St.James College of Pharmaceutical Sciences St.James medical Academy River Bank, Chalakudy			
Programme:	M. PHARM	Sem.:	I semester
Name of Course: (*Subject*)	PHARMACEUTICAL VALIDATION	Course Code:	MPA 103T
Teaching faculty of the course			

Summary of the Lecture Plan

Topic	Lectures	Hours
Definition of Qualification and validation	Advantages of validation	2
	Streamlining of Qualification	1
	Validation process and Validation Master Plan	2
	Qualification and Validation	2
Qualification	User Requirement Specification	1
	DesignQualification,Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT)	1
	Installation, Qualification, Operational Qualification, Performance Qualification	1
	Maintaining status- Calibration Preventive Maintenance, Change management	2
	Qualification of Manufacturing Equipment's, Qualification of, Analytical Instruments and Laboratory equipment's.	3
Qualification of analytical instrument	Electronic balance	2
	pH meter, UV- Visible spectrophotometer	1
	FTIR, GC,	3
	HPLC, HPTLC	2
Qualification of Glassware	Volumetric flask, pipette, Measuring cylinder, beakers and burette	3

Validation of Utility systems	Pharmaceutical Water System & pure steam, HVAC system	4
	Compressed air and nitrogen	1
Cleaning Validation	Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning	1
	CleaningofEquipment, Cleaning of Facilities. Cleaning in place	5
Analytical method validation	General principles, Validation of analytical method as per ICH guidelines and USP.	5
Computerized system validation	Electronic records and digital significance-21 CFR part 11 and GAMP 5	5
General Principles of Intellectual Property	Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property	3
	copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry	3
	Types patent applications-provisional and non-provisional, PCT and convention patent applications	4
	International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file	2
	Patent infringement meaning and scope. Significance of transfer technology (TOT)	3

Major Issues or Core Aspects to Be Addressed/ Covered:

Introduction
Validation process and Validation Master Plan.
Advantage of Validation
Streamlining of Qualification
Definition of Qualification and Validation

User Requirement Specification
Qualification of Analytical Instruments
Qualification of analytical instruments:
Electronic balance
pH meter, UV- Visible spectrophotometer
FTIR, GC,
HPLC, HPTLC
General Principles of Intellectual Property
Concepts of Intellectual Property
Mechanism for protection of Intellectual Property
Factors affecting choice of IP protection
Patenting requirement procedures and costs
Practical aspects regarding maintaining of a Patent file
Penalties for violation
Significance of transfer technology (TOT)
Cleaning Validation
Cleaning Method development
Validation of analytical method used in cleaning
Validation of Utility systems
Pharmaceutical Water System
Compressed air and nitrogen
Pure steam HVAC system
Qualification
User Requirement Specification

Analytical Instruments and Laboratory equipment's.
Operational Qualification and Performance Qualification

Sample Questions

Validation Introduction
Validation process and Validation Master Plan.
Advantage of Validation
Streamlining of Qualification
Definition of Qualification and Validation
User Requirement Specification
Qualification of Analytical Instruments
Qualification
Qualification of Manufacturing Equipment's
Operational Qualification and Performance Qualification
Qualification of Electronic balance
Cleaning Validation
Cleaning Method development
Validation of analytical method used in cleaning
General Principles of Intellectual Property
Concepts of Intellectual Property
Patenting requirement procedures and costs
Practical aspects regarding maintaining of a Patent file
Penalties for violation
Computerized system validation
Electronic records and digital significance
CFR part 11 and GAMP 5