PANIPAT INSTITUTE OF ENGINEERING AND TECHNOLOGY, PANIPAT

DEPARTMENT OF PHARMACY

Course: B. Pharmacy

LESSON PLAN

Faculty Name: Kavita Sangwan **Subject Name: P'ceutical Regulatory Science**

Class: B. Pharmacy – 8th Semester **Subject Code: BP804 ET**

Scope of the Subject: 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 outcome: Upon completion of the subject 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

Number of Lectures: 45 + 5 **Each lecture**: 01 hour

Lecture No.	Particular	Remark/Date
Introduction		
1.	General discussion about Pharmaceutical Regulatory Science	
Module 1: New Drug Discovery and development		
2.	Stages of drug discovery	
3.	Drug development process	
4.	Drug development process	
5.	Pre-clin guidance,ical studies	
6.	Non-clinical activities	
7.	Clinical studies	
8.	Innovator and generics	
9.	Concept of generics	
10.	Generic drug product development	
Module 2: Regulatory Approval Process & Regulatory authorities and agencies		
11.	Approval processes	
12.	Timelines involved in Investigational New Drug (IND)	
13.	New Drug Application (NDA)	
14.	Abbreviated New Drug Application (ANDA)	
15.	Changes to an approved NDA / ANDA.	
16.	Overview of regulatory authorities of India	
17.	Overview of regulatory authorities of United States	

18.	Overview of regulatory authorities of European Union	
19.	Overview of regulatory authorities of Australia and Japan	
20.	Overview of regulatory authorities of Canada	
Module 3: Registration of Indian drug product in overseas market		
21.	Procedure for export of pharmaceutical products	
22.	Technical documentation	
23.	Drug Master Files (DMF)	
24.	Drug Master Files (DMF)	
25.	Drug Master Files (DMF)	
26.	Common Technical Document (CTD)	
27.	electronic Common Technical 163Document (eCTD)	
28.	electronic Common Technical 163Document (eCTD)	
29.	ASEAN Common Technical Document (ACTD)research	
30.	ASEAN Common Technical Document (ACTD)research	
Module 4: Clinical trials		
31.	Developing clinical trial protocols	
32.	Institutional Review Board / Independent Ethics committee- formation and working procedures	
33.	Institutional Review Board / Independent Ethics committee- formation and working procedures	
34.	Informed consent process and procedures	
35.	Informed consent process and procedures	
36.	GCP obligations of Investigators, sponsors & Monitors	
37.	Managing and Monitoring clinical trials	
38.	Pharmacovigilance- safety monitoring in clinical trials	
Module 5: Regulatory Concepts		
39.	Basic terminology	
40.	Guidance, guidelines, regulations	
41.	Laws and Acts	
42.	Orange book	
43.	Federal Register	
44.	Code of Federal Regulatory	
45.	Purple book	
Revision		
46.	Revision of previous question papers	
47.	Revision of previous question papers	
48.	Revision of previous question papers	
49.	Revision of previous question papers	
50.	Revision of previous question papers	

Teacher in-charge **HOD** **Principal**