M.PHARM (2020) REGULATIONS AND SYLLABUS

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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

<table>
<thead>
<tr>
<th>Theory-Criteria</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance</td>
<td>5</td>
</tr>
<tr>
<td>Student-Teacher Interaction</td>
<td>5</td>
</tr>
<tr>
<td>Theory sessional examination</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total theory internal assessment</strong></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Practical-Criteria</th>
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</tr>
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<tbody>
<tr>
<td>Attendance</td>
<td>5</td>
</tr>
<tr>
<td>Record + Viva-voce</td>
<td>10</td>
</tr>
<tr>
<td>Practical sessional examination</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total practical internal assessment</strong></td>
<td><strong>30</strong></td>
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</table>

2
2.2.1.1. Guidelines for the allotment of marks for attendance

<table>
<thead>
<tr>
<th>Percentage of Attendance</th>
<th>Theory/Practical</th>
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<tbody>
<tr>
<td>95-100</td>
<td>5</td>
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<tr>
<td>90-94</td>
<td>4</td>
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<tr>
<td>85-89</td>
<td>3</td>
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<tr>
<td>80-84</td>
<td>2</td>
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<tr>
<td>Less than 80</td>
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</tbody>
</table>

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 \textit{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:

<table>
<thead>
<tr>
<th>Criteria of Evaluation</th>
<th>Marks</th>
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</thead>
<tbody>
<tr>
<td>Seminar/Presentation of work</td>
<td>20</td>
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<tr>
<td>Objective(s) of the work done</td>
<td>20</td>
</tr>
<tr>
<td>Methodology adopted</td>
<td>40</td>
</tr>
<tr>
<td>Results and Discussion</td>
<td>40</td>
</tr>
<tr>
<td>Conclusions and Outcomes</td>
<td>30</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>150</strong></td>
</tr>
</tbody>
</table>

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 sessionals. 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.

<table>
<thead>
<tr>
<th>Percentage of marks</th>
<th>Grade</th>
<th>Grade points</th>
</tr>
</thead>
<tbody>
<tr>
<td>90.00 - 100</td>
<td>O</td>
<td>10.0</td>
</tr>
<tr>
<td>80.00 - 89.99</td>
<td>A</td>
<td>9.0</td>
</tr>
<tr>
<td>70.00 – 79.99</td>
<td>B</td>
<td>8.0</td>
</tr>
<tr>
<td>60.00 – 69.99</td>
<td>C</td>
<td>7.0</td>
</tr>
<tr>
<td>50.00 – 59.99</td>
<td>D</td>
<td>6.0</td>
</tr>
<tr>
<td>40.00 – 49.99</td>
<td>E</td>
<td>5.0</td>
</tr>
<tr>
<td>&lt; 40.00</td>
<td>F (Fail)</td>
<td>0.0</td>
</tr>
</tbody>
</table>

The grade W represents failure due to insufficient attendance in the semester or year

Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)

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:

\[ \text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4} \]

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:

\[ \text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 \times \text{ZERO}}{C_1 + C_2 + C_3 + C_4} \]

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:

\[ \text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4} \]

Where \( C_1, C_2, C_3, C_4 \ldots \) is the total number of credits for semester I, II, III and IV and \( S_1, S_2, S_3 \) and \( S_4 \) 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 \hspace{1cm} \text{Max. Marks: 70}

Part A (Question Numbers 1-5)
Answer any four questions out of five questions \hspace{1cm} 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) \hspace{1cm} 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>
<thead>
<tr>
<th>Code</th>
<th>Course</th>
<th>Credits</th>
<th>Hours/week</th>
<th>Internal Assessment</th>
<th>Semester End Exam</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Continuous mode</td>
<td>Sessional Exam</td>
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<tr>
<td>I Semester</td>
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<tr>
<td>MRA 101T</td>
<td>Good Regulatory Practices</td>
<td>4</td>
<td>4</td>
<td>10</td>
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<tr>
<td>MRA 102T</td>
<td>Documentation and Regulatory Writing</td>
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<td>10</td>
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<td>MRA 103T</td>
<td>Clinical Research Regulations</td>
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<tr>
<td>MRA 104T</td>
<td>Regulations and Legislation for Drugs &amp; Cosmetics, Medical Devices, Biologica</td>
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<td>MRA 105P</td>
<td>Regulatory Affairs Practical - I</td>
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**Total:** 650
### Table 7: Pharmaceutical Regulatory Affairs (MRA) continued

#### II Semester

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<td>MRA 201T</td>
<td>Regulatory Aspects of Drugs &amp; Cosmetics</td>
<td>4</td>
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<td>MRA 202T</td>
<td>Regulatory Aspects of Herbal &amp; Biologicals</td>
<td>4</td>
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<td>MRA 204T</td>
<td>Regulatory Aspects of Food &amp; Neutraceuticals</td>
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<td>MRA 205T</td>
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<td>MRA 207</td>
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#### III Semester

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<tr>
<td>MRM 301T</td>
<td>Research Methodology and Biostatistics*</td>
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<td>Journal Club*</td>
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<td>Discussion /Presentation (Dissertation Title &amp; Project Proposal)*</td>
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#### IV Semester

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* 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:

<table>
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<th>Class</th>
<th>Course / Course code</th>
<th>Course objectives</th>
<th>Course outcomes</th>
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</thead>
<tbody>
<tr>
<td>M.Pharm Semester -I</td>
<td>GOOD REGULATORY PRACTICES (MRA 101T)</td>
<td>This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food &amp; 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.</td>
<td>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.</td>
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| 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 & Herbs, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbs, and Food & Nutraceuticals. | 1. Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals  
2. The approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals |
### 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, clinical trial protocol, 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.
| 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 supplements in India, USA and Europe. | 1. Regulatory Requirements for Nutraceuticals.  
2. Regulation for registration and labelling of Nutraceuticals and food supplements in India, USA and Europe. |
### 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.

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<th>Class / course</th>
<th>Learning code</th>
<th>Learning outcome</th>
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<tr>
<td>GOOD REGULATORY PRACTICES (MRA 101T)</td>
<td>LMRA 101T-1</td>
<td>U.S and E.U GMP, GMAP-5, GHTF documents</td>
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<tr>
<td>M.Pharm Semester -I</td>
<td>LMRA 101T-2</td>
<td>USFDA regulation process, audits, documentation, and inspection process.</td>
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<td>LMRA 101T-3</td>
<td>Principles, documentation, requirements and SOPs of GALP and relevant standards of ISO.</td>
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<td>LMRA 101T-5</td>
<td>QMS, OOS, validation, HVAC and ICH guidelines</td>
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<td>DOCUMENTATION AND REGULATORY</td>
<td>LMRA 102T-1</td>
<td>EPDB, PDP, PDR, records, CoA, DMF and master file.</td>
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<td>LMRA 102T-2</td>
<td>CTD, ECTD, NEES, ACTD, SUGAM system of CDSCO.</td>
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<td>LMRA</td>
<td>Audits its types, preparation, submissions,</td>
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<td>Course Title (MRA 102T)</td>
<td>LMRA 102T-3</td>
<td>Description</td>
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<td>WRITING M.Pharm Semester -I</td>
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<td>strategies, and timelines of audits.</td>
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<td>LMRA 102T-4</td>
<td>inspections, drug distribution channels, good manufacturing practices, route cause analysis and CAPA</td>
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<td>LMRA 102T-5</td>
<td>ICH Q12, life cycle management, FDA inspection and enforcement, warning letters, recalls, and ISO risk manufacture standards</td>
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<td>LMRA 103T-1</td>
<td>Types of clinical studies, phases of studies, clinical evaluation and clinical investigation</td>
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<td>LMRA 103T-2</td>
<td>Ethics in clinical research, ICH-GCP, CRO roles and responsibilities.</td>
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<td>LMRA 103T-3</td>
<td>Clinical research regulations in INDIA, U.S and EUROPE.</td>
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<td>LMRA 103T-4</td>
<td>ICH GCP guidelines, CDSCO guidelines, ICH-E7,E8,E4,E10,E11,ICMR Ethical Guidelines for Biomedical Research</td>
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<td>LMRA 103T-5</td>
<td>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 Pharmacoepidemiologic Assessment</td>
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<tr>
<td>REGULATIONS AND LEGISLATION FOR DRUGS &amp; COSMETICS, MEDICAL DEVICES, BIOLOGICALS &amp; HERBALS, AND FOOD &amp;NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T) M.Pharm Semester -I</td>
<td>LMRA 104T-1</td>
<td>Drug and cosmetic act and rules, schedule M, NPPA and DPCO, Narcotics act, magic remedies act, Pharmacy act</td>
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<td>LMRA 104T-2</td>
<td>regulatory requirements and regulatory approval of drugs and cosmetics, herbals and biologicals, food and Nutraceuticals as per CDSCO and state licensing authority</td>
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<td>LMRA 104T-3</td>
<td>ISO, Indian pharmacopeia, and BIS standards. Packaging regulations and requirements.</td>
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<td>LMRA 104T-4</td>
<td>BA&amp;B E studies, ICH and WHO guidelines for drug testing, CPCSEA and ICMR guidelines for stem cell research.</td>
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<td>LMRA 104T-5</td>
<td>Patent, trade mark, copyright, industrial designs and difference between IPR and regulatory affairs.</td>
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<td>LMRA 201T-2</td>
<td>Organization and Structure of EMA and EDQM, ASMF system in EU, IMPD, Marketing Authorization Procedure in EU, Regulatory consideration for Manufacturing.</td>
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<tr>
<td>REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)</td>
<td>In India, Applicable regulations and Guidelines, Principles and Post marketing surveillance for development of similar biologies, Data requirements for Preclinical studies, Clinical Trial application, and Market authorization application.</td>
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<td>REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)</td>
<td>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.</td>
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<tr>
<td>LMRA 201T-3</td>
<td>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</td>
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<td>LMRA 201T-4</td>
<td>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.</td>
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<td>LMRA 201T-5</td>
<td>Regulatory Prerequisites related to marketing authorization requirements for drugs and post approval changes in CIS countries and GCC countries</td>
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<td>LMRA 202T-1</td>
<td>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.</td>
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<tr>
<td>LMRA 202T-2</td>
<td>Clinical evaluation, market authorization, registration/licensing, quality assessment, pharmacovigilance, blood and blood product regulation in India, US and EU</td>
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<td>LMRA 202T-3</td>
<td>Regulatory requirements for blood/ its components, label requirements, ISBT, IHN.</td>
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<td>LMRA 202T-4</td>
<td>Legislation of Herbal Products in India, US and EU</td>
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<td>LMRA 203T-1</td>
<td>Clinical investigation and plan for medical devices, Good clinical practices, ISO 14155:2011, ISO 13485, validation, verification and adverse reporting of</td>
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<td>LMRA 203T-3</td>
<td>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.</td>
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<td>LMRA 203T-4</td>
<td>Regulatory approval process, in-vitro diagnostics, CE certification in EU</td>
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<tr>
<td>LMRA 203T-5</td>
<td>Regulatory registration process, Quality system requirements and clinical evaluation and investigation, IMDRF and guidance documents, medical device 2017 regulation in ASEAN, China and Japan.</td>
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<tr>
<td>LMRA 204T-1</td>
<td>History of Food and Nutraceuticals regulations, scope and opportunities in Nutraceuticals market.</td>
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<tr>
<td>LMRA 204T-2</td>
<td>WHO guidelines on nutrition, NSF, HACCP.</td>
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<td>LMRA 204T-3</td>
<td>Food safety and Standards act, Authority, Recommended dietary allowances in India.</td>
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<tr>
<td>LMRA 204T-4</td>
<td>US food safety modernization act, Dietary supplement Health and Education act, Regulations, Recommended dietary allowance in US.</td>
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<tr>
<td>LMRA 204T-5</td>
<td>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.</td>
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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
3. Laboratory Auditing for Quality and Regulatory Compliance - Donald C Singer. Drugs and The Pharmaceutical Sciences, Vol. 150.
5. Good Pharmaceutical Manufacturing Practice, Rationale and Compliance - John Sharp. CRC Press.
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).

Unit 2:

Unit 3:

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).

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.

REFERENCES
11. The Quality Toolbox - Nancy R Tague. 2nd ed. ASQ Publications.

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:

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:

12 Hours

Unit 5:


12 Hours

REFERENCES

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

Unit 1:

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

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).
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 – CDSCO.
10. 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. Comparative 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:

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
6. Drugs: From Discovery to Approval – N.G. Rick. 2nd ed.
15. The World Bank, Washington DC.
17. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low
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
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
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).

Unit 2:

Unit 3:

Unit 4:

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.

REFERENCES
3. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics - Carmen Medina.

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.

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

**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**

**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
6. Preparation of submission to EMA using eCTD software
7. Preparation of submission to MHRA using eCTD software
8. Preparation of Biologics License Applications (BLA)
9. Preparation of documents required for Vaccine Product Approval
10. Comparison of clinical trial application requirements of US, EU and India of Biologics.
11. Preparation of Check list for Registration of Blood and Blood Products
12. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
13. 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
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 (Wilcoxon 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-malefeasance, 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
4. www.cpcsea.nic.in
5. www.wma.net