FACULTY OF PHARMACY
Second Semester Master of Science
In Effect from Academic Year 2020-21

Subject Code: 1PA1010202	**Subject Title:** VALIDATION AND REGULATORY AFFAIRS
Pre-requisite Subject	**- NONE -**

Teaching Scheme (Hours per week)				**Evaluation Scheme (Marks)**		
				Theory (T)		**Total Marks**
Lecture	**Tutorial**	**Practical**	**Credit**	**University Assessment**	**Continuous Assessment**	**Theory**
4	NA	NA	4	80	20	100

Scope and Objectives:

The main purpose of the subject is to understand about validation and how it 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. The course also covers basic regulatory requirements for product registration with necessary documents in India and other countries. The course also covers IPR and patent.

Learning Outcome:

- Student shall be able to learn the concepts of validation
- Student shall be able to understand the requirements of regulatory aspects for product registration
- Student shall be able to understand the concept of IPR, Patent and Trademark

Unit	**Content**	**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 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	15
3	Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling, USFDA guidelines on Process Validation, Analytical method validation-ICH guidelines. Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Validation of facilities in sterile and non-sterile plant.	15
4	Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents. Filing a patent applications; patent application forms and guidelines. Types of patent applications- provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Patent infringement meaning and scope. Significance of transfer technology (TOT)	10

5	Regulatory requirements for product approvals: API, Biologics, Novel therapies, special categories, herbal medicines and Homeopathic. Investigational New drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), CTD, eCTD, Drug Master File (DMF). Introduction to general requirements of health regulatory agencies such as US FDA, MCA, TGA, WHO, ANVISA etc.	10

References:

1 B. T.Loftus& R. A.Nash, Pharmaceutical Process Validation, Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed.,Marcel Dekker Inc.,N.Y.
2 The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3 Pharmaceutical Process Validation, 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker
4 Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
5 Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
6 Pharmaceutical Quality Assurance by Manohar A. Potdhar, 2nd edition, Nirali Prakashan
7 Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
8 The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144
9 The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers
10 New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
11 Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
12 FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
13 Analytical Method validation and Instrument Performance Verification by Churg Chan, HeimanLam,Y.C.Lee,Yue .Zhang, Wiley Interscience
14 Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
15 Drugs: From Discovery to Approval, Second Edition By Rick Ng
16 New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
17 Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
18 Medical Device Development: A Regulatory Overview By Jonathan S. Kahan
19 Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh
20 www.ich.org (Q2R1)