St.James College of Pharmaceutical Sciences St.James medical Academy River Bank, Chalakudy			
Programme:	B.Pharm	Sem.:	VII
Name of Course: (*Subject*)	Industrial Pharmacy	Course Code:	BP702T
Teaching faculty of the course	Ms. Dony Lonappan & Ms. Sminu Jos		

Summary of the Lecture Plan

Topic	Lectures	Hours
Unit I Pilot plant scale up techniques:	General considerations	3
	Documentation	2
	SUPAC guidelines	3
	Introduction to Platform technology	2
Unit II Technology development and transfer:	WHO guidelines for Technology Transfer	1
	Granularity of TT Process	2
	Premises and equipments	2
	Quality control	1
	Approved regulatory bodies and agencies	2
	TOT agencies in India	2
Unit III Regulatory affairs	Introduction	3
	Regulatory authorities	3
	Regulatory requirements for drug approval	4
Unit IV Indian Regulatory Requirements	Central Drug Standard Control Organization (CDSCO)	2
	State Licensing Authority	3
	Certificate of Pharmaceutical Product (COPP)	3
Unit V Industrial Safety	Plant Location & layout	2
	Hazards	3
	Accident records	2

Major issues or Core aspects to be addressed/ covered:

Pilot plant scale up techniques:
General considerations: significance
Personnel requirements & space requirements
Raw materials
Pilot plant scale up considerations for solids, liquid orals, semi solids
Relevant documentation
SUPAC guidelines
Introduction to Platform technology
Technology development and transfer

WHO guidelines for Technology Transfer
Terminologies, Technology transfer protocol
Quality risk management
Transfer from R & D to production (Process, packaging and cleaning)
Granularity of TT Process (API, excipients, finished products, packing materials)
Documentation, Premises and equipments
Qualification and validation, quality control
Analytical method transfer
Approved regulatory bodies and agencies
Commercialization - practical aspects and problems.
TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI
Technology of Transfer (TOT) related documentation - confidentiality agreements
Licensing, MoUs, legal issues
Regulatory affairs
Introduction, Historical overview of Regulatory Affairs
Regulatory authorities
Role of Regulatory affairs department
Responsibility of Regulatory Affairs Professionals
Regulatory requirements for drug approval
Drug Development Teams
Non-Clinical Drug Development
General considerations of Investigational New Drug (IND) Application
Investigator's Brochure (IB) and New Drug Application(NDA)
Data Presentation for FDA Submissions
Indian Regulatory Requirements
Central Drug Standard Control Organization (CDSCO)
State Licensing Authority: Organization, Responsibilities
Common Technical Document (CTD)
Certificate of Pharmaceutical Product (COPP)
Regulatory requirements and approval procedures for New Drugs.
Industrial Safety
Plant Location & layout
utility services
Mechanical hazards, Chemical hazards, Electrical hazards, Fire Hazards
Pharmaceutical hazards and their safety
Accident records

Sample Questions

Pilot plant scale up techniques:
What do you mean by pilot plant scale-up? Give examples
What is the significance of pilot plant scale-up with routine production procedure?
Explain the procedure for pilot plant scale-up for liquid orals
Explain the procedure for pilot plant scale-up for liquid dosage form

What do you mean SUPAC?
Write a short note on pilot plant scale-up for solid dosage form
Technology development and transfer
Define technology transfer. What is sending unit and receiving Unit? Write the principles of technology transfer
What is the information required for technology transfer of starting materials from SU to RU?
Write briefly on the information required for process and finished product
Which agencies are working for Technology Transfer in India? Write about any two agencies
What is QRM? Describe the principle and process of QRM.
Regulatory affairs
What is an NDA? Discuss the requirements of data while filing a NDA
Comment on the bioequivalence requirements according to ICH guidelines
Discuss the Intellectual Property protection laws in India in brief
What is PCT? Discuss the content of PCT and its applications
Write a note on Drug Master Files
Briefly discuss Master Formula Record and its importance
Write short notes on Investigator Brochure
Indian Regulatory Requirements
Explain the details of CDSCO and give its functions
Write about various Drug Regulatory agencies
Explain about Central Drugs Laboratory and its function
What is COPP and its importance?
What is RDTL and its function?
Write short note on State Licensing authorities
What are the regulatory requirements and approval procedures for new drugs?
Industrial Safety
Explain utility services
Chemical hazards and Electrical hazards
Pharmaceutical hazards and their safety
Accident records