FACULTY OF PHARMACY

Marwadi University

B. PHARMACY

Syllabus ◆ Semester-8

Elective subject-**2** name with code: **13PH0804 Pharmaceutical Regulatory Science**

Course Objective

This course is designed to impart fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like the US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Course Outcomes

Upon completion of the course, the student shall be able to

1. Know about the process of drug discovery and development.
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
3. Know the regulatory approval process and their registration in Indian and international markets.

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)	
3	1	0	4	10	15	75	0	0	100

Theory syllabus **Teaching hours: 45 Hours**

Unit-1 10 Hours

New drug discovery and development: Stages of drug discovery, drug development process, pre-clinical studies, nonclinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit-2 10 Hours

Regulatory approval process: Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an Approved NDA/ ANDA. Regulatory authorities and agencies: Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).

Unit-3 10 Hours

Registration of Indian drug products in the overseas market: Procedure for export of pharmaceutical products, technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit-4 8 Hours

Clinical trials: Developing clinical trial protocols, Institutional Review Board/ Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.

Unit-5 7 Hours

Regulatory concepts: Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

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

Recommended references (Latest edition)

1. Drug Regulatory Affairs by Sachin Itkar, Dr N. S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185. Informa Healthcare Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.

7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene.
9. Drugs: From Discovery to Approval, Second Edition by Rick Ng.