ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2. Every student, selected for admission to PG 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.

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance 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 respective courses.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes 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

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 The Semester grade point average (SGPA):

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 five 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:

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

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:

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

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. 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 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:

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

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 7: Pharmaceutical Regulatory Affairs (MRA)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MRA 101T	Good Regulatory Practices	4	4	10	20	30	70	100
MRA 102T	Documentation and Regulatory Writing	4	4	10	20	30	70	100
MRA 103T	Clinical Research Regulations	4	4	10	20	30	70	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals, Herbals & Food and Neutraceuticals in India & Intellectual Property Rights	4	4	10	20	30	70	100
MRA 105P	Regulatory Affairs Practical - I	2	6	15	15	30	70	100
MRA 106P	Regulatory Affairs Practical - II	2	6	15	15	30	70	100
MRA 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**

Table 7: Pharmaceutical Regulatory Affairs (MRA) continued

II Semester								
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	10	20	30	70	100
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	10	20	30	70	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	10	20	30	70	100
MRA 204T	Regulatory Aspects of Food & Neutraceuticals	4	4	10	20	30	70	100
MRA 205P	Regulatory Affairs Practical - III	2	6	15	15	30	70	100
MRA 206	Comprehensive Viva	2	---	---	---	---	---	50
MRA 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**
III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MRA 302	Journal Club*	2	2	50	---	---	---	50
MRA 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MRA 304	Seminar on selected topic	4	4	---	---	---	100	100
MRA 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MRA 401	Journal Club*	2	2	50	**---**	**---**	---	50
MRA 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MRA 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

DRUG REGULATORY AFFAIRS

PROGRAM OUTCOMES

PO1: This program is designed to impart fundamental knowledge on various Good Regulatory Practices

PO2: The student can prepare and implement the check lists and SOPs for various Good Regulatory Practices

PO3: Student can understand the various documentation pertaining to drugs in pharmaceutical industry.

PO4: Student can understand the basics of regulatory compilation

PO5: Student can understand the ethics of clinical and biomedical research and evaluation

PO6: This program is designed to impart fundamental knowledge on regulations and legislation in India

PO7: Student will be able to know about the clinical trial protocol.

PO8: Student will have the knowledge on comparison between brand and generics, BA/BEstudies

PO9: Student can gain professional knowledge on the regulatory requirements and management of pharmaceuticals, cosmetics, and food products

PROGRAM SPECIFIC OUTCOMES

Upon completion of the program, the student will be able

PSO1: To prepare for the readiness and conduct of audits and inspections

PSO2: To implement the goals of laboratory quality audit

PSO3: To study USP, GDP(Supply chain integrity), relevant CDSCO guidance and ISO standards

PSO4: To gain knowledge on various aspects of pharmaceutical regulatory affairs and management

PROGRAM EDUCATIONAL OBJECTIVES

Upon completion of the program, the student will be able

1. To know 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 study about ICH guidelines Q2,Q3,Q7,Q8,Q9,Q10&Q11
3. To assemble the regulatory submissions as per the regulatory agency requirements
4. To learn about guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research
5. To impart knowledge on Code of Federal Regulations regarding clinical trials and application processes.

DRA Course outcomes:

Class	Course / Course code	Course objectives	Course outcomes
M.Pharm Semester -I	GOOD REGULATORY PRACTICES (MRA 101T)	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 and will propose ways and means of complying with them.	1. Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices. 2. Prepare and implement the check lists and SOPs for various Good Regulatory Practices 3. Implement Good Regulatory Practices in the Healthcare and related Industries 4. Prepare for the readiness and conduct of audits and inspections.
M.Pharm Semester -I	DOCUMENTATION AND REGULATORY WRITING (MRA 102T)	This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.	1. Various documents pertaining to drugs in pharmaceutical industry. 2.understand the basics of regulatory compilation 3.Create and assemble the regulation submission as per the requirements of agencies 4.Follow up the submissions and post approval document requirements

M.Pharm Semester -I	CLINICAL RESEARCH REGULATIONS (MRA 103T)	This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.	1. History, origin and ethics of clinical and biomedical research and evaluation. 2.Clinical drug, medical device development process and different types and phases of clinical trials 3.Regulatory requirements and guidance for conduct of clinical trials and research
M.Pharm Semester -I	REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)	This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.	1. Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India. 2. The approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

		For manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.	
M.Pharm Semester -I	REGULATORY AFFAIRS PRACTICAL-I (MRA 105P)	This course is designed to impart the fundamental knowledge on the good manufacturing practices,quality control tests,stability and validation. It prepares the student to learn in detail on BA/BE studies,CTD, IND.NDA and ANDA.	1 GPP,Analytical reports, clinicaltrialprotocol, reports. 2. Comparison between brand and generics, BA/BE studies,requirements of CTD, IND, ANDA and NDA submissions. 3. Regulatory approval of drugs by CDSCO, Indian patent scenario.
M.Pharm Semester -I	REGULATORY AFFAIRS PRACTICAL-II (MRA 106P)	This course is designed to impart the fundamental knowledge on USFDA warning letters,IMPD for EU submissions, Marketing Authorization,DMF systems in EU, US and JAPAN.It prepares the students to learn in detail on CTA, conduction of clinical trials and compiling dossier and site master file.	1.USFDA authorities,IMPD for EU submissions,comparative study of regulatory requirements. 2.Regulatory requirements for ECTD in EU, US and India. 3.Writing validation and stability protocols. 4. Compiling of dossier and site master file.

M.Pharm Semester -II	REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)	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.	1. The process of drug discovery and development and generic product development 2. Regulatory approval process and registration procedures for API and drug products in US, EU 3. Cosmetics regulations in regulated and semi-regulated countries 4. A comparative study of India with other global regulated markets
M.Pharm Semester -II	REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)	This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products	1. Regulatory Requirements for Biologics and Vaccines 2. Regulation for newly developed biologics and biosimilar 3. Pre-clinical and clinical development considerations of biologics 4. Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

M.Pharm Semester -II	REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)	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 and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.	1.Basics of medical devices and IVDs, process of development, ethical and quality considerations. 2. Harmonization initiatives for approval and marketing of medical devices and IVDs 3.Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN 4.Clinical evaluation and investigation of medical devices and IVDs
M.Pharm Semester -II	REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)	This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labelling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for Nutraceuticals and food	1. Regulatory Requirements for Nutraceuticals. 2. Regulation for registration and labelling of Nutraceuticals and food supplements in India, USA and Europe.

		supplements.	
M.Pharm Semester -II	REGULATORY AFFAIRS PRACTICAL-III (MRA 205T)	This course is designed to impart the fundamental knowledge on Deviations, CAPA, and submission of FDA,MHRA,and EMA.It prepares the registration of blood product and BLA,comparison study on emerging markets and medical devices facility.	1. The change controls, deviations,submission to EMA, MHRA,and FDA. 2. Vaccine product approvals,clinical trial applications and registration of blood and blood products. 3. Comparative study on emerging markets of WHO and BRICS.

Class / course	**Learning code**	**Learning outcome**
GOOD REGULATORY PRACTICES (MRA 101T) M.Pharm Semester -I	LMRA 101T-1	U.S and E.U GMP, GMAP-5,GHTF documents
	LMRA 101T-2	USFDA regulation process, audits, documentation, and inspection process.
	LMRA 101T-3	Principles, documentation, requirements and SOPs of GALP and relevant standards of ISO.
	LMRA 101T-4	WHO and US GDP, CDSCO guidance and ISO standards.
	LMRA 101T-5	QMS, OOS, validation, HVAC and ICH guidelines
DOCUMENTATION AND REGULATORY	LMRA 102T-1	EPDB, PDP, PDR, records, CoA, DMF and master file.
	LMRA 102T-2	CTD, ECTD, NEES, ACTD, SUGAM system of CDSCO.
	LMRA	Audits its types, preparation, submissions,

WRITING (MRA 102T) M.PharmSemester -I	102T-3	strategies, and timelines of audits.
	LMRA 102T-4	inspections, drug distribution channels, good manufacturing practices, route cause analysis and CAPA
	LMRA 102T-5	ICH Q12, life cycle management, FDA inspection and enforcement, warning letters, recalls, and ISO risk manufacture standards
CLINICAL RESEARCH REGULATIONS (MRA 103T) M.Pharm Semester -I	LMRA 103T-1	Types of clinical studies, phases of studies, clinical evaluation and clinical investigation
	LMRA 103T-2	Ethics in clinical research, ICH-GCP, CRO roles and responsibilities.
	LMRA 103T-3	Clinical research regulations in INDIA, U.S and EUROPE.
	LMRA 103T-4	ICH GCP guidelines**,** CDSCO guidelines ,ICH-E7,E8,E4,E10,E11,ICMR Ethical Guidelines for Biomedical Research
	LMRA 103T-5	USFDA CFR parts and EMA guidance documents of clinical research. FDA Safety Reporting Requirements for INDs and BA/BE Studies, FDA Med Watch ,Good Pharmacovigilance Practices and Pharmaco-epidemiologic Assessment
REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD &NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T) M.Pharm Semester -I	LMRA 104T-1	Drug and cosmetic act and rules, schedule M, NPPA and DPCO. Narcotics act ,magic remedies act , Pharmacy act
	LMRA 104T-2	regulatory requirements and regulatory approval of drugs and cosmetics, herbals and biologicals, food and Nutraceuticals as per CDSCO and state licensing authority
	LMRA 104T-3	ISO, Indian pharmacopeia, and BIS standards. Packaging regulations and requirements.
	LMRA 104T-4	BA&BE studies, ICH and WHO guidelines for drug testing.CPCSEA and ICMR guidelines for stem cell research.
	LMRA 104T-5	Patent, trade mark, copyright, industrial designs and difference between IPR and regulatory affairs.
REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T) M.Pharm Semester -II	LMRA 201T-1	FDA, CFR, Food Drug and Cosmetic Act, Hatch Waxman Act, Orange book, Purple book, ANDA, NDA, SNDA, IND, Drug Master File, Regulatory requirements for Orphan drugs, Regulations for Import, Manufacture, distribution of sale and cosmetic in USA and Canada.
	LMRA 201T-2	Organization and Structure of EMA and EDQM, ASMF system in EU, IMPD, Marketing Authorization Procedure in EU, Regulatory consideration for Manufacturing,

		labelling and packaging in EU, Compliance of Human Pharmacopeia/Certificate of suitability, Legislation and regulations for Import, Manufacture in EU, Australia
	LMRA 201T-3	Emerging Market(Countries Covered, Study of various committees among the world, Regulatory requirements for registration of drugs and post approval requirements, Certificate of Pharmaceutical Product
	LMRA 201T-4	Brazil, ASEAN, CIS and CGS Countries (Introduction to ACTD, Regulatory requirements for drugs and post approval changes in China, South Korea, and Association of Southeast Asian Nations i.e.; Vietnam, Malaysia, Philippines, Singapore, and Thailand.
	LMRA 201T-5	Regulatory Prerequisites related to marketing authorization requirements for drugs and post approval changes in CIS countries and GCC countries
REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T) M.Pharm Semester -II	LMRA 202T-1	In India , Applicable regulations and Guidelines, Principles and Post marketing surveillance for development of similar biologics, Data requirements for Preclinical studies, Clinical Trail application, and Market authorization application.
	LMRA 202T-2	In USA and EU, biological and biosimilar products, difference between generic and biosimilar, development and approval of biologics [NDA, IND, PMA, BLA,], preclinical and clinical considerations.
	LMRA 202T-3	Clinical evaluation, market authorization, registration/licensing, quality assessment, pharmacovigilance, blood and blood product regulation in India, US and EU
	LMRA 202T-4	Regulatory requirements for blood/ its components, label requirements, ISBT, IHN.
	LMRA 202T-5	Legislation of Herbal Products in India, US and EU
REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T) M.Pharm Semester -II	LMRA 203T-1	Risk based classification and principals of medical devices, IVD's and combination products, History of medical device regulation, Product life cycle and classification of medical devices, IMDRF/GHTF.
	LMRA 203T-2	Clinical investigation and plan for medical devices, Good clinical practices, ISO 14155:2011, ISO 13485, validation, verification and adverse reporting of

		medical devices.
	LMRA 203T-3	Regulatory approval process, 510k, post market approval, IDE and in-vitro diagnostics, CFR part 820, 801, post marketing surveillance and unique device identification in US.
	LMRA 203T-4	Regulatory approval process, in-vitro diagnostics, CE certification in EU
	LMRA 203T-5	Regulatory registration process, Quality system requirements and clinical evaluation and investigation, IMDRF and guidance documents, medical device 2017 regulation in ASEAN, China and Japan.
REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (MRA 204T) M.Pharm Semester -II	LMRA 204T-1	History of Food and Nutraceuticals regulations, scope and opportunities in Nutraceuticals market.
	LMRA 204T-2	WHO guidelines on nutrition, NSF, HACCP.
	LMRA 204T-3	Food safety and Standards act, Authority, Recommended dietary allowances in India.
	LMRA 204T-4	US food safety modernization act, Dietary supplement Health and Education act, Regulations, Recommended dietary allowance in US.
	LMRA 204T-5	European Food Safety Authority, EU directives and regulations for manufacturing, sale of Nutraceuticals, EU regulations on novel foods and food ingredients, Recommended dietary allowances in EU.

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

First Semester

GOOD REGULATORY PRACTICES (MRA 101T)

Unit 1:

Current Good Manufacturing Practices (cGMP): 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 and IVDs Global Harmonization Task Force (GHTF) Guidance docs. **12 Hours**

Unit 2:

Good Laboratory Practices (GLP): 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 Quality Council of India (QCI) Standards. **12 Hours**

Unit 3:

Good Automated Laboratory Practices (GALP): Introduction to GALP, principles of GALP, GALP requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21 CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards. **12 Hours**

Unit 4:

Principles, personnel, documentation, premises and equipment, deliveries to customers, returns, self-inspection, provision of information, stability testing principles, WHO Good Distribution Practices. USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards. **6 Hours**

Unit 5:

Quality management systems: Concept of quality, Total Quality Management, quality by design, six sigma concept, Out of Specifications (OOS), change controls.

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 Council for Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Schedule M-III and other relevant CDSCO regulatory guidance documents.

ICH Guidelines: Emphasis on Q2, Q3, Q7, Q8, Q9, Q10 & Q11 (draft Form) **18 Hours**

REFERENCES

1. Good Laboratory Practice Regulations - Sandy Weinberg, 4th ed. Drugs and The Pharmaceutical Sciences, Vol.168.
2. How to Practice GLP – P.P. Sharma. Vandana Publications.
3. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer. Drugs and The Pharmaceutical Sciences, Vol. 150.
4. Drugs & Cosmetics Act, Rules & Amendments, Government of India.
5. Good Pharmaceutical Manufacturing Practice, Rationale and Compliance - John Sharp. CRC Press.
6. Establishing a cGMP Laboratory Audit System, A Practical Guide - David M Bleisner. Wiley.

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Unit 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). **12 Hours**

Unit 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. Pharmaceutical Inspection & Convention Scheme and Pharmaceutical Inspection & Cooperation Scheme (PIC/S), ASEAN Pharmaceutical harmonization on initiative. **12 Hours**

Unit 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, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485. **12 Hours**

Unit 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)

. **12 Hours**

Unit 5:

Product life cycle management: ICH life cycle management (Q12), 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 Hours**

REFERENCES

1. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer, Raluca-loana Stefan & Jacobus F Van Staden. Taylor and Francis, 2005.
2. Handbook of Microbiological Quality Control - Rosamund M Baird, Norman A Hodges & Stephen P Denyar. CRC Press, 2000.
3. Juran's Quality Handbook - Joseph M Juran & Joseph A De Feo. 6th ed. ASQ Publications.
4. Compliance Auditing for Pharmaceutical Manufacturers - Karen Ginsbury & Gil Bismuth. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
5. Pharmaceutical Manufacturing Handbook: Regulations and Quality - Shayne Cox Gad. Wiley-Interscience, A John Wiley and Sons, Inc., Publications.

6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results - Al Endres. Wiley, 2000.
7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases - Jiju Antony. David Preece, Routledge, 2002.
8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report - Edward E Lawler III, Susan Albers Mohrman & George Benson. Jossey-Bass, 2001.
9. Corporate Culture and the Quality Organization - James W Fairfield-Sonn. Quorum Books, 2000.
10. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery & Diane Zabel. Routledge, 1997.
11. The Quality Toolbox - Nancy R Tague. 2nd ed. ASQ Publications.
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action - Duke Okes. ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

CLINICAL RESEARCH REGULATIONS (MRA 103T)

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 endpoints. 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 - PMS), 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 Hours**

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. The 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. **12 Hours**

Unit 3:

Regulations governing clinical trials in India: Clinical research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA). NDA505(b)(1) of the FD&C Act (Application for approval of a new drug) NDA505(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 Hours**

Unit 4:

Clinical research related guidelines: Good Clinical Practice Guidelines (ICHGCP E6), Indian GCP Guidelines. ICMR Ethical Guidelines for biomedical research. CDSCO guidelines GHTF study group 5 guidance documents, 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. General biostatistics principle applied in clinical research. **12 Hours**

Unit 5:

USA & EU Guidance: FDA Guidance. CFR 21 Part 50: Protection of human subjects. CFR 21 Part 54: Financial disclosure by clinical investigators. CFR 21 Part 312: IND Application. CFR 21 Part 314: Application for FDA Approval to market a new drug. CFR 21 Part 320: Bioavailability and bioequivalence requirements. CFR 21 Part 812: Investigational device exemptions. CFR 21 Part 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 Hours**

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance - Fay A Rozovsky & Rodney K Adams.
2. FDA Regulatory Affairs: a Guide for Prescription Drugs, Medical Devices, and Biologics - Douglas J Pisano & David Mantus. CRC Press, USA.
3. New Drug Approval Process: The Global Challenge – Guarino & A. Richard. Marcel Dekker Inc.
4. HIPAA and Human Subjects Research: A Question and Answer Reference Guide - J.D. Mark Barnes & J.D. Jennifer Kulynych.
5. Principles and Practices of Clinical Research, John I Gallin & Frederick P Ognibene. 2nd ed.
6. Reviewing Clinical Trials: A Guide for the Ethics Committee - Johan P E Karlberg & Marjorie A Speers. Hong Kong.
7. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy - Anthony C Cartwright. Taylor & Francis Inc., USA.

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS, HERBALS, FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Unit 1:

Drugs Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 1) Drugs and Cosmetics Act 1940 and Rules 1945: Schedule M, DPCO & NPPA. 2) Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotic Drugs and Psychotropic Substances Act; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act. **12 Hours**

Unit 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. **12 Hours**

Unit 3:

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards. Regulations for packaging material, packaging requirements & labeling requirements as per Rules 94, 95, 96, 97 & 105 D& C Rules 1945. **12 Hours**

Unit 4:

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, CPCSEA guidelines. Ethical guidelines for human participants. ICMR-DBT guidelines for stem cell research. **12 Hours**

Unit 5:

Intellectual property rights: Patent, trademark, copyright, industrial designs and geographical indications, Indian patent scenario, IPR vs regulatory affairs. **12 Hours**

REFERENCES

1. Manual of Patent Practice & Procedure - The Patent Office of India. 3rd ed.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put Innovators at Risk - James Bessen & Michael J Meurer.
3. Principles and Practice of Clinical Trial Medicine - Richard Chin & Bruce Y. Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants - 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 Guidelines — Good Clinical Practice - 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).
9. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
10. Guidelines for Import and Manufacture of Medical Devices – CDSCO.
11. Guidelines from official website of CDSCO.

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

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

REGULATORY AFFAIRS PRACTICAL – II (MRA 106P)

1. Case studies on response with scientific rationale to USFDA Warning Letter
2. Preparation of submission check list of IMPD for EU submission
3. Comparison study of marketing authorization procedures in EU
4. Comparative study of DMF system in US, EU and Japan
5. Preparation of regulatory submission using eCTD software
6. Preparation of Clinical Trial Application (CTA) for US submission
7. Preparation of Clinical Trial Application (CTA) for EU submission
8. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form
9. Regulatory requirements check list for conducting clinical trials in India
10. Regulatory requirements check list for conducting clinical trials in Europe
11. Regulatory requirements check list for conducting clinical trials in USA
12. Writing Stability Protocols as per ICH
13. Writing Validation Protocol of Water & AHU Systems
14. Writing & Compiling a Dossier
15. Writing & Compiling Site Master File

Second Semester

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Unit 1:

USA & Canada: Organization and functions of FDA. Federal register and Code of 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 Hours**

Unit 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. **12 Hours**

Unit 3:

Emerging market: Introduction, countries covered, study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC). 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 (India, South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana. **12 Hours**

Unit 4:

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. **12 Hours**

Unit 5:

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 and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries. **12 Hours**

REFERENCES

1. Generic Drug Product Development: Solid Oral Dosage Forms - Leon Shargel. Marcel Dekker Series, Vol. 143.
2. The Pharmaceutical Regulatory Process - Ira R Berry. Marcel Dekker Series, Vol.144.
3. Guidebook for Drug Regulatory Submissions - Sandy Weinberg. John Wiley & Sons. Inc.
4. New Drug Approval Process: Accelerating Global Registrations - Richard A Guarino, Vol 190. 5th ed. Drugs and the Pharmaceutical Sciences.
5. Drugs and the Pharmaceutical Sciences. Vol.185. Informa Health Care Publishers.
6. Drugs: From Discovery to Approval – N.G. Rick. 2nd ed.
7. New Drug Development: A Regulatory Overview - Mark Mathieu. 8th ed.
8. Pharmaceutical Risk Management - Jeffrey E Fetterman, Wayne L Pines & Gary H Slatko.
9. Preparation and Maintenance of the IND Application in eCTD Format - William K Sietsema.
10. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/List MRAWebsites
11. Roadmap to an ASEAN economic community - Denis Hew. ISEAS Publications. Singapore, 2005.
12. ASEAN - Rodolfo C. Severino. ISEAS Publications, Singapore.
13. Building a Future with Brics: The Next Decade for Offshoring - Mark Kobayashi-Hillary.
14. Outsourcing to India: The Offshore Advantage - Mark Kobayashi-Hillary. Springer Trade Performance and Regional Integration of the CIS Countries - Lev Freinkman.
15. The World Bank, Washington DC.
16. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World - Frederick M Abbott & Graham Dukes. Edward Elgar Publishing Inc.
17. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low

& Lorraine Carlos Salazar. ISEAS Publishing.
18. Doing Business in the Asean Countries - Balbir Bhasin. Business Expert Press.
19. Realizing the ASEAN Economic Community: A Comprehensive Assessment - Michael G Plummer & Chia Siow Yue. Published by Institute of Southeast Asian studies, Singapore.
20. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF HERBAL AND BIOLOGICS (MRA 202T)

Unit 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 Hours**

Unit 2:

USA & European Union: Introduction to biologics; biologics, biological and biosimilar, 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, labeling and packing of biologics in USA and EU. **12 Hours**

Unit 3:

Vaccine regulations in India, US and European Union: Clinical evaluation, marketing authorization, registration or licensing, quality assessment, pharmacovigilance, additional requirements. Blood and blood products regulations in India, US and European Union.

12 Hours

Unit 4:

Regulatory Requirements of Blood and/or its components including blood products, label requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemo vigilance Network). **12 Hours**

Unit 5:

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union. **12 Hours**

REFERENCES

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

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Unit 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 Life cycle 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 Hours**

Unit 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 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. **12 Hours**

Unit 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.

12 Hours

Unit 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. **12 Hours**

Unit 5:

ASEAN, China & Japan: Medical devices and IVDs, regulatory registration procedures. Quality system requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents. Medical Devices Act, 2017 Regulations. **12 Hours**

REFERENCES

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices - John J Tobin & Gary Walsh**.**
2. Medical Device Development: A Regulatory Overview - Jonathan S Kahan.
3. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics - Carmen Medina.
4. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (MRA 204T)

Unit 1:

Nutraceuticals: Introduction, history of Food and Nutraceutical Regulations, meaning of nutraceuticals, dietary supplements, functional foods, medical foods. Scope and opportunities in nutraceutical market**.** **12 Hours**

Unit 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, Hazard Analysis & Critical Control Point (HACCP). **12 Hours**

Unit 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. **12 Hours**

Unit 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. Labeling requirements and label claims for dietary supplements, Recommended dietary allowances (RDA) in the U.S. **12 Hours**

Unit 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 labeling. European regulation on novel foods and novel food ingredients. Recommended dietary allowances (RDA) in Europe. **12 Hours**

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective - Clare M Hasler. Wiley Online Library.
2. Nutraceutical and Functional Food Regulations in the United States and Around the World - 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/IPOLSTU (2015)536324_EN.pdf
5. Handbook of Nutraceuticals - Yashwant Pathak. CRC Press.
6. Food Regulation: Law, Science, Policy and Practice - Neal D Fortin. Wiley.
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL – III (MRA 205P)

Case studies on:

1. Change Management/ Change control. Deviations
2. Corrective & Preventive Actions (CAPA)
3. Documentation of raw materials analysis as per official monographs
4. Preparation of audit checklist for various agencies
5. Preparation of submission to FDA using eCTD software
8. Preparation of submission to EMA using eCTD software
9. Preparation of submission to MHRA using eCTD software
10. Preparation of Biologics License Applications (BLA)
11. Preparation of documents required for Vaccine Product Approval
12. Comparison of clinical trial application requirements of US, EU and India of Biologics.
13. Preparation of Check list for Registration of Blood and Blood Products
14. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization

16. STED Application for Class III Devices
17. Audit Check list for Medical Device Facility
18. Clinical Investigation Plan for Medical Devices.

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

General research methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, 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. **12 Hours**

Unit 4:

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net