Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard, Amargadh – Bhichari, Rajkot. Mo. 9099063150, 9727753360

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL VALIDATION
Subject Code: MQA202T

Scope: The main purpose of the subject is to understand about validation and howit can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application .

Objectives: Upon completion of this course the student should be able to

1. The concepts of calibration, qualification and validation
2. The qualification of various equipments and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipments employed in the manufacture of pharmaceuticals.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	0	0	4	80	20	0	0

Sr No	Course Contents	Total Hrs
1	Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status Calibration Preventive Maintenance, Change management).	10
2	Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS	10
3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	10
4	Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated	10

	tablets, Capsules, Ointment/Creams, Liquid Orals andaerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation-A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP	
5	Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place(CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature-21CFR Part11and GAMP	10
6	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 –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications;International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices	10

REFERENCES:

1. B. T.Loftus &R. A.Nash, "Pharmaceutical Process Validation",Drugs and Pharm Sci. Series, Vol. 129,3rdEd.,MarcelDekkerInc.,N.Y.
2. The Theory &Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4. Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton &Agalloco
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton(Ed.)and James Agalloco(Ed.),Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,Y.C.Lee,Yue .Zhang, WileyI nterscience
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good ITPractice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

LEARNING OUTCOMES:

UNIT	LEARNING OUTCOME
1	Knowledge about Introduction to validation.
2	Understand the Qualification of manufacturing equipment.
3	Appreciate the Qualification of laboratory equipments
4	Understand the Process Validation.
5	Appreciate the Cleaning Validation.
6	Understand the concept of General Principles of Intellectual Property.

BOOK LIST:

Sr. no	Book name	Price (Rs.)
1	B. T.Loftus &R. A.Nash, "Pharmaceutical Process Validation",Drugs and Pharm Sci. Series, Vol. 129,3rdEd.,MarcelDekkerInc.,N.Y.	1,550/-
2	The Theory &Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.	652/-
3	Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton & Agalloco.	31,932/-
4	Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.	9,770/-
5	Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider.	3,203/-
6	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.Cloud, Interpharm Press.	13,004/-
7	Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,Y.C.Lee,Yue .Zhang, WileyI nterscience.	11,921/-
8	Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare.	11,914/-
9	Wingate G. Validating Corporate Computer Systems: Good ITPractice for Pharmaceutical Manufacturers. Interpharm Press.	3,322/-
10	LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.	15,500/-