INSTITUTE	**FACULTY OF SCIENCE**
PROGRAM	**MASTER OF SCIENCE (CHEMISTRY)**
SEMESTER	**4**
COURSE TITLE	**PHARMA REGULATORY AFFAIRS**
COURSE CODE	**02CY1553**
COURSE CREDITS	**4**

Objective:

1 To understand the role of Pharma Regulatory Affairs, ICH Guidelines, DMF and importance of validation and calibration in research as well as Industrial level.

Course Outcomes: After completion of this course, student will be able to:

1 Able to understand ICH guidelines and DMF.

2 Capable to validated analytical method with respect to ICH guideline.

3 Able to perform calibration of various sophisticated instruments.

4 Primary exposure towards lab to plant scale pharma manufacturing unit.

Pre-requisite of course: To understand the role of Pharma Regulatory Affairs, ICH Guidelines, DMF and importance of validation and calibration in research as well as Industrial level

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	50	30	20	25	25

Contents : Unit	Topics	Contact Hours
1	**Introduction** Introduction and Overview of entire ICH guidelines, Introduction to DMF (RA, QA, QC and Process Chemistry),	
2	**Detail study of ICH Guidelines** Detail study of ICH guideline Q1 (Stability), Q2 (Analytical Validation), Q.3 (Impurity), Q7 (Good manufacturing practice).	
3	**Essential knowledge of manufacturing units** Introduction, Quality Control (QC) and Quality Assurance (QA) system, IPQC and IPQA, Requirements of QA and QC, Certified standard materials, Site master file, GLP Audit, Laboratory control, Personnel Training, Regulations for Safety management, Safety training, Role of Analytical Development Laboratory, Role of Research and Development Laboratory, Primary knowledge regarding pilot plant, manufacturing plant.	

DR. VICKY DEVENDRA JAIN
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Contents : Unit	Topics	Contact Hours
4	**Calibration and Validation** Introduction, Importance of Validation and Calibration, Analytical method development, Validation of developed method, Various validation parameters such as Accuracy, Precision, Linearity, LOD, LOQ, Robustness, Range, Specificity study, Degradation study, Stability study as per different climatic zones, Calibration requirements, SOP preparation for Validation of analytical method, Calibration of various types of Analytical instruments.	
Total Hours		

Textbook :

1 Textbook on Pharmaceutical Regulatory Affairs - Regulatory Affairs of Pharmaceuticals, Anasuya Patil, Shashwat Publication, 2023

2 A Concise Textbook of Drug Regulatory Affairs, N UdupaKrishnamurthy Bhat, Manipal University Press, 2015

References:

1 FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics , FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics , Douglas J. Pisano , CRC Press, 2008

2 Flow Cytometry in Drug Discovery and Development, Flow Cytometry in Drug Discovery and Development, V Litwin, John Wiley & Sons Inc, 2010

3 Fundamentals of Analytical Chemistry, Fundamentals of Analytical Chemistry, Douglas A. Skoog, Saunders College Pub, 1996

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery and evaluation					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking**
10.00	20.00	25.00	25.00	10.00	10.00

Instructional Method:

1 The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

2 The internal evaluation will be done on the basis of continuous evaluation of students in the laboratory and class-room.

3 Students will use supplementary resources such as online videos, NPTEL videos, e-courses, Virtual Laboratory

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Digitally signed by (Name of HOD)

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Supplementary Resources:

1 http://www.nptel.ac.in/courses/104103069/#
2 http://ocw.mit.edu/courses/chemistry/
3 http://vlab.amrita.edu/index.php?sub=2
4 http://www.vlab.co.in/ba_labs_all.php?id=9

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