., Ph.D., Professor and Chief Rheumatic Diseases Division, University of Texas Southwestern Medical Center and Vice-Chair LFA, Medical-Scientific Advisory Council. "Their discoveries illuminated a fundamental process in the immune system that has paved the way for important research and further discoveries that have aided in unlocking the mysteries of the immune system, particularly in diseases like lupus."

Beutler and Hoffmann"s work is especially relevant to lupus, as it represents a pathway believed to be responsible for the immune response to the DNA and RNA nucleic acids that characterize this disease. Steinman discovered the dendritic cells of the immune system, which is important in regulating both immunity and tolerance. This research aided in the understanding of how the adaptive immune system responds when invaders, such as bacteria or viruses, are removed from the body. It is believed that dysfunction of the dendritic cells may be responsible for the production of auto antibodies in individuals with lupus and other autoimmune diseases. The role of dendritic cells and toll-like receptors is currently at the heart of many of the novel treatment strategies that are being actively explored for people with lupus.

"The LFA congratulates these well-deserving honorees," said Sandra C. Raymond, President and CEO, Lupus Foundation of America. "They are all trailblazers in autoimmune diseases, and much of the research and discoveries funded through the LFA"s National Research Program, relates to, or is a result of their work."

The LFA"s National Research Program: ***Bringing Down the Barriers™***,is dedicated to addressing research issues that have for decades obstructed basic biomedical, clinical, epidemiological, behavioral, and translational lupus research. The LFA"s approach to research is unique because it directs its funding to areas of research where gaps exist in the understanding of lupus, and to promising areas of study in which other public and private organizations have not focused their efforts. Using a three-pronged strategy, the LFA and its national network are committed to advancing the science and medicine of lupus by: directly funding research to close the gaps in lupus research; advocating for expanded investment in research from public and private sources; and leading special initiatives and forging collaborative efforts among stakeholders to address critical issues to advancing the science and medicine of lupus. For more information about the LFA"s National Research Program, visit www.lupus.org/research.

About Lupus

Lupus is an acute and chronic autoimmune disease in which the immune system is out of balance, causing inflammation and tissue damage to virtually any organ in the body. Lupus can be unpredictable and is potentially fatal. An estimated 1.5 million Americans and at least five million people worldwide have a form of lupus. Its health effects include heart attacks, strokes, seizures, miscarriages, and organ failure.

About the LFA

The LFA is the foremost national nonprofit health organization dedicated to finding the causes of and cure for lupus, and providing support, services, and hope to all people affected by lupus. The LFA and its national network of chapters, branches, and support groups conduct programs of research, education, and advocacy.