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Course Structure and Syllabus

of

M.Pharm

(Pharmaceutical Regulatory Affairs)

School of Pharmacy and Life Sciences

2024

COURSE STRUCTURE AND SYLLABI

M. Pharm (Pharmaceutical Regulatory Affairs)

2024-25 Batch

Centurion UNIVERSITY

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School of Pharmacy and Life Sciences
CENTURION UNIVERSITY OF TECHNOLOGY & MANAGEMENT
Odisha-752050, India

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CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT, ODISHA

CERTIFICATE

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This is to certify that the syllabus of the M. Pharm (Pharmaceutical Regulatory Affairs) Programme of the School of Pharmacy and Life sciences is approved in the 14th Academic Council Meeting held on 22nd November 2024.

Dean
School of Pharmacy and Life Sciences
CUTM, Odisha

SCHOOL OF PHARMACY AND LIFE SCIENCES

SCHEME & SYLLABUS

M.PHARM (PHARMACEUTICAL REGULATORY AFFAIRS)

FOR

THE MASTER OF PHARMACY (M. PHARM.)
COURSE REGULATION 2014
(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

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CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT

BHUBANESWAR, ODISHA

2024

VISION:

To be a globally recognized centre for Teaching, Research and Entrepreneurial Training in Pharmaceutical Sciences and to provide Healthcare services for Societal needs.

MISSION:

- To nurture young minds into knowledgeable, skillful and ethical professionals to serve for the society.
- To support research in diverse ways by launching partnerships and collaborations.
- To ensure affordable health care by developing pharmaceutical formulations using in house resources.
- To inculcate the mindset for entrepreneurship and innovativeness to enrich the healthcare system.

Programme Objectives:

1. To develop advanced knowledge and technical expertise in Pharmacy.
2. To cultivate research skills, innovations and professional practice in the Pharmaceutical industry.
3. To Nurture and support an inclination for higher education and entrepreneurship.

PROGRAMME OUTCOMES (POs):

At successfully completing the M. Pharm program, student should have achieved the following program outcomes mentioned below:

Sl No.	Programme Outcomes
PO 1	**Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
PO 2	**Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
PO 3	**Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
PO 4	**Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
PO 5	**Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
PO 6	**Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO 7	**Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
PO 8	**Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
PO 9	**The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
PO 10	**Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO11	**Entrepreneurship**: Develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development.
PO 12	**Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

PSO (Program Specific Outcomes)

Sl No.	Program Specific Outcomes
PSO1	**Regulatory Knowledge and Compliance:** Proficiency in understanding and applying global regulatory guidelines, standards, and procedures (such as FDA, EMA, ICH) for the approval and marketing of pharmaceutical products.
PSO2	**Regulatory Documentation and Submissions:** Ability to prepare, review, and manage regulatory documents, dossiers, and submissions, ensuring compliance with regulatory requirements for drug approvals, clinical trials, and manufacturing.
PSO3	**Pharmaceutical Policy and Quality Assurance:** Expertise in assessing the impact of regulatory policies on drug development, manufacturing, and commercialization, while ensuring adherence to quality assurance and Good Manufacturing Practices (GMP).

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 programs 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 semester shall 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 23 are distributed semester-wise as shown in Table 5. 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 – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB

8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2. 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 – 2.

Table – 2: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./k	Marks
Semester I					
MRA101T	Good Regulatory Practices	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA105P	Regulatory Affairs Practical I	12	6	12	150
MRA106P	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205P	Regulatory Affairs Practical II	12	6	12	150
MRA206P	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology Biostatistics*	4	4
MRA302P	Journal Club	1	1
MRA303P	Discussion / Presentation(Proposal Presentation)	2	2
MRA304P	Research Work	28	14
Total		35	21

* Non University Exam

Table – 4: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRA401P	Journal Club	1	1
MRA402P	Research Work	31	16
MRA403P	Discussion / Final Presentation	3	3
Total		35	20

Table – 5: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

Table – 6: Guidelines for Awarding Credit Points for Co-curricular Activities

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

Note: International Conference: Held Outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the 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 eachM.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 sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end-semester examinations are given in Table – 7.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted 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.

Tables – 7: Schemes for internal assessments and end semester (Pharmaceutical Regulatory Affairs-MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA102T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA103T	Clinical Research Regulations	10	15	1 Hr	25	75	3Hrs	100
MRA104T	Regulations and	10	15	1 Hr	25	75	3 Hrs	100

	Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights							
MRA105P	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MRA106P	Seminar /Assignment	-	-	-	-	-	-	-
Total								650
Semester II								
MRA201T	Regulatory Aspects of Drugs & Cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	10	15	1 Hr	25	75	3 Hrs	100
MRA203T	Regulatory Aspects of Medical Devices	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	10	15	1 Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MRA206P	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 8: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics *	10	15	1 Hr	25	75	3 Hrs	100
MRA302P	Journal Club	-	-	-	25	-	-	25
MRA303P	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MRA304P	Research work	-	-	-	-	350	-	350
Total								525
Semester IV								
MRA401P	Journal club	-	-	-	25	-	-	25
MRA402P	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MRA403P	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*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 – 9: Scheme for awarding internal assessment: Continuous mode

Theory	
Attendance (Refer Table – 10)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 10)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 10: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95-100	8	10
90-94	6	7.5
85-89	4	5
80-84	2	2.5
Less than 80	0	0

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 in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

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 11. The exact dates of examinations shall be notified from time to time.

Table – 11: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

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 –12.

Table – 12: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	0	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

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:

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

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and 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:

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

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) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

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

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

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:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks

Total	250 Marks

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 I 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 condo nation fee.

SEMESTER I

GOOD REGULATORY PRACTICES (MRA101T)

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Course Objective:

- To impart fundamental knowledge on various Good Regulatory Practices
- To understand critical regulatory and compliance elements concerning Good Manufacturing Practices
- To Prepare and implement SOPs for various Good Regulatory Practices

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** key regulatory and compliance elements concerning Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.	PO1, PO2,PO3, PO7, PO12
CO-2	***Prepare*** for the readiness and conduct of audits and inspections	PO1, PO2,PO3, PO7, PO12
CO-3	**P*repare and implement*** the check lists and SOPs for various Good Regulatory Practices	PO1, PO2,PO3, PO12
CO-4	**Implement** Good Regulatory Practices in the Healthcare and related Industries	PO1, PO2,PO3, PO12
CO-5	**Explain** Quality management systems	PO1, PO2,PO3, PO12

THEORY **60 Hours**

12 Hrs

1. Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.

12 Hrs

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

12 Hrs

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

12 Hrs

4. Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers,

Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards.

12 Hrs

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

REFERENCES

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

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Course Objective:

- To impart fundamental knowledge on documentation
- To understand the basics of regulatory compilation
- To know general principles involved in regulatory writing and submission to agencies.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** various documents pertaining to drugs in pharmaceutical industry	PO1, PO2,PO3, PO12
CO-2	**Explain** the basics of regulatory compilation	PO1, PO2,PO3, PO12
CO-3	**Create and assemble** the regulation submission as per the requirements of agencies	PO1, PO2,PO3,PO7 PO12
CO-4	**Follow up** the submissions and post approval document requirements	PO1, PO2,PO3, PO12
CO-5	**Understand** key concepts in product life cycle management, including regulatory processes	PO1, PO2,PO3, PO12

THEORY **60 Hours**

12 Hrs

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

12 Hrs

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

12 Hrs

3. Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory

agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

12 Hrs

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

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

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge,1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Course Objective:

- To impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices,
- To learn regulations and guidance governing the conduct of clinical research in India, USA and EU
- To learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** History, origin and ethics of clinical and biomedical research and evaluation	PO1, PO2,PO3, PO7,PO12
CO-2	***Explain*** Clinical drug, medical device development process and different types and phases of clinical trials	PO1, PO2,PO3, PO7,PO12
CO-3	**Learn** Regulatory requirements and guidance for the conduct of clinical trials and research	PO1, PO2,PO3, PO7,PO12
CO-4	**Explain** To learn regulations and guidance governing the conduct of clinical research in India, USA and EU	PO1, PO2,PO3, PO7,PO12
CO-5	**Describe** Regulatory Guidance on Efficacy and Safety ICH Guidance's	PO1, PO2,PO3, PO7,PO12

THEORY **60 Hours**

12 Hrs

1. Clinical Drug Development Process

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

Clinical Investigation and Evaluation of Medical Devices & IVDs
Different Types of Studies
Key Concepts of Medical Device Clinical Evaluation
Key concepts of Clinical Investigation

12 Hrs

2. **Ethics in Clinical Research:**

- Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

12 Hrs

3. **Regulations governing Clinical Trials India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance**

USA: Regulations to conduct drug studies in USA (FDA)

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

EU: Clinical Research regulations in European Union (EMA)

12 Hrs

4. **Clinical Research Related Guidelines**

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

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the
- Pediatric Population
- General biostatics principle applied in clinical research

5. **USA & EU Guidance**

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR) Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html

4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/
6. Federal Food Drug and Cosmetic Act FDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://wwwmhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

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

Course Objective:

- To impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- To learn regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- To learn about manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & herbs, and the Food & Nutraceuticals industry in India.	PO1, PO2,PO3, PO7,PO11,PO12
CO-2	***Explain*** the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals	PO1, PO2,PO3, PO7,PO12
CO-3	**Impart** knowledge on Indian Pharmacopoeial Standards, BIS standards	PO1, PO2,PO3, PO7,PO12
CO-4	**Analyse** Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs	PO1, PO2,PO3, PO7,PO12
CO-5	**Describe** Intellectual Property Rights	PO1, PO2,PO3, PO7,PO11,PO12

THEORY **60 Hours**

12 Hrs

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

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

12 Hrs

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

CDSCO (Central Drug Standard Control Organization) and State

Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals.
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

12 Hrs

3. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards.

12 Hrs

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

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

REFERENCES

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

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

Course Objective:

- To analyze and apply Good Pharmaceutical Practices through case studies.
- To develop skills in preparing Standard Operating Procedures (SOPs), analytical reports, and regulatory dossiers by national and international guidelines.
- To Gain practical knowledge in preparing and submitting regulatory documents.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	**Demonstrate** an understanding of Good Pharmaceutical Practices through the analysis of case studies	PO1, PO2,PO3, PO12
CO-2	**Gain** the ability to prepare detailed documentation for in-process and finished product quality control tests for various dosage forms as per GMP standards**.**	PO1, PO2,PO3, PO7,PO12
CO-3	**prepare** comprehensive regulatory dossiers, including clinical trial protocols, for submission in India and international markets	PO1, PO2,PO3, PO7,PO12
CO-4	**Compare** marketing authorization procedures and regulatory requirements for conducting clinical trials in India, the US, EU, and Japan, and develop checklists to ensure regulatory compliance	PO1, PO2,PO3, PO7,PO12
CO-5	**Develop** knowledge in registering intellectual property rights and preparing Indian patent applications, and understand the regulatory requirements for conducting bioequivalence studies	PO1, PO2,PO3, PO7,PO12

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter

17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Course Objective:

- To impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- To learn in detail the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products
- To know about Cosmetics regulations in regulated and semi-regulated countries

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** process of drug discovery and development and generic product development	PO1, PO2,PO3,PO12
CO-2	***Explain*** regulatory approval process and registration procedures for API and drug products in US, EU	PO1, PO2,PO3, PO7,PO12
CO-3	**Impart** knowledge on Cosmetics regulations in regulated and semi-regulated countries	PO1, PO2,PO3, PO7,PO12
CO-4	**Analyze a** comparative study of India with other global regulated markets	PO1, PO2,PO3,PO12
CO-5	**Describe** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in key global markets	PO1, PO2,PO3, PO7,PO12

THEORY **60 Hours**

12 Hrs

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

12 Hrs

2. European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval

process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

12 Hrs

3. Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan.

12 Hrs

4. Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP)-General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana).

12 Hrs

5. Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

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

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Course Objective:

- To impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe
- To learn to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products
- To understand regulation for newly developed biologics and biosimilars.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** the regulatory Requirements for Biologics and Vaccines	PO1, PO2,PO3,PO12
CO-2	***Explain*** the regulation for newly developed biologics and biosimilars	PO1, PO2,PO3, PO7,PO12
CO-3	**Impart** knowledge of Indian Pharmacopeial Standards, BIS standards.	PO1, PO2,PO3, PO7,PO12
CO-4	**Analyse** pre-clinical and clinical development considerations of biologics.	PO1, PO2,PO3,PO12
CO-5	**Describe** quality, safety standards, and regulatory frameworks for herbal products in India, the USA, and the European Union.	PO1, PO2,PO3, PO7,PO12

THEORY **60 Hours**

12 Hrs

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

12 Hrs

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

12 Hrs

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

12 Hrs

4. Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network).

12 Hrs

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

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/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/Guidance Compliance Regulatory Information (Biologics).

REGULATORY ASPECTS OF MEDICAL DEVICE (MRA 203T)

Course Objective:

- To impart fundamental knowledge on medical devices and in vitro diagnostics
- To learn the basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries
- To learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe the*** basics of medical devices and IVDs, the process of development, ethical and quality considerations .	PO1, PO2,PO3, PO4,PO12
CO-2	***Explain*** harmonization initiatives for approval and marketing of medical devices and IVDs	PO1, PO2,PO3, PO4,PO7,PO12
CO-3	**Impart** knowledge regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN	PO1, PO2,PO3, PO4PO7,PO12
CO-4	**Analyse** clinical evaluation and investigation of medical devices and IVDs.	PO1, PO2,PO3, PO4PO7,PO12
CO-5	**Describe** Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In-vitro Diagnostics	PO1, PO2,PO3, PO4PO7,PO12

THEORY **60 Hours**

12 Hrs

1. Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination. Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device, Nomenclature (GMDN).

12 Hrs

2. Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.

12 Hrs

3. USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption

(IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

12 Hrs

4. European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

12 Hrs

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.

REFERENCES

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

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Course Objective:

- To impart fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe
- To learn in detail about the Regulatory Aspects of nutraceuticals and food supplements.
- To know about Understand the regulation for registration and labeling of nutraceuticals and food supplements

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Describe*** the History of Food and Nutraceutical Regulations.	PO1, PO2,PO3, PO12
CO-2	***Explain*** WHO guidelines on nutrition & NSF International for Food And Dietary Supplements	PO1, PO2,PO3,PO7, PO12
CO-3	**Impart** knowledge of Food Safety and Standards Act by the Food Safety and Standards Authority of India	PO1, PO2,PO3,PO7, PO12
CO-4	**Describe** US FDA Food Safety Modernization Act	PO1, PO2,PO3,PO7, PO12
CO-5	**Explain** the European Food Safety Authority (EFSA) organisational structure and function	PO1, PO2,PO3,PO7, PO12

THEORY **60 Hours**

12 Hrs

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

12 Hrs

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

12 Hrs

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

12 Hrs

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

12 Hrs

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

REFERENCES

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

REGULATORY AFFAIRS PRACTICAL – II (MRA 205P)

Course Objective:

- To prepare regulatory submissions for the FDA, EMA, and other agencies using eCTD software
- To Acquire the necessary skills to implement effective change management, handle deviations, and execute CAPA procedures in a regulated environment, ensuring compliance with global standards.
- To Analyze the regulatory requirements for market authorization in multiple emerging markets (BRICS, ASEAN, GCC)

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Gain*** proficiency in preparing regulatory submissions (eCTD) for FDA, EMA, MHRA, and other global agencies, including Biologics License Applications (BLA) and vaccine product approvals..	PO1, PO2,PO3,PO4,PO7, PO12
CO-2	***Understand and apply*** best practices in change management, deviation handling, and Corrective & Preventive Actions (CAPA) in compliance with industry standards.	PO1, PO2,PO3,PO4,PO7, PO12
CO-3	**Prepare** comprehensive market authorization checklists for various products, including biologics, devices, and blood products.	PO1, PO2,PO3,PO4,PO7, PO12
CO-4	**Master** the process of documenting raw materials analysis per official monographs and create audit checklists for regulatory compliance across multiple agencies and markets.	PO1, PO2,PO3,PO4,PO7, PO12
CO-5	**Gain** expertise in preparing detailed documentation for medical devices (510(k), PMA, CE marking) and biologics	PO1, PO2,PO3,PO4,PO7, PO12

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval

11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

SEMESTER III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM301T)

Course Objective:

- To provide value addition and current requirement in clinical research and pharmacovigilance
- To conceptualizing, designing, conducting, managing and reporting of clinical trials.
- To develop drug safety data in Pre-clinical and clinical phases of Drug development and post-market surveillance.

Course Outcomes: On completion of this course, the successful students should be able to:

CO	Statements	Cos & POs Mapping
CO-1	***Explain*** the regulatory requirements for conducting clinical trial	PO1, PO2,PO3, PO7, PO12
CO-2	***Demonstrate*** the types of clinical trial designs	PO1, PO2,PO3, PO7, PO12
CO-3	***Execute*** safety monitoring, reporting and close-out activities	PO1, PO2,PO3, PO7, PO12
CO-4	***Describe*** the principles of Pharmacovigilance	PO1, PO2,PO3, PO7, PO12
CO-5	***Perform*** the adverse drug reaction reporting systems and communication in Pharmacovigilance	PO1, PO2,PO3, PO7, PO12

THEORY **60 Hours**

12 Hrs

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.

12Hrs

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

12 Hrs

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

12 Hrs

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 Hrs

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

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Paralakhemundi, Dist.- Gajapati
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Bhubaneswar Campus
Ramchandrapur
P.O. – Jatni, Bhubaneswar
Dist.- Khurda, Odisha,
India, PIN– 752050

Balangir Campus
Behind BSNL Office
IDCO land, Rajib Nagar
Dist.- Balangir, Odisha
India, PIN-767001

Rayagada Campus
IDCO Industrial Area
Pitamahal, Rayagada
Dist.-Rayagada, Odisha
India, PIN-765001

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