SAURASHTRA UNIVERSITY

Accredited Grade 'A'

By NAAC

FACULTY OF PHARMACY

Master of Pharmacy (M. Pharm) in Pharmaceutical Regulatory Affairs

Ordinances and Regulations

Effective from

June 2017

(Two-Year full-time PG Course)

Department of Pharmaceutical Sciences

Saurashtra University

Rajkot - 360 005

www.saurashtrauniversity.edu

PROGRAM OUTCOMES
POs OF M. PHARM (Pharmaceutical Regulatory Affairs)

Students of all post undergraduate pharmacy degree programs at the time of graduation will be able to learn:

PO 1: Research and development

The students will be able to generate ideas for research, analyse them, execute them and publish the findings.

PO 2: Domain knowledge:

Students will be able to acquire knowledge and comprehension of the core and specialization subjects of the respective pharmacy specialization.

PO 3: Communication skills:

Students will be able to learn communication by giving seminars, journal club and other organizational activities. They will be able to comprehend and write effective reports, make effective presentations and documentation.

PO 4: Planning skills:

Students will be able to demonstrate effective planning abilities including time management, resource management, and organizational skills. They will be able to develop and implement plans and organize work to meet deadlines.

PO 5: Problem analysis:

Students will be able to develop, critical thinking and analytical skills while solving problems and making decisions in dissertation research.

PO 6: Usage of contemporary research tools and techniques:

Students will be able to learn, select, and apply appropriate current methods and procedures in modern pharmaceutical research with an understanding of the limitations.

PO 7: Social responsibilities:

Students will be able to understand, analyse and communicate the value of their professional roles in society (e.g. as health care professionals, promoters of health, educators, managers, employers, employees).

PO 8: Continuous learning:

They will be able to recognize the need for continuous up gradation of their knowledge and skills

PROGRAM SPECIFIC OUTCOMES
PSOs OF M. PHARM (Pharmaceutical Regulatory Affairs)

PSO 1: Learn about the Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices as well as Good Documentation Practices.

PSO 2: Learn about the preparation and implementation of checklist for audits and inspections of pharmaceutical industries.

PSO 3: Learn about the preparation of different documents for the compilation of dossier, required for marketing approval process of pharmaceutical product.

PSO 4: Understand about the documentation requirement of different pharmaceutical drugs, medical devices, biological, cosmetics, herbals, food & nutraceuticals in different countries.

PSO 5: Learn about the history, origin of various ethical guidelines related to clinical research as well as understand the different types and methods for conduct of clinical trials.

PSO 6: Learn about the drug discovery and development of API, new drugs and generic products.

PSO 7: Get acquainted with the regulatory requirement of India compare to other regulated and non-regulated markets.

PSO 8: Understand the basic concepts of recall, risk management system, life cycle of pharmaceutical product etc.

DEPARTMENT OF PHARMACEUTICAL SCIENCES
Course Structure and Scheme of Examination
(with effective from June -2017)

Semester I

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weight for Semester End Examination	Total Marks	Duration of Semester End Exam in hrs.
MRA 101T	Good Regulatory Practices	4	4	25	75	100	3 Hrs.
MRA 102T	Documentation and Regulatory Writing	4	4	25	75	100	3 Hrs.
MRA 103T	Clinical Research Regulations	4	4	25	75	100	3 Hrs.
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights	4	4	25	75	100	3 Hrs.
MRA 105P	Regulatory Affairs Practical – I	6	12	50	100	150	6 Hrs.
-	Seminar/Assignment	4	7	-	-	100	-
Total		**26**	**-**	**-**	**-**	**650**	**-**

Semester II

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weight for Semester End Examination	Total Marks	Duration of Semester End Exam in hrs.
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	25	75	100	3 Hrs.
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	25	75	100	3 Hrs.
MRA 203T	Regulatory Aspects of Medical Devices	4	4	25	75	100	3 Hrs.
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	4	4	25	75	100	3 Hrs.
MRA 205P	Regulatory Affairs Practical – II	6	12	50	100	150	6 Hrs.
-	Seminar/Assignment	4	7	-	-	100	-
Total		**26**	**-**	**-**	**-**	**650**	**-**

Semester III

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weight for Semester End Examination	Total Marks	Duration of Semester End Exam in hrs.
MRM 301T	Research Methodology & Biostatistics*	4	4	25	75	100	3 Hrs.
-	Journal Club	1	1	25	-	25	-
-	Discussion / Presentation (Proposal Presentation)	2	2	50	-	50	-
-	Research Work	14	28	-	350	350	1 Hrs.
Total		**21**	**-**	**-**	**-**	**525**	**-**

*Non university exam

Semester IV

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weight for Semester End Examination	Total Marks	Duration of Semester End Exam in hrs.
-	Journal Club	1	1	25	-	25	-
-	Discussion / Presentation	3	3	75	-	75	-
-	Research Work	16	31	-	400	400	1 Hrs.
Total		**20**	**-**	**-**	**-**	**500**	**-**

M. PHARM SEMESTER I (RA)
Good Regulatory Practices (MRA 101T)
Theory: 4 Hrs. /Week

Scope:

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.

Objectives:

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

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
- Implement Good Regulatory Practices in the Healthcare and related Industries.
- Prepare for the readiness and conduct of audits and inspections.

Course Outcome:

CO1: Understanding and implementation of Current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Practices and Good Distribution Practices in routine industrial work.

CO2: Awareness regarding the Change control, Validation etc.

CO3: Understanding the requirement of ISO and ICH guidelines and implementing the same in document preparation.

CO4: Determination of basic concept of GMP, GLP and GDP requirement of USFDA and CDSCO.

Course content

Unit 1 **12 Hrs**.

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.

Unit 2 **12 Hrs.**

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

Unit 3 **12 Hrs.**

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.

Unit 4 **12 Hrs.**

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.

Unit 5 **12 Hrs.**

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

References:

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition, Drugs and the Pharmaceutical Sciences, Vol.168.
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press.
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act 1040, Rules 1045 & Amendments.

M. PHARM SEMESTER I (RA)
Documentation and Regulatory Writing (MRA 102T)
Theory: 4 Hrs. /Week

Scope:

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

Objectives:

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

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

Course Outcome:

CO1: Understanding different types of documents required in pharmaceutical industry.

CO2: Awareness regarding Audit and Inspection kind of activities, their requirements and related rules and regulations.

CO3: Gives idea regarding post approval changes and their document requirements.

CO4: Understanding basic concepts like recall, risk management system, life cycle management etc.

Course content

Unit 1 **12 Hrs.**

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

Unit 2 **12 Hrs.**

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.

Unit 3 **12 Hrs.**

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.

Unit 4 **12 Hrs.**

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

Unit 5 **12 Hrs.**

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

References:

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

13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

M. PHARM SEMESTER I (RA)
Clinical Research Regulations (MRA 103T)
Theory: 4 Hrs. /Week

Scope:

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

Objectives:

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

- History, origin and ethics of clinical and biomedical research and evaluation.
- Clinical drug, medical device development process and different types and phases of clinical trials.
- Regulatory requirements and guidance for conduct of clinical trials and research.

Course Outcome:

CO1: Awareness regarding different types and phases of clinical trials.

CO2: Understanding regulations history, origin & concept of different ethical guidelines related to clinical trials.

CO3: Gives idea regarding requirements of conduct of clinical trial in India, US and Europe.

Course content

Unit 1 **12 Hrs.**

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

Unit 2 **12 Hrs.**

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

Unit 3 **12 Hrs.**

Regulations governing Clinical Trials

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

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

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

EU: Clinical Research regulations in European Union (EMA)

Unit 4 **12 Hrs.**

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,
- E11 – Clinical Investigation of Medicinal Products in the Pediatric Population
- General biostatics principle applied in clinical research

Unit 5 **12 Hrs.**

- **USA & EU Guidance**

  USA: FDA Guidance

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

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

References:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams.
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD.

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

Recommended Websites:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application:
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/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/ethical_guidelines.pdf

M. PHARM SEMESTER I (RA)
Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights (MRA 104T)
Theory: 4 Hrs. /Week

Scope:

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.

Objectives:

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

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

Course Outcome:

CO1: Gives idea regarding the concept of Bioavailability and Bioequivalence.

CO2: Understanding the rules, regulations and guidelines of different countries for pharmaceutical products, food & nutraceuticals, biological & herbs as well as medical devices.

CO3: Recognize the Indian pharmacopoeial, BIS and ISO standards.

Course content

Unit 1 **12 Hrs.**

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.

Unit 2 **12 Hrs.**

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 filling clinical trial/investigations

Unit 3 **12 Hrs.**

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

Unit 4 **12 Hrs.**

- Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study.
- **Stability requirements:** ICH and WHO
- **Guidelines for Drug testing in animals**/Preclinical Studies
- Animal testing: Rationale for conducting studies, CPCSEA Guidelines
- Ethical Guidelines for human participants
- ICMR-DBT Guidelines for Stem Cell Research

Unit 5 **12 Hrs.**

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

References:

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

M. PHARM SEMESTER I (RA)
Regulatory Affairs Practical – I (MRA 105P)
Practical: 12 Hrs./Week

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.

M.PHARM SEMESTER II (RA)
Regulatory Aspects of Drugs & Cosmetics (MRA 201T)
Theory: 4 Hrs./Week

Scope:

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.

Objectives:

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

- Process of drug discovery and development and generic product development
- Regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

Course Outcome:

CO1: Acquired the knowledge of regulatory approval process and registration procedures for drug products in USA, Canada, EU, Australia, Japan and Brazil

CO2: Understand the role of various committees across the globe like APEC, EAC, GCC, PANDRH, SADC, etc.

CO3: Learnt the requirements for registration of drugs and post approval requirements in ASEAN countries

CO4: Learned the regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries

CO5: Understand the concept of Certificate of Pharmaceutical Product (CoPP) in General and Country Specific

Course content

Unit 1 **12 Hrs**

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

Unit 2 **12 Hrs**

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.

Unit 3 **12 Hrs**

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

Unit 4 **12 Hrs**

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)

Unit 5 **12 Hrs**

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 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

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, SpringerTrade 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

M.PHARM SEMESTER II (RA)
Regulatory Aspects of Herbal and Biologicals (MRA 202T)
Theory: 4 Hrs./Week

Scope:

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products.

Objectives:

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Course Outcome:

CO1: Understand the regulation for newly developed biologics and biosimilars

CO2: Took information about of the pre-clinical and clinical development considerations of biologics

CO3: Acquired Knowledge about the regulatory requirements of blood and/or its components including blood products and label requirements

CO4: Learned the legislation, quality and safety of herbal products

CO5: Learned about the regulatory requirements for herbal products, biologics and vaccines

Course content

Unit 1 **12 Hrs**

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

Unit 2 **12 Hrs**

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

Unit 3 **12 Hrs**

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 consideration, stability, safety, advertising, labelling and packaging of biologics in EU

Unit 4 **12 Hrs**

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)

Unit 5 **12 Hrs**

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

References:

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

M.PHARM SEMESTER II (RA)
Regulatory Aspects of Medical Devices (MRA 203T)
Theory: 4 Hrs./Week

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and 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.

Objectives:

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

- Basics of medical devices and IVDs, process of development, ethical and quality considerations
- Harmonization initiatives for approval and marketing of medical devices and IVDs
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- Clinical evaluation and investigation of medical devices and IVDs

Course Outcome

CO1: Understand the new era of digitalisation

CO2: Developed the knowledge of the different ethics, clinical investigation regarding medical devices

CO3: Learnt about regulatory approval process of medical devices in USA and EU

CO4: Acquired knowledge of IMDRF and guidance of documents in ASEAN, China & Japan

Course content

Unit 1 **12 Hrs**

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)

Unit 2 **12 Hrs**

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

Unit 3 **12 Hrs**

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

Unit 4 **12 Hrs**

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

Unit 5 **12 Hrs**

ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.

IMDRF study groups and guidance documents

References:

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

M.PHARM SEMESTER II (RA)
Regulatory Aspects of Food & Nutraceuticals (MRA 204T)
Theory: 4 Hrs./Week

Scope:

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.

Objectives:

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

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labelling of nutraceuticals and food supplements in India, USA and Europe

Course Outcome:

CO1: Learn the history of nutraceuticals and their regulations

CO2: Discuss the scope and opportunities in nutraceuticals market, Information regarding regulatory approval process of medical devices in USA and EU

CO3: Learn the global aspects of regulations in food and nutraceuticals markets, and regulation in India, USA and EU

CO4: Understand and compare the Recommended Dietary Allowance in various regulated countries

Course content

Unit 1 **12 Hrs**

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

Unit 2 **12 Hrs**

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

Unit 3 **12 Hrs**

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

Unit 4 **12 Hrs**

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

Unit 5 **12 Hrs**

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

References:

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

M.PHARM SEMESTER II (RA)
Regulatory Affairs Practical – II (MRA 205P)
Practical: 12 Hrs./Week

1. Case studies on

2. Change Management/ Change control. Deviations

3. Corrective & Preventive Actions (CAPA)

4. Documentation of raw materials analysis as per official monographs

5. Preparation of audit checklist for various agencies

6. Preparation of submission to FDA using eCTD software

7. Preparation of submission to EMA using eCTD software

8. Preparation of submission to MHRA using eCTD software

9. Preparation of Biologics License Applications (BLA)

10. Preparation of documents required for Vaccine Product Approval

11. Comparison of clinical trial application requirements of US, EU and India of Biologics

12. Preparation of Checklist for Registration of Blood and Blood Products

13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization

14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization

15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization

16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization

17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization

18. Checklists for 510k and PMA for US market

19. Checklist for CE marking for various classes of devices for EU

20. STED Application for Class III Devices

21. Audit Checklist for Medical Device Facility

22. Clinical Investigation Plan for Medical Devices

M.PHARM SEMESTER III (RA)
Research Methodology & Biostatistics (MRM 301T)
Theory: 4 Hrs./Week

Scope

This subject deals with various established methods used in pharmaceutical research.

Objectives

Upon completion of the course student shall be able to understand

Learn general research methodology and the basic concepts of biostatistics.

Understand the functions of ethics committees in medical research.

Course Outcomes

CO1: Able to carry out different parametric and non-parametric tests.

CO2: Lean about the ethics committee and its function in medical research.

CO3: Learn the guidelines for the experimentation on animals

CO4: Prepare protocol for Animal study.

Course content

Unit 1. **12 Hrs**

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.

Unit 2. **12 Hrs**

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.

Unit 3. **12 Hrs**

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.

Unit 4. **12 Hrs**

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.

Unit 5. **12 Hrs**

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