MANIPAL
ACADEMY of HIGHER EDUCATION
(Deemed to be University under Section 3 of the UGC Act, 1956)

Academic Program Regulations – 2017

Based on PCI Notification in the Gazette of India, No 362, dated 11 December, 2014

Program Title: MPharm (Master of Pharmacy)

CBCS (Choice Based Credit System)

Specialization: Pharmaceutical Regulatory Affairs

Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education
Manipal-576 104, Karnataka, India

MANIPAL
ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

July 1, 2023

Academic Program Regulations – 2017 : MPharm, CBCS – Approval

The Master of Pharmacy (MPharm) program, CBCS of Manipal Academy of Higher Education being offered at Manipal College of Pharmaceutical Sciences under the title "Academic Program Regulations – 2017: MPharm, CBCS" has been duly approved by the Academic Council of Manipal Academy of Higher Education.

REGISTRAR

MANIPAL ACADEMY OF HIGHER EDUCATION * INSTITUTION OF EMINENCE DEEMED TO BE UNIVERSITY * MANIPAL - 576 104 *

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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCL—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

CHAPTER I: REGULATIONS

1. Short title and commencement

These regulations shall be called as "Master of Pharmacy (MPharm) Degree Program-Regulations - Choice Based Credit System (CBCS). The program regulations are based on the PCI notification in the Gazette of India, No. 362, dated 11 December 2014.

They shall come into effect from the academic year 2017-18. The regulations framed are subject to modifications from time to time by the authorities of the Manipal Academy of Higher Education.

2. Minimum qualification for admission

A pass in the following examinations

a) BPharm degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55% of the maximum marks (aggregate of 4 years of BPharm).
b) Every student, selected for admission to postgraduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.
c) Any foreign pharmacy degree approved by the Pharmacy Council of India.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (BPharm)

3. Duration of the program

The program of study for MPharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Manipal Academy of Higher Education based on the inputs from Pharmacy Council of India, New Delhi.

4. Medium of instruction and examination

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of July/August to November/December and the even semesters shall be conducted for the month of December/January to May/June in an academic year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering the theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars etc., are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of Lecture (L) and tutorial (T). Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course are dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture/tutorial and a multiplier of half (½) for practical (laboratory) hours. Thus, for example, a theory course, having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout the semester carries a credit of 2. The contact hours of seminars, and research work and journal club shall be treated as that of practical courses for the purpose of calculating credits, i.e., the contact hours shall be multiplied by ½.

7.2. Minimum credit requirements

The minimum credit points required for the award of MPharm degree is 95. However, based on the credit points earned by the students under the heads of co-curricular activities and choice based inter/multidisciplinary courses, a student shall earn a maximum of 100 credit points. These credits are divided into theory courses, practical, seminars, research work, journal club and co-curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicate certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in theory, practical, seminar, assignment, journal club, discussion with the supervisor, research work presentation and dissertation shall be maintained by the department/teaching staff of the respective courses.

9. Course work of study

The specializations in MPharm program are given in Table 1.

Table 1. List of MPharm specializations and their codes

S. No.	Specialization	Code
1	Pharmaceutics	MPH
2	Industrial Pharmacy	MIP
3	Pharmaceutical Chemistry	MPC
4	Pharmaceutical Analysis	MPA
5	Pharmaceutical Quality Assurance	MQA
6	Pharmaceutical Regulatory Affairs	MRA
7	Pharmaceutical Biotechnology	MPB
8	Pharmacy Practice	MPP
9	Pharmacology	MPL
10	Pharmacognosy	MPG

The course work of MPharm specializations shall include semester wise theory and practical as given in Table 2 to 13. The number of hours to be devoted to each theory lectures (L), tutorials (T) and practical (P) course in any semester shall not be less than that shown in Table 2 to 13.

Table 2. Course work of MPharm – Pharmaceutics (MPH) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPH101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCE-MPH102T	Drug Delivery Systems	4	1	--	5	100
PCE-MPH103T	Modern Pharmaceutics	4	1	--	5	100
PRM-MPH104T	Regulatory Affairs	4	1	--	5	100
PCE-MPH105P	Pharmaceutics Practical I	--	--	12	6	150
PCE-MPH106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCE-MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	1	--	5	100
PCE-MPH202T	Advanced Biopharmaceutics and Pharmacokinetics	4	1	--	5	100
PCE-MPH203T	Computer Aided Drug Delivery Systems	4	1	--	5	100
PCE-MPH204T	Cosmetic and Cosmeceuticals	4	1	--	5	100
PCE-MPH205P	Pharmaceutics Practical II	--	--	12	6	150
PCE-MPH206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode						

Table 3. Course work of MPharm –Industrial Pharmacy (MIP) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MIP101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCE-MIP102T	Pharmaceutical Formulation Development	4	1	--	5	100
PCE-MIP103T	Novel Drug Delivery Systems	4	1	--	5	100
PRM-MIP104T	Intellectual Property Rights	4	1	--	5	100
PCE-MIP105P	Industrial Pharmacy Practical I	--	--	12	6	150
PCE-MIP106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCE-MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	1	--	5	100
PCE-MIP202T	Scale-up and Technology Transfer	4	1	--	5	100
PCE-MIP203T	Pharmaceutical Production Technology	4	1	--	5	100
PRM-MIP204T	Entrepreneurship Management	4	1	--	5	100
PCE-MIP205P	Industrial Pharmacy Practical II	--	--	12	6	150
PCE-MIP206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 4. Course work of MPharm – Pharmaceutical Chemistry (MPC) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPC101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCH-MPC102T	Advanced Organic Chemistry I	4	1	--	5	100
PCH-MPC103T	Advanced Medicinal Chemistry	4	1	--	5	100
PCH-MPC104T	Chemistry of Natural Products	4	1	--	5	100
PCH-MPC105P	Pharmaceutical Chemistry Practical I	--	--	12	6	150
PCH-MPC106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCH-MPC201T	Advanced Spectral Analysis	4	1	--	5	100
PCH-MPC202T	Advanced Organic Chemistry II	4	1	--	5	100
PCH-MPC203T	Computer Aided Drug Design	4	1	--	5	100
PCH-MPC204T	Pharmaceutical Process Chemistry	4	1	--	5	100
PCH-MPC205P	Pharmaceutical Chemistry Practical II	--	--	12	6	150
PCH-MPC206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 5. Course work of MPharm – Pharmaceutical Analysis (MPA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPA101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCH-MPA102T	Advanced Pharmaceutical Analysis	4	1	--	5	100
PCH-MPA103T	Pharmaceutical Validation	4	1	--	5	100
PCH-MPA104T	Food Analysis	4	1	--	5	100
PCH-MPA105P	Pharmaceutical Analysis Practical I	--	--	12	6	150
PCH-MPA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCH-MPA201T	Advanced Instrumental Analysis	4	1	--	5	100
PCH-MPA202T	Modern Bioanalytical Techniques	4	1	--	5	100
PCH-MPA203T	Quality Control and Quality Assurance	4	1	--	5	100
PCH-MPA204T	Herbal and Cosmetic Analysis	4	1	--	5	100
PCH-MPA205P	Pharmaceutical Analysis Practical II	--	--	12	6	150
PCH-MPA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 6. Course work of MPharm – Pharmaceutical Quality Assurance (MQA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MQA101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PQA-MQA102T	Quality Management Systems	4	1	--	5	100
PQA-MQA103T	Quality Control and Quality Assurance	4	1	--	5	100
PQA-MQA104T	Product Development and Technology Transfer	4	1	--	5	100
PQA-MQA105P	Pharmaceutical Quality Assurance Practical I	--	--	12	6	150
PQA-MQA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PQA-MQA201T	Hazards and Safety Management	4	1	--	5	100
PQA-MQA202T	Pharmaceutical Validation	4	1	--	5	100
PQA-MQA203T	Audits and Regulatory Compliance	4	1	--	5	100
PQA-MQA204T	Pharmaceutical Manufacturing Technology	4	1	--	5	100
PQA-MQA205P	Pharmaceutical Quality Assurance Practical II	--	--	12	6	150
PQA-MQA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 7. Course work of MPharm – Pharmaceutical Regulatory Affairs (MRA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PRM-MRA101T	Good Regulatory Practices	4	--	--	4	100
PRM-MRA102T	Documentation and Regulatory Writing	4	1	--	5	100
PRM-MRA103T	Clinical Research Regulations	4	1	--	5	100
PRM-MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights	4	1	--	5	100
PRM-MRA105P	Regulatory Affairs Practical I	--	--	12	6	150
PRM-MRA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PRM-MRA201T	Regulatory Aspects of Drugs and Cosmetics	4	1	--	5	100
PRM-MRA202T	Regulatory Aspects of Herbal and Biologicals	4	1	--	5	100
PRM-MRA203T	Regulatory Aspects of Medical Devices	4	1	--	5	100
PRM-MRA204T	Regulatory Aspects of Food and Nutraceuticals	4	1	--	5	100
PRM-MRA205P	Regulatory Affairs Practical II	--	--	12	6	150
PRM-MRA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 8. Course work of MPharm – Pharmaceutical Biotechnology (MPB) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPB101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PBT-MPB102T	Microbial and Cellular Biology	4	1	--	5	100
PBT-MPB103T	Bioprocess Engineering and Technology	4	1	--	5	100
PBT-MPB104T	Advanced Pharmaceutical Biotechnology	4	1	--	5	100
PBT-MPB105P	Pharmaceutical Biotechnology Practical I	--	--	12	6	150
PBT-MPB106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PBT-MPB201T	Proteins and Protein Formulations	4	1	--	5	100
PBT-MPB202T	Immunotechnology	4	1	--	5	100
PBT-MPB203T	Bioinformatics and Computational Biotechnology	4	1	--	5	100
PBT-MPB204T	Biological Evaluation of Drug Therapy	4	1	--	5	100
PBT-MPB205P	Pharmaceutical Biotechnology Practical II	--	--	12	6	150
PBT-MPB206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 9. Course work of MPharm – Pharmacy Practice (MPP) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PPR-MPP101T	Clinical Pharmacy Practice	4	--	--	4	100
PPR-MPP102T	Pharmacotherapeutics I	4	1	--	5	100
PPR-MPP103T	Hospital and Community Pharmacy	4	1	--	5	100
PPR-MPP104T	Clinical Research	4	1	--	5	100
PPR-MPP105P	Pharmacy Practice Practical I	--	--	12	6	150
PPR-MPP106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PPR-MPP201T	Principles of Quality Use of Medicines	4	1	--	5	100
PPR-MPP202T	Pharmacotherapeutics II	4	1	--	5	100
PPR-MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	1	--	5	100
PPR-MPP204T	Pharmacoepidemiology and Pharmacoeconomics	4	1	--	5	100
PPR-MPP205P	Pharmacy Practice Practical II	--	--	12	6	150
PPR-MPP206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 10. Course work of MPharm – Pharmacology (MPL) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPL101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PHA-MPL102T	Advanced Pharmacology I	4	1	--	5	100
PHA-MPL103T	Pharmacological and Toxicological Screening Methods I	4	1	--	5	100
PHA-MPL104T	Cellular and Molecular Pharmacology	4	1	--	5	100
PHA-MPL105P	Pharmacology Practical I	--	--	12	6	150
PHA-MPL106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PHA-MPL201T	Advanced Pharmacology II	4	1	--	5	100
PHA-MPL202T	Pharmacological and Toxicological Screening Methods II	4	1	--	5	100
PHA-MPL203T	Principles of Drug Discovery	4	1	--	5	100
PHA-MPL204T	Clinical Research and Pharmacovigilance	4	1	--	5	100
PHA-MPL205P	Pharmacology Practical II	--	--	12	6	150
PHA-MPL206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 11. Course work of MPharm – Pharmacognosy (MPG) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PQA-MPG101T	Modern Pharmaceutical Analytical Techniques	4	--	--	4	100
PCO-MPG102T	Advanced Pharmacognosy I	4	1	--	5	100
PCO-MPG103T	Phytochemistry	4	1	--	5	100
PCO-MPG104T	Industrial Pharmacognostical Technology	4	1	--	5	100
PCO-MPG105P	Pharmacognosy Practical I	--	--	12	6	150
PCO-MPG106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PCO-MPG201T	Medicinal Plant Biotechnology	4	1	--	5	100
PCO-MPG202T	Advanced Pharmacognosy II	4	1	--	5	100
PCO-MPG203T	Indian Systems of Medicine	4	1	--	5	100
PCO-MPG204T	Herbal Cosmetics	4	1	--	5	100
PCO-MPG205P	Pharmacognosy Practical II	--	--	12	6	150
PCO-MPG206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Table 13. Course work for MPharm III and IV semesters (Common for all specializations)						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
PHA-MRM301T	Research Methodology and Biostatistics*	**4**	**--**	**--**	**4**	**100**
MJC302P	Journal Club*	**--**	**--**	**2**	**1**	**100**
MRW401P	Research Work	**--**	**--**	**70**	**35**	**600**
	Total	**4**	**--**	**72**	**40**	**800**
***** No end-semester examination. Only continuous mode						

Table 14. Semester wise course work credits distribution	
Semester	**Credit Points**
I	26
II	27
III and IV	40
Total course work credits	93
Co-curricular activities (Attending conference, scientific presentations, other scholarly activities and choice based inter/multidisciplinary courses)	Minimum=02* Maximum=07*
Total credit points	**Minimum=95 Maximum=100**

*Credit points for co-curricular activities (Table 15A) and choice based inter/multidisciplinary courses (Table 15B).

Table 15A. Guidelines for awarding credit points for co-curricular activities	
Name of the Activity	**Maximum Credit Points Eligible/ Activity**
Participation in National level seminar/Conference/Workshop/Symposium/Training programs (related to the specialization of the student)	01
Participation in International level seminar/Conference/Workshop/Symposium/Training programs (related to the specialization of the student)	02
Academic award/ Research award from State level/National agencies	01
Academic award/Research award from International agencies	02
Research/ Review publication in National journals (Indexed in Scopus/Web of Science)	01
Research/ Review publication in International journals (Indexed in Scopus/Web of Science)	02
Note: International conference: Held outside India International journal: The editorial board outside India *The credit points assigned for extracurricular and or co-curricular activities shall be given by the principal of the college and the same shall be submitted to the university. The criteria to acquire this credit point shall be defined by the college from time to time.	

Table 15B. List of choice based inter/multidisciplinary courses			
Course Code	**Course Title**	**Credits**	**Department/Institution offering the Course**
Interdisciplinary courses			
PCE-001E	Generic Drug Development	1	Pharmaceutics, MCOPS
PCE-002E	Pharmaceutical Dissolution Technology	1	Pharmaceutics, MCOPS
PCE-003E	Particulate Drug Delivery Systems	1	Pharmaceutics, MCOPS
PCE-004E	3D Printing in Pharmaceutical Manufacturing	1	Pharmaceutics, MCOPS
PCH-001E	Preparative Separation Techniques	1	Pharmaceutical Chemistry, MCOPS
PCH-002E	Molecular Modeling and Drug Design	1	Pharmaceutical Chemistry, MCOPS
PCH-003E	Hyphenated Techniques	1	Pharmaceutical Chemistry, MCOPS
PCH-004E	Chemicals - Environment, Health and Safety	1	Pharmaceutical Chemistry, MCOPS
PQA-001E	Theory and Practice of Analytical and Bioanalytical Method Development and Validation	1	Pharmaceutical Quality Assurance, MCOPS
PQA-002E	Good Documentation Practices and e-Documentation Practices in Pharmaceutical Industry	1	Pharmaceutical Quality Assurance, MCOPS
PQA-003E	Trouble Shooting in High Performance Liquid Chromatography	1	Pharmaceutical Quality Assurance, MCOPS
PQA-004E	Professional Development	1	Pharmaceutical Quality Assurance, MCOPS

PQA-005E	Stability Testing of Drugs and Biologicals	1	Pharmaceutical Quality Assurance, MCOPS
PQA-006E	USFDA Drug Regulatory Affairs	1	Pharmaceutical Quality Assurance, MCOPS
PQA-007E	Rest of the World Drug Regulations	1	Pharmaceutical Quality Assurance, MCOPS
PQA-008E	Evaluation of Medical Devices	1	Pharmaceutical Quality Assurance, MCOPS
PBT-001E	Clean Room Concepts	1	Pharmaceutical Biotechnology, MCOPS
PBT-002E	Biosimilars	1	Pharmaceutical Biotechnology, MCOPS
PBT-003E	Principles of Gene Cloning	1	Pharmaceutical Biotechnology, MCOPS
PBT-004E	Tissue Engineering	1	Pharmaceutical Biotechnology, MCOPS
PPR-001E	Retail Pharmacy Practice	1	Pharmacy Practice, MCOPS
PPR-002E	Fundamentals of Medical Writing	1	Pharmacy Practice, MCOPS
PPR-003E	Systematic Review and Meta-Analysis	1	Pharmacy Practice, MCOPS
PPR-004E	Pharmacokinetics Data Analysis (Employing WinNonlin)	1	Pharmacy Practice, MCOPS
PHA-001E	Cancer Biology	1	Pharmacology, MCOPS
PHA-002E	Screening Methods for Drug Development	1	Pharmacology, MCOPS
PHA-003E	Free Radical Biology and Medicine	1	Pharmacology, MCOPS
PHA-004E	Regulatory Toxicology in Drug Discovery and Development	1	Pharmacology, MCOPS
PCO-001E	Nutraceuticals	1	Pharmacognosy, MCOPS
PCO-002E	Extraction, Separation and Purification of Phytoconstituents	1	Pharmacognosy, MCOPS
PCO-003E	Nanophytopharmaceuticals	1	Pharmacognosy, MCOPS
PCO-004E	Herbal Monographs	1	Pharmacognosy, MCOPS
PRM-001E	Retail Business Management	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
PRM-002E	Intellectual Property Management	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
PRM -003E	General Management Principles	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
PRM -004E	Entrepreneurship Development	1	Pharmaceutical Regulatory Affairs & Management, MCOPS
Multidisciplinary courses			
MU-001E	Certificate Course in Bioinformatics	3	School of Life Sciences, MU
MU-002E	Project Management	4	Department of Humanities and Social Science, MIT
MU-003E	Certificate Course in Bioethics	2/4	Centre for Bioethics, MU
MU-004E	Academic Research and Writing	3	Manipal Centre for Philosophy and Humanities, MU
MU-005E	Certificate Course in Biosecurity	5	Dept. of Public Health, MU
CR-001E	Any one of the Online courses	1 and above	Coursera

10. Program committee

1. The MPharm program shall have a program committee constituted by the Head of the Institution in consultation with all the Heads of the Departments.

2. The composition of the program committee shall be as follows: A teacher at the cadre of professor shall be the Chairperson; One teacher from each MPharm specialization and four student representatives (two from each academic year), nominated by the Head of the Institution.

3. Duties of the program committee:

i. Periodically reviewing the progress of the classes.
ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
iv. Communicating its recommendation to the Head of the Institution on academic matters.
v. The program committee shall meet at least twice in a semester, preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end-semester examinations are given in Table 16.

Table 16. Schemes for internal assessments and end semester examinations

Course	Internal Assessment				End-Semester Exams		Total Marks
	Continuous Mode	Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
Semester I and II							
Theory	10	15	1 hr each	25	75	3 hrs	100
Practical	20	30	6 hrs	50	100	6 hrs	150
Seminar	--	--	--	100	--	--	100
Semester III and IV							
PHA-MRM301T Research Methodology and Biostatistics*	20	40+40	2 hrs each	100	--	--	100
MJC302P Journal Club*	--	--	--	100	--	--	100
MRW401P Research Work	--	100+100	1 hr each	200	400	--	600
***** No end-semester examination. Only continuous mode							

11.1. Internal assessment: Continuous mode

The marks allocated for continuous mode of internal assessment of theory courses shall be awarded based on the students' performance in the assignments/surprise tests, etc., while in the lab course it is based on the practical record, regular viva-voce etc.

11.1.1. Sessional exams

Two sessional exams for each theory course and one sessional examination for a practical course shall be conducted as per the schedule fixed by the college. The schemes of question papers for theory and practical sessional examinations are given below. The average marks of two sessional examinations of theory courses shall be computed for internal assessment of 15 marks as given in Table 16.

Question paper pattern – MPharm Theory sessional examinations

Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education, Manipal

MPharm Theory Sessional Examinations, Month and Year

Course Code. Course Title

Date: dd-mm-yyyy | Duration: 2 hrs | Max. Marks: 45

Instructions: Answer ALL questions

Long Essays (2x 10 marks) = 20 marks
1. Question
2. Question
Short Essays (4 x 5 marks) = 20 marks
3. Question
4. Question
5. Question
6. Question
7. Short answers (1 mark × 5 = 5 marks)
7A.
7B.
7C.
7D.
7E.

Question paper pattern – MPharm practical sessional examinations
Manipal College of Pharmaceutical Sciences **Manipal Academy of Higher Education, Manipal** **MPharm Practical Sessional Examinations, Month and Year** **Course Code. Course Title** Date: dd-mm-yyyy Duration: 6 hrs Max. Marks: 60 **Instructions: Answer ALL questions.** 1. Synopsis (10 marks) 2. Major Experiment (25 marks) 3. Minor Experiment (15 marks) 4. Viva-Voce (10 marks)

MPharm seminar evaluation scheme						
PRESENTATION (50 Marks)					**Marks awarded for each criteria**	
Criteria					Teacher 1	Teacher 2
1	Preparedness (10 marks)					
2	Response to questions (10 marks)					
3	Audio-visual aids (10 marks)					
4	Clarity of presentation (10 marks)					
5	Breadth and depth of material presented (10 marks)					
				Marks awarded		
				Average marks awarded for presentation out of 50 (A) =		
WRITE UP (50 Marks)						
Marks awarded for each criterion						Marks awarded for write up out of 50 (B)
Content (optimum and relevant to topic) (10 marks)	Recent information or out of date (10 marks)	Organization (sequent and methodical) (10 marks)	Diagram, illustrations & references (10 marks)	Originality (10 marks)		
Remarks if any:						
Seminar marks awarded out of 100 = (A+B) =						

11.2 End-semester examination

End-semester examinations are conducted for eligible students twice at the end of the semester, namely, the main examination for regular students and the make-up/supplementary examinations for the failed students only before the commencement of the next semester (Table 17). In case a failed student could not clear the course in the make-up/supplementary examination, the student would have his next examination along with the regular students only in the main examination.

Table 17. Tentative schedule of end-semester examinations		
Semester	**Main Examination**	**Make-up/Supplementary Exams**
I and III	November/December	December/January
II and IV	May/June	July/August

Question paper pattern – MPharm theory end-semester examinations

Manipal Academy of Higher Education, Manipal

MPharm Theory End-Semester Examinations, Month and Year

Course Code. Course Title

Date: dd-mm-yyyy Duration: 3 hrs Max. Marks: 75

Instructions: Answer ALL questions.

Answer the following (5 marks × 10 = 50 marks)
1. Question
2. Question
3. Question
4. Question
5. Question

Answer the following with specific answers (5 marks × 5 = 25 marks)
6A.
6B.
6C.
6D.
6E.

Question paper pattern – MPharm practical end-semester examinations

MPharm Practical End-Semester Examinations, Month and Year

Manipal Academy of Higher Education, Manipal

Course Code. Course Title

Date: dd-mm-yyyy Duration: 6 hrs Max. Marks: 100

Instructions: Answer ALL questions.

1. Synopsis (15 marks)
2. Major Experiment (45 marks)
3. Minor Experiment (25 marks)
4. Viva-Voce (15 marks)

12. Pass and award of performance grades

12.1: Minimum for a pass in a course

A student should obtain a minimum of 35% marks in the end-semester exam of each course. A student shall be declared PASS if, the candidate secures E-grade separately in each course, in a 10-

Point-Relative-Letter Grading-Scheme. Accordingly, no candidate shall be declared to have passed in any course unless he/she obtains a grade not less than E-grade.

12.2 Award of performance grades

The marks obtained in the end semester and internal assessments in a course are added together and a 10-Point-Relative-Letter Grading Scheme is used to allot an appropriate letter grade to the student's performance in that course.

12.3 The 10-Point-Relative-Letter-Grading- Scheme

The letter grades and grade points that are used to assess the students' performance in a course are given in the Table 18

Table 18. 10-Point-Relative-Letter Grading-Scheme

Letter Grade	Grade Point	Performance
A+	10	Outstanding
A	9	Excellent
B	8	Good
C	7	Fair
D	6	Average
E	5	Pass
F/I/DT/ab	0	Fail

F: Fails, I: Incomplete, DT: Detained, ab: Absent

Note the following:

1. Internal assessment marks and end-semester examination marks put together are taken into account for the 10-Point-Relative-Letter Grading-Scheme in each course separately. However, the scheme is applied to a student who scores minimum 35% marks in the end-semester examination of each course.
2. Appropriate letter grades, from E to A+, are awarded, in each theory and lab courses, to only such candidate who has passed the course in first attempt. However, grades E to C are only awarded to a student who makes multiple attempts to pass a course; except in case of I-grade.
3. A candidate who is eligible and registers for the end-semester examination but fails to appear in the end-semester examination or fails in the course gets a grade 'ab', indicating failure.
4. A student who is eligible and registers for the end-semester examination but fails to appear in the end-semester examination due to valid reasons will get a grade 'I', indicating incomplete. However, it needs prior approval of the HOI and the Registrar Evaluation, Manipal Academy of Higher Education.
5. The grade DT is given to a candidate who fails to put in the minimum required attendance for appearing the end-semester examination for a course.
6. A student who earns a grade 'E' or above in a course is declared to have successfully completed the course and earns the credits assigned to that particular course. A course successfully completed cannot be repeated for the purpose of improving the grade.
7. Final evaluation of the performance of a student in each course (theory and lab separately) will be carried out on a 10-Point-Letter Grading-Scheme corresponding to the marks obtained in that course. Eventually each letter grade of the course is converted into a specific grade point associated with the letter grade as given in the table above.

12.4 The Semester Grade Point Average (SGPA)

<u>Note</u>: For the calculation of SGPA and CGPA, the credits assigned for course work are only taken for account.

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes four courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$\mathrm{SGPA} = \frac{\mathrm{C1G1} + \mathrm{C2G2} + \mathrm{C3G3} + \mathrm{C4G4}}{\mathrm{C1} + \mathrm{C2} + \mathrm{C3} + \mathrm{C4}}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ab-grade awarded in that semester. For example if a learner has F or ab-grade in course 4, the SGPA shall then be computed as:

$$\mathrm{SGPA} = \frac{\mathrm{C1G1} + \mathrm{C2G2} + \mathrm{C3G3} + \mathrm{C4} * \mathrm{ZERO}}{\mathrm{C1} + \mathrm{C2} + \mathrm{C3} + \mathrm{C4}}$$

12.5. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in the final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\mathrm{CGPA} = \frac{\mathrm{C1S1} + \mathrm{C2S2} + \mathrm{C3S3} + \mathrm{C4S4}}{\mathrm{C1} + \mathrm{C2} + \mathrm{C3} + \mathrm{C4}}$$

where C1, C2, C3,.... is the total number of credits for semester I,II,III,…. and S1,S2, S3,....is the SGPA of semester I,II,III,…. .

12.6. Conversion of GPA/CGPA into a percentage

The performance of students who are pursuing pharmacy programs in the Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal is awarded on a 10-Point-Relative-Letter Grading-Scheme.

In this system the top band (top 10%) of students who score highest marks are placed at A+ which is equivalent to 10 grade point (maximum). Thus, 10 GPA or CGPA is equivalent to 100%. Accordingly, 1 GPA or CGPA is equivalent to 10%.

Based on this, the following formula is applied to convert GPA or CGPA to an appropriate percentage:

Percentage secured by the candidate = GPA or CGPA × 10

13. Make-up/Supplementary examination

In case, a student fails to secure an E-grade in any theory or practical courses, he/she shall reappear for the end-semester examination of that course. However, his/her marks of the internal assessment shall be carried over, and he/she is entitled for a maximum grade of 'C' only, irrespective of the students' top order performances.

However, the candidates with DT-grade will also be allowed to take this examination provided they meet the eligibility criteria laid for the candidates to appear in the end-semester examinations of the courses of the programs.

Important to Note: A student who once failed (F-grade) or DT (Detained) grade in any course, a maximum of C-grade will only be awarded in subsequent end-semester examinations, irrespective of the student's high performances in that particular course. However, those who miss regular examinations due to valid reasons (I-grade) will be allowed to retain whatever the grades they secure in the make-up/supplementary examinations. In case a candidate with DT-grade reregisters for the course to repeat the entire education process in the subsequent academic year, after paying the required course fee, the DT status in that particular course is removed and he/she is allowed to retain the grades that he/she secures in the end-semester examination.

After the results are declared, grade cards will be issued to each student, which will contain the list of courses for that semester and the grades obtained by the student.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end-semester theory examinations.

15. Promotion to the next higher class

A student shall be eligible to carry forward all the courses of I and II semesters till the III/IV semester examinations. However, the results of IV semester (Research project) of the student shall be declared only when the student passes in all the courses of I and II semesters.

16. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of 7.50 and above
First Class = CGPA of 6.00 to 7.49
Second Class = CGPA of 5.00 to 5.99

17. Research project work

17.1 Dissertation submission

All the students shall undertake a research project under the supervision of a teacher in semester III and IV and submit a dissertation at the end of the IV semester. Four copies of the dissertation shall be submitted.

Note: If any candidate fails to submit the dissertation on or before the date prescribed, the end-semester examination of such candidate shall be at a later date, which shall not be earlier than 6 months from the date fixed in the first instance.

17.2 Dissertation evaluation

The performance of student in the dissertation work is assessed as per the scheme given in the Table 19.

Table 19. MPharm dissertation evaluation scheme

Internal Assessment			**University Examination**					**Grand Total**
Presentation 1 (III semester)	**Presentation 2 (IV semester)**	**Total**	**Dissertation Evaluation (300) by Examiners**		**Viva Voce Joint Evaluation by Internal and External Examiners (100)**		**Total**	
			Internal	External	Presentation	Viva-voce		
i	ii	i+ii=A	i	ii	iii	iv	i+ii+iii+iv =B	A+B
100	**100**	**200**	**150**	**150**	**50**	**50**	**400**	**600**

The internal and external examiners appointed by the university shall evaluate the dissertation of the research project separately as per the following evaluation criteria.

Evaluation of Dissertation: For 150 marks each separately by Internal and External Examiners

	Marks
Objective(s) of the study	25
Literature search	25
Methodology adopted	30
Results and discussions	30
Conclusions and outcomes	20
Bibliography	20
Total	**150**

Evaluation of Presentation and Viva-voce: For 100 marks jointly by Internal and External Examiners

	Marks
Presentation of work	30
Communication skills	20
Total	**50**
Viva-voce	**50**

18. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree.

19. Duration for completion of the program

The duration for the completion of the program shall be four academic years (double the duration of the prescribed duration). In case, a student is not able to complete the program within this period, the candidate has to reregister for the program.

20. Revaluation of answer papers

There is a provision for revaluation of the answer papers of the end-semester examination as per Manipal Academy of Higher Education policy, however, the candidates have to apply separately by paying the prescribed fee.

21. Re-admission after break of study

The candidate who seeks re-admission to the program after taking a break of the study, has to get the approval from the university.

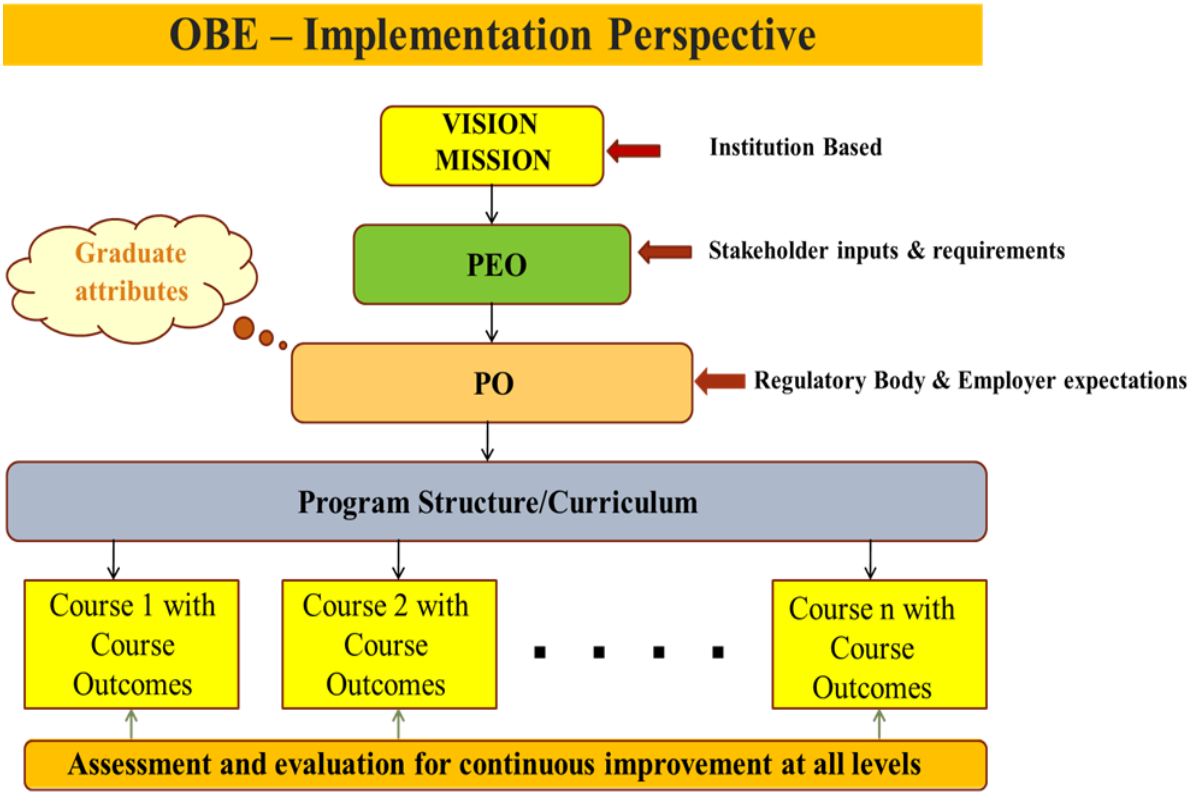
*****

OUTCOME BASED EDUCATION (OBE)

FRAMEWORK

Chapter II

Outcome Based Education (OBE) Framework



MCOPS Vision Mission

Vision:

“Excellence in Pharmaceutical Education and Research”

Mission:

“Marching with the Times”

Quality Policy

- **MCOPS is committed towards providing value-based pharmaceutical education to meet industry, hospital and community needs through continuous improvement of infrastructure and facility for learning, practice and research.**

- **MCOPS shall provide an environment conducive to the development of staff and students.**

MPharm Pharmaceutical Regulatory Affairs

Program Educational Objectives

The **Department of Pharmaceutical Quality Assurance**, Manipal College of Pharmaceutical Sciences, Manipal accomplishes to cultivate an attitude conducive to self-learning and lifelong learning that would:

PEO No	Education Objectives
PEO 1	Build an education leading to a Masters' degree in Pharmaceutical Regulatory Affairs with integrated professional knowledge and skills in interpreting regulatory guidelines and practices in a changing regulatory environment.
PEO 2	Equip the Masters' students with comprehensive knowledge and skills to deliver regulatory services in regulated, semi-regulated and poorly regulated markets.
PEO 3	Cultivate an inclination for higher education, consultancy and entrepreneurship.
PEO 4	Foster the best in-class hands-on training in dossier submissions as per global standards.
PEO 5	Empower and sensitize the regulatory affairs professionals to serve the pharmaceutical industry, academia, society and the business.

MPharm Pharmaceutical Regulatory Affairs
Program Outcomes (POs)

After successful completion of MPharm Pharmaceutical Regulatory Affairs program, students will be able to:

PO No	Attribute	Competency
PO 1	**Domain knowledge**	Demonstrate competency in regulatory guidance on drug approval research, registration and good regulatory practices (GxP).
PO 2	**Problem analysis**	Develop competency in problem identification, root cause analysis and solving.
PO 3	**Design/develop solutions**	Demonstrate competency in designing regulatory case studies and suggest remedies in situations of issuance of warning letters.
PO 4	**Conduct investigations of complex problems**	Implement the knowledge for conducting regulatory audits and investigations on quality issues in drug manufacturing and clinical research.
PO 5	**Modern tool usage**	Demonstrate competency in implementing modern tools like electronic Common Technical Document (e-CTD).
PO 6	**Business and society**	Demonstrate competency to be entrepreneurs in the Pharmaceutical field to serve the society.
PO 7	**Environment and sustainability**	Comprehend the impact of pharmaceutical industry operations on the environment and strive to make the pharmaceutical manufacturing sustainable.
PO 8	**Ethics**	Inculcate ethical values in the conduct of clinical research and in profession.
PO 9	**Individual / Teamwork**	Cultivate a sense of compliant partnering collaborative spirit in professional duties; develop transdisciplinary approaches in the area of pharmaceutical sciences through choice / problem-based learning.
PO 10	**Communication**	Conceptualize research ideas, develop oral and written communication skills including soft skills, frame and evaluate hypothesis by collating and interpreting data to draw meaningful conclusions.
PO 11	**Project management and finance**	Students will be skilled in managing human, financial and other resources efficiently to achieve the project objectives and stake holder's satisfaction.
PO 12	**Life-long learning**	Cultivate a temperament that would enable individuals to work towards self-driven performance-goals, entrepreneurial ventures and overall leadership to tackle future challenges through lifelong learning and staying ahead of times.

CHAPTER – III

- **Course Work**
- **COs POs Mapping**
- **Course Outcomes**
- **Course Content and Assessment Plan**
- **Syllabus in detail**

Course work of MPharm – Pharmaceutical Regulatory Affairs (MRA) specialization						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
Semester I						
PRM-MRA101T	Good Regulatory Practices	4	--	--	4	100
PRM-MRA102T	Documentation and Regulatory Writing	4	1	--	5	100
PRM-MRA103T	Clinical Research Regulations	4	1	--	5	100
PRM-MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights	4	1	--	5	100
PRM-MRA105P	Regulatory Affairs Practical I	--	--	12	6	150
PRM-MRA106S	Seminar*	--	--	2	1	100
	Total	**16**	**3**	**14**	**26**	**650**
Semester II						
PRM-MRA201T	Regulatory Aspects of Drugs and Cosmetics	4	1	--	5	100
PRM-MRA202T	Regulatory Aspects of Herbal and Biologicals	4	1	--	5	100
PRM-MRA203T	Regulatory Aspects of Medical Devices	4	1	--	5	100
PRM-MRA204T	Regulatory Aspects of Food and Nutraceuticals	4	1	--	5	100
PRM-MRA205P	Regulatory Affairs Practical II	--	--	12	6	150
PRM-MRA206S	Seminar*	--	--	2	1	100
	Total	**16**	**4**	**14**	**27**	**650**
* No end-semester examination. Only continuous mode.						

Course work for MPharm III and IV semesters (Common for all specializations)						
Course Code	**Course Title**	**Credit hours/week**			**Credit Points**	**Marks**
		Lecture (L)	**Tutorial (T)**	**Practical (P)**		
PHA-MRM301T	Research Methodology and Biostatistics*	**4**	--	--	**4**	**100**
MJC302P	Journal Club*	--	--	**2**	**1**	**100**
MRW401P	Research Work	--	--	**70**	**35**	**600**
Total		**4**	--	**72**	**40**	**800**
***** No end-semester examination.						

PROGRAM OUTCOMES (POs) AND COURSE OUTCOMES (COs) MAPPING

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
1	PRM-MRA101T	Good Regulatory Practices	4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO3 CO4	CO1 CO2 CO4	CO1 CO3 CO4	CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4
2	PRM-MRA102T	Documentation and Regulatory Writing	5	CO1 CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO2 CO3 CO4 CO5	CO3 CO4	CO2 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO3 CO4	CO1 CO3 CO4	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5
3	PRM-MRA103T	Clinical Research Regulations	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3	CO1 CO2 CO3	CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1	CO1 CO2 CO3	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5
4	PRM-MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights	5	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4		CO2	CO1 CO2 CO3 CO4			CO1 CO2 CO3 CO4	
5	PRM-MRA105P	Regulatory Affairs Practical I	6	CO1 CO2	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2	CO1 CO2
6	PRM-MRA106S	Seminar*	1	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3		CO2	CO2	CO1 CO2 CO3	CO1 CO2 CO3		CO1 CO2 CO3
7	PRM-MRA201T	Regulatory Aspects of Drugs and Cosmetics	5	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3				CO1 CO2 CO3	CO1 CO2 CO3	CO1 CO2 CO3
8	PRM-MRA202T	Regulatory Aspects of Herbal and Biologicals	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5		CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5

S No	Course Code	Course Name	Credits	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO1O	PO11	PO12
9	PRM-MRA203T	Regulatory Aspects of Medical Devices	5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5	CO1 CO2 CO3 CO4 CO5		CO2 CO3 CO4	CO1 CO2		CO1 CO2 CO3 CO4 CO5		CO1 CO2 CO3 CO4 CO5
10	PRM-MRA204T	Regulatory Aspects of Food and Nutraceuticals	5	CO1 CO2 CO3	CO2	CO1 CO2 CO3	CO1 CO3	CO1 CO2 CO3	CO2	CO1 CO2 CO3	CO1 CO2 CO3		CO1 CO2 CO3		CO1 CO2 CO3
11	PRM-MRA205P	Regulatory Affairs Practical II	6	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4		CO1 CO2 CO3 CO4		CO2 CO4	CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4		CO1 CO2 CO3 CO4	CO1 CO2 CO3 CO4
12	PRM-MRA206S	Seminar*	1	CO1	CO1 CO2		CO2 CO5					CO3	CO3 CO4 CO5		CO6
13	PHA-MRM301T	Research Methodology and Biostatistics*	4	CO1		CO1	CO2	CO2						CO1	
14	MJC302P	Journal Club*	1	CO1	CO1		CO1					CO2 CO3	CO3		CO4
15	MRW401P	Research Work	35	CO1	CO1	CO4	CO5	CO5	CO6	CO3	CO3		CO5 CO6	CO2	

Chapter III

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I

PRM-MRA101T: GOOD REGULATORY PRACTICES

COURSE CODE	PRM-MRA101T
COURSE TITLE	GOOD REGULATORY PRACTICES (Theory)

SCOPE / SUMMARY	OBJECTIVES / COURSE OUTCOMES
This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements to comply them.	After completion of this course, it is expected that students will be able to understand: 1. The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices. 2. To prepare and implement the checklists and SOPs for various Good Regulatory Practices. 3. To implement Good Regulatory Practices in the Healthcare and related Industries. 4. The preparation and conduct of audits and inspections.

Course Content and Assessment Plan

Sl. No	Course Content	Syllabus (Chapters or Units with hours)	Marks of assessment	Distribution of marks of assessment		
				Sessional exam (*30% of marks of assessment)*		End Sem exam (*70% of marks of assessment)*
				S1	S2	
1	Will learn the good manufacturing guidelines of United States of America, European Union and World Health Organization.	Unit 1 (10 hrs)	20	5		15
2	Will learn the good laboratory practice guidelines of United States of America, ISO and Quality Council of India along with inspection process and documentation.	Unit 2 (8 hrs)	16	6		10
3	Will understand the laboratory automation and evaluation of software.	Unit 3 (10 hrs)	20	4	1	15
4	Will learn the distribution principle, supply chain management and good practices of World Health Organisation, United States of America and India.	Unit 4 (12 hrs)	24		9	15
5	Will learn the various methods, guidelines and deployment of quality management systems	Unit 5 (12 hrs)	25		5	20
		Total Marks of Assessment	105	15	15	75

PRM-MRA101T: GOOD REGULATORY PRACTICES

THEORY **52 hrs**

1. Current Good Manufacturing Practices: Introduction, US cGMP, Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device – International Medical Device Regulation Forum (IMDRF) guidance documents. **10 hrs**

2 Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and QCI Standards **08 hrs**

3 Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards **10 hrs**

4 Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards **12 hrs**

5 Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents. **12 hrs**

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150. 6. Drugs & Cosmetics Act, Rules & Amendments.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I

PRM-MRA102T: DOCUMENTATION AND REGULATORY WRITING

COURSE CODE	PRM-MRA102T
COURSE TITLE	DOCUMENTATION AND REGULATORY WRITING

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.	Upon completion of this course the student should be able to: 1. Understand various documents pertaining to drugs in pharmaceutical industry 2. Understand the basics of regulatory compilation 3. Understand the auditing activities in Pharmaceutical industry 4. Inspection activities and quality system requirements in Pharmaceutical industry 5. Create and assemble the regulation submission as per the requirements of agencies and follow up the submission and post approval document requirements.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Will understand the documentation in pharmaceutical industry such as EPDB, PD, PDR, BMR, BPR, CoA, SMF, DMF etc.	Unit I (08 hrs)	16	6		10
2	Will understand about the dossier preparation and submission in ACTD, CTD, NeeS and validating the submissions. Organizing, processing and validation of submission. Submission in Sugam system of CDSCO.	Unit II (12 hrs)	24	9		15
3	Will understand the concept of Auditing in pharmaceutical industry, GHTF and ISO documents on audit, inspection of	Unit III (10 hrs)	19		4	15

	manufacturing facilities by regulatory agencies.					
4	Will understand about the inspection of pharmaceutical manufacturers, drug distribution channels, inspection reports and CAPA.	Unit IV (10 hrs)	19		4	15
5	Will understand the concept of Product life cycle management, prior approval supplements, scale up post approval changes, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard.	Unit V (12 hrs)	27		7	20
Total Marks of Assessment			105	15	15	75

PRM-MRA102T: DOCUMENTATION AND REGULATORY WRITING

THEORY **52 hrs**

1. Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF). **08 hrs**

2. Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO. **12 hrs**

3. Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance documents. ISO 13485. **10 hrs**

4. Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA). **10 hrs**

5. Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard. **12 hrs**

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001.
8. Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001.
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997.
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications.
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications.
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I

PRM-MRA103T: CLINICAL RESEARCH REGULATIONS

COURSE CODE	PRM-MRA103T
COURSE TITLE	CLINICAL RESEARCH REGULATIONS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices and related guidelines.	Upon completion of the course, the student shall be able to understand the regulations governing: 1. Clinical drug development process. 2. The importance of ethical conduct of clinical research and the clinical research regulations of India, US and EU. 3. The GCP guidelines of India and ICH 4. The Safety and Efficacy guidance of ICH on clinical research. 5. Biostatistics principles in clinical research, BA/BE requirements, post marketing requirements, MedWatch, and Pharmacovigilance practices.

Course Content and Assessment Plan

Sl No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Students should be able to learn the types and phases of clinical trials	Unit I (12 hrs)	27	7		20
2	Students should be able to learn the importance of ethics in clinical trials and regulatory guidelines on clinical research in India, US and EU	Unit II (12 hrs)	28	8		20
3	Students should be able to learn ICH GCP and Indian GCP guidelines	Unit III (4 hrs)	7		2	5
4	Students should be able to learn ICH efficacy guidelines on clinical trials	Unit IV (12 hrs)	22		7	15
5.	Students should be able to learn biostatics principles in clinical research, safety reporting, pharmacovigilance and other related guidelines	Unit V (12 hrs)	21		6	15
	Total marks of assessment		105	15	15	75

PRM-MRA103T: CLINICAL RESEARCH REGULATIONS

THEORY **52 hrs**

Unit 1. Clinical Drug Development Process: Different types of Clinical Studies, Phases of clinical trials, Clinical Trial protocol, Phase 0 studies, Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points, Phase II studies (proof of concept or principle studies to establish efficacy), Phase III studies (Multi ethnicity, global clinical trial, registration studies), Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies, Key Concepts of Medical Device Clinical Evaluation, Key concepts of Clinical Investigation. **12 hrs**

Unit 2. Ethics in Clinical Research: Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki

Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. The ethics of randomized clinical trials, role of placebo in clinical trials, Ethics of clinical research in special population, Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data, Data safety monitoring boards.

Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research, Ethical principles governing informed consent process, Patient Information Sheet and Informed Consent Form. The informed consent process and documentation.

Regulations governing Clinical Trials

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA), NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug), NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant), ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)

FDA Guidance for Industry - Acceptance of Foreign Clinical Studies, FDA Clinical Trials Guidance Document: Good Clinical Practice,

EU: Clinical Research regulations in European Union (EMA) **12 hrs**

Unit 3: Clinical Research Related Guidelines: Good Clinical Practice Guidelines (ICH GCP E6), Indian GCP Guidelines, ICMR Ethical Guidelines for Biomedical Research, CDSCO guidelines, GHTF study group 5 guidance documents. **04 hrs**

Unit 4: Regulatory Guidance on Efficacy and Safety ICH Guidance's
E4 – Dose Response Information to support Drug Registration
E7 – Studies in support of General Population: Geriatrics
E8 – General Considerations of Clinical Trials
E10 – Choice of Control Groups and Related Issues in Clinical Trials,
E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population **12 hrs**

Unit 5: General biostatics principle applied in clinical research, USA & EU Guidance USA: FDA Guidance, CFR 21Part 50: Protection of Human Subjects, CFR 21Part 54: Financial Disclosure by Clinical Investigators, CFR 21Part 312: IND Application, CFR 21Part 314: Application for FDA Approval to Market a New Drug, CFR 21Part 320: Bioavailability and bioequivalence requirements, CFR 21Part 812: Investigational Device Exemptions, CFR 21Part 822: Post-market surveillance, FDA Safety Reporting Requirements for INDs and BA/BE Studies,
FDA Med Watch
Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, European Union: EMA Guidance, EU Directives 2001, EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use, EU Annual Safety Report (ASR), Volume 9A – Pharmacovigilance for Medicinal Products for Human Use, EU MDD with respect to clinical research, ISO 14155. **12 hrs**

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.

5.International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6.New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7.FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8.Country Specific Guidelines from official websites.
9.Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts /cdrh /cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org /products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application:
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDruga ndCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://www .mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I

PRM-MRA104T: REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

COURSE CODE	PRM-MRA104T
COURSE TITLE	REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart fundamental knowledge on regulations and legislations on manufacture, import registration, export, sale, and marketing authorization for Drugs & Cosmetics, Medical Devices, Biologicals, Herbals, and Food & Nutraceuticals in India.	Upon the completion of the course the student shall be able to: 1. Distinguish various acts and guidelines pertaining to Drugs & Cosmetics, Medical Devices, Biologicals, Herbals, and Food & Nutraceuticals industry in India. 2. Understand the regulatory requirements and approval process for Drugs & Cosmetics, Medical Devices, Biologicals, Herbals, and Food & Nutraceuticals in India 3. Comprehend the pharmacopoeia standards and stem cell regulation in India along with stability requirements under global scenario. 4. Understand the practice of Intellectual Property Rights (IPR) in India.

Course Content and Assessment Plan

Sl No	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Will understand various acts governing Drugs and cosmetics, Biologics, Herbals, Medical Devices and Food and Nutraceuticals in India	Unit I (14 hrs)	27	7		20

2	Will comprehend the governance of State and Central licensing authorities of India and understand the format of regulatory dossier filing for branded and generic products	Unit II (14 hrs)	28	8		20
3	Will understand the global standards of various regulatory agencies on BABE, stability studies and ethics in clinical and pre-clinical studies including stem cell research.	Unit III (14 hrs)	29		9	20
4	Will understand various aspects of IPR and significance in Pharma industry.	Unit IV (10 hrs)	21		6	15
Total Marks of Assessment			105	15	15	75

PRM-MRA104T: REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

THEORY **52 hrs**

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA, Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act. **14 hrs**

2. Regulatory requirements and approval procedures for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities.

Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

Format and contents of Regulatory dossier filing, Clinical trial/ investigations. **14 hrs**

3. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards, Bioavailability and Bioequivalence data (BA & BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study.

Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies

Animal testing: Rationale for conducting studies.

Ethical guidelines for human participants

ICMR-DBT Guidelines for Stem Cell Research **14 hrs**

4. Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs **10 hrs**

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO 10. Guidelines from official website of CDSCO

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I

PRM-MRA105P: REGULATORY AFFAIRS PRACTICAL I

COURSE CODE	PRM-MRA105P
COURSE TITLE	REGULATORY AFFAIRS PRACTICAL I

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This subject helps the students to gain an understanding of established procedures of industrial practice and the formats and contents of regulatory documents.	Upon completion of this course the student should be able to: 1. Consolidate the theory which they have studied. 2. Develop technical and cognitive skills. 3. Promote team work and increase motivation.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	**Distribution of assessment marks**	
				Sessional exam (25 *% of total marks of assessment)*	**End Sem exam** (75 *% of total marks of assessment)*
				S1	
1	Learn good documentation practices	Experiment No. 1 (6 hours)	10	5	5
2	Understand the preparation of quality documentation in pharmaceutical industry	Experiment Nos. 2 to 5 and 11 (30 hours)	20	5	15
3	Educate oneself on quality documentation	Experiment Nos. 6, 7 and 21 to 26 (48 hours)	40	10	30
4	Erudition of regulatory document contents and format of various countries	Experiment Nos. 8 to 10 and 12 to 20 (72 hours)	60	10	50
		Total Marks of Assessment	130	30	100

PRM-MRA105P: REGULATORY AFFAIRS PRACTICAL I

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I

PRM- MRA 106S: SEMINAR IN PHARMACEUTICAL REGULATORY AFFAIRS

COURSE CODE	PRM- MRA 106S
COURSE TITLE	SEMINAR IN PHARMACEUTICAL REGULATORY AFFAIRS

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This activity is designed to balance the transition of students to real life topics with curricular content.	Upon completion of the course the student shall be able to: 1. Develop communication skills both written and spoken. 2. Develop critical thinking. 3. Acquire the skills of group interaction, integrative discussion, exploring and mining literature and professional community connect. 4. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Content and Assessment Plan

Sl No.	**Course Content**	**Hours**	**Total Marks of assessment**	**Marks**
				End Sem exam
1	The students should be able to develop skills to gather, organize information, prepare a write up and present the information using AV tools, and defend a given topic in Pharmaceutical Regulatory Affairs.	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER II

PRM-MRA201T: REGULATORY ASPECTS OF DRUGS AND COSMETICS

COURSE CODE	PRM-MRA201T
COURSE TITLE	REGULATROY ASPECTS OF DURGS AND COSMETICS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.	Upon completion of the course, the student shall be able to know: 1. The regulatory approval process, registration procedures and regulations for API, drug products and cosmetics in US and Canada. 2. The regulatory approval process, registration procedures and regulations for API, drug products and cosmetics in EU, Australia and Japan. 3. The regulatory approval process, registration procedures and regulations for API, drug products and cosmetics in emerging markets.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Will understand US regulations NDA, ANDA, Supplemental drug application, Orphan drug and Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals.	Unit I (12 hrs)	21	6		15
2	Will learn the regulatory approval process, registration procedures and post marketing surveillance for API and drug product in EU, Australia and Japan.	Unit II (16 hrs)	34	9		25
3	Will understand the emerging markets in pharmaceutical industry and various committees across the	Unit III (24 hrs)	50		15	35

	globe, Cosmetic regulations in semi-regulated markets. Regulatory requirements for registration of drugs and post approval requirements in semi-regulated markets.					
Total Marks of Assessment			105	15	15	75

PRM-MRA201T: REGULATORY ASPECTS OF DRUGS AND COSMETICS

THEORY **52 hrs**

1. USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. **12 hrs**

2. European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post

marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan. **16 hrs**

3. Emerging Market: Introduction, Countries covered, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC).

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana), Brazil, ASEAN, CIS and GCC Countries, ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. **24 hrs**

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. 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.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu

8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asian Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instituute of South East Asian Studies, Singapore.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER II

PRM-MRA202T: REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

COURSE CODE	PRM-MRA202T
COURSE TITLE	REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOME**
This course is designed to impart fundamental knowledge on Regulatory Requirements for Biologics, Vaccine and herbals in India, USA and Europe.	Upon the completion of the course the student shall be able to: 1. Understand the regulatory requirements for development of Biosimilars in India. 2. Understand the USFDA regulations on Biologics and Biosimilars. 3. Understand the EU guidelines on biologics and similar biologics in the EU. 4. Understand the regulatory requirements for vaccine development and for blood and blood products in India, US and EU. 5. Understand the regulatory requirements and guidelines for herbal drug development.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Students should be able to learn the biosimilar development guidelines of India	Unit I (12 hrs)	27	7		20
2	Students should be able to learn the biologics and biosimilar development guidelines of USFDA	Unit II (12 hrs)	28	8		20
3	Students should be able to learn the biologics and biosimilar development guidelines of EU	Unit III (12 hrs)	22		7	15

4	Students should be able to learn the regulations on vaccine development and for blood and blood products in India, US and EU	Unit IV (12 hrs)	21		6	15
5.	Students should be able to learn the guidelines for herbal drug development	Unit V (4 hrs)	7		2	5
Total Marks of Assessment			105	15	15	75

PRM-MRA202T: REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

THEORY **52 hrs**

1. India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data, Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP. **12 hrs**

2 USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics. **12 hrs**

3 European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU. **12 hrs**

4 Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label

Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network). **12 hrs**

5 Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union. **04 hrs**

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh; Wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava; Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformatio/www.ihn-org.com
6. www.isbtweb.org
7. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
8. www.cdsco.nic.in
9. www.ema.europa.eu › scientific guidelines › Biologicals
10. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER II

PRM-MRA203T: REGULATORY ASPECTS OF MEDICAL DEVICES

COURSE CODE	PRM-MRA203T
COURSE TITLE	REGULATORY ASPECTS OF MEDICAL DEVICES (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU, ASEAN and various other countries along with WHO regulations.	Upon completion of the course, the student shall be able to understand 1. The classification and technical requirements of medical devices and IVDs and global standards 2. The ethical practices during clinical investigations, quality management and validation of medical devices. 3. Regulatory approval process for medical devices and IVDs and the life cycle management in the US 4. The classification and directive for various types of medical devices and IVDs in the European Union 5. The regulatory requirements and approval procedures in China, Japan and ASEAN countries.

Course Content and Assessment Plan

Sl. No	**Course contents**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam *(30% of marks of assessment)*		**End Sem exam** *(70% of marks of assessment)*
				S1	S2	
1	Will understand the life cycle and evaluate the principle of classification of Medical Devices and IVDs under GHTF	Unit I (12 hrs)	28	8		20
2	Will understand global standards and ethics to perform the clinical investigation pertaining to Medical device and related software and adverse event report system	Unit II (10 hrs)	22	7		15
3	Will learn the approval procedures and post marketing surveillance requirements of USFDA.	Unit III (10 hrs)	21		6	15
4	Will learn classification criteria and CE certification process for medical devices and IVDs under EMA.	Unit IV (10 hrs)	20		5	15
5	Will understand the registration process of Medical Devices and IVDs in ASEAN, China and Japan	Unit V (10 hrs)	14		4	10
		Total Marks of Assessment	105	15	15	75

PRM-MRA203T: REGULATORY ASPECTS OF MEDICAL DEVICES

THEORY **52 hrs**

1. Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.
   IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). **12 hrs**
2. Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)
   Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device **10 hrs**
3. USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.**10 hrs**
4. European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process. **10 hrs**
5. ASEAN, China & Japan: Medical Devices and IVDs, Regulatory 12 registration procedures, Quality System requirements and clinical Hrs evaluation and investigation.
   IMDRF study groups and guidance documents. **10 hrs**

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER II

PRM-MRA204T: REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS

COURSE CODE	PRM-MRA204T
COURSE TITLE	REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals and dietary supplements in India, USA and Europe.	Upon completion of the course, the student shall be able to: 1. Know the regulatory Requirements for nutraceuticals 2. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe. 3. Understand the import and export procedures of nutraceuticals.

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*30% of marks of assessment)*		**End Sem exam** (*70% of marks of assessment)*
				S1	S2	
1	Should learn the basics and history of nutraceuticals	10	20	5		15
2	Should learn the global nutraceutical requirements	10	20	5		15
3	Should understand Indian regulations governing nutraceuticals and recommended dietary allowances	10	20	5	-	15
4	Should understand the regulations, good manufacturing practices and labelling requirements for nutraceuticals in United States of America.	12	25		5	20
5	Should understand the European Union regulations governing nutraceuticals and learn the importance of recommended dietary allowances.	10	20		10	10
	Total Marks of Assessment		105	15	15	75

PRM-MRA204T: REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS

THEORY **52 hrs**

1. Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market. **10 hrs**

2 Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals. **10 hrs**

3 India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India. **10 hrs**

4 USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S **12 hrs**

5 European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe. **10 hrs**

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER II

PRM-MRA205P: REGULATORY AFFAIRS PRACTICAL II

COURSE CODE	PRM-MRA 205P
COURSE TITLE	REGULATORY AFFAIRS PRACTICAL II

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOME**
This course is designed to gain practical knowledge on various regulatory requirements to attain marketing authorization and dossier submission via eCTD for new/ generic pharmaceutical products and biologics to various regulatory agencies.	Upon completion of the course, the student shall be able to: 1. Understand change management, CAPA and preparing an audit checklist for various agencies. 2. Comprehend dossier preparation and submission via eCTD for drugs/ biologics to be submitted to various regulatory agencies. 3. Understand and comprehend the registration requirements and checklist for marketing authorization under various emerging markets in global scenario 4. Distinguish the requirements for CE marking for various classes of medical devices under the European union

Course Content and Assessment Plan

Sl No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Total Marks of assessment**	Distribution of assessment marks	
				Sessional exam (*30 % of total marks of assessment)*	**End Sem exam** (*70 % of total marks of assessment)*
				S1	
1	Experiments via case studies on change management/ change control and deviation. Document the analysis of raw materials as per official monograph and preparation of audit checklist for various agencies	Experiments 1 to 5 (40 hrs)	32	7	25
2	Preparation and submission of dossier via eCTD software for Drugs and Biologics to various agencies and compare the clinical trial application and prepare a checklist for registration of biologics under US, EU and India	Experiments 6 to 12 and 18 (40hrs)	32	7	25
3	Registration requirement comparison study in various emerging markets and prepare check list for market authorization	Experiments 13 to 17 (52 hrs)	46	11	35
4	Prepare a clinical investigation plan, checklist for CE marking and STED application for medical devices under European Union	Experiments 19 to 22 (24 hrs)	20	5	15
		Total Marks of Assessment	130	30	100

PRM-MRA205P: REGULATORY AFFAIRS PRACTICAL II

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER II

PRM- MRA 206S: SEMINAR IN PHARMACEUTICAL REGULATORY AFFAIRS

COURSE CODE	PRM- MRA 206S
COURSE TITLE	SEMINAR IN PHARMACEUTICAL REGULATORY AFFAIRS

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
The course is designed to create an environment where student gather information about an assigned topic in the relevant field. The student will develop writing skills, presentation skills and also defend their presentation effectively.	Upon completion of the course the student shall be able to: 1. Acquire knowledge to gather, organize, deliver information, and defend a given topic in the Pharmaceutical regulations. 2. Develop skills for communication on presenting concepts using audio-visual aids. 3. Effectively defending the presentation. 4. Acquire the skills of group interaction, integrative discussion, exploring and mining literature and professional community connect. 5. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Content and Assessment Plan

Sl. No.	**Course Content**	**Hours**	**Total Marks of assessment**	**Marks**
				End Sem exam
1	The students should be able to develop skills to gather, organize information, prepare a write up and present the information using AV tools, and defend a given topic in Pharmaceutical Regulatory Affairs.	2 hours/ week	100	No end-semester examination. Only continuous mode.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER III

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

COURSE CODE	PHA-MRM301T
COURSE TITLE	RESEARCH METHODOLOGY AND BIOSTATISTICS (Theory)

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with descriptive statistics principles and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.	Upon completion of the course the student shall be able to 1. Know the various components of research design and methodology. 2. Appreciate advanced statistical techniques in solving the research problems.

Course Content and Assessment Plan

Sl No.	**Course Content**	**Syllabus (Chapters or Units with hours)**	**Marks of assessment**	**Distribution of marks of assessment**		
				Sessional exam (*80% of marks of assessment)*		**End Sem exam**
				S1	S2	
1	Understand the General Research Methodology, and study design.	Unit I (10 hrs)	20	20		-
2	Study the statistical principles and their application in biostatistics. Besides, learning various techniques of biostatistics to interpret the study outcomes.	Unit II (12 hrs)	20	20		-
3	Learn the CPCSEA guidelines, records and SOPs related to handling and care of experimental animals.	Unit III (10 hrs)	15		15	-
4	Student will learn the history, principles and concepts of medical research.	Unit IV (10 hrs)	15		15	-
5	Learn history, basic principles for all medical research and additional principles for medical research combined with medical care.	Unit V (10 hrs)	10		10	-
		Total Marks of Assessment	80	40	40	-

PHA-MRM301T: RESEARCH METHODOLOGY AND BIOSTATISTICS

UNIT – I

General Research Methodology: Research objectives, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, null hypothesis, P values, degree of freedom, interpretation of P values. Type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi square test),

UNIT – III

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities and laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – IV

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships fatality.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research and additional principles for medical research combined with medical care.

MPHARM – PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER III

MJC 302P: JOURNAL CLUB IN PHARMACEUTICAL REGULATORY AFFAIRS

COURSE CODE	MJC 302P
COURSE TITLE	JOURNAL CLUB IN PHARMACEUTICAL REGULATORY AFFAIRS

SCOPE / SUMMARY	**OBJECTIVES / COURSE OUTCOMES**
The subject is designed to create an environment where students present a published research paper, and critically analyze it, that would enhance the communication, presentation and analytical skills of the students.	Upon completion of the course the student shall be able to: 1. Learn to organize complex research concepts using audio-visual aids. 2. Acquire communication and presentation skills. 3. Effectively respond to the questions raised by peers and stand scientific scrutiny. 4. Cultivate a sense of upgradation of knowledge through self and continuous learning

Course Outcome and Assessment Plan

Sl. No.	**Course Contents**	**Hours**	**Total Marks of assessment**	**Marks**
				End Sem exam
1	The students should be able to develop skills to gather, organize, deliver information, and defend a given research topic in pharmaceutical Regulatory Affairs.	2 hours/week	100	No end-semester examination. Only continuous mode.

MPHARM – CHOICE BASED INTERDISCIPLINARY COURSES

PCE-001E: GENERIC DRUG DEVELOPMENT

(15 hrs)

Introduction to Generic Drug Product Development, API, Analytical Methods Development and Methods Validation for Solid Oral Dosage Forms, Experimental formulation development, Scale-Up, Process Validation, Technology Transfer, Drug stability, QC, QA. Drug product performance in vitro, ANDA Regulatory approval process, BE and drug product assessment in vivo, SUPAC, Outsourcing BA and BE studies to CROs, Legal and legislative hurdles.

REFERENCES

1. Handbook of Pharmaceutical Generic Development, (oral dosage form volume 24 of Drug development series), Locum publishing house, USA.
2. Generic Drug Product Development-Solid Oral dosage form, Leon Shargel and Isadore Kanfer, Marcel Dekker, USA, ISBN: 0-8247-5460-3.

PCE-002E: PHARMACEUTICAL DISSOLUTION TECHNOLOGY

(15 hrs)

Introduction and importance of dissolution. Different Pharmacopoeial requirements (Ph. Eu. JP) on dissolution.	**2 hrs**
Theories of dissolution. Noyes & Whitney equation and Hixson & Crowell Cube root.	**2 hrs**
Compendial methods and official dissolution test apparatus.	**2 hrs**
Principles, concepts and requirements of new dissolution method developments.	**2 hrs**
Alternative methods for drug release studies.	**1 hr**
Recommended apparatus for drug release studies of suppositories, topical, transdermal, powder dosage forms, controlled release products, etc.	**1 hr**
Computation of dissolution data with statistical approaches, model dependent approaches and model independent approaches.	**2 hrs**
Development of IVIVC models.	**1 hr**
Brief account on Biosimilar, Biowaiver, ICH Q4B and new regulatory prospective in dissolution.	**2 hrs**

REFERENCES

1. Pharmaceutical Dissolution Testing by Umesh V. Banakar; Singapore: CRC Press – Taylor & Francis Group.
2. Pharmaceutical Dissolution Testing by Jennifer Dressman and Johannes Krämer; Singapore: Taylor & Francis Group.

PCE-003E: PARTICULATE DRUG DELIVERY SYSTEMS

(15 hrs)

Microparticulate drug delivery Systems: Introduction, advantages, disadvantages, types, methods of preparation & characterization, in vitro & in vivo evaluations and applications.

6 hrs

Nanoparticulate drug delivery Systems: Introduction, advantages, disadvantages, types, methods of preparation & characterization, in vitro & in vivo evaluations and applications.

9 hrs

REFERENCES

1. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
2. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)
3. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
4. Nanoteachnology in Drug Delivery, Melgardt M. De Villers, Pornanong Aramwit and Glen S Kwon, Springer.
5. Nanoparticulate Drug Delivery Systems, Deepak Thassu, Michel Delees and Yashwant Pathak, Informa Healthcare, NY, USA.
6. Nanoparticulates as Drug Carriers, Vladimir P Torchilin, Imperial College Press, London.

PCE-004E: 3D PRINTING IN PHARMACEUTICAL MANUFACTURING

(15 hrs)

Introduction, 3D printing technologies, printing based inkjet systems, Nozzle based deposition systems, Laser based writing systems, 3D printing for customized drug delivery systems, Limitations and challenges.

REFERENCES

1. 3D printing in pharmaceutics: A new tool for designing customized drug delivery systems. Goole Jonathan and Amighi Karim, Int. J Pharm. 499 (2016), 376-394.
2. 3D fabricated polymer-based drug delivery systems, Simon Moulton and Gordon G Wallace, J of Cont. Rel. 193 (2014), 27-34.
3. Fabrication of printed drug delivery systems. Natalja Genina, Ruzica Kolakovic, Mirja Palo, Daniela Fors, Helka Juvonen, Petri Ihalainen, Jouko Peltonen, Niklas Sandler, NIP 29 and Digital Fabrication (2013), 236-238.

PCH-001E: PREPARATIVE SEPARATION TECHNIQUES

(15 hrs)

1. Column chromatography: Introduction, stationary phase, mobile phase selection, column selection, sample loading techniques, elution technique. **9 hrs**
2. Flash chromatography: Principle, advantages, instrumentation, mobile phase selection, column selection, sample loading techniques, elution technique. **6 hrs**

PCH-002E: MOLECULAR MODELLING AND DRUG DESIGN

(15 hrs)

1. Molecular Geometry, Molecular mechanics, Quantum mechanics, Molecular dynamics, Pharmcophore, Molecular docking, Library generation and structure-based drug design. **12 hrs**
2. Database and Software Resources **3 hrs**

PCH-003E: HYPHENATED TECHNIQUES

(15 hrs)

Principle and applications of following hyphenated techniques

1. GC-MS	4. EC-MS	7. LC-MS-MS	10. GC-AES
2. LC-MS	5. CE-MS	8. GC-MS-MS	
3. LC-NMR	6. GC-IR	9. GC-NMR	

PCH-004E: CHEMICALS-ENVIRONMENT, HEALTH AND SAFETY

(15 hrs)

Chemical safety, Chemical hazards, handling of chemicals/gases, storage of chemicals, chemical waste disposal. **8 hrs**

First aid procedures **1 hr**

Good laboratory practices: **2 hrs**

Personal protection **1 hr**

Radioactive materials: Regulatory requirements, hazards, handling, storage, disposal, emergency procedures. **2 hrs**

Fire safety **1 hr**

PQA-001E: THEORY AND PRACTICE OF ANALYTICAL AND BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION

(15 hrs)

1. Introduction to the concept of validation. **1 hr**
2. Development of analytical method using UV/PDA spectroscopy, Fluorimetry, HPLC, LC-MS/MS. **4 hrs**
3. Validation of the analytical method as per ICH-Q2(R1). **3 hrs**
4. Development of bioanalytical method using HPLC and LC-MS/MS. **2 hrs**
5. Validation of bioanalytical method as per USFDA guidance. **3 hrs**
6. Introduction to Novel upcoming technologies in bioanalysis like dry matrix spot analysis. **1 hr**
7. Introduction to Analysis of therapeutic proteins and peptides. **1 hr**

Evaluation

Formative: Development of validation protocols & problem-based learning. (30%)

Summative: Open book periodical tests & end semester exam. (70%)

PQA-002E: GOOD DOCUMENTATION PRACTICES AND E-DOCUMENTATION PRACTICES IN PHARMACEUTICAL INDUSTRY

(15 hrs)

1. Introduction to GDP and E – documentation **3 hrs**
2. Basic levels of documentation **6 hrs**
    a. Level -1, Level-2, Level-3 and Level-4 documentation
3. Case studies in each level **3 hrs**
4. Open lab and e-documentation concept **3 hrs**

PQA-003E: TROUBLE SHOOTING IN HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

(15 hrs)

1. Introduction to HPLC modules and source of errors/malfunction in HPLC **5 hrs**
2. Startup preliminary checks for trouble shooting **6 hrs**
3. Trouble shooting in HPLC module wise including demonstration **4 hrs**

PQA-004E: PROFESSIONAL DEVELOPMENT

(15 hrs)

1. Introduction to Professional Career Development
2. Introduction to Career Planning: Self Assessment
3. Identifying Your Professional Talents
4. Introduction to Career Planning: Career Exploration
5. Developing Your Professional Resume
6. Enhancing Your Professional Resume
7. Preparing Your Career and Internship Cover Letters
8. Professional Communications
9. Preparing for Your Employment an Internship Interviews
10. Conducting Your Employment and Internship Interviews
11. Introduction to the Career Fair Search Process
12. Exploring Internship Options within Your Profession
13. Networking Search Strategies
14. Developing Your Professional Career Portfolio
15. Influencing Your Networking Partners
16. Essential practical skills and problem solving
17. communication of scientific information
18. IT skills.

Assessments:

- assignments
- case studies
- portfolios
- presentations

PQA-005E: STABILITY TESTING OF DRUGS AND BIOLOGICALS

(15 hrs)

1. Introduction to drug stability and its importance. **2 hrs**
2. Stability testing of drug substances and drug products as ICH Q1 series guidelines **11 hrs**
3. Stability testing of biotechnological/biological products as per ICH Q5C guidelines**. 2 hrs**

PQA-006E: USFDA DRUG REGULATORY AFFAIRS

(15 hrs)

1. Process of new drug development.
2. Contents of IND, NDA, CTD and eCTD, ANDA
3. SMF and DMF
4. Post marketing regulatory requirements.

PQA-007E: REST OF THE WORLD DRUG REGULATIONS

(15 hrs)

Legislation and regulations for import, manufacture, distribution and sale of drugs and pharmaceuticals in:

1. Brazil
2. ASEAN countries
3. CIS countries
4. GCC Countries.

PQA-008E: EVALUATION OF MEDICAL DEVICES

(15 hrs)

A. Biological evaluation of medical devices **10 hrs**

Scope, General principles applying to biological evaluation of medical devices, categorization of medical devices, testing, selection of biological evaluation tests, Assurance of test methods

B. Clinical evaluation of Medical devices **5 hrs**

Importance, scope, clinical evaluation in brief

PBT-001E: CLEAN ROOM CONCEPTS

(15 hrs)

Unit 1. Fundamental aspects of microbiology **3 hrs**

Morphology, Microscopy, Growth and Controlling Growth of Microorganisms.

Unit 2. Clean Room aspects **6 hrs**

Clean Room concepts, layout, facilities, HEPA and ULPA Filter, biosafety cabinets and various classes, biosafety levels, personnel controls.

Unit 3. Microbial monitoring, detection and enumeration of microorganisms **6 hrs**

Monitoring techniques, air samples, microbiological assessment of liquids, solids and semisolids, disposal of cultures.

REFERENCES

1. Cleanroom Microbiology for the Non-microbiology by David M. Carlberg, Second Edition CRC press, 2005.
2. Biopharmaceutical, Biochemistry and Biotechnology, Second Edition, Gary Walsh, Wiley Publishers, 2003.

PBT-002E: BIOSIMILARS

(15 hrs)

Unit -I Biosimilars- Introduction **7 hrs**

Definitions, Generics and Branded drugs, biosimilars, introduction to biologics, differences between biosimilars and generics, manufacturing process and technical challenges associated with production of biosimilar molecules, status of biosimilars. The role of patents in the drug industry and protein-based biopharmaceuticals.

Unit –II Guidelines on Similar Biologic: Regulatory Requirements for Registration and Marketing Authorization in India **8 hrs**

Principles for Development of Similar Biologics, Competent authorities, Selection of reference biologics, Quality consideration of similar biologics, Quality comparability study, Data requirement for preclinical study, clinical application and market authorisation, Post market data for similar biologics.

REFERENCES

1. Proposed guidelines for similar biologics in India, CDSCO.
2. Biosimilars and Interchangeable Biologics: Strategic Elements By Sarfaraz K. Niazi
3. Guidelines from Indian regulatory bodies such as CDSCO, DBT etc. issued time to time.
4. Relevant journals and periodicals.

PBT-003E: PRINCIPLES OF GENE CLONING

(15 hrs)

Unit I **3 hrs**

The aims of Gene Cloning: Techniques of gene manipulation, Outline of gene cloning.

Unit II **6 hrs**

Gene Cloning: Gene cloning procedure, tools required for gene cloning, cloning strategy, techniques for selection of clones, preservation of clones.

Unit III **6 hrs**

Applications of Gene Cloning: In production of therapeutic proteins, diagnostic proteins, transgenic animals and plants.

REFERENCES

1. Molecular biotechnology, Bernard R. Glick, Jack J. Pasternak, Cheryl L. Patten, 2010, ASM Press.
2. Biotechnology: The Biological Principles, M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury. 1998, Tata McGraw Hill Edition.

PBT-004E: TISSUE ENGINEERING

(15 hrs)

Unit I **5 hrs**

Introduction to Tissue Engineering: Animal cell culture fundamentals, concept and need of tissue engineering, historical prospective, current status, industry challenges

Unit II **5 hrs**

Biomaterials for Tissue Engineering: Overview, features of scaffold and biomaterials, types of biomaterials, nanofiberous material as biomaterial.

Unit III **5 hrs**

Applications of Tissue Engineering: in Bone tissue regeneration, vascular tissue engineering, skin regeneration, cardiac tissue engineering and neural tissue engineering.

REFERENCES

1. Principles of Tissue Engineering, 4th Edition, Robert Vanza, Robert Langer, Joseph Vacanti. 2014, Academic Press.
2. Exploring Nanotechnology in Healthcare, Edited by N. Udupa,, 2013, Manipal University Press.

PPR-001E: RETAIL PHARMACY PRACTICE

(15 hrs)

1. Retail Pharmacy Management: Site selection, acquisition of premises for a retail pharmacy, layout of drug store, Legal aspects of retail pharmacy (includes Schedule N requirement), role of retail pharmacist and Code of ethics for practicing pharmacists. **4 hrs**
2. Purchase and inventory control, stocking, sale promotion, maintenance of records, economics and management **5 hrs**
3. Communication skills **2 hrs**
4. Medication therapy management **2 hrs**
5. Patient counselling **2 hrs**

REFERENCES

1. Philip P. Gerbino. Remington: The Science and Practice of Pharmacy. Philadelphia, PA. Lippincott Williams & Wilkins. (latest edition)
2. Revikumar KG,Miglani BD. A Text Book of Pharmacy Practice. Career Publications (latest edition)
3. G Parthasarathi, Karin Nyfort Hansen, Milep C Nahata. A Textbook of Clinical Pharmacy Practice Essential Concept and Skill. Oriental Longman Private Limited (latest edition)
4. Ashley WE, Justin J. Community and clinical pharmacy services: A step-by-step approach. The McGraw-Hill Companies, Inc, USA

PPR-002E: FUNDAMENTALS OF MEDICAL WRITING

(15 hrs)

I. Introduction **2 hrs**

- Brief overview of scientific writing
- Scope and importance
- Different types and areas of writing
- Career and opportunities

2. Basic Need To Be A Good **4 hrs**

- Language and Style in Medical Writing
- Literature search

  -Data bases (Medline, PubMed, Cochrane)

- Searching principles (using MeSH, Pub Med)
- Developing searching strategy by PICO

- Cortical Analysis Scientific Paper
- Ethics in Publication (Plagiarism, Copy Rights etc)
- Reference Writing

- Different bibliographic styles
-Citation databases
-Software used in reference writing

3. Different Types of Medical Writing **7 hrs**

- Structured abstract writing
- Report writing and sub-types
- Medication leaflets/pills
- Clinical research form
- Informed consent
- Protocol writing
- Case record form
- PSUR
- News letter

4. MANUSCRIPT WRTING AND PUBLICATION **2 hrs**

- ICMJE guidelines
- How to prepare structured manuscript (IMRA)
- Presentation of data (tables , figures and algorithms)
- Conflict of interest
- Acknowledgement
- Publication issues

Assignments: Preparation of power point, poster, abstract writing, review article with hand on training in publication issues

REFERENCES

1.Janice R Mathews, Jobin M Bowen and Robert W Mathews .Successful scientific writing- A step by step guide for the biological and medical sciences; 1996

2. Piyush Gupta, Navjeevan Singh. How to write thesis and thesis protocol-A primer for medical, dental & nursing courses; 2014
3. John Kirkman. Good style –Writing for science & Technology; 1994
4. Jennifer peat, Elizabeth Elliot, Louise Bour. Scientific writing-Easy when you know how; 1994.

PPR-003E: SYSTEMATIC REVIEW AND META-ANALYSIS

(15 hrs)

1. Study designs: Introduction to Case-control studies, Cohort studies, Randomized controlled trials **1 hr**
2. Applied statistics: Descriptive statistics, Hypothesis, Null-hypothesis, type-1 & type-2 errors, power, p-value, Confidence intervals, Odds ratio, Relative risk (risk ratio), Fixed effects & Random effects, Concept of homogeneity & heterogeneity and tests for heterogeneity, Various types bias and methods to detect bias, Funnel plot, Effect size & effect size indices, Forest plot **3 hrs**
3. Evidence based clinical practice: Definition, importance, levels of evidence. **1 hr**
4. Systematic review and meta-analysis: Definition, types, importance, applications, Meta-analysis groups (Campbell Collaboration, Cochrane Collaboration) **1 hr**
5. Steps involved in conducting Systematic review and Meta-analysis: **5 hrs**
   a. Framing the question
   b. Literature search
   c. Assessing the quality of studies
   d. Selection of studies
   e. Data synthesis & Analysis
   f.Summarizing the evidence
   g. Interpretation of the findings
6. Introduction to softwares used in meta-analysis: MedCalc, Comprehensive Meta-analysis software, RevMan, Open meta-analysis **1 hr**
7. Writing a meta-analysis protocol, Literature search, Data synthesis &analysis (Assignments) **3 hrs**

REFERENCES:

1. Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.6 [updated September 2006]. In: The Cochrane Library, Issue 4, 2006. Chichester, UK: John Wiley & Sons, Ltd.

2. Borenstein, M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to Meta-Analysis. John Wiley & Sons, Ltd., 2009.

Pre-requisites: Knowledge of Biostatistics & Research Methodology, Web-based literature search

Evaluation: Based on Assignments

PPR-004E: PHARMACOKINETICS DATA ANALYSIS

(Employing WinNonlin)

(15 hrs)

1. Introduction to pharmacokinetic parameters: Elimination rate constant (ke), Elimination half-life, Bioavailability & AUC, Volume of distribution, Clearance, Bioequivalence 2 hrs
2. Bioavailability studies: In animal & human **2 hrs**
3. PK parameters for Oral & IV administration: Calculation of PK parameters for oral & IV administration by plotting concentration vs time graph (using semi-log graph paper) **2 hrs**
4. Introduction Phoenix WinNonlin: Data entry and data tools, graphs **2 hrs**
5. Non-compartmental analysis using (NCA) Phoenix WinNonlin: For Oral, IV, IV infusion, Sparse sampling and urinary excretion data **3 hrs**
6. Pharmacokinetic modeling: Compartment modelling, choosing the right compartment model, Simulating using PK model **2 hrs**
7. Bioequivalence data analysis: Parallel, Cross-over study data analysis **2 hrs**

REFERENCES

1. Gibaldi M, Perrier D. Pharmacokinetics. 2nd edition. Informa Healthcare; 2007.
2. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts & Applications. 4th edition. Lippincott Williams& Wilkins;2011.
3. Phoenix WinNonlin examples guide. Pharsight. A Certara Company; 2012
4. Phoenix WinNonlin Users guide. Pharsight. A Certara Company; 2012.
5. Guidance for Industry: Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs- General Considerations. US FDA. 2014.

Pre-requisites: Knowledge of basic pharmacokinetics.

Evaluation: Based on Assignments.

PHA-001E: CANCER BIOLOGY

(15 hrs)

Objectives/Course Outcomes

This course aims to provide students an extensive understanding about cancer and its effects on the human body. This course will also discuss the historical aspect of cancer research, basic chemotherapeutics and future scope in cancer research. All the topics will be presented in a simplified scientific manner with an emphasis on gaining a broad understanding of the disease.

1. Advanced Cell Biology- Structural and functional basis of cell, structure of chromosome and DNA, Cell cycle and its regulation. **3 hrs**
2. Molecular and genetic basis of cancer- Growth signaling, dysfunction of cell cycle leading to cancer, Oncogene, tumor suppressor gene, Apoptosis **6 hrs**
3. Cellular aspect of cancer- History of cancer, six hallmarks of cancer, Types of cancer, Metastasis, Cancer Prevention and Treatment. **3 hrs**
4. Current trends in Cancer research- Targets for development of cancer chemotherapeutics, its identification and relevance, Recent advancements in cancer therapy. **3 hrs**

PHA-002E: SCREENING METHODS FOR DRUG DEVELOPMENT

(15 hrs)

The course aims at providing the conceptual learning of a few basic pharmacological approaches to elucidate the pharmacological activity of a new chemical entity. The knowledge of screening methods facilitates the understanding of animal models, which closely mimics the human pathology, to screen the promising molecules for developing a new drug.

1. Introduction: General Screening techniques
2. Screening methods for local anesthetics
3. Screening methods for anti-hypertensive drugs
4. Screening methods for anti-arrhythmic drugs
5. Screening methods for anti-inflammatory drugs
6. Screening methods for analgesic drugs
7. Screening methods for antipyretic drugs
8. Screening methods for anticancer drugs
9. Screening methods for antidiabetic drugs

10. Screening methods for anti-dyslipidemia drugs
11. Screening methods for antiepileptic drugs
12. Screening methods for antidepressant drugs
13. Screening methods for antianxiety drugs
14. Screening methods for antiparkinsonian drugs
15. Screening methods for Alzheimer's disease related dementia

PHA-003E: FREE RADICAL BIOLOGY AND MEDICINE

(15 hrs)

Objectives

To provide fundamentals which are essential for researchers who wish to pursue problems of human health that involve free radicals, related oxidants, antioxidants, and antioxidant enzymes. Students will be able to understand, interpret, and critically think on issues associated with major causes of health problems.

1. Basics of free radicals in biology and medicine
2. Concept of oxidative stress in biology and diseases
3. Oxidative stress markers
4. Radical scavengers: The concept of antioxidants
5. Redox signaling and NRF2-ARE signaling mechanisms
6. Free radicals in inflammation and immune disorders
7. Free radicals in diabetes, obesity and metabolic disorders
8. Free radicals in cancer
9. Free radicals in cardiovascular diseases
10. Free radicals in neurodegenerative disorders
11. Free radicals and ageing
12. Free radicals in infectious diseases and antimicrobial-resistance
13. Free radicals in hepato-biliary diseases
14. Antioxidants screening methods: *In vitro* and *in vivo*
15. Recent advances in antioxidant discovery and development

Study material: Recent journal articles from reputed and Open Access Journals

PHA-004E: REGULATORY TOXICOLOGY IN DRUG DISCOVERY AND DEVELOPMENT

(15 hrs)

Objectives

This subject is to project the importance of safety testing in pre-clinical research and harmonized standards that they have to adopt for safety testing procedures.

Introduction: General Principles of Toxicology, Agencies and their guidelines regarding Toxicology studies, Concept of Good Laboratory practices. **3hrs**

Guidelines for safety testing

Pharmacological studies: Safety Pharmacology Studies for Human Pharmaceuticals, QT interval prolongation study in animals. **3 hrs**

Toxicity testing: Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies, Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies, Acute, subacute and Chronic toxicity in animals **4 hrs**

Special toxicity studies: Non-clinical Carcinogenicity studies, Genotoxicity studies, Reproductive toxicology, Immunotoxicity, Safety evaluation of Biotechnology- derived products. **5 hrs**

PCO-001E: NUTRACEUTICALS

(15 hrs)

Scope

Nutraceuticals:The food or part of food with additional health benefits are emerging as major health supplements for prevention, management and some-times cure of various diseases. In the current fast lifestyle, nutraceuticals are encroaching pharma markets not only in the developed but also in the developing countries. Therefore, an additional knowledge in nutraceuticals or health supplements add an edge to the student.

Objectives

The course proposes to offer a comprehensive knowledge on the nutraceuticals and their importance to prepare the student for a pursuit in the health food sector.

1. Introduction to nutraceuticals: Overview, classification, benefits of nutraceuticals, functional foods **3 hrs**
2. In organic supplements and vitamins **1 hr**
3. Probiotics, prebiotics and digestive enzymes **1 hr**
4. Dietary supplements and fibres **1 hr**
5. Antioxidants and PUFAs **2 hrs**

6. Herbs as health foods: Poly phenols and flavonoids (*Ginkgo biloba*, Tea, Citrus fruits, Grape, Soy); Carotene and fatty acids: (Curcuma, Tomato, Flax seed, Olive oil) **5 hrs**
7. Current market scenario of nutraceuticals **1 hr**
6. Regulatory requirements for nutraceuticals **1 hr**

REFERENCES

1. Biren Shah and A.K. Seth. Text Book of Pharmacognosy and Phytochemistry, Ed1, Elsevier Health Sciences, Gurgaon, Haryana, 2010. Pp 471-83
2. S.S. Agrawal and M. Paridhavi. Herbal Drug Technology, Ed2, Universities Press, Hyderabad, Telangana, 2012. Pp 710-21
3. Alberta N.A. Aryee and Joyce Irene Boye, Current and Emerging Trends in the Formulation and Manufacture of Nutraceuticals and Functional Food products, In, Nutraceutical and Functional Food Processing Technology Edt. Joyce Irene Boye, Ed.1. Wiley Blackwell, West Sussex UK, 2015. Pp 01-52
4. Rorimi E. Aluko, Functional Foods and Nutraceuticals Springer, New York, USA, 2012.
5. C.K Kokate, A.P. Purohot and S.B. Gokhale, Pharmacognosy, Vol 1 and 2, Ed. 46, Nirali Prakashan, Pune, 2010. Pp 6.01-6.16

PCO-002E: EXTRACTION, SEPARATION AND PURIFICATION OF PHYTOCONSTITUENTS

(15 hrs)

Scope

Herbal drugs are emerging as major source of biomedicines worldwide. Secondary metabolites or phytoconstituents are responsible for medicinal attributes of a plant. Extraction, separation, and purification of these secondary metabolite is an area of interest for researchers. Therefore, this subject will provide an insight on the topic so as to enable the students to carry their research on natural products effectively**.**

Objectives

To impart stronger scientific base in the area of extraction, isolation and purification principles and methodologies of crude drugs.

1.	Introduction to plant metabolites.	**1 hr**
2.	Extraction techniques: Principle, merits & demerits, applications of maceration, decoction, infusion, percolation, soxhlet extraction, supercritical fluid extraction, microwave-assisted extraction, ultrasound extraction (sonication), advanced phytonics method of extraction, expression and enfleurage method.	**5 hrs**
3.	Phytochemical screening of natural products	**2 hrs**
4.	Separation and purification of phytoconstituents: Fractional distillation, fractional liberation, sublimation, fractional crystallization, gel filtration, counter current extraction and chromatographic techniques like Paper Chromatography, TLC, HPLC, HPTLC, column chromatography, gas-liquid chromatography, droplet counter current chromatographyand electro-chromatography (Electrophoresis).	**7 hrs**

REFERENCES

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders, 2002. 16th Ed.
2. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, Phytochemistry, Medicinal Plants. Lavoisier, 1999
3. Kokate C.K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, Nirali Prakashan, Pune, 2008
4. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons, 2002.

PCO-003E: NANOPHYTOPHARMACEUTICALS

(15 hrs)

Scope

Nanotechnology is a cutting-edge technology that provides optimal effectiveness in low doses. The course addresses and provides an overview of phytopharmaceuticals in nano size for better therapeutic benefits along with toxicity. Students will be able to understand the benefits of nano-phytopharmaceuticals.

Objectives

To study the effectiveness in low doses and enhancement of bioavailability of phytopharmaceuticals for better therapeutic values

1. Definition and history of nanotechnology **1 hr**
2. Properties – optical, electrical and magnetic properties of nanomaterials **2 hrs**
3. Preparation techniques – Polymeric nanoparticles, liposomes, micelles and herbal nanoparticles **6 hrs**
4. Toxicity studies **2 hrs**
5. Applications of phytopharmaceuticals, nanophytopharmaceuticals in the treatment of certain diseases **4 hrs**

REFERENCES

1. Nano: The Essentials: Understanding Nanoscience and Nanotecnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
2. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G. U. Kulkarni, Springer (2007)
3. Nanostructures & Nanomaterials: Synthesis, Properties & Applications, Guozhong Cao, Imperial College Press (2004).
4. Nanoparticles as Drug carriers, Vladimir P Torchilin, Imperial College Press, USA, 2006
5. Multifunctional Pharmaceutical Nanocarriers, Vladimir Torchilin, Springer Publishing, New York, NY, 2008.

PCO-004E: HERBAL MONOGRAPHS

(15 hrs)

Scope

A monographs is written document intended to promote information exchange and international harmonised standards for the quality control and use of herbal medicines. It contains scientific information on selected medicinal plants that serves as a summary for quality assurance, clinical applications and dosage forms. The proposed course is designed to study and understand herbal monographs

Objectives

To impart knowledge on systematic study of herbal drugs with reference its identity, quality and purity

1. Introduction to monographs, purpose and content of the monographs, use of the monographs **3 hrs**
2. Systematic study of the following important plants for their monographs; **12 hrs**

   Leaf: Vasaka (*Adhatoda zeylanica)*

   Root: Shatavari (*Asparagus racemosus)*

   Rhizome:Rasna *(Alpinia galanga)*

   Bark: Cinchona (*Cinchona officinalis)*

   Fruit: Pepper (*Piper nigrum)*

   Entire herb: Kalmegh *(Andrographis paniculata).*

REFERENCES

1. WHO monographs on selected medicinal plants. – Geneva: WHO. – Vol. 1. 1999, – Vol. 2. 2002, – Vol. 3: 2004, – Vol. 4. 2005.
2. Quality Standards of Indian Medicinal Plants – Indian Council of Medical Research, New Delhi.
3. Indian Herbal Pharmacopoeia – A Joint Publication of RRL, Jammu and IDMA, Mumbai.

PRM-001E: RETAIL BUSINESS MANAGEMENT

(15 hrs)

Scope

This course is formulated to impart knowledge on retail management. It also provides an overview about the nitty-gritties of managing a pharmacy store and an overview of Online Pharmacies.

1. Introduction to Retail Management **3 hrs**
2. Strategies in Retailing **3 hrs**
3. Retail Marketing in rural areas **3 hrs**
4. Pharmacy Store Management **4 hrs**
5. Online Pharmacy Retailing **2 hrs**

REFERENCES

1. Retail Management by Barry Berman. Person Education 11th Edition.
2. Retail Management by Chetan Bajaj. Oxford 2nd Edition.
3. Retail Management: Text and Cases by UC Mathur. IK International Publishing House Pvt. Ltd.

PRM-002E: INTELLECTUAL PROPERTY MANAGEMENT

(15 hrs)

Scope

This course deals with Intellectual Property Rights with special emphasis on Patents.

1. Basic Concepts of Intellectual Property Rights	**3 hrs**
2. Patent Administration in India and Patent Filing	**3 hrs**
3. Revocation of Patents and Patent Infringement Cases	**3 hrs**
4. Data Protection and Exclusivity	**3 hrs**
5. Patent as a business tool	**3 hrs**

REFERENCES

1. Basic Concepts of Intellectual Property Rights by Manthan D Janodia. Manipal University Press, 2015.

2. Intellectual Property Rights by SRS Rosedar. Lexis Nexis 2016.

3. Intellectual Property Rights in India by VK Ahuja. Lexis Nexis, 2015.

4. Law relating to Intellectual Property by BL Wadehra. Universal Law Publishing, 2016.

PRM-003E: GENERAL MANAGEMENT PRINCIPLES

(15 hrs)

Scope

This course is designed to facilitate students to inculcate managerial skills. It includes major concepts of management.

1. Introduction to management concepts	**3 hrs**
2. Decision Making	**3 hrs**
3. Leadership and Motivation	**4 hrs**
4. Conflict Management	**3 hrs**
5. Ethical Issues related to Management	**2 hrs**

REFERENCES

1. Organisational Behaviour by Stephen P. Robbins, Prentice – Hall, India

2. Management, A global Perspective by Heinz, Weihrich and Harold Koontz. Mc Graw Hill publishing company.

3. Management, tasks, responsibilities and practices by Drucker. Peter. F., Alfied Publisher Pvt. Ltd.

4. Principles and Practice of Management by L M Prasad, Sultan Chand & Sons.

PRM-004E: ENTREPRENEURSHIP DEVELOPMENT

(15 hrs)

Scope

This course is designed to impart knowledge and skills on entrepreneurship development.

1. Entrepreneur and Entrepreneurship	**3 hrs**
2. Entrepreneurial Development	**3 hrs**
3. Launching and Organizing an enterprise	**3 hrs**
4. Cost and Pricing	**3 hrs**
5. Project proposal development for start-up	**3 hrs**

REFERENCES

1. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.

2. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.

3. Entrepreneurship Management by Vasant Desai. Himalaya Publishing House, 2011.

MPHARM – CHOICE BASED MULTIDISCIPLINARY COURSE

- **MU-001E: Certificate Course in Bioinformatics**
- **MU-002E: Project Management**
- **MU-003E: Certificate Course in Bioethics**
- **MU-004E: Academic Research and Writing**
- **MU-005E: Certificate Course in Biosecurity**

(As prescribed from time to time)