NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VIII)

L	T	P	C
3	1	-	4

Course Code	**BP804ET**
Course Title	**Pharmaceutical Regulatory Science**

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.

Objectives:

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

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Discuss about the process of drug discovery and development
2. Understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Discuss the regulatory approval process and their registration in Indian and international markets
4. Explain the requirement to conduct clinical trials along with safety monitoring
5. Describe basic regulations, laws and documents like orange book, Code of Federal Regulatory, Purple book

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

- **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 **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 III **10 Hours**

- **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 (eCTD), ASEAN Common Technical Document (ACTD)research.

UNIT IV **08 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 V **07 Hours**

- **Regulatory Concepts**
  Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Suggested Readings^: (Latest edition)

1. Vyawahare, Ns. & Itkar, S.C. Drug regulatory affairs, Nirali Prakashan.
2. Berry, I. R., & Martin, R. P. The pharmaceutical regulatory process. CRC Press.
3. Guarino, R. A., & Guarino, R. (Eds.). New drug approval process. CRC Press.
4. Weinberg, S. Guidebook for Drug Regulatory Submissions. John Wiley & Sons.
5. Pisano, D. J., & Mantus, D. S. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. CRC Press.
6. Shargel, L., & Kanfer, I. Generic drug product development: solid oral dosage forms. CRC Press.
7. Rozovsky, F. A., & Adams, R. K. Clinical trials and human research: A practical guide to regulatory compliance. John Wiley & Sons.
8. Gallin, J. I., & Ognibene, F. P. (Eds.). Principles and practice of clinical research. Academic Press.
9. Ng, R. Drugs: from discovery to approval. John Wiley & Sons.

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list