Two-Year Post graduate Programme

Master of Pharmacy

Regulatory Affairs

Faculty of Pharmacy

Parul University

Vadodara, Gujarat, India

Faculty of Pharmacy
Master of Pharmacy in Regulatory Affairs

1. Vision of the Department

To nurture pharmacy aspirants to serve the society with comprehensive subject knowledge, high professional values, excellent skills and outstanding research aptitude.

2. Mission of the Department

M1 Foster humanitarian values, passion for learning and creativity.
M2 Move towards high quality, futuristic educational and research ecosystem.
M3 Develop socially responsible future pharmacists; committed to creating self-reliant India.

3. Program Educational Objectives

PEO 1	A robust regulatory affairs curriculum teaches students the basics of the industry, as well as strategies for lifelong learning and development.
PEO 2	Our Post Graduates would be compassionate, skilled, ethical professionals and researchers shall commit to the cause of health and wellness with regulatory standards understandings.

4. Program Learning Outcomes

Program Learning outcomes are statements conveying the intent of a program of study.

PLO 1	**In-depth Knowledge of Pharmaceutical Science**	Acquire in-depth knowledge of all the theories and principle involved in pharmaceutical science.
PLO 2	**Professional and Interpersonal Skill Development**	Demonstrate necessary skills in pharmaceutical science like working independently, communication, coordination, time management and organizational skills. The students will demonstrate an adaptable, flexible and effective approach towards organizational development.
PLO 3	**Competency Development**	Develop an ability to communicate scientific knowledge in in non-expert/lay term by adopting various modes of scientific
PLO 4	**Technical Expertise**	Enable student handle pharmaceutical instruments in experiments. The student will also learn to draft the protocols and results based on the various research experiments.
PLO 5	**Knowledge Enhancement and**	Gain the knowledge by continue updating of technologies involving management of Pharmaceutical Quality System for

	Project management abilities	continual improvement of Process Performance and Product Quality.
PLO 6	**Innovative Approach for research**	Develop critical thinking quality, which leads to development of the novel ideas in the field of pharmaceutical science
PLO 7	**Individual and Team work**	Function individually as a member or as a leader in diverse team with technical expertise.
PLO 8	**Instrument handling skills**	Understand theoretical and practical skills of the instruments. To apply suitable methods, resources and standard procedures to handle all types of equipment for demonstrating Pharmaceutical activities
PLO 9	**Regulatory Compliance**	Understand the fine regulatory requirements for Pharmacy profession starting from drug discovery to final product marketing.
PLO 10	**Knowledge about Current Affairs and lifelong learning**	Exhibit latest and updated knowledge in the field of pharmacy and will developed the attitude and aptitude for lifelong learning.
PLO 11	**Environment and sustainability**	Understand the impacts of any research in societal and environmental contexts and develop any innovation with a second eye on environment and sustainability.

5. Program Specific Learning Outcomes

PSO 1	**Regulatory documentation and submission**	Learn basic skills of documentation, regulatory writing and submission to authorities.
PSO 2	**Technical skills and IPR**	Demonstrate information technology skills in the use of software applicable to regulatory affairs submissions, Intellectual Property Rights, and in the use of the Internet for research

6. Credit Framework

Semester wise Credit distribution of the programme	
Semester-1	26

Category wise Credit distribution of the programme	
Category	**Credit**
Major Core	32

Semester-2	26
Semester-3	21
Semester-4	20
Total Credits:	**93**

Multidisciplinary	4
Skill Development Courses	20
Research Project/Dissertation	37
Total Credits:	**93**

7. Program Curriculum

Semester 1						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MRA101T	Good Regulatory Practice	4	4	-	-
2	MRA102T	Documentation and Regulatory Writing	4	4	-	-
3	MRA103T	Clinical research regulations	4	4	-	-
4	MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food	4	4	-	-
5	MRA105P	Regulatory Affairs Practical I	6	-	12	-
6	MRASEM I	Seminar sem I	4	7	-	-
		Total	**26**	**23**	**12**	**-**
Semester 2						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	-	-
2	MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	-	-
3	MRA203T	Regulatory Aspects of Medical Devices	4	4	-	-
4	MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	-	-
5	MRA205P	Regulatory Affairs Practical II	6	-	12	-
6	MRASEM II	Seminar sem II	4	7	-	-
		Total	**26**	**23**	**12**	**-**
Semester 3						

Sr. No.	Subject Code	Subject Name	Credit	Lect	Lab	Tut
1	MRA301T	Research Methodology and Biostatistics	4	4	-	-
2	MRA302P	Pre-Dissertation-I	1	-	1	-
3	MRA303P	Pre-Dissertation-II	2	-	2	-
4	MRA304P	Pre-Dissertation-III	14	-	28	-
		Total	**21**	**4**	**31**	

Semester 4

Sr. No.	Subject Code	Subject Name	Credit	Lect	Lab	Tut
1	MRA401P	Dissertation-I	1	-	1	-
2	MRA402P	Dissertation-II	16	-	30	-
3	MRA403P	Dissertation-III	3	-	3	-
		Total	**20**	**-**	**34**	**-**

8. Detailed syllabus

ANNEXURE-III

Semester I

a. **Course Name: Good Regulatory Practices**
b. **Course Code: MRA101T**
c. **Prerequisite:** Basic Knowledge of Good manufacturing practices and other good regulatory practices and QMS.
d. **Rationale:** 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.
e. **Course Learning Objective:**

CLOBJ 1	Learn the key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, and Good Automated Laboratory Practices.
CLOBJ 2	Understand the key regulatory and compliance elements with respect to Good Documentation Practices.
CLOBJ 3	Understand the check lists and SOPs for various Good Regulatory Practices

CLOBJ 4	Explain the Good Regulatory Practices in the Healthcare and related Industries
CLOBJ 5	Discuss the readiness and conduct of audits and inspections

f. Course Learning Outcomes:

CLO 1	Define and explain the key regulatory, compliance elements with respect to Good Manufacturing Practices and learn relevant GHTF guidance documents.
CLO 2	Relate and understand the key regulatory, compliance elements with respect to Good Laboratory Practices and learn relevant ISO and QCI standards.
CLO 3	Define and summarize the key regulatory, compliance elements with respect to Good Automated Laboratory Practices and learn relevant ISO and QCI standards.
CLO 4	Relate and Understand the key regulatory, compliance elements with respect to Good Documentation Practices and learn relevant CDSCO guidance and ISO standards.
CLO 5	Recall and summarize the concepts of QMS system with aspect to industrial implementation.

g. Teaching & Examination Scheme:

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
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.	**20**	**12**
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	**20**	**12**

	regulations, relevant ISO and Quality Council of India(QCI) Standards.		
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.	**20**	**12**
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 standard	**20**	**12**
5	Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	**20**	**12**
Total		**100%**	**60**

i. Text Book and Reference Book:

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

a. **Course Name: Documentation and Regulatory Writing**
b. **Course Code: MRA102T**
c. **Prerequisite:** Basic Knowledge of product development process and documentation.
d. **Rationale:** This course deals with fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agency.
e. **Course Learning Objective:**

CLOBJ 1	Learn the various documents pertaining to drugs in pharmaceutical industry
CLOBJ 2	Understand the basics of regulatory compilation
CLOBJ 3	Learn the regulation submission as per the requirements of agencies
CLOBJ 4	Understand the regulatory importance of audit and inspection
CLOBJ 5	Recognize the follow up of submissions and post approval document requirements

f. **Course Learning Outcomes:**

CLO 1	Understand and categorize the various documentation related to pharmaceutical industry.
CLO 2	Summarize and compare the dossier preparation and submission as per ICH, ASEAN and CDSCO regulatory requirements.
CLO 3	Explain and Discover the concepts of global regulatory requirements and guidance for audits.
CLO 4	Learn and compare the concepts of global regulatory requirements and guidance for Inspections.
CLO 5	Understand the product life cycle management and ISO risk management standards.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	Content	Weightage (%)	Teaching Hours
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.	**20**	**12**
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.	**20**	**12**
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.	**20**	**12**
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).	**20**	**12**
5	Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post	**20**	**12**

	approval Labelling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard.		
Total		**100%**	**60**

i. Text Book and Reference Book:

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 145
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. FairfieldSonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP.

a. **Course Name: Clinical Research Regulations**
b. **Course Code: MRA103T**
c. **Prerequisite:** Basic knowledge of clinical trials and clinical study design.
d. **Rationale:** This course impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.
e. **Course Learning Objective:**

CLOBJ 1	Recognizing the history, origin and ethics of clinical and biomedical research and evaluation
CLOBJ 2	Discuss the clinical drug, medical device development process and different types and phases of clinical trials
CLOBJ 3	Understand the regulatory requirements and guidance for conduct of clinical trials and research in India
CLOBJ 4	Learn the regulatory requirements and guidance for conduct of clinical trials and research in USA
CLOBJ 5	Describe the regulatory requirements and guidance for conduct of clinical trials and research in EU

f. **Course Learning Outcomes:**

CLO 1	Recall and summarize the clinical drug and medical device development process, different types and phases of clinical trials.
CLO 2	Recall and Explain the history, origin and ethics of clinical research for evaluation of drugs and medical devices as well as roles and responsibilities of different bodies involve in clinical trials.
CLO 3	Interpret and compare the various regulations governing clinical trials as per India, USA and EU requirements.
CLO 4	Explain and Justify the different aspects of GCP and regulatory guidance on efficacy and safety for ICH region
CLO 5	Illustrate and compare the various guidance documents for clinical trial process as well as post marketing surveillance guidance for USA and EMA.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	

4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	● Clinical Drug Development Process ● Different types of Clinical Studies ● Phases of clinical trials, Clinical Trial protocol ● Phase 0 studies ● Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points ● Phase II studies (proof of concept or principle studies to establish efficacy) ● Phase III studies (Multi ethnicity, global clinical trial, registration studies) ● Phase IV studies (Post Marketing Studies; PSUR) Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation	**20**	**12**
2	● Ethics in Clinical Research ● Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki ● Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. ● The ethics of randomized clinical trials ● The role of placebo in clinical trials ● Ethics of clinical research in special population ● Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data ● Data safety monitoring boards. ● Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research ● Ethical principles governing informed consent process ● Patient Information Sheet and Informed Consent Form ● The informed consent process and documentation.	**20**	**12**
3	● Regulations governing Clinical Trials India: Clinical Research regulations in India – Schedule Y & Medical	**20**	**12**

	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 ● 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	**20**	**12**
5	● USA & EU Guidance USA: FDA Guidance ● CFR 21Part 50: Protection of Human Subjects ● CFR 21Part 54: Financial Disclosure by Clinical Investigators ● CFR 21Part 312: IND Application ● CFR 21Part 314: Application for FDA Approval to Market a New Drug ● CFR 21Part 320: Bioavailability and bioequivalence requirements ● CFR 21Part 812: Investigational Device Exemptions ● CFR 21Part 822: Post-market surveillance ● FDA Safety Reporting Requirements for INDs and BA/BE Studies FDA Med Watch ● Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment European Union: EMA Guidance ● EU Directives 2001 ● Eudralex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use	**20**	**12**

	● EU Annual Safety Report (ASR) ● Volume 9A – Pharmacovigilance for Medicinal Products for Human Use ● EU MDD with respect to clinical research ● ISO 14155		
Total		**100%**	**60**

i. Text Book and Reference Book:

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

a. **Course Name: Regulation and Legislation for drug & cosmetics, medical devices, biologicals & herbals, and food & Nutraceutical in India and Intellectual Property Rights**
b. **Course Code: MRA104T**
c. **Prerequisite:** Basic knowledge of acts and regulations in India for pharmaceuticals.
d. **Rationale:** 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.
e. **Course Learning Objective:**

CLOBJ 1	Discuss the different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices.
CLOBJ 2	Explain different Acts and guidelines that regulate Biologicals & Herbals, and Food & Nutraceuticals industry in India
CLOBJ 3	Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices.
CLOBJ 4	Learn the approval process and regulatory requirements for Biologicals & Herbals, and Food & Nutraceuticals
CLOBJ 5	Understand the regulatory requirements for registration of IPR.

f. **Course Learning Outcomes:**

CLO 1	Recall and categorize the different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
CLO 2	Explain and List the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biological, Herbals, Food and Nutraceuticals
CLO 3	Define and Explain the Indian Pharmacopoeial standards, BIS and ISO standards
CLO 4	Relate and justify the regulation standards and evaluation parameter of BA/BE studies and ethical guideline for animal studies and human participants
CLO 5	Recall and compare the concepts of various IPRs and regutory requirements of IPR

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**		
L	**T**	**P**	**C**	**Internal Evaluation**	**ESE**	**Total**

				MSE	CE	P	Theory	P	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA 2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	**20**	**12**
2	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: ● Organization, Responsibilities ● Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals ● Format and contents of Regulatory dossier filing Clinical trial/ investigations.	**20**	**12**
3	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards.	**20**	**12**
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human	**20**	**12**

	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	**20**	**12**
Total		**100%**	**60**

i. Text Book and Reference Book:

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 Tripartit
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

ANNEXURE-IV
Semester I

a. **Course Name: Regulatory Affairs Practical-I**
b. **Course Code: MRA105P**
c. **Prerequisite:** Basic knowledge of drug application and CTD formats.
d. **Rationale:** This course provides knowledge of IND, ANDA and NDA submission to different countries as well as documentation which have been done in pharmaceutical industries.
e. **Course Learning Objective:**

CLOBJ 1	Prepare the SOPs and Analytical reports
CLOBJ 2	Evaluate the case studies in the area of the regulatory affairs
CLOBJ 3	Understand the Clinical study, clinical research and clinical trials

f. **Course Learning Outcomes:**

CLO 1	Preparation of different pharmaceutical documents, application of different intellectual properties and GMP audit checklist.
CLO 2	Preparation of different drug application like IND, ANDA, NDA and comparative study of DMF, and clinical trial application for India, Europe and USA

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**	**-**	**-**	**50**	**-**	**100**	**150**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**

1. Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory
2. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite

i. **Experiment List:**

Exp. No.	**Name of the Experiment**
1	Case studies of each of Good Pharmaceutical Practices

Exp. No.	Name of the Experiment
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	Labelling comparison between brand & generics
6	Preparation of clinical trial protocol for registering trial in India
7	Registration for conducting BA/ BE studies
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 Indi
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
25	Regulatory requirements checklist for conducting clinical trials in Europe
26	Regulatory requirements checklist for conducting clinical trials in USA

ANNEXURE-III
Semester II

a. **Course Name: Regulatory Aspects of Drug and Cosmetics**
b. **Course Code: MRA201T**
c. **Prerequisite:** Basic knowledge of drug registration regulations**.**
d. **Rationale:** 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.
e. **Course Learning Objective:**

CLOBJ 1	Describe the basics of medical devices and IVDs, process of development, ethical and quality considerations.
CLOBJ 2	Identify the regulatory approval process and registration procedures for API and drug products in US, EU
CLOBJ 3	Understand the regulatory approval process and registration procedures for API and drug products in Japan
CLOBJ 4	Learn about cosmetics regulations in regulated and semi-regulated countries.
CLOBJ 5	Understand the comparative study of India with other global regulated market.

f. **Course Learning Outcomes:**

CLO 1	Relate and compare the various regulatory approval process for drug products registration and legislation for import, manufacture, distribution and sale of cosmetics in UFDA and Health Canada.
CLO 2	Relate and summarize the various regulatory approval process for drug products registration and legislation for import, manufacture, distribution and sale of cosmetics in European Union member states and Australia.
CLO 3	Summarize the various regulatory approval process for drug products registration and legislation for import, manufacture, distribution and sale of cosmetics in Japan.
CLO 4	Translate the emerging market concept, drug approval and post approval requirement as per WHO.
CLO 5	Explain and distinguish the regulatory approval process for drug products registration and legislation for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC countries.

g. **Teaching & Examination Scheme:**

Teaching Scheme				Evaluation Scheme					
L	T	P	C	Internal Evaluation			ESE		Total
				MSE	CE	P	Theory	P	
4	-	-	4	15	10	-	75	-	100

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
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.	20	12
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,	20	12

	distribution and sale of cosmetics in European Union & Australia.		
3	Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	**20**	**12**
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)	**20**	**12**
5	Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.	**20**	**12**
Total		**100%**	**60**

i. Text Book and Reference Book:

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

3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew.ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes139
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

a. **Course Name: Regulatory Aspects of Herbal and Biologicals**
b. **Course Code: MRA202T**
c. **Prerequisite:** Basic knowledge of biologicals and regulations for herbals.
d. **Rationale:** This course designed for 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.
e. **Course Learning Objective:**

CLOBJ 1	Recognize the regulatory Requirements for Biologics and Vaccines as per regulations of India, USA, EU
CLOBJ 2	Understand the regulation for newly developed biologics and biosimilars
CLOBJ 3	Discuss the pre-clinical and clinical development considerations of biologics
CLOBJ 4	Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements.
CLOBJ 5	Learn the regulatory requirements of Herbal Products as per regulation of India, US, EU.

f. **Course Learning Outcomes:**

CLO 1	Recall and summarize the guidance and regulatory Requirements of biologics for marketing authorization and pharmacovigilance in India.
CLO 2	Recall and Translate the guidance and regulatory requirements of Biologics preclinical, clinical development considerations, and approval in USA.
CLO 3	Define and Explain the directives and regulatory Requirements of biologics for approval in Europe.
CLO 4	Explain and relate to regulatory requirements of Blood and/or Its Components Including Blood Products and label requirements for USA, Europe and India along with introduction of ISBT and ISHN.
CLO 5	Explain and categorize the regulatory requirements with guidelines of safety, efficacy and Quality of Herbal product in India, USA and EU.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
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.	**20**	**12**
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.	**20**	**12**
3	Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	**20**	**12**
4	Emerging Market: Introduction, Countries covered, Study of the world map,study of various committees across the	**20**	**12**

	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)		
5	Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.	**20**	**12**
Total		**100%**	**60**

i. Text Book and Reference Book:

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

a. Course Name: Regulatory Aspects of Medical Devices

b. Course Code: MRA203T

c. **Prerequisite:** Basic knowledge of medical devices regulations around globe.

d. **Rationale:** This course deals with 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.

e. **Course Learning Objective:**

CLOBJ 1	Understand the basics of medical devices and IVDs, process of development, ethical and quality considerations
CLOBJ 2	Explain the harmonization initiatives for approval and marketing of medical devices and IVD
CLOBJ 3	Describe the regulatory approval process for medical devices and IVDs in India, US, Canada and Europe.
CLOBJ 4	Discuss the clinical evaluation and investigation of medical devices and IVDs
CLOBJ 5	Learn the regulatory approval process for medical devices and IVDs in Developing countries like ASEAN, China & Japan

f. **Course Learning Outcomes:**

CLO 1	Recall and explain the basic concepts of medical devices and IVDs, process of development and summary of IMDRF/GHTF
CLO 2	Summarize and find the ethical and quality consideration for clinical investigation of medical devices and IVDs and understand the ISO regulation for clinical investigation of medical devices
CLO 3	Give an outline of the regulatory approval process, clinical evaluation and investigation for medical devices and IVDs in USA
CLO 4	Summarize the regulatory approval process, clinical evaluation and investigation for medical devices and IVDs in EU
CLO 5	List and compare the regulatory approval process, clinical evaluation and investigation for medical devices and IVDs in ASEAN, China & Japan

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).	**20**	**12**
2	Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.	**20**	**12**
3	USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process	**20**	**12**
4	European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process	**20**	**12**
5	ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System	**20**	**12**

	requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents		
Total		**100%**	**60**

i. Text Book and Reference Book:

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.

a. **Course Name: Regulatory Aspects of Food and Nutraceuticals**
b. **Course Code: MRA204T**
c. **Prerequisite:** Basic knowledge of food and regulations of nutraceuticals.
d. **Rationale:** This course provides 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.
e. **Course Learning Objective:**

CLOBJ 1	Understand the term and history: Food and Nutraceuticals
CLOBJ 2	Understand the global aspects of food and nutraceuticals
CLOBJ 3	Explain the regulatory approval process of food and nutraceuticals in India, USA and Europe
CLOBJ 4	Learn the regulatory requirements for Manufacturing and sale of food and nutraceuticals in India, USA and Europe
CLOBJ 5	Describe the Knowledge of RDA requirements in India, USA and Europe

f. **Course Learning Outcomes:**

CLO 1	Define and Explain the term and history Nutraceutical, dietary supplement, function food, medical food
CLO 2	Find and summarize the global aspects and regulatory requirements of food and nutraceutical
CLO 3	Explain and Relate the regulatory Requirements for approval, registration and labeling of food and nutraceuticals in India
CLO 4	Illustrate the regulatory Requirements for approval, registration and labeling of food and nutraceuticals in USA
CLO 5	Summarize the regulatory Requirements for approval, registration and labeling of food and nutraceuticals in Europe

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	**20**	**12**
2	Global Aspects: WHO guidelines on nutrition. NSF International: It's Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	**20**	**12**
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.	**20**	**12**
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	**20**	**12**
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	**20**	**12**
Total		**100%**	**60**

i. Text Book and Reference Book:

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.

ANNEXURE-IV
Semester II

a. **Course Name: Regulatory Affairs Practical-II**
b. **Course Code: MRA205P**
c. **Prerequisite:** Basic knowledge of e-CTD submission.
d. **Rationale:** This course provides understanding of different countries requirements of e-CTD submission and FDA, EMA and MHRA and other different countries**.**
e. **Course Learning Objective:**

CLOBJ 1	Understand Requirements for the approval of the medical devices in the different parts of the world.
CLOBJ 2	Application of regulatory guidelines for the new drug approval
CLOBJ 3	Understand the application of quality system in the different parts of the world

f. Course Learning Outcomes:

CLO 1	Understand the concept of CAPA, monographs, audit, e-CTD software, vaccine product approval and applying a knowledge to prepare relevant documents like audit checklist, submission of drug application using e-CTD software for FDA, EMA and MHRA
CLO 2	Preparation of marketing authorization application of emerging market like WHO, BRICS, China & South Korea, ASEAN, GCC and various documents of medical devices.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**	**-**	**-**	**50**	**-**	**100**	**150**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Text Book and Reference Book:

1. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
2. www.who.int/biologicals/en

3. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
4. www.ihn-org.com
5. www.isbtweb.org
6. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
7. www.cdsco.nic.in
8. www.ema.europa.eu › scientific guidelines › Biologicals
9. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

i. Experiment List:

Exp. No.	Name of the Experiment
1	Case study on Change Management/ Change control Deviations
2	Case study on Corrective & Preventive Actions
3	Documentation of raw materials analysis as per official monographs
4	Preparation of audit checklist for various agencies
5	Preparation of submission to FDA using eCTD software
6	Preparation of submission to EMA using eCTD software
7	Preparation of submission to MHRA using eCTD software
8	Preparation of Biologics License Applications (BLA)
9	Preparation of documents required for Vaccine Product Approval
10	Comparison of clinical trial application requirements of US, EU and India of Biologics
11	Preparation of Checklist for Registration of Blood and Blood
12	Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
13	Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization.
14	Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
15	Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
16	Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
17	Checklists for 510k and PMA for US market
18	Checklist for CE marking for various classes of devices for EU
19	STED Application for Class III Devices
20	Audit Checklist for Medical Device Facility
21	Clinical Investigation Plan for Medical Devices

ANNEXURE-III

Semester III

a. **Course Name: Research Methodology and Biostatistics**
b. **Course Code: MRM301T**
c. **Prerequisite:** Basic knowledge of research and concept of statistical analysis.
d. **Rationale:** The course is designed to study research methodology in terms of basic concepts of statistical analysis, principles of medical research, ethics and patents, maintenance of laboratory animals and design research work.
e. **Course Learning Objective:**

CLOBJ 1	Analyze the value, scope, objectives and requirements of research
CLOBJ 2	Discuss the basic concepts of statistical analysis
CLOBJ 3	Apply the basic principles of medical research and ethics.
CLOBJ 4	Understand the guidelines for the maintenance of laboratory animals.
CLOBJ 5	Create efficiency in solving practical difficulties and Understand to design research work.

f. **Course Learning Outcomes:**

CLO 1	Learn general research methodology helps to select the appropriate study design and develop appropriate research hypothesis for a research project
CLO 2	Understand the basic concepts of biostatistics and Learn different parametric and non-parametric tests
CLO 3	Understand the functions of ethics committees in medical research
CLO 4	Learn CPCSEA guidelines for laboratory animal facility
CLO 5	Study the genesis of bioethics with special reference to Helsinki declaration

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	**UNIT – I** General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	**20**	**12**
2	**UNIT – II** Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**20**	**12**
3	**UNIT – III** Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	**20**	**12**
4	**UNIT – IV** CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	**20**	**12**

5	**UNIT – V** Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**20**	**12**
Total		**100%**	**60**

i. Text Book and Reference Book:

1. Research Methodology: Methods & Techniques, C.R. Kothari, Viswa Prakashan,
2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications.
3. Pharmaceutical Statistics: Practical and Clinical Applications, Sanford Bolton and Charles
Bon.
4. Thesis projects in Science & Engineering – Richard M. Davis.
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