INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**BACHELOR OF PHARMACY**
SEMESTER	**8**
COURSE TITLE	**PHARMACEUTICAL REGULATORY SCIENCE**
COURSE CODE	**13PH0804**
COURSE CREDITS	**4**

Objective:

1 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: After completion of this course, student will 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.

Pre-requisite of course: 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.

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
3	1	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**New drug discovery and development** 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.	10

Contents : Unit	Topics	Contact Hours
2	**Regulatory approval process** 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).	10
3	**Registration of Indian drug products in the overseas market** 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.	10
4	**Clinical trials** 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.	8
5	**Regulatory concepts** Regulatory concepts: Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.	7
Total Hours		**45**

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	**Tutorials** Tutorial 1, Tutorial 2, Tutorial 3, Tutorial 4, Tutorial 5, Tutorial 6, Tutorial 7, Tutorial 8, Tutorial 9, Tutorial 10, Tutorial 11, Tutorial 12, Tutorial 13, Tutorial 14, Tutorial 15	15
Total Hours		**15**

Textbook :

1 Drug Regulatory Affairs, by Sachin Itkar, Dr N. S. Vyawahare, Nirali Prakashan., 1905

References:

1 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.

2 New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.

References:

3 Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

4 FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.

5 Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.

6 Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.

7 Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene.

8 Drugs: From Discovery to Approval, Second Edition by Rick Ng.

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking / Creative**
20.00	30.00	25.00	15.00	10.00	0.00

Instructional Method:

1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

DR. RAMESH BHANAJIBHAI PARMAR
Digitally signed by (Name of HOD)

DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)