PREAMBLE OF CERTIFICATE COURSE

Success of a nation always depends on the skilled manpower

CERTIFICATE COURSE ON PHARMACEUTICAL ANALYSIS

To ensure the quality and safety of medicines in the country, the Ministry of health and family welfare, Govt. of India set up the Indian pharmacopoeia commission (IPC) with the vision to promote highest standards of drugs, pharmaceuticals and health care devices / technologies for use in humans and animals. Skills and knowledge are the driving force of economic growth of the country, to cater the need for skilled manpower in pharmaceutical analysis and Pharmacovigilance. IPC also provides extensive training to analysts and pharmacists from pharmaceutical industry and academia.

VISION of IPC

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

MISSION of IPC

To promote public and animal health in India by bringing out authoritative and officially accepted standard for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.

STRENGTH OF IPC

- Expertise in the field of quality and safety of medicines
- Well equipped, state-of- art analytical laboratory at par with international standards
- Accredited at nationally (NABL) and internationally (WHO) for the compliance of ISO:IEC 17025:2005

RATIONALE FOR THE COURSE

Quality of education offered by pharmacy institution varies widely. Most of the institutions could not able to cope up with the current regulatory and analytical requirements. Our recent study shows that industry is still grappling to meet the expectation in terms of assay and dissolution but the very concern are documentation and data manipulation. These issues are

linked to data integrity and quality culture, which advocates the need for certificate course on pharmaceutical analysis, regulatory sciences, quality assurance and product safety.

The first and foremost is students should understand industry profile, accordingly their competency level needs to be improved. To cater this need IPC in collaboration with Delhi Pharmaceutical Sciences and Research University (DPSRU) started three month certificate course on pharmaceutical analysis for the graduate and post graduate students interested to develop their career in this specialised arena.

MENTORS FOR THE COURSE

Module for the course were designed under the guidance of Pioneers and experts in the pharmaceuticals Industry, who have realized the vast gap between knowledge gained at academic institutions and expectations of the pharmaceutical industry. The industry looks for candidates with industrial exposure which will help them to fasten their productivity/outcome. The course is structured in such a manner to help the student having a clear and focused insight into the functioning and deliverable activities of quality analysis of medicines.

COURSE INFORMATION

IPC in collaboration with DPSRU conducts skill development in five streams-Pharmaceutical analysis, regulatory sciences, medical devices, product safety and quality assurance. The first *Certificate course on Pharmaceutical Analysis* is initiated. Pharmaceutical analysis determines the quality of medicines, the course provides deep and practical knowledge on method validation, handling raw materials and finished products and documentations impacts the quality of pharmaceutical products.

The training modules are designed to provide an in-depth theoretical knowledge of various techniques and concomitantly to provide adequate exposure to handle the instruments/experiments independently. Students learn about Quality Assurance (QA), Quality Control (QC) and regulatory affairs which are crucial aspects when working in industry.

TARGET GROUP

To provide pharmacists and other chemical or related science graduates with the necessary knowledge and expertise in pharmaceutical analysis and the scientific principles underlying quality control for a career in the pharmaceutical industry, health service, research institutes or regulatory authorities. The programme is science-based concerned with the Quality Assurance (QA) and Quality Control (QC) of products as molecular entities.

Who is eligible: Graduates & Post Graduates in Chemistry/Biotechnology/Pharmacy/Microbiology

BENEFITS OF THE COURSE

- In-depth knowledge on elements of pharmaceutical analysis
- Out-of-Specs (OOS) and how to conduct OOS investigation
- Validation requirements for analytical procedures as per national and international guidelines
- Impurity analysis
- Good documentation practices for maintaining data integrity in quality analysis of medicine
- Key factors for analytical records and reports
- Analysis of pharmaceutical products for better medicines and provide regulatory data ensuring product integrity

Pioneers/Mentors