PANIPAT INSTITUTE OF ENGINEERING AND TECHNOLOGY,PANIPAT
DEPARTMENT OF PHARMACY
Course: B.Pharmacy

LESSON PLAN

Faculty Name: Ms. Garima Mittal | **Subject: Industrial Pharmacy**
Class: B. Pharmacy – VIIth Sem. | **Subject Code: BP-702T**

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market.

Course objectives: To let students:
1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry in India and US
4. Understand the approval process and regulatory requirements for drug products

Course Outcomes: Upon completion of this course the student should be able to:
1. Understand the process scaling up of pharmaceutical dosage forms.
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry in India and US
4. Understand the approval process and regulatory requirements for drug products

Number of Lectures: 45 **Each Lect. Time**: 01 hour

Sr. No.	Particular	Remark/Date
UNIT-1:- Pilot plant scale up techniques (10 hrs)		
1.	Introduction	
2.	General considerations	
3.	General considerations - including significance of personnel requirements	
4.	General considerations - space requirements	
5.	General considerations- raw materials	
6.	General considerations- Pilot plant scale up considerations for solids	
7.	General considerations- Considerations for liquids	
8.	General considerations- Considerations for semi solids	
9.	Pilot plant- Relevant documentation	
10.	SUPAC guidelines	
11.	Introduction to Platform technology	
UNIT-2:- Technology development and transfer (10 hrs.)		
11.	WHO guidelines for Technology Transfer	
12.	Terminologies & Technology transfer protocol, Quality risk management	
13.	Transfer from R & D to production (Process, packaging and cleaning)	
14.	Granularity of TT Process (API, excipients, finished products, packing materials) Documentation	
15.	Premises and equipments, qualification and validation	
16.	Quality control, analytical method transfer	
17.	Approved regulatory bodies and agencies	
18.	Commercialization - practical aspects and problems (case studies)	
19.	TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI	
20.	Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues	
UNIT- 3:- Regulatory affairs & Regulatory requirements for drug approval (10 hrs)		
21.	Introduction, Historical overview of Regulatory Affairs	
22.	Regulatory authorities, Role of Regulatory affairs department	
23.	Responsibility of Regulatory Affairs Professionals	
24.	Drug Development Teams & Non-Clinical Drug Development	
25.	Pharmacology, Drug Metabolism and Toxicology	
26.	General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA)	
27.	Clinical research / BE studies	
28.	Clinical Research Protocols	

29.	Biostatistics in Pharmaceutical Product Development	
30.	Data Presentation for FDA Submission, Management of Clinical Studies	
UNIT-4:- Quality management systems (8 hrs)		
31.	Quality management & Certifications	
32.	Concept of Quality	
33.	Total Quality Management	
34.	Quality by design, Six Sigma concept	
35.	Out of Specifications (OOS)	
36.	Change control	
37.	Introduction to ISO 9000 series of quality systems standards	
38.	ISO 14000, NABL, GLP	
UNIT-5:- Indian Regulatory Requirements (7 hrs)		
39.	Central Drug Standard Control Organization (CDSCO)	
40.	State Licensing Authority	
41.	Organization, Responsibilities	
42.	Common Technical Document (CTD)	
43.	Certificate of Pharmaceutical Product (COPP)	
44.	Regulatory requirements	
45	Approval procedures for New Drugs.	

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