Revised Regulations for the
Master of Pharmacy Degree Program
(w.e.f. June 2016)

Credit Based Semester System

M.PHARM. PHARMACEUTICAL REGULATORY
AFFAIRS (MRA)

Pharmacy Council of India
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg,
New Delhi-110 002
CHAPTER – I: REGULATIONS

1. Short Title and Commencement
These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission
A Pass in the following examinations
   a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

   b) Every student, selected for admission to post graduate 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.

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

3. Duration of the program
The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations
Medium of instruction and examination shall be in English.

5. Working days in each semester
Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.
6. Attendance and progress
A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

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

7.1. Credit assignment
7.1.1. Theory and Laboratory courses
Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements
The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table V. Courses generally progress in sequence, building competencies and their positioning indicates certain academic
maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work
A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study
The specializations in M.Pharm program is given in Table 1.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Specialization</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cosmeceutics</td>
<td>MCC</td>
</tr>
<tr>
<td>2.</td>
<td>Industrial Pharmacy</td>
<td>MIP</td>
</tr>
<tr>
<td>3.</td>
<td>Pharmaceutical Analysis</td>
<td>MPA</td>
</tr>
<tr>
<td>4.</td>
<td>Pharmaceutical Biotechnology</td>
<td>MPB</td>
</tr>
<tr>
<td>5.</td>
<td>Pharmaceutical Chemistry</td>
<td>MPC</td>
</tr>
<tr>
<td>6.</td>
<td>Pharmaceutics</td>
<td>MPH</td>
</tr>
<tr>
<td>7.</td>
<td>Pharmacognosy</td>
<td>MPG</td>
</tr>
<tr>
<td>8.</td>
<td>Pharmacology</td>
<td>MPL</td>
</tr>
<tr>
<td>9.</td>
<td>Pharmacy Practice</td>
<td>MPP</td>
</tr>
<tr>
<td>10.</td>
<td>Pharmaceutical Quality Assurance</td>
<td>MQA</td>
</tr>
<tr>
<td>11.</td>
<td>Pharmaceutical Regulatory Affairs</td>
<td>MRA</td>
</tr>
</tbody>
</table>

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – II to XIII. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – II to XIII.
<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs/wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Semester I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRA101T</td>
<td>Good Pharmaceutical Practices</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA102T</td>
<td>Pharmaceutical Regulations in India</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA103T</td>
<td>International Pharmaceutical Regulations I</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA104T</td>
<td>Clinical Research Regulations</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA105T</td>
<td>Pharmaceutical Regulatory Affairs Practical I</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>- Seminar/Assignment</td>
<td>7</td>
<td>4</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>35</td>
<td>26</td>
<td>35</td>
<td>650</td>
</tr>
<tr>
<td></td>
<td>Semester II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRA201T</td>
<td>Documentation and Regulatory Writing</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA202T</td>
<td>Biologicals Regulations</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA203T</td>
<td>International Pharmaceutical Regulations II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA204T</td>
<td>Medical Device Regulations</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MRA205P</td>
<td>Pharmaceutical Regulatory Affairs Practical II</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>- Seminar/Assignment</td>
<td>7</td>
<td>4</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>35</td>
<td>26</td>
<td>35</td>
<td>650</td>
</tr>
</tbody>
</table>
Table – 13: Course of study for M. Pharm. III Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRM101T</td>
<td>Research Methodology and Biostatistics*</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Journal club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Discussion / Presentation</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>(Proposal Presentation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Research Work</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>21</strong></td>
</tr>
</tbody>
</table>

* Non University Exam

Table – 14: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Journal Club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Research Work</td>
<td>31</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Discussion/Final Presentation</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>35</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>

Table – 15: Semester wise credits distribution

<table>
<thead>
<tr>
<th>Semester</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>26</td>
</tr>
<tr>
<td>II</td>
<td>26</td>
</tr>
<tr>
<td>III</td>
<td>21</td>
</tr>
<tr>
<td>IV</td>
<td>20</td>
</tr>
<tr>
<td>Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)</td>
<td>Minimum=02 Maximum=07*</td>
</tr>
<tr>
<td>Total Credit Points</td>
<td>Minimum=95 Maximum=100*</td>
</tr>
</tbody>
</table>

*Credit Points for Co-curricular Activities
Table – 16: Guidelines for Awarding Credit Points for Co-curricular Activities

<table>
<thead>
<tr>
<th>Name of the Activity</th>
<th>Maximum Credit Points Eligible / Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)</td>
<td>01</td>
</tr>
<tr>
<td>Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)</td>
<td>02</td>
</tr>
<tr>
<td>Academic Award/Research Award from State Level/National Agencies</td>
<td>01</td>
</tr>
<tr>
<td>Academic Award/Research Award from International Agencies</td>
<td>02</td>
</tr>
<tr>
<td>Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)</td>
<td>01</td>
</tr>
<tr>
<td>Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)</td>
<td>02</td>
</tr>
</tbody>
</table>

Note: International Conference: Held Outside India
International Journal: The Editorial Board Outside India

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows:

   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

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

11. Examinations/Assessments
The schemes for internal assessment and end semester examinations are given in Table – XVII.

11.1. End semester examinations
The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall be conducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.
<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous Mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sessional Exams</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEMESTER I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRA101T</td>
<td>Good Pharmaceutical Practices</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA102T</td>
<td>Pharmaceutical Regulations in India</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA103T</td>
<td>International Pharmaceutical Regulations I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA104T</td>
<td>Clinical Research Regulations</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA105T</td>
<td>Pharmaceutical Regulatory Affairs Practical I</td>
<td>20</td>
<td>30</td>
<td>6 Hrs</td>
</tr>
<tr>
<td>-</td>
<td>Seminar /Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total 650</td>
</tr>
<tr>
<td>SEMESTER II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRA201T</td>
<td>Documentation and Regulatory Writing</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA202T</td>
<td>Biologicals Regulations</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA203T</td>
<td>International Pharmaceutical Regulations II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA204T</td>
<td>Medical Device Regulations</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MRA205P</td>
<td>Pharmaceutical Regulatory Affairs Practical II</td>
<td>20</td>
<td>30</td>
<td>6 Hrs</td>
</tr>
<tr>
<td>-</td>
<td>Seminar /Assignment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total 650</td>
</tr>
</tbody>
</table>
Tables – 28: Schemes for internal assessments and end semester examinations (Semester III & IV)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous Mode</td>
<td>Sessional Exams</td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marks</td>
<td>Duration</td>
<td>Total Marks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEMESTER III</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRM101T</td>
<td>Research Methodology and Biostatistics*</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td></td>
<td>- Journal club</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>- Discussion / Presentation (Proposal Presentation)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>- Research work*</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>100</td>
<td>1 Hr</td>
<td>525</td>
</tr>
<tr>
<td>SEMESTER IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Journal club</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>- Discussion / Presentation (Proposal Presentation)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>- Research work and Colloquium</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>500</td>
<td>1 Hr</td>
<td>500</td>
</tr>
</tbody>
</table>

*Non University Examination
11.2. Internal assessment: Continuous mode
The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

<table>
<thead>
<tr>
<th>Theory</th>
<th>Maximum Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria</td>
<td></td>
</tr>
<tr>
<td>Attendance (Refer Table – 30)</td>
<td>8</td>
</tr>
<tr>
<td>Student – Teacher interaction</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Practical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance (Refer Table – 30)</td>
</tr>
<tr>
<td>Based on Practical Records, Regular viva voce, etc.</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

11.2.1. Sessional Exams
Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

12. Promotion and award of grades
A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks
In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

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

15. Reexamination of end semester examinations
Reexamination of end semester examination shall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

<table>
<thead>
<tr>
<th>Table – 31: Tentative schedule of end semester examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semester</td>
</tr>
<tr>
<td>I and III</td>
</tr>
<tr>
<td>II and IV</td>
</tr>
</tbody>
</table>

16. Allowed to keep terms (ATKT):
No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances
17.1. Letter grades and grade points allocations:
Based on the performances, 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 in Table – 32:
A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. 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:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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 ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4*ZERO}{C_1 + C_2 + C_3 + C_4}$$

19. 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 $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I, II, III, \ldots and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I, II, III, \ldots.

20. Declaration of class
The class shall be awarded on the basis of CGPA as follows:
- First Class with Distinction = CGPA of 7.50 and above
- First Class = CGPA of 6.00 to 7.49
- Second Class = CGPA of 5.00 to 5.99

21. Project work
All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.
**Evaluation of Dissertation Book:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective(s) of the work done</td>
<td>50</td>
</tr>
<tr>
<td>Methodology adopted</td>
<td>150</td>
</tr>
<tr>
<td>Results and Discussions</td>
<td>250</td>
</tr>
<tr>
<td>Conclusions and Outcomes</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>500</strong></td>
</tr>
</tbody>
</table>

**Evaluation of Presentation:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation of work</td>
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</tr>
<tr>
<td>Communication skills</td>
<td>50</td>
</tr>
<tr>
<td>Question and answer skills</td>
<td>100</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>250</strong></td>
</tr>
</tbody>
</table>

22. **Award of Ranks**

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. **Award of degree**

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

24. **Duration for completion of the program of study**

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. **Revaluation / Retotaling of answer papers**

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. **Re-admission after break of study**

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.
M.PHARM. PHARMACEUTICAL REGULATORY AFFAIRS
(MRA)
GOOD REGULATORY PRACTICES (MRA 101T)

Scope
This course is designed to impart fundamental knowledge biological and medical devices on various—Good Regulatory Practices viz., cGMP, GLP, GALP and GDP pharmaceutical industries and understand the rationale behind these requirements and will propose ways and means of complying them.

Objectives
At completion of this course it is expected that students will be able to understand—
- The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices
- The check lists for various Good Regulatory Practices and
- Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Regulatory Practices in the Health care Industries and
- Prepare for the Audit of the Pharmaceutical Industries.
- Prepare for the rediness and conduct of the audit/inspections

THEORY
60Hrs


12Hrs

2. Good Laboratory Practices: Introduction,USFDA GLP Regulations (Subpart A to Subpart K),Controlling the GLP inspection process,GLP Documentation,Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, ISO

12Hrs


12Hrs


12Hrs

5. Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and
REFERENCES
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
REGULATIONS LEGISLATIONS FOR FOOD PMBC IN INDIA (MRA 102T)

Scope:
This course is designed to impart fundamental knowledge on regulations and legislations in India with respect to PMBC. It prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives:
Upon the completion of the course the student shall be able to:
- Know different Acts and guidelines that regulate PMBC industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices.

THEORY 60 HOURS

UNIT I
Study of Relevant provisions of FPMBC

Acts and Rules (with latest amendments):
- Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC , Rules 1945: DPCO and NPPA
- Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs & Packing of drugs & other related Acts-Narcotic etc

Central Drug Standard Control Organization and State Licensing Authority:
1. Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations
2. Format and contents of Regulatory dossier filling
3. Clinical trials /Investigations
   - Clinical Trials
     - New Drugs
   - Medical Devices
   - Fixed Dose Combinations

12 Hrs
UNIT II
Regulatory requirements FNPCMB and approval procedures for: 12 Hrs

UNIT III
Indian Pharmacopoeial standards
   BIS Standards & ISO and other relevant standards
UNIT IV
BA/BE: Bioavailability and Bioequivalence data, 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 Hrs

UNIT V

REFERENCES
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO
INTERNATIONAL REGULATORY ASPECTS OF FNPCMB (MRA103T)

Scope:
This course is designed to impart the fundamental knowledge on the drug development general regulatory requirements for approval of FNPCMB Japan. It prepares the students to have elementary knowledge on the regulatory requirements, documentation requirements, and registration procedures for marketing the products in above countries.

Objectives: Upon completion of the course, the student shall be able to understand the Regulatory registration and landscape

THEORY 60 Hours

Unit-I 12 Hours

Unit-II 12 Hours
EUROPEAN UNION and 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

Unit-III 12 Hours
Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations
for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

UNIT IV
BRAZIL and CHINA

UNIT V
ASEAN and SOUTH ASIA

REFERENCES:
Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144

4. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
CLINICAL RESEARCH REGULATIONS (MRA 104T)

Scope:
This course is designed to impart the fundamental knowledge on the clinical development process of FNPCMB, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in INDIA. 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 trials and investigations.

Objectives: Upon completion of the course, the student shall be able to (know, do and appreciate)
- Clinical drug development process and different phases of clinical trials, investigations
- History, origin and ethics of clinical research
- Regulatory requirements for conducting clinical trials investigations and research
- Regulations and guidance governing the conduct of clinical research,

THEORY 60 Hours
Unit-I 12 Hours
Basics for Clinical trials for drug development process
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

Unit-II 12 Hours
Basic CT for MD Ethics in Clinical Research:
- 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

Unit-III 12 Hours

Regulations governing Clinical Trials

USA: Regulations to conduct drug studies in USA (FDA)
- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

India: Clinical Research regulations in India – Schedule Y

Unit-IV 12 Hours

Clinical Research Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

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

Unit-V 12 Hours

USA & EU Guidance

USA: FDA Guidance
- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
CFR 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

**REFERENCES:**

2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA

**RECOMMENDED WEBSITES:**

8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf
PRACTICALS (MRA105P)
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
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA
DOCUMENTATION AND REGULATORY WRITING (MRA 201T)

Scope
This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives
Upon completion of the course the student shall be able to:
1. Know the 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

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).

   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


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)

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

REFERENCES

5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
BIOLOGICS REGULATIONS (MRA 203T)

Scope
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.

Objectives
Upon the completion of the course the student shall be able to:
- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory 60 Hrs

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

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

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

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

12 Hrs

Unit V


12 Hrs

REFERENCES

2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
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
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics)
INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (MRA 203T)

**Scope**

This course is designed to impart fundamental knowledge on Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO and emerging market (rest of world countries) like CIS, GCC, LATAM, ASIAN and African region.

**Objectives**

At completion of this course it is expected that students will be able to understand-
- Know the regulatory Requirements for drug and medical device registration in emerging market;
- Understand the registration requirements of emerging market by comparison; and
- Prepare dossiers for the registration of the products in emerging market.

**THEORY**

60 HOURS

1. **Emerging Market**: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)  

2. **WHO**: WHO GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)  

3. **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.  

4. **CIS (Commonwealth Independent States)**: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine  

5. **GCC (Gulf Cooperation Council) for Arab states**: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE
REFERENCES

5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore
INDIA MEDICAL DEVICE REGULATIONS (MRA 204T)

Scope:

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 ASEAN
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 in regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know
- basics of medical devices, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing medical devices
- regulatory approval process for medical devices in US, EU and Asia
- clinical aspects of medical devices

THEORY 60 Hours

Unit-I 12 Hours
Medical Devices: Introduction, differentiating medical devices from IVDs and Combination
Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices,
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-II 12 Hours
Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical
Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)
Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk
Management of Medical Devices: ISO 14971, Validation and Verification of Medical device,
Adverse Event Reporting of Medical device

Unit-III 12 Hours
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

\textbf{Unit-IV} \hspace{1cm} \textbf{12 Hours}
\textbf{European Union:} Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and \textit{In vitro} Diagnostics (\textit{In Vitro} Diagnostics Directive), CE certification process. Basics of \textit{In vitro} diagnostics, classification and approval process.

\textbf{Unit-V} \hspace{1cm} \textbf{12 Hours}
\textbf{Medical Device Regulations in World Health Organization (WHO):} Registration Procedures, Quality System requirements and Regulatory requirements
\textbf{Asia:} Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

\textbf{REFERENCES:}

2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
PRACTICAL (MRA205P)

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