18BP089 PHARMACEUTICAL REGULATORY SCIENCE

Hours Per Week :

L	T	P	CP	CL
3	1	-	-	-

Total Hours :

L	T	P
45	1	-

WA/RA	SSH/HSH	CS	SA	S	BS

SCOPE:

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

COURSE OUTCOMES:

Upon completion of the course, the student will be able to achieve the following outcomes:

COs	Course Outcomes	POs	PSOs
1	Know about the process of drug discovery and development	1 ,4	1, 2
2	Know regulatory authorities and agencies governing the manfacture and sale of pharmaceuticals	1 ,4	1, 2
3	Know the regulatory approval process and their registration in Indian and international markets	1 ,4	1, 2

UNIT - I **10HOURS**

NEW DRUG DISCOVERY AND DEVELOPMENT: Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

UNIT - II **10HOURS**

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 - III **10HOURS**

REGISTRATION OF INDIAN DRUG PRODUCT IN OVERSEAS MARKET: Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical; Document (etch), ASEAN Common Technical Document (ACTD) research.

UNIT - IV **08HOURS**

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 - V **07HOURS**

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

RECOMMENDED BOOKS (LATEST EDITION):

1. Drug Regulatory Affairs by Sachem 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. Informal Health care 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 ByFayA. 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 RickNg.