Marwadi University
Faculty of Pharmacy

Subject code: 13PH0702
Subject name: Industrial Pharmacy-II

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

Objective: Upon completion of the course the student shall be able to
1. Know the process of pilot plant and scale-up of pharmaceutical dosage forms.
2. Understand the process of technology transfer from lab scale to commercial batch.
3. Know different Laws and Acts that regulate the pharmaceutical industry.
4. Understand the approval process and regulatory requirements for drug products.

Teaching and assessment scheme:

Teaching Scheme (Hours)			Credits	Theory/ Tutorial Marks			Practical Marks		Total Marks
Theory	Tutorial	Practical		CSE	IA (I)	ESE (E)	TW	Viva (V)	
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Theory syllabus: **Teaching hours: 45 Hours**

Unit-1 **10 Hours**

Pilot plant scales up techniques: General considerations – including the significance of personnel requirements, space requirements, raw materials, Pilot plant scale-up considerations for solids, liquid orals, semi-solids and relevant documentation, SUPAC guidelines, Introduction to platform technology.

Unit-2 **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipment, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues.

Unit-3 **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals. Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

Unit-4 **8 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS),

Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

Unit-5 7 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Tutorials will be based on the above syllabus. **Teaching hours: 15 Hours**

Recommended References (Latest edition):

1. Regulatory Affairs from Wikipedia, the free encyclopaedia modified on 7th April. Available at https://en.wikipedia.org/wiki/Regulatory_affairs
2. International Regulatory Affairs Updates, 2005. Available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Textbook of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. Available at http://www.cgmp.com/ra.htm.