Academic Programme Guide

of

Master of Pharmacy

(Pharmaceutical Regulatory Affairs)

Based on Choice Based Credit System (CBCS) / Elective Course System

CHITKARA UNIVERSITY

w.e.f.

Academic Year: 2024-2025

Approved by the 26th Academic Council vide agenda item AC 26.4a dated 10th August 2024

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Chitkara University
Vision and Mission

Vision	To be a globally recognized organization promoting academic excellence through interdisciplinary applied research and to expand realms of knowledge through innovation.
Mission	• To carry out the academic processes in accordance with global standards through active teacher-student-industry participation.
	• To promote research, innovation and entrepreneurship in collaboration with industry, research laboratories and academic institutions of global repute.
	• To inculcate high moral, ethical and professional values amongst our students, faculty & staff.
	• To contribute in building skillful society.

Institute Vision and Mission

Vision	To excel as a premiere Centre of Excellence in Pharmaceutical Education, Research, Development & Innovation with Global Interaction.
Mission	• To contribute in building skillful society by preparing competent pharmacist.
	• To prepare globally recognized pharmaceutical professionals who can effectively contribute in new molecule research, formulation, preclinical and clinical growth and regulatory submissions.
	• To prepare efficient leaders providing academic and other interactions in various stages of pharmaceutical operations, marketing and distribution.
	• To provide applied, industry relevant pharmaceutical education relevant globally.
	• To enhance and impart innovation, entrepreneurship, and social skills.

1. General Information:

The Academic Programme Guide is a comprehensive document detailing course scheme, associated credits per course and the distribution of each course in lecture, tutorial and Practical hours. It also details the eligibility criteria for admission, for award of degree, the assessment and evaluation procedures along with a glimpse of the pedagogical aspects of the programmes. This Guide is to be used in association with the Academic Regulations of the University to make a complete rule set. The course schemes given in this document are approved by respective Board of Studies in line with regulations of Pharmacy council of India and the Academic Council of Chitkara University, Punjab.

Programme Objective:

Objective of M. Pharm. Pharmaceutical Regulatory Affairs Programme is

1) To make understand students about key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices
2) Prepare and implement the check lists and SOPs for various Good Regulatory Practices;
3) Implement Good Regulatory Practices in the Healthcare and related Industries
4) Prepare for the readiness and conduct of audits and inspections.

The Programme Educational Objectives (PEOs) and Programme Outcomes (POs) of M. Pharm Pharmaceutical Regulatory Affairs are:

2. Programme Outcomes for M. Pharm (Pharmaceutical Regulatory Affairs)

The proposed outcomes for the M. Pharmacy Pharmaceutical Regulatory Affairs Programme are designed to provide industrial level education regarding the applicable laws and regulations. It focuses on laws and regulations which a healthcare industry must comply to sell their product effectively in the market. The course also provides the knowledge of filling of information regarding new drug development, manufacture, control, stability studies, packaging, labeling etc. with regulatory agencies in a prescribed format. They are further classified as follows:

PO1: Demonstrate a comprehensive understanding of the regulatory frameworks governing drugs, cosmetics, medical devices, biologicals, herbals, food, and nutraceuticals in India, including key legislation and guidelines.

PO2: Prepare and implement the check lists and SOPs for various Good Regulatory Practices.

PO3: Apply principles of clinical research regulations to ensure compliance with ethical guidelines and legal requirements in the conduct of clinical trials.

PO4: Develop and refine documentation and regulatory writing skills essential for preparing and submitting high-quality regulatory submissions and reports.

PO5: Implement good regulatory practices to ensure compliance with regulatory requirements, enhance regulatory processes, and improve product safety and efficacy.

PO6: Formulate and execute regulatory strategies for the development, approval, and marketing of drugs and cosmetics, ensuring compliance with national and international standards.

PO7: Understand and navigate the regulatory pathways for herbal and biological products, including preclinical and clinical requirements, quality control, and post-market surveillance.

PO8: Gain expertise in the regulatory requirements for medical devices, including classification, approval processes, quality management systems, and post-market obligations.

PO9: Acquire knowledge of the regulatory landscape for food and nutraceuticals, including safety assessments, labeling requirements, and health claims validation.

PO10: Develop an awareness of global regulatory practices and harmonization efforts, particularly those of major regulatory agencies such as the FDA, EMA, and WHO.

PO11: Integrate ethical and legal considerations into regulatory practices, ensuring that regulatory decisions uphold public health, safety, and welfare.

***Mission*:**

M1: To carry out the academic processes in accordance with global standards through active teacher-student-industry participation.

M2: To promote research, innovation and entrepreneurship in collaboration with industry, research laboratories and academic institutions of global repute.

M3: To inculcate high moral, ethical and professional values amongst our students, faculty & staff.

M4: To contribute in building skillful society by preparing competent pharmacist.

M5: To prepare globally recognized pharmaceutical professional who can effectively contribute in new molecule research, formulation, preclinical and clinical growth and regulatory submissions.

M6: To become efficient leaders providing academic and other interactions in various stages of pharmaceutical operations, marketing and distribution.

The mapping of POs with University Mission is shown in Table 1.

PO No.	**PO Statement**	**Mission Statement**		**Vision Statement**
PO1	Demonstrate a comprehensive understanding of the regulatory frameworks governing drugs, cosmetics, medical devices, biologicals, herbals, food, and nutraceuticals in India, including key legislation and guidelines.	M2, M5		To be a globally recognized university, promoting academic excellence through interdisciplinary applied research and to expand realms of knowledge through innovation.
PO2	Prepare and implement the check lists and SOPs for various Good Regulatory Practices.	M3, M5		
PO3	Apply principles of clinical research regulations to ensure compliance with ethical guidelines and legal requirements in the conduct of clinical trials.	M4, M5		
PO4	Develop and refine documentation and regulatory writing skills essential for preparing and submitting high-quality regulatory submissions and reports.	M6, M5		
PO5	Implement good regulatory practices to ensure compliance with regulatory requirements, enhance regulatory processes, and improve product safety and efficacy.	M1, M5		
PO6	Formulate and execute regulatory strategies for the development, approval, and marketing of drugs and cosmetics, ensuring compliance with national and international standards.	M6, M5		

PO7	Understand and navigate the regulatory pathways for herbal and biological products, including preclinical and clinical requirements, quality control, and post-market surveillance.	M2, M5		
PO8	Gain expertise in the regulatory requirements for medical devices, including classification, approval processes, quality management systems, and post-market obligations.	M5, M2		
PO9	Acquire knowledge of the regulatory landscape for food and nutraceuticals, including safety assessments, labeling requirements, and health claims validation.	M5, M3		
PO10	Develop an awareness of global regulatory practices and harmonization efforts, particularly those of major regulatory agencies such as the FDA, EMA, and WHO	M4, M5		
PO11	Integrate ethical and legal considerations into regulatory practices, ensuring that regulatory decisions uphold public health, safety, and welfare.	M2, M5, M6		

The Programme outcomes in M. Pharmacy **(**Pharmaceutical Regulatory Affairs**)** are well-designed based on the mission of providing the graduating students with knowledge and for expertise required for professional practices in Health and pharmaceutical services. The graduating students are prepared for demonstrating knowledge of and ability to use principles of therapeutics, quality improvement, communication, economics, health behavior, social and administrative sciences, health policy and legal issues in the practice of pharmacy. Each year, experts from different universities and pharmaceutical industry across the globe visits Chitkara College of Pharmacy, Chitkara University, Punjab to provide international exposure to students.

Aiming at developing student's personality through community service, NSS activities are offered to students to instill the idea of social welfare and to provide service to society without bias. To enrich student's interpersonal skills, variety of extracurricular activities have been inculcated in the course curriculum in the form of national level technical and cultural festivals such as Pharma-fest, International Pharmacist Day and National Pharmacy Week respectively on a yearly basis. A vital role is played by the institutional technical cell (FPSDPS) department for overall progress & grooming of the student through organizing industrial visits, workshops, debate, technical quizzes

and research project paper presentation competitions in events like Pharma tech Trends, Pharmacy Practice Module & international conferences. The students are motivated to participate or organize such events. These value-added activities have been designed taken into account various Programme Objectives (POs) such as PO6, PO7, PO8, PO9 and PO11.

The main aim of service training with focus on good health and well-being is accomplished by delivering sport-related events, NSS and NCC. The programme also aims to develop professional with awareness of international standards as of global health has transcended beyond the idea of confining the pharmacist's work to a specific geographical location and broadened it to the global level. PO1, PO2, PO3, PO4, PO5, PO6 and PO7 promotes development of skills in graduates for pharmaceutical formulations, analytical experts, regulatory and dispensing skillsfor good practices in global health system.
Pharmacists have the opportunity to play an important role in both public health and global health. In particular, pharmacists can look at the varied global health practices established in medicine and use this as a framework to understand the potential role of the pharmacist within global health practice and programme delivery, research, and policy. According to the Consortium of Universities for Global Health, global health should refer to the scope of a wider problem rather than a geographical location. The scope of work of pharmacists in diverse settings faces challenges of global health such as self-care & self-medication, management of diseases through medication therapy management, resistance to existing drugs or recreational drugs being abused, medicines supplied through unregistered online pharmacies, online advertising of prescription drugs, direct-to-consumer websites and the distribution of substandard & spurious, falsely- labeled, falsified or counterfeit medicines. POs are designed and oriented to meet the mission of university in professional ethics. The POs ensure that the graduating students are well equipped with strong fundamental concepts and high technical competence in pharmaceutical sciences who shall be able to use the tools in pharmaceutical arena for success. POs helps to develop a sense of teamwork and awareness amongst students towards the importance of interdisciplinary approach for developing competence in solving complex problems in the area of Pharmaceutical Sciences. The POs helps to train the students to contribute towards health care system and encourage the students to participate in life-long learning process for a highly productive career, and to relate the concepts of Pharmaceutical Sciences towards serving the betterment of the society.

3. Eligibility for Admission

3.1. Pass in the following examinations:

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.). 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.).

3.2. Migration/Credit Transfer Policy

The following procedures will be followed for credit transfer for student under migration, studied in other Universities in India and Abroad:

"The credits earned by the student from the other universities in India or abroad shall be transferred as such. The Degree shall only be awarded to candidate subject to the condition that student earned the minimum no. of credit defined by Academic Regulation/APG of the Programme run by the Chitkara University." In case a student undergoes international exchange programme or internship for 1 semester/ 1 year, then the courses, credits and grades earned by the student in abroad during that period should be reflected on the grade card issued by the Chitkara University. The courses will be marked as (*) on the grade card/transcript. The description of the (*) will be "credits and grades as adopted university/institute name during international exchange programme. The minimum credit points required for the award of M. Pharm. degree is 100. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 105 credit points. If consolidated credits are less than 100 credits, then the student has to earn extra credits to attain minimum credits requirement for M. Pharmacy degree. The instructions regarding this will be informed to the students by the department from time to time.

4. Programme Duration

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

4.1 Medium of instruction and examinations

Medium of instruction and examination shall be in English.

4.2 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.

5. Pedagogical Aspects

Each course will be taught for 52-65 hrs. Everyday there will be three to four lecture sessions of three to four courses of 1 hours each and twelve-hour practical divided into two days (pre-lunch and post-lunch). Activity and project hours will be other than these lecture hours depending upon the subject and relevance of the project. At least one week prior to the commencement of aparticular course, the concerned faculty member or the course coordinator will circulate among the students the following pertaining to the course:

a) The course outlines containing the syllabus along with text books, reference books and other study material.

b) Day to day schedule to be followed — detailing the pace, coverage, prior reading assignments, case studies, home assignments to be perused by the students etc.

c) Various components of evaluation, such as quizzes (announced or unannounced), assignment, open book test, field work, group discussion, seminar, assignments, tests/examinations, class participation, mid-term and end term grading with relative weightage etc.

d) Other matters found desirable and relevant.

6. Apprenticeship/Internship embedded degree programmes (AEDP)

The apprenticeship or internship is optional for M. Pharm students during their research work in Semester III & IV. The primary aim of the internship is to provide hands-on experience in a real-world setting. The internship is typically conducted in approved pharmacy institutions, hospitals, or pharmaceutical industries, where students can apply their academic knowledge to practical scenarios. The duration of the internship is usually specified by the university or institution in alignment with PCI guidelines.

7. Programme 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 associatedwith 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 isdependent 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 semestercarries 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 100. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 105 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 7. 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.

7.3 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.

7.4 Course of study

M. Pharm Pharmaceutical Regulatory Affairs programme code is MRA**.** The course of study for M. Pharm Pharmaceutical Regulatory Affairs shall include Semester wise Theory & Practicalas given in Table 2 and 3. The number of hours to be devoted to each theory and practical coursein any semester shall not be less than that shown in Table 4 to 5.

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

Course Code	Name of Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MRA 101T	Good Regulatory Practices	4	4	4	100
MRA 102T	Documentation and Regulatory Writing	4	4	4	100
MRA 103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA 105P	Regulatory Affairs Practical I	12	6	12	150
MRA106S	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA 205P	Regulatory Affairs Practical II	12	6	12	150
MRA206S	Seminar/Assignment	7	4	7	100
DM 101	Disaster Management	3	3	3	50
	Total	**38**	**29**	**38**	**700**

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

Course Code	Name of Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
MPR 302J	Journal club	1	1
MPR 302P	Discussion / Presentation (Proposal Presentation)	2	2
MPR302R	Research Work	28	14
HR 101	Human Values and Professional Ethics	2	2
	Total	**37**	**23**

* Non-University Exam

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

Course Code	Name of Course	Credit Hours	Credit Points
MPR 401J	Journal Club	1	1
MPR 401R	Research Work and Colloquium	31	16
MPR 401D	Discussion/Final Presentation	3	3
MPR401C	Co-Curricular Activities	--	7*
	Total	**35**	**20**

Table – 5: Semester wise credits distribution

Semester	Credit Points
I	26
II	29
III	23
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=100 Maximum=105*

*Credit Points for Co-curricular Activities

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 Programmes (related to the specialization of the student)	**01**
Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programmes (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.

7.5. Programme Committee

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.
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.

7.5.1 Duties of the Programme Committee:

Periodically reviewing the progress of the classes. Discussing the problems concerning curriculum, syllabus and the conduct of classes. 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. Communicating its recommendation to the Head of the institution on academic matters. 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.

8. Assessments & Evaluation

The schemes for internal assessment and end semester examinations are given in Table 6 and 7.

8.1 End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table 1 and 2 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 examinations(Pharmaceutical Regulatory Affairs)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous Mode	Sessional Exams		Total	Marks	Duration	Marks
			Marks	Duration				
SEMESTER I								
MRA 101T	Good Regulatory Practices	10	15	1.5 Hrs	25	75	3 Hrs	100
MRA 102T	Documentation and Regulatory Writing	10	15	1.5 Hrs	25	75	3 Hrs	100
MRA 103T	Clinical Research Regulations	10	15	1.5 Hrs	25	75	3 Hrs	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	10	15	1.5 Hrs	25	75	3 Hrs	100
MRA 105P	Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MRA 106S	Seminar /Assignment	-	-	-	-		-	100
							Total	**650**
SEMESTER II								
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	10	15	1.5 Hrs	25	75	3 Hrs	100

MRA 202T	Regulatory Aspects of Herbal & Biologicals	10	15	1.5 Hrs	25	75	3 Hrs	100
MRA 203T	Regulatory Aspects of Medical Devices	10	15	1.5 Hrs	25	75	3 Hrs	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	10	1.5	1.5 Hrs	25	75	3 Hrs	100
MRA 205 P	Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MRA 206S	Seminar /Assignment	-	-	-	-	-	-	100
DM 101	Disaster Management	5	10	1 Hr	15	35	1.5Hrs	50
							Total	**700**

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

Course Code	**Course**	**Internal Assessment**				**End Semester Exams**		**Total**
		Continuous Mode	**Sessional Exams**		**Total**	**Marks**	**Duration**	**Marks**
			Marks	**Duration**				
SEMESTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1.5 Hrs	25	75	3 Hrs	100
MPR 302J	Journal club	-	-	-	25	-	-	25
MPR 302 P	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MPR 302R	Research work*	-	-	-	-	350	1 Hr	350
HR 101	Human Values and Professional Ethics	5	10	1 Hr	15	35	1.5 Hrs	50
							Total	**575**
SEMESTER IV								
MPR 401J	Journal club	-	-	-	25	-	-	25
MPR 401D	Discussion / Final Presentation	-	-	-	75	-	-	75
MPR 401R	Research work and Colloquium	-	-	-	-	400	1 Hr	400
							Total	**500**

***Non-University Examination**

8.2 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	
Criteria	**Maximum Marks**
Attendance (Refer Table 9)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table 9)	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

9. Rules for Attendance

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

10. Promotion & Award of grades

The Pharmacy Council of India (PCI) has established guidelines to ensure uniformity in the promotion and grading of M. Pharm students across PCI-approved institutions. These guidelines emphasize the importance of internal assessments, which are mandatory and contribute significantly to the final grades. Assessments include both formative (continuous evaluation) and summative (end-semester exams) components, aligned with the PCI syllabus. To be promoted to the next semester, students must secure a minimum of 50% marks in both internal assessments and end-semester examinations. Those failing to meet this criterion must reappear for supplementary exams conducted by their institution, with all subjects required to be cleared within the stipulated time frame outlined by PCI regulations. The grading system follows a credit-based semester system (CBSS), awarding grades from "O" (Outstanding) for scores 90% and above to "F" (Fail) for scores below 50%, with students needing at least a "B" grade (50%-59%) to pass. Additionally, students must maintain a minimum of 75% attendance in theory and practical sessions, with exceptions granted only under exceptional circumstances like medical emergencies, subject to academic council approval. M. Pharm programmes also require students to undertake research projects or dissertations in their final year, evaluated through internal assessments by supervisors and external viva voce examinations conducted by PCI-appointed examiners, with significant weightage given to project work in determining final grades. Students who fail any subject are allowed supplementary examinations, with a maximum number of

attempts specified by PCI guidelines, typically within twice the duration of the programme. Migration between PCI-approved institutions is permitted only under exceptional circumstances and requires fulfilment of academic requirements at the current institution along with approvals from both institutions involved. These guidelines ensure standardization in academic progression while maintaining rigorous evaluation standards for postgraduate pharmacy education.

11. 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.

12. 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.

13. Re-examination of end semester examinations

Re-examination 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

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Short Answer Questions (3 out of 4) = 5 x 3 = 15

II. Long Answers (Answer 6 out of 7) = 6 x10 = 60

Total = 75 marks

Question paper pattern for end semester practical examinations

I. Synopsis	=	10
II. Major Experiments	=	35
II. Minor Experiments	=	25
IV. Viva voce + File	=	30
Total	=	100 marks

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14. Allowed to keep terms (ATKT)

The Pharmacy Council of India (PCI) has reiterated its guidelines regarding the "allowed to keep terms" policy for pharmacy students. This policy is crucial for ensuring that students maintain the necessary academic standards to progress through their respective programmes. According to the latest updates, institutions must adhere strictly to the Education Regulations set forth by the PCI, which include maintaining adequate faculty qualifications, infrastructure, and equipment.

Students are generally allowed to keep terms if they meet specific criteria, such as maintaining a minimum attendance percentage and achieving passing marks in internal assessments. Institutions are responsible for monitoring these criteria closely and must report any non-compliance to the PCI. Additionally, the PCI has emphasized that institutions must apply through the DIGI-PHARMed portal for any approvals related to course continuations or admissions, ensuring that all processes are transparent and standardized. Institutions failing to comply with these guidelines risk not being included in the approved list for future admissions, which could lead to a "No Admission year" scenario for them.

To summarize, adherence to PCI regulations is essential for pharmacy institutions and students alike, ensuring the educational standards are upheld and that students are given fair opportunities to progress in their studies.

No student shall be admitted to any examination unless he/she fulfills the norms given in section 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the coursesof I and II semesters 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.

15. Grading System

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.

15.1. 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

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	O	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.

16 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 inthese 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:

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

17 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:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

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

18. 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

19. 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**

20. 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 programme shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm programme in minimum prescribed number of years, (two years) for the award of Ranks.

21. Award of degree Candidates:

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

22. Duration for completion of programme of study

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

23. 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.

24. Readmission after break of study

Candidate who seeks re-admission to the programme after break of study has to get the approval from the university by paying a condonation fee.

25. Promotion and Registration

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.

26. Provision of Grace-Marks

The following rule for the award of grace marks to the students was approved by the Academic Council:
The University shall award grace-marks as per following:
"One percent of the total marks of theory examination of all the semesters may be given for improving the division of a candidate. Grace marks given to a candidate in semester examination may be deducted from total grace marks to be given for improvement of the division."
A maximum of One percent of the total marks of theory examination as grace marks at the end of the each semester/year, provided that a student secures a minimum of 15% marks in the respective subject/s of the End Semester/yearly Examination.

OR

The remainder or part there of the 1% grace marks of first semester/year plus 1 percent grace-marks of second year, provided that a student secures a minimum of 15% marks in the respective subject/s of the End Semester Examination, similarly for next semesters/years.

For internal Examination:

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.

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.

27. Placement Opportunities

a. Research & Formulation Development Executive: Development of new formulations

b. Production Executive: Managing and supervising production of formulations

c. Project Manager: Coordinating the research, production and marketing activities in a pharmaceutical organization, deciding as to what and how to develop a new product and plan production and marketing activity as per available capacity.

d. Project Manager: coordinating & erection, installation commissioning of production in a new plant / facility and ensuring that all installation and procedures are as per compliance norms laid out by regulatory agencies.

e. Manager (Administration & Finance): in a pharmaceutical organization.

f. Executive / Manager, Regulatory affairs: Helping the research team to compile drug master files for new drug products for registration and approval with the food & Drug authority of different countries.

28. Programme Overview: M. Pharmacy PRA (MPR)

The Programme consists of subjects under the following categories:

Table 13: Programme Scheme: **M. Pharmacy PRA**

Year 1; Semester 1												
S. No.	Course Name	Course Code	Level	Category (Type of Course)	Credits (Course wise)	Hours per Week			Marks Distribution			Total Credits (Semester wise)
						L	T	P	I	E	TL	
1	Good Regulatory Practices	MRA 101T	500-599	DC	4	4			25	75	100	26
2	Documentation and Regulatory Writing	MRA 102T	500-599	DC	4	4			25	75	100	
3	Clinical Research Regulations	MRA 103T	500-599	DC	4	4			25	75	100	
4	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food &Nutraceuticals In India and Intellectual Property Rights	MRA 104T	500-599	DC	4	4			25	75	100	
5	Regulatory Affairs Practical I	MRA 105P	500-599	DC	6			12	50	100	150	
6	Seminar /Assignment	MRA106S	500-599	DC	4	7			100		100	
Year 1 Sem 2												
7	Regulatory Aspects of Drugs& Cosmetics	MRA 201T	500-599	DC	4	4			25	75	100	29
8	Regulatory Aspects of Herbal& Biologicals	MRA 202T	500-599	DC	4	4			25	75	100	
9	Regulatory Aspects of Medical Devices	MRA 203T	500-599	DC	4	4			25	75	100	
10	Regulatory Aspects of Food	MRA 204T	500-599	DC	4	4			25	75	100	

	& Nutraceuticals											
11	Regulatory Affairs Practical II	MRA 205 P	500-599	DC	6			12	50	100	150	
12	Seminar /Assignment	MRA 206S	500-599	DC	4	7			100		100	
13	Disaster Management	DM 101	500-599	DC	3	3			15	35	50	
Year 2 Sem 3												
14	**Research Methodology and Biostatistics***	MRM 301T	500-599	DC	4	4			25	75	100	
15	**Journal club**	MPR 302J	500-599	DC	1	1			25		25	
16	**Discussion / Presentation (Proposal Presentation)**	MPR 302P	500-599	DC	2	2			50		50	**23**
17	**Research Work**	MPR 302R	500-599	DC	14	28				350	350	
18	**Human Values and Professional Ethics**	HR 101	500-599	DC	3	3			15	35	50	
Year 2 Sem 4												
19	**Journal Club**	MPR 401J	500-599	DC	1	1			25		25	
20	**Research Work and Colloquium**	MPR 401R	500-599	DC	16	31				400	400	**20**
21	**Discussion/Final Presentation**	MPR 401D	500-599	DC	3	3			75		75	

Programme overview: M. Pharmacy Pharmaceutical Regulatory Affairs (MRA)
1st SEMESTER

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)
GOOD REGULATORY PRACTICES (MRA 101T)

Scope and objective

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Course Outcomes

At completion of this course, it is expected that students will be able to understand,

CO1: Understand regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Distribution Practices.

CO2: Prepare and implement the check lists and SOPs for various Good Regulatory Practices

CO3: Apply Good Regulatory Practices in the Healthcare and related Industries

CO4: Prepare for the readiness and conduct of audits and inspections.

CO5: Understand the concept of quality management systems

THEORY ***60 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. 12Hrs
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 ofIndia (QCI) Standards 12Hrs
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. 12Hrs
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 12Hrs
5. **Quality management systems:** Concept of Quality, Total Quality 12Hrs

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 by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope and objective

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

Course Outcomes

Upon completion of the course the student shall be able to,

CO1: Understand the various documents pertaining to drugs in pharmaceutical industry
CO2: Assess the basics of regulatory complications.
CO3: Critically assess and assemble the regulation submission as per the requirements of agencies
CO4: Impart the learning opportunities to understand follow up the submissions and post approval document requirements
CO5: Understand and utilise the concerns related to drug development and product life cycle management.

THEORY ***60 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). 12Hrs
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. 12Hrs
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. 12Hrs
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). 12Hrs
5. **Product life cycle management:** Prior Approval Supplement (PAS), Post 12Hrs

Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE- 30), Annual Report, Post marketing Reporting Requirements, Post approval Labelling 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 Programme (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Scope and objective

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related tosafety, efficacy, ethical conduct and regulatory approval of clinical research.

Course Outcomes

Upon completion of the course, the student shall be able to (know, do and appreciate)

CO1: Understand the history, origin and ethics of clinical and biomedical research

CO2: Design and implement various types of clinical studies, different types and phases of clinical trials

CO3: Critically assess the regulatory requirement, guidance and documentation for conduct of clinical trials and research of drug and medical devices of Various regulatory agencies (e.g. USFDA, EMEA, ISO, GHTF etc.)

CO4: Analyse FDA guidance for bioavailability and bioequivalence requirements for medicinal products.

CO5: Understand Indian GCP, CDSCO and ICMR guidelines for biomedical research.

Theory ***60 Hrs***

1. **Clinical Drug Development Process** 12Hrs
   - 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

2. Ethics in Clinical Research: 12Hrs
   - 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
3. **Regulations governing Clinical Trials** 12Hrs

   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)

4. **Clinical Research Related Guidelines** 12Hrs

- 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** 12Hrs

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

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

Scope and objective

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Course Outcomes

Upon the completion of the course the student shall be able to:

CO1: Understand the different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.

CO2: Demonstrate the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CO3: Identify Guidelines for conducting clinical studies, preclinical studies, Bioavailability and Bioequivalence studies and stem cell research

CO4: Analyse standards for attainment of Quality, safety and efficacy

CO5: Understand basics of Intellectual property rights

THEORY ***60 Hrs***

1. **Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):** 12Hrs
    1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
    2. Other relevant provisions (rules schedules and guidelines forapproval 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.

2. **Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals** 12Hrs
   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
3. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards 12Hrs
4. Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study 12Hrs
   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 12Hrs

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 Outcomes

CO1: Understand various documents pertaining to drugs in pharmaceutical industry
CO2: Understand the basics of regulatory guidelines used in industry to file IND, NDA, BLA
CO3: Analyse and assemble the regulation submission as per the requirements of agencies in industries
CO4: Categorize the requirements for the various types of submission application for US, EU and Japan and to understand the Regulatory guidance's and guidelines for filing and approval process
CO5: Impart learning opportunities to practically assess the criticality of various case studies related to GMP, Checklists for registration of IND, ANDA etc.

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)

Scope and objective

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Course Outcomes

Upon completion of the course, the student shall be able to know

CO1: Provide learning opportunities of the regulatory procedures involved in drug discovery, research development and generic product development.

CO2: Understand regulatory approval processes and registration procedures for APIs and drug products in the US and EU

CO3: Evaluate Drug and Cosmetics regulations in regulated and semi-regulated countries

CO4: Analyse a comparative study drug and drug product registration in India with other global regulated markets

CO5: Analyse differences in regulatory approval approaches of cosmetics in global regulated markets

Theory 60 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. — 12Hrs

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. — 12Hrs

3. **Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory — 12Hrs

approval process, Regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan

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) 12Hrs

5. **Brazil, ASEAN, CIS and GCC Countries:** ASIAN Countries: Introductionto ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of SoutheastAsian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. **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 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. 12Hrs

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 By Frederick 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)

Scope and objective

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

Course Outcomes

Upon the completion of the course the student shall be able to:

CO1: Understand the regulatory Requirements for Biologics and Vaccines used for filling their approval requests by the industries.

CO2: Acquire the regulatory knowledge for registration of newly developed biologics and biosimilars

CO3: Provide learning opportunities in pre-clinical and clinical development considerations for the development of new biologics for diseases by the industries

CO4: Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

CO5: Understand the regulation and registration of herbals as per US, Europe and India.

Theory ***60Hrs***

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

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/GuidanceComplianceRegulatoryInfo rmation/
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/GuidanceCompliance Regulatory Information (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES
(MRA 203T)

Scope and objective

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Course Outcomes

Upon completion of the course, the student shall be able to know

CO1: Understand the basics of medical devices and IVDs, process of development, ethical and quality considerations

CO2: Provide learning opportunities to enhance knowledge of organizational structure, regulatory guidelines and functions of IMDRF/GHTF.

CO3: Understand the quality system regulations and quality risk management of medical devices.

CO4: Critically assess the regulatory approval process for medical devices and IVDs in US and Europe.

CO5: Understand the regulatory approval process for medical devices and IVDs in China, Japan and ASEAN countries.

Theory ***60 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. 12Hrs
   IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).
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) 12Hrs
   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
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, Labelling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of *In vitro* diagnostics, classification and approval process. 12Hrs

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. 12Hrs
   Basics of In vitro diagnostics, classification and approval process.

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. 12Hrs

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)

Scope and objective

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labelling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Course Outcomes

Upon completion of the course, the student shall be able to

CO1: Understand the regulatory requirements for nutraceuticals

CO2: Impart knowledge of regulation for registration and labeling of nutraceuticals and food supplements in India.

CO3: Analyze the regulation for registration and labeling of nutraceuticals and food supplements in USA.

CO4: Understand the regulation for registration and labeling of nutraceuticals and food supplements in Europe

CO5: Evaluate the global aspects of dietary supplements and nutraceuticals

Theory 60 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. 12Hrs
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. 12Hrs
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. 12Hrs
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 12Hrs
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. 12Hrs

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 Outcomes

CO 01: Understand various documents pertaining to drugs in pharmaceutical industry
CO 02: Understand regulatory guidelines basics.
CO 03: Analyse and assemble the regulation submission as per the requirements of agencies
CO 04: Categorize the requirements for the various types of submission application for US, EU and Japan and to understand the Regulatory guidance's and guidelines for filing and approval process
CO 05: Critically assess the case studies related to GMP, Checklists for registration of IND, BLA, Vaccine approval, ANDA etc.

1. Case studies
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

DM 101 Disaster Management (Theory) 3Hours/week

Scope and Objectives of the Course

1. To provide students an exposure to disasters, their significance and types
2. To ensure that students begin to understand the relationship between vulnerability, disasters, disaster prevention and risk reduction
3. To gain a preliminary understanding of approaches of Disaster Risk Reduction (DRR)
4. To enhance awareness of institutional processes in the country
5. To develop rudimentary ability to respond to their surroundings with potential disaster response in areas where they live, with due sensitivity

CO1: Classify different types of disasters, including natural technological and human made hazards using specific examples.
CO2: Apply strategies for preparedness, response and recovery across disaster management cycle.
CO3: Conduct disaster risk assessment with tools like hazard mapping and early warning systems.
CO4: Evaluate National and global disaster management policies to inform disaster planning and response.
CO5: Operate disaster technologies like GIS, GPS and remote sensing for disaster management.
CO6: Design a disaster mitigation of response plan based on project based learning and real world case studies.

Disasters: Classification, Causes, Impacts

- Introduction to Disasters: Concepts, and definitions (Disaster, Hazard, Vulnerability, Resilience, Risks)
- Impacts (including social, economic, political, environmental, health, psychosocial, etc. Differential impacts- in terms of caste, class, gender, age, location, disability) Classification of hazards/disasters and causes

Principles of disaster management

- Approaches to Disaster Risk reduction: Disaster cycle - its analysis, Phases, Culture of safety, prevention, mitigation and preparedness,
- Community based DRR, Components of Disaster Relief: Water, Food, Sanitation, Shelter, and Health,

Structural and non-structural measures.

Hazard Profile (India) , Disaster Risk Management in India

- Hazard and Vulnerability profile of India

Institutional arrangements (Mitigation, Response and Preparedness, DM Act and Policy, Other related policies, plans, programmes and legislation), Role of Panchayati Raj Institutions/Urban Local Bodies (PRIs/ULBs), states, Centre, and other stake-holders.

Disaster and Development

- Inter-relationship between Disasters and Development: Factors affecting Vulnerabilities, impact of Development projects such as dams, embankments, changes in Land-use etc. urban disasters, Waste Management

Global trends in disasters & Adaptation: Global Trends, Complex emergencies, Pandemics Climate change and Adaptation, Relevance of indigenous knowledge, appropriate technology and local resources

Research Methodology and Biostatistics
(MRM301T)

Scope:

This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, non-parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

COURSE OUTCOMES:

Upon completion of the course the student shall be able to

CO 01: Develop the ability to apply the statistical techniques and methods while working on a research project work by using softwares.

CO 02: Understand the appropriate statistical methods required for a particular research design.

CO 03: Choose the appropriate research design and develop an appropriate research hypothesis for a research project.

CO 04: Develop a appropriate framework for research studies, study designs and their strengths and limitations.

CO 05: Analyze of statistical results and communicate findings effectively.

Theory Course content: **60 Hours**

UNIT I:

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples.

UNIT II

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique.

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

UNIT III:

Preview of statistical parameters. Different distributions, fiducial limits, linear regression and correlation analysis, and their significance, parametric tests, type of errors, hypothesis testing, experimental designs, statistics in bioequivalence testing, statistical quality control, in-vitro in-vivo correlation. Probability determination, student T-test and chi square test and wilcoxan's rank sum tests.

UNIT IV:

Application and Methodology of One way, two-way, three way and repeated measures ANOVA. With post hoc tests like Fischer LSD test Tukey's multiple range tests, Bonferroni's test, Sheffe's test and Dennett's test.

Unit-VI

Design and Analysis of experiments:
Factorial Design: Definition, 2^2, 2^3 designs. Advantage of factorial design
Response Surface methodology: Central composite design, Historical design, Optimization Techniques

- **Recommended Books:**
- Clinical Pharmacokinetics Concepts and Applications 3 edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1987.
- Gupta, S. (2003) Research Methodologies and Statistical Techniques, Deep and Deep Publications Pvt. Ltd., New Delhi.
- Kothari, C.R. (2003) Research Methodologies: Methods and Techniques, Wishwa Prakashan, New Delhi.
- Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
- Fundamental of Statistics – Himalaya Publishing House- S.C. Guptha
- Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
- Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

HR 101 Human Values and Professional Ethics 2 Hours/ Week

. Scope & Objective of the Course:

The course provides a vide scope of learning & understanding of the subject and after completion of the subject the student will have the ability to develop human values and its importance in their professional life. The student will also have good knowledge of human rights.

Course outcomes:

CO 01: Develop critical thinking about character formation, Personal development and value education.

CO 02: Enhance the knowledge in understanding National and Professional Values.

CO 03: Deepen the awareness about Fundamental Rights.

CO 04: Promote compliance with International and National concepts of Human Rights.

CO 05: Nurture respect to women and children by clearing he concept of their human rights.

General Concepts Introduction about human rights and value education, aim of education, concept of human values and its type

Personal development: Self -analysis, gender equality, respect to age, experience, maturity, family member, coworker. Personality development and its importance in professional world

Character formation through human values: Truthfulness, sacrifice, sincerity, self-control,tolerance, positive attitude, dignity, ethics

National values: Democracy, socialism, secularism, equality, justice, liberty, freedom

Social values: sympathy, universal brother-hood, duty towards our society

Professional Values: Knowledge thirst, sincerity towards responsibility, ethics, regularity, punctuality, and faith

Religious values: Accept and respect others believes, tolerance, understanding, faith

Fundamental rights: Introduction and importance of fundamental rights of Indian constitution

Right to Equality: Introduction and its importance, types of rights of equality, equality before law, abolition of untouchability, abolition of titles

Rights to freedom: Introduction and its importance, types of rights, freedom of speech freedom to reside and settle, freedom to practice any profession

Rights against exploitation and right to freedom of religion: Introduction and its importance and its effects on human life.

Cultural and educational rights and rights to constitutional remedies

Right to property and right to education: Introduction and its importance, importance of education on our life

Human rights-general: Concepts of human rights and its Indian and international perspective, evolution of human rights, Universal Declaration of Human Rights, significance of the UDHR, analysis of the declaration

Therapeutic Measures: Control of mind through physical exercise, meditation

Meditation and Yoga: Introduction and its effects on human mind, types of yoga, how to control our thought through yoga and meditation

Human rights of women and children: Social practice and constitutional safeguards, gender discrimination in workplace

Female feticide, physical assault and harassment, domestic violence, condition of workingof

women, child labor, violation by individuals, nuclear weapons and terrorism safeguard

1. **Recommended Books (Reference Books/Text Books):**

   a. **RB01:** Value Education and Human Rights, R.P. Shukla
   b. **TB01:** Introduction to Human Rights and Duties, Dr. T. S. N. Sastry
   c. **TB02:** Value Education and Education For Human Rights, V.C. Pandey

29. Examples of few questions statements pertaining to different levels of Bloom's Taxonomy

Remember

A lot of emphasis is laid on, so as to make sure that all assessment components are conducted while following different levels of Bloom's Taxonomy as mentioned in figure.

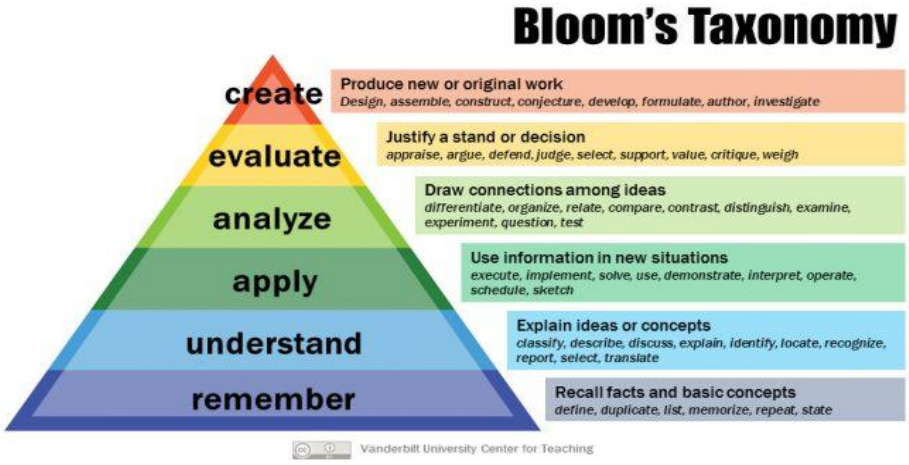

Figure 1. Bloom's Taxonomy [7]

Further a focused effort if also made to align every single Further a focused effort if also made to align every single test item in assessment components with one or the other course learning outcome.

Retrieving, recognizing, and recalling relevant knowledge from long-term memory.

Sample Questions

1. Classify antitubercular drugs into first line and second line drugs.

2. Enlist the major classes of antithyroid drugs.

Understand

Constructing meaning from oral, written and graphic messages through interpreting, exemplifying, classifying, summarizing, inferring, comparing and explaining.

Sample Questions

1. Explain the different types of oral contraceptives.

2. How can an understanding of chronotherapy, which involves timing medication administration based on circadian rhythms, help in the management of these conditions?

Applying

Carrying out or using a procedure through executing or implementing.

Sample Questions

1. Enumerate the different types of oral contraceptives. Mention composition of each. What are the primary mechanisms of action of these oral contraceptives, and what are some common side effects associated with their use, aiding in a foundational understanding of how these medications prevent pregnancy and their potential risks?

2. What are the main classes of oral hypoglycemic medications, and how do they work to lower blood sugar levels in patients with diabetes, fostering a foundational understanding of their pharmacological mechanisms? Mention the side effect of each drug.

Analysing

Breaking material into constituent parts, determining how the parts relate to one another and to an overall structure or purpose through differentiating, organizing and attributing

Sample Questions

1. Compile the main mechanisms of action of antitubercular drugs aiding in the treatment of tuberculosis? Mention briefly the management of tuberculosis emphasizing the main goals of antitubercular chemotherapy.

2. Enumerate the primary mechanisms of action of antithyroid drugs in individuals with hyperthyroidism, facilitating a basic comprehension of their pharmacological effects?

Creating & Evaluating

Putting elements together to form a coherent or functional whole; reorganizing elements into a new pattern or structure through generating, planning or producing. Making judgments based on criteria and standards through checking and critiquing

Sample Questions

1. Review how corticosteroids exert their pharmacological effects in the body, fostering a basic understanding of their uses. What are the pharmacological actions of these drugs on various organs and site the side effects of these drugs?

2. Define circadian rhythm, and how does it influence various bodily functions and disease processes such as cardiovascular disease, diabetes, asthma, and peptic ulcer?

30. Course Handout

An elaborate document named 'Course Handout' providing details about every single course is shared with students at the beginning of every semester. This document typically has various components like –

Course Handout

Institute/School Name			
Department Name			
Programme Name			
Course Name		Session	
Course Code		Semester/Batch	
L-T-P (Per Week)		Course Credits	
Pre-requisite		NHEQF Level[1]	
Course Coordinator			

1. Objectives of the Course

<< Provide a brief overview and objectives of this course in not more than 100 words. >>

2. Course Learning Outcomes (CLOs)

Student should be able to:

	CLOs	Programme Outcomes (PO)	NHEQF Level Descriptor[2]	No. of Lectures
CLO01				
CLO02				
CLO03				
CLO04				
CLO05				
CLO06 (Only for lab components)				
Total Contact Hours				

CLO-PO Mapping

CLO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CLO01												
CLO02												
CLO03												
CLO04												
CLO05												
CLO06												

H=High, M=Medium, L=Low

3. Recommended Books:

[1] National Higher Education Qualification Framework Level, Refer to annexure

[2] NHEQF Level Descriptor, Refer to Annexure & Learning outcomes descriptors for qualification for all levels on the NHEQF

B01:
B02:
B03:
B04:
B05

4. Other readings and relevant websites:

Serial No.	Link of Journals, Magazines, websites and Research Papers
1.	
2.	
3.	
4.	
5.	

5. Recommended Tools and Platforms

<<Mention Tools and Platforms required for the course if required>>

6. Course Plan: Theory+ Lab Plan Theory

Plan

Lect. No.	Topic(s)
ST1	
ST2	
End Term Exam	

Lab Plan

Lab No.	Topic(s)
Continuous Evaluation1 (15marks)	
Continuous Evaluation2 (15Marks)	

7. Delivery/Instructional Resources Theory Plan:

Lect. No.	Topics	Book No, CH No, Page No	TLM[3]	ALM[4]	Web References	Audio-Video
		B01, CH 1.1-1.5, Page no 3-13				

Lab Plan:

Lab No.	Experiment	TLM	ALM	Web References	Audio-Video

8. Remedial Classes[5]

<<Supplement course handout, which may perhaps include special lectures and discussions that would be planned, and schedule notified

[3] Teaching Learning Methods, Refer to Annexure
[4] Active Learning Methods
[5] Refer to Annexure

accordingly.>>

9. Self-Learning[6]

Assignments to promote self-learning, survey of contents from multiple sources.

S. No.	Topics	CO	ALM	References/MOOCS

10. Delivery Details of Content Beyond Syllabus[7]

Content beyond syllabus covered (if any) should be delivered to all students that would be planned, and schedule notified accordingly.

S. No.	Advanced Topics, Additional Reading, Research papers and any	CO	POs	ALM	References/MOOCS

11. Evaluation Scheme & Components:

Assessment Type[8]	Evaluation Component[9]	Type of Component[10]	No. of Assessments[11]	% Weightage of Component	Max. Marks	Mode of Assessment
Formative	Component1	Continuous Lab Evaluations	02*	30%		Offline
Summative	Component2	Sessional Tests(STs)	02**	20%		Offline
Summative	Component3	End Term Examination	01***	50%		Offline
	Total		**100%**			

Note: Details in above table are sample for the reference, The department decides the assessment policy for each course.

12. Syllabus of the Course:

Subject:			
S. No.	**Topic(s)**	**No. of Lectures**	**Weightage %**

13. Academic Integrity Policy:

Education at Chitkara University builds on the principle that excellence requires freedom where Honesty and integrity are its prerequisites. Academic honesty in the advancement of knowledge requires that all students and Faculty respect the integrity of one another's work and recognize the importance of acknowledging and safeguarding intellectual property. Any breach of the same will be tantamount to severe academic penalties.

[6] Refer to Annexure
[7] Refer to Annexure
[8] Refer to Annexure 2 of NCrF
[9] Refer to Annexure
[10] Refer to Annexure
[11] Refer to Annexure

This Document is approved by:

Designation	Name	Signature
Course Coordinator		
Head-Academic Delivery		
Dean		
Date (DD/MM/YYYY)		

Faculty members are expected to religiously follow the contents of the course handout in complete letter and spirit.

13. Appendix A: Mapping of Programme Outcomes (POs) with Course Outcomes (COs):

S. No.	Course Name	Course Code	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
1.	Good regulatory practices	MRA-101T	CO 1: Understand regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Distribution Practices	H	H	L			M					
			CO 2: Prepare and implement the check lists and SOPs for various Good Regulatory Practices			H	M					L		
			CO 3: Apply Good Regulatory Practices in the Healthcare and related Industries	H	L			M		H				
			CO 4: Prepare for the readiness and conduct of audits and inspections.			H	H		L		M			
			CO 5: Understand the concept of quality management systems		H				L			M		
			CO 01: Understand the various documents pertaining to drugs in	H	M	H	H	H	M	H				

2.	Documentation and Regulatory Writing	MRA-102T	pharmaceutical industry											
			CO 02: Assess the basics of regulatory complications.	M	L	M	H	H	L	H				
			CO 03: Critically assess and assemble the regulation submission as per the requirements of agencies	M		L	H	H	H	L				
			CO 04 Impart the learning opportunities to understand follow up the submissions and post approval document requirements	L	M	L	H	H	M	L				
			CO 05: Understand and utilise the concerns related to drug development and product life cycle management.	M	L	L	H	H	H	L		M		
3.	Clinical research Regulations	MRA-103T	CO 01: Understand the history, origin and ethics of clinical and biomedical research	L	H	M	L	H	M	M	L			
			CO 02: Design and implement various types of clinical studies, different types and phases of clinical trials		L	L	L	H	M	M	L			
			CO 03 Critically assess the regulatory requirement, guidance and documentation for conduct of clinical trials and research of drug and medical devices of Various regulatory agencies (e.g. USFDA, EMEA, ISO, GHTF etc.)	M	L	H	H	H	H	H	M			
			CO04: Analyse FDA guidance for bioavailability and bioequivalence requirements for medicinal products.	M	L	H	M	H	H					
			CO05: Understand Indian GCP, CDSCO and ICMR guidelines for biomedical research.	M	L	H	L	M	H	H	H	L		

4.	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	MRA-104T	CO1: Understand the different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.	H	H	L					H	M		
			CO2: Demonstrate the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals	H	H			L			M	H		
			CO3: Identify Guidelines for conducting clinical studies, preclinical studies, Bioavailability and Bioequivalence studies and stem cell research		M			H	H	H		L		
			CO4: Analyse standards for attainment of Quality, safety and efficacy	M		H	L			H				
			CO5: Understand basics of Intellectual Property Rights			H	H		M		L			
5.	Regulatory affairs PracticalI	MRA-105P	CO 01: Understand various documents pertaining to drugs in pharmaceutical industry	H	H			H		H				
			CO 02: Understand the basics of regulatory guidelines used in industry to file IND, NDA, BLA	H	H	M	H	M	H	H	M			
			CO 03: Analyse and assemble the regulation submission as per the requirements of agencies in industries	M	H	M	H			H	M	L		
			CO 04: Categorize the requirements for the various types of submission application for US, EU and Japan and to understand the Regulatory guidance's and guidelines for filing and approval process	L	L	L	M	H	H		H	L		

			CO 05: Impart learning opportunities to practically assess the criticality of various case studies related to GMP, Checklists for registration of IND, ANDA etc.	H	H		H	L			M			
7.	Regulatory Aspects of Drugs & Cosmetics	MRA 201T	CO 1: Provide learning opportunities of the regulatory procedures involved in drug discovery, research development and generic product development.	H	H	H	H	H	H	H				
			CO 2: Understand regulatory approval processes and registration procedures for APIs and drug products in the US and EU	H	H	L	H	M	M	H				
			CO 3: Evaluate Drug and Cosmetics regulations in regulated and semi-regulated countries	H	M	L	M	M	M	L				
			CO4: Analyse a comparative study drug and drug product registration in India with other global regulated markets	H	M	L	M	L	M	L	M			
			CO 5: Analyse differences in regulatory approval approaches of cosmetics in global regulated markets	H	M	L	M	L	L	L	L	L	L	L
8.	Regulatory Aspects of Herbal & Biologicals	MRA 202T	CO 1: Understand the regulatory Requirements for Biologics and Vaccines used for filling their approval requests by the industries.	H	L	H		H		H	L			
			CO 2: Acquire the regulatory knowledge for registration of newly developed biologics and biosimilars	H	L	H	H	M	H	H	H	H		

			CO 3: Provide learning opportunities in pre-clinical and clinical development considerations for the development of new biologics for diseases by the industries			H		H		M	L				
			CO 4: Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements	H	L	H	H	H	H	H	L	H		
			CO 5: Understand the regulation and registration of herbals as per US, Europe and India.	H	L		H		H		H	H			
9.	Regulatory Aspects of Medical Devices	MRA 203T	CO 1: Understand the basics of medical devices and IVDs, process of development, ethical and quality considerations	H	M	M	M	L	M		M				
			CO 2: Provide learning opportunities to enhance knowledge of organizational structure, regulatory guidelines and functions of IMDRF/GHTF.	L	L	L	H		H		M				
			CO 3: Understand the quality system regulations and quality risk management of medical devices.	H		L	M	L	L		M				

			CO 4: Critically assess the regulatory approval process for medical devices and IVDs in US and Europe.	L	L		M	H	H	M	H			
			CO 5: Understand the regulatory approval process for medical devices and IVDs in China, Japan and ASEAN countries.	L			M	H						
10.	Regulatory Aspects ofFood & Nutraceuticals	MRA 204T	CO 1: Understand the regulatory requirements for nutraceuticals	M	H	L	H	L			H	H		
			CO 2: Impart knowledge of regulation for registration and labelling of nutraceuticals and food supplements in India	H	M	L	L	L	L	L	H	H		
			CO 3: Analyze the regulation for registration and labeling of nutraceuticals and food supplements in USA.	M	H	L			L	L	H	H		
			CO 4: Understand the regulation for registration and labeling of nutraceuticals and food supplements in Europe	M	H		L	L			H	H		

			CO 5: Evaluate the global aspects of dietary supplements and nutraceuticals		M			L	H		H	H		
11.	Regulatory affairs Practical II	MRA-205P	CO 1: Understand various documents pertaining to drugs in pharmaceutical industry	H	H				H		H	H		
			CO 2: Understand regulatory guidelines basics.	H	M	H	H		H	M	H	H		
			CO 3: Analyse and assemble the regulation submission as per the requirements of agencies	H	M	M		M	H	M	H	H		
			CO 4: Categorize the requirements for the various types of submission application for US, EU and Japan and to understand the Regulatory guidance's and guidelines for filing and approval process	H	L		H		H		H	H		
			CO 5: Critically assess the case studies related to GMP, Checklists for registration of IND, BLA, Vaccine approval, ANDA etc.	M	M	M		M	H	M	H	H		

12.	Disaster Management	DM 101	C01: Understand the relationship between vulnerability, disasters, prevention and disaster	H			M			L		L		
			CO2: Enhance knowledge on disasters, impact on social, economic, political, psychosocial, health etc.		H		M		M				L	
			CO3: Comprehend the significance of disasters and their types.	H		M					L			
			CO 4: Analyze the global trends of disasters and adaptation.	H		M					L			
			CO5: Impart the learning opportunities to understand the vulnerabilities, urban disasters and waste management		H			M				L		

13.	Research Methodologyand Biostatistics	MRM 301T	CO1: Develop the ability to apply the statistical techniques and methods while working on a research project work by using softwares.										H	
			CO2: Understand the appropriate statistical methods required for a particular research design.										H	
			CO3: Choose the appropriate research design and develop an appropriate research hypothesis for a research project.										H	
			CO4: Develop a appropriate framework for research studies, study designs and their strengths and limitations.										H	
			CO5: Analyze of statistical results and communicate findings effectively.										H	

14.	Human Values & Professional Ethics	HR101	CO1: Develop critical thinking about character formation, Personal development and value education.	H	H			M	M			M	L	
			CO2: Enhance the knowledge in understanding National and Professional Values.	H			H	M				L	L	
			CO3: Deepen awareness about Fundamental Rights.	H		M					L			
			CO4: Promote compliance with International and National concepts of Human Rights.		H			M		L				
			CO5: Nurture respect to women and children by clearing the concept of their human rights.	H		M			L				M	