KERALA UNIVERSITY OF HEALTH SCIENCES

Thrissur - 680596

SYLLABUS

POST GRADUATE COURSE IN PHARMACY

Master of Pharmacy (M. Pharm.)

PHARMACEUTICAL REGULATORY AFFAIRS	MRA
KUHS Course Code	529

(2022-23 Academic year onwards)

2022

Course of study for M.Pharm. I & II Semester

MRA	Pharmaceutical Regulatory Affairs				
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
Semester I					
MRA 101T	Good Regulatory Practices	4	4	4	100
MRA 102T	Documentation and Regulatory Writing	4	4	4	100
MRA 103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Drug Regulations & Intellectual Property Rights	4	4	4	100
MRA 105P	Regulatory Affairs Practical - I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA 202T	Regulatory Aspects of Herbals & Biologicals	4	4	4	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA 205P	Regulatory Affairs Practical – II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Course of study for M. Pharm. III & IV Semester

Course Code	**Course**	**Credit Hours**	**Credit Points**	**Marks**
Semester III				
MRM 301T	Research Methodology and Biostatistics	4	4	100
-	Journal Club	1	1	25
-	Discussion / Presentation (proposal presentation)	2	2	25
-	Research Work	28	14	350
Total		**35**	**21**	**500**
Semester IV				
-	Journal Club	1	1	25
-	Pre submission Discussion / Presentation	3	3	75
-	Research Work	31	16	400
Total		**35**	**20**	**500**

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

SEMESTER I
GOOD REGULATORY PRACTICES (MRA 101T)

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.

THEORY **60 Hrs**

1. **Current Good Manufacturing Practices:** 12 Hrs

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.

2. **Good Laboratory Practices:** 1 2 H rs

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

3. **Good Automated Laboratory Practices:** 12 Hrs

Introduction to GALP,Principles of GALP, GALP Requirements, SOPs of GALP,Training Documentation, 21 CFR Part 11, General check list of21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

4. **Good Distribution Practices:** 12 Hrs

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

5. **Quality management systems:** 12 Hrs

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 EditionDrugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance byJohn 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 DonaldC. Singer, Drugs and the Pharmaceutical Sciences, Vol.150
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope:

This course is designed to impart fundamental knowledge on documentationand 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 pharmaceuticalindustry
- _ Understand the basics of regulatory compilation
- _ Create and assemble the regulation submission as per therequirements of agencies
- _ Follow up the submissions and post approval document requirements

THEORY **60 Hrs**

1. **Documentation in pharmaceutical industry:** 12 Hrs

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).

2. **Dossier preparation and submission:** 12 hrs

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.

3. **Audits:** 12 Hrs

Introduction, Definition, Summary, Types of audits, GMPcompliance 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.

4.**Inspections:** 12Hrs

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

5. **Product life cycle management:** 12 Hrs

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

REFERENCES:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David

Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

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 andappreciate)

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

THEORY **60 Hrs**

1. **Clinical Drug Development Process:** 12 Hrs
   - Different types of Clinical Studies
   - Phases of clinical trials, Clinical Trial protocol
   - Phase 0studies
   - Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK endpoints
   - Phase IIstudies (proof of concept or principle studies to establish efficacy)
   - Phase IIIstudies (Multi ethnicity, global clinical trial, registration studies)
   - Phase IV studies (Post Marketing Studies; PSUR)

   Clinical Investigation and Evaluation of Medical Devices & IVDs

2 **Ethics in Clinical Research:** 12 Hrs

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

3 **Regulations g o v e r n i n g Clinical Trials** 12 Hrs

   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 ClinicalPractice

   EU: Clinical Research regulations in European Union (EMA)

4 **Clinical Research R e l a t e d Guidelines** 12 Hrs

   - 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 DrugRegistration
_ E7 – Studies in support of General Population: Geriatrics
_ E8 – General Considerations of Clinical Trials
_ E10 – Choice of Control Groups and Related Issues inClinical Trials,
_ E 11 – Clinical Investigation of Medicinal Products in thePediatric Population
_ General biostatics principle applied in clinical research

5 USA & EU GuidanceUSA: FDA Guidance 12 Hrs

_ 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 aNew Drug
_ CFR 21Part 320: Bioavailability and bioequivalencerequirements
_ 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 Practicesand Pharmacoepidemiologic Assessment
European Union: EMA Guidance
_ EU Directives 2001
_ EudraLex (EMEA) Volume 3 – Scientific guidelines formedicinal products for human use
_ EU Annual Safety Report (ASR)
_ Volume 9A – Pharmacovigilance for Medicinal Products forHuman Use
_ EU MDD with respect to clinical research
_ ISO 14155

REFERENCES

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

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
7. Central Drugs Standard Control Organization Guidance for Industry:http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

DRUG REGULATIONS AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

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

THEORY **60 Hrs**

1. **Biologicals & Herbals, and Food & NutraceuticalsActs and Rules (with latest amendments):** 12 Hrs

(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.

2. **Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals:** 12 Hrs

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

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

3. **Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards** 12 Hrs

4. Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study 12 Hrs
Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies

Animal testing: Rationale for conducting studies, CPCSEAGuidelines
Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research

5. **Intellectual Property Rights:** 12 Hrs
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 Officeof India.
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators atrisk by James Bessen and Michael J. Meurer.
3. Principles and Practice of Clinical Trial Medicine by Richard Chin andBruce Y. Lee.
4. Ethical Guidelines for Biomedical Research on Human Participants byIndian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for thepurpose of control and supervision on experiments on animals (CPCSEA).

6. ICH E6 Guideline — Good Clinical Practice| by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL – I (MRA 105P)

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 submissionin 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 Japanof a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Scope

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 productdevelopment
- Regulatory approval process and registration procedures for API anddrug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

THEORY **60 Hrs**

1. **USA & CANADA:** 12 Hrs

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.

2. **European Union & Australia:** 1 2 H r s

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.

3. **Japan:** 12 Hrs

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

4. **Emerging Market:** 12 Hrs

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)

5. **Brazil, ASEAN, CIS and GCC Countries:** 12 Hrs

ASIAN Countries: Introduction to ACTD, R e g u l a t o r y 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 Drugs Approval Process: Accelerating Global Restrictions By Richard A. Guarino MD, 5th Edn, Drugs and Pharmaceuticals, Vol. 190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By JohnWiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By MarkMathieu
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 ByWilliam K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South East Asian studies, Singapore.

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe
It prepares the students to learn in detail on Regulatory Requirements for
biologics, Vaccines and Blood Products

Objectives

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

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

THEORY **60 Hrs**

1. India: 12 Hrs

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.

2. USA: 12 Hrs

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

3. European Union: 12 Hrs

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

4. Vaccine regulations in India, US and European Union: 12 Hrs

Clinicalevaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and EuropeanUnion: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT(International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

5. Herbal Products: 12 Hrs

Quality, safety and legislation for herbalproducts 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; WeiWang, Manmohan Singh; Wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; ManmohanSingh, 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 MarketingAuthorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Scope:

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, ethicaland quality considerations
- harmonization initiatives for approval and marketing of medical devicesand 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

THEORY **60 Hrs**

1. **Medical Devices:** 12 Hrs

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 andClassification of Medical Devices.
IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

2. **Ethics:** 1 2 H rs

Clinical Investigation of Medical Devices, ClinicalInvestigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO13485, Quality Risk Management of Medical Devices: ISO14971, Validation and Verification of Medical device, AdverseEvent Reporting of Medical device

3. **USA:** 12 Hrs

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.

4. **European Union:** 12 Hrs

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.

5. **ASEAN, China & Japan:** 12 Hrs

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, andbiologics 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 andBiologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope:

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling 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 labeling of nutraceuticalsand food supplements in India, USA and Europe.

THEORY **60 Hrs**

1. **Nutraceuticals:** 12 Hrs

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

2. **Global Aspects**: 12 Hrs

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

3. **India:** 12 Hrs

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.

4. **USA:** 12 Hrs

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

5. **European Union:** 12 Hrs

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

REGULATORY AFFAIRS PRACTICAL - II(MRA 205P)

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

SEMESTER-III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

UNIT –I

General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

Review of literature - Sources of information. Searching of library documents and databases online and offline (Pubmed, Biological abstracts, other databases in pharmaceutical sciences). Introduction to internet searching using advanced search tools.

UNIT – II

Collection and analysis of data: Types of data and data collection techniques, processing of data, coding, tabulation and analysis of data.

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Student's 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, different software for statistical analysis.

UNIT – III

Medical Research: History, values in medical ethics, strategies to eliminate errors/bias, controls, randomisation, cross over design, placebo, blinding techniques 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, vendor relationships, treatment of family members.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Technical writing, thesis/research report writing, structure of thesis, editing and formatting, reference citations, abstracting, plagiarism and paraphrasing, tools for writing good research report.

UNIT – VI

Research reporting - poster presentation, seminar and conference presentation, publishing in journals, copyright.

REFERENCE BOOKS

19. Atiya Khanum Irfan Ali Khan, Biostatistics for Pharmacy, 2nd Edition, 2007, UkaazPublications, Hyderabad.
20. C. George Thomas. Research Methodology and Scientific Writing First edition, 2016, AneBooks Pvt. Ltd.; New Delhi.
21. C. R Kothari. Research Methodology: Methods and Techniques. New Age International

(P)Ltd, Publishers. New Delhi.
22. Mahajan, B.K. Methods in Biostatistics for Medical Students and Research workers, 7thEdition 2008 Jaypee Brothers.
23. Putul Mahanta , Medical Writing: A Guide for Medicos, Educators and Researchers JaypeeBrothers Medical Publishers; First edition (2018).
24. Ranjan Das, Biomedical Research Methodology: Including Biostatistical Applications. 1stEdn. Jaypee Brothers.
25. Ranjit Kumar, Research Methodology: A Step-by-Step Guide for Beginners, 3rd Edition 2011,Sage Publications India Pvt. Ltd., New Delhi.
26. Sharma Suresh. Research Methodology and Biostatistics- A Comprehensive Guide for HealthCare Professionals. 1st Edn. Elsevier India.
27. Sunder Rao. P.S.S and Richard. J. An introduction to Biostatistics: A manual for students inhealth sciences. Prentice-Hall of India Pvt. Ltd Publishers.

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Q P CODE REG NO

MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - I – GOOD REGULATORY PRACTICES (MRA 101T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Write in detail about USGMP with reference to part210 and part 211.
2. Write in detail about USFDA GLP regulations
3. Write in detail about the principles and requirements of GALP

SHORT NOTES (9X5=45)

4. Write briefly about WHO cGMP guidelines
5. Write briefly about concept of ISO
6. Write a note on software evaluation checklist
7. Write a note on stability testing principles
8. Describe the goals of laboratory quality audit
9. Write briefly about cleaning validation
10. Write a note on validation master plan
11. Write briefly about training documentation of GALP
12. Write a note on total quality management

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MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - II – DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. What is product development report (PDR) Discuss the significance of PDR
2. Define CTD and eCTD. Describe the modules of ICH -CTD format with granularity
3. Discuss the Root cause analysis of deviation. Describe the corrective and preventive action.

SHORT NOTES **(9×5=45)**

4. Describe about Batch Manufacturing record and its calculations
5. What is Drug Master file (DMF) Discuss the types of DMFs
6. Outline the contents and organization of dossiers
7. Differentiate Internal, External, second party and external third-party audits.
8. Describe the quality systems requirements of national good distribution practices
9. Discuss the post approval changes (SUPAC) process for an approved drug product
10. Describe the process of post approval labelling changes
11. Discuss the electronic submission process and validating the submission
12. Discuss the Non eCTD electronic submission (NeeS) format and its difference with CTD.

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MODEL QUESTION PAPER
M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS
FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – III CLINICAL RESEARCH REGULATIONS (MRA 103T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Explain the responsibilities of sponsors, CRO and investigator in ethical conduct of clinical research
2. Enumerate the application procedure for approval of NDA 505 (b) (1).
3. Explain the principles of ICMR Ethical Guidelines for biomedical research

SHORT NOTES (9×5=45)

4. Write a note on Phase 0 studies
5. Define and explain ethical principles of informed consent process
6. Write a note on role of placebo in clinical trials
7. Explain the clinical trial protocol
8. Write a note on ANDA and its approval procedure
9. Explain regulatory requirements of BA/BE studies
10. Discuss on EU directives 2001
11. Enumerate the Indian GCP guidelines
12. Write a note on 21 CFR part 312 (IND application)

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MODEL QUESTION PAPER

M.PHARM PHARMACEUTICAL REGULATORY AFFAIRS

FIRST SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – IV - REGULATIONS AND LEGISLATIONS FOR DRUGS &COSMETICS, MEDICAL DEVICES, BIOLOGICALS &HERBALS, AND FOOD &NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Describe in detail about WHO patent IPR and its types
2. Discuss Indian pharmacopoeial standards BIS and ISO in detail
3. Ethical guidelines for human participants ICMR -DBT

SHORT NOTES (9×5=45)

4. Guidelines for stem cell research
5. Write about the parts of patent
6. DPCO and NPPA
7. CDSCO responsibilities
8. Guidelines for preclinical studies
9. Regulatory requirements for bioequivalence study
10. Guidelines for stem cell research
11. ICH stability requirements
12. BCS classification of drugs

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER - I – REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Discuss in detail the organization and structure of EMA. Also discuss one marketing authorization procedure in EU.
2. Give regulatory requirements for Investigational New Drug (IND) submission, Format & content of IND,content of Investigation Brochure.
3. What are the Legislation and Regulations for manufacture and sale of cosmetics in ASEAN and CIS?

Short notes (9x5=45)

4. What are the regulatory considerations for manufacturing in Japan?
5. Write the full form of the following: a. CFR b. FFDCA DMF c. CIS d. ANDA e. ASEAN
6. What is Drug Master Files (DMF)? Discuss different types of DMFs.
7. Explain the regulatory consideration for packaging and labelling of pharmaceutical in EU.
8. Explain the Pharmaceuticals and Medical Devices Agency (PMDA) and discuss its functions.
9. Write a note on WHO in relation to registration.
10. Explain the relation of Hatch Waxman act with respect to 30 month stay.
11. Discuss the regulation approval process for NDA.
12. Write a role of FDA in various countries in the new drug development.

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – II – REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS (MRA 202T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. What are the various requirements and procedures for registering and marketing vaccines in India?
2. Compare the pre-clinical and clinical development considerations for biologicals in USA and European Union.
3. Write in the detail about various data requirements for Pre-clinical and clinical studies in India.

Short notes (9x5=45)

4. Write not on Pharmacovigilance.
5. Labelling and packaging requirements for Blood products for European market
6. Process and requirements for BLA
7. Discuss about format and contents of an IND application.
8. Describe about regulations for quality and safety of herbal products in India.
9. Discuss about laws and regulations on biologics and biosimilars.
10. Write not on Plasma master file.
11. Discuss about stability, safety guidelines in European Union.
12. Describe about GMP requirements for equipment, container and closures.

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – III – REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Explain in detail the validation and verification of Medical devices.
2. Explain the Quality system requirements (21 CFR Part 820) and labeling requirements (21 CFR Part 801) ofmedical devices in US.
3. Discuss the major highlights for the devices and *in vitro* diagnostics as per European Union?

Short notes (9X5=45)

4. Discuss IVD's.
5. Write note on Summary Technical Documents.
6. What is the clinical evaluation and investigation procedure of medical devices in China?
7. What are post marketing surveillance of medical devices?
8. What are the necessary requirements for Premarket Notification 510K Submission for Medical Device?
9. Pre-marketed approval as per US FDA.
10. Give risk-based classification and essential principles of medical devices with examples.
11. Explain the regulatory registration procedure of IVDs in Japan.
12. Explain the adverse event reporting of medical devices.

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MODEL QUESTION PAPER
M.PHARM REGULATORY AFFAIRS
SECOND SEMESTER M. PHARM DEGREE EXAMINATIONS

PAPER – IV – REGULATORY ASPECTS OF FOOD & NEUTRACEUTICALS (MRA 204T)

Answer all questions

Time: 3 hours Maximum Marks: 75

Essays (3x10=30)

1. Discuss the regulations for import of nutraceuticals according to FSSAI.
2. Explain regulatory requirements and its approval procedure for Nutraceuticals, Cosmetics and Biologics in India.
3. What are dietary supplements and medical foods? Giving examples critically explain their role in human body.

Short notes (9X5=45)

4. Mention the critical considerations about good manufacturing practices for nutraceuticals
5. Write the functions of Food Safety and Standards Authority of India (FSSAI).
6. Comment on the chemicals other than vitamins and minerals whose addition to food is prohibited according toEFSA.
7. Discuss the US FDA dietary supplement health and education act.
8. What are dietary fibres? Explain their importance as functional foods.
9. What are medical foods, functional foods and nutraceuticals? Giving examples explain their role in healthcare.
10. Summarize the prohibition orders served under FSSAI Act.
11. Labelling requirements for dietary supplements in USA.
12. Write a note on the RDA for calcium and iron in US.