PANIPAT INSTITUTE OF ENGINEERING AND TECHNOLOGY, PANIPAT

DEPARTMENT OF PHARMACY

Course: B. Pharmacy

LESSON PLAN

Faculty Name: Kavita Sangwan **Subject Name: P'ceutical Quality Assurance**

Class: B. Pharmacy – 6th Semester **Subject Code: BP606T**

Scope of the Subject: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Course outcome: Upon completion of this course the student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry.
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

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

Lecture No.	Particular	Remark/Date
Introduction		
1.	General discussion about Pharmaceutical Quality Assurance	
Module 1: Quality Assurance and Quality Management concepts		
2.	Definition and concept of Qualitycontrol, Quality assurance and GMP	
3.	Total Quality Management (TQM): Definition, elements, philosophies	
4.	ICH Guidelines: purpose, participants, process of harmonization	
5.	Brief overview of QSEM, with special emphasis on Q-series guidelines	
6.	ICH stability testing guidelines	
7.	Quality by design (QbD): Definition, overview	
8.	Elements of QbD program, tools	
9.	ISO 9000 & ISO14000: Overview, Benefits, Elements	
10.	ISO 9000 & ISO14000: steps for registration	
Module 2: Organization and personnel, Premises, Equipments and raw materials		
11.	Personnel responsibilities, training, hygiene and personal records.	
12.	Premises: Design, construction and plant layout	
13.	Premises : maintenance, sanitation, environmental control, utilities	
14.	Premises : Maintenance of sterile areas	
15.		
16.	Premises : control of contamination	
17.	Equipments and raw materials: Equipment selection	

18.	. Equipments and raw materials: purchase specifications, maintenance	
19.	Equipments and raw materials: purchase specifications	
20.	Equipments and raw materials: maintenance of stores for raw materials.	
Module 3: Quality Control and Good Laboratory Practices		
21.	Quality control test for containers	
22.	Quality control test for rubber closures	
23.	Quality control test for secondary packing materials	
24.	Good Laboratory Practices: General Provisions	
25.	Organization and Personnel, Facilities	
26.	Equipment, Testing Facilities Operation	
27.	Test and Control Articles	
28.	Protocol for Conduct of a Nonclinical Laboratory Study	
29.	Records and Reports	
30.	Disqualification of Testing Facilities	
Module 4: Complaints and Document maintenance in pharmaceutical industry		
31.	Complaints and evaluation of complaints	
32.	Handling of return good	
33.	Recalling and waste disposal	
34.	Batch Formula Record, Master Formula Record	
35.	SOP, Quality audit	
36.	Quality Review and Quality documentation	
37.	Reports and documents	
38.	distribution records	
Module 5: Calibration and Validation, Warehousing		
39.	Introduction, definition and general principles of calibration	
40.	Qualification and validation, , importance and scope of validation	
41.	Types of validation, validationmaster plan. Calibration of pH mete	
42.	Qualification of UV-Visible spectrophotometer,	
43.	General principles of Analytical method Validation	
44.	Warehousing: Good warehousing practice	
45.	Warehousing: materials management	
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**