Maharshi Dayanand University, Rohtak

Department of Pharmaceutical Sciences

M.PHARM. DRUG REGULATORY AFFAIRS (DRA)

PROGRAM SPECIFIC OUTCOMES

PSO1 Evaluate real and/or simulated regulatory submissions for appropriateness of the submission to the regulatory requirements of product design, manufacturing, testing, and post-market surveillance strategies.

PSO2 Demonstrate the ability to investigate case studies related to various regulatory topics.

PSO3 Identify and utilize the laws and regulations apply to the development, testing, and production of new medical products, including medical devices, In-Vitro Diagnostics (IVDs), pharmaceuticals, biotechnology-derived therapeutics, and biologics.

PSO4 Provides the knowledge to assess current U.S. –Food and Drug Administration (FDA) regulations that focus on drugs and medical devices and their impact on regulatory submissions such as New Drug Applications (NDA), Abbreviated NDAs, Investigational New Drug (IND) Applications, 510k, and Pre-Market Authorizations PMAs

PSO5 Identify a specific regulatory issue for either a drug or device and be able to justify an appropriate position or strategy through presentation and written skills that permits students to acquire analytic and reasoning skills along with effective communication skills.

SCHEME OF EXAMINATION

Table- Schemes for internal assessments and end semester examinations

(Drug Regulatory Affairs)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER I								
DRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
DRA102T	Pharmaceutical Regulations in India	10	15	1 Hr	25	75	3 Hrs	100
DRA103T	International Pharmaceutical Regulations I	10	15	1 Hr	25	75	3 Hrs	100
DRA104T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
DRA105P	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
DRA201T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
DRA202T	Biologicals Regulations	10	15	1 Hr	25	75	3 Hrs	100
DRA203T	International Pharmaceutical Regulations II	10	15	1 Hr	25	75	3 Hrs	100
DRA204T	Medical Device Regulations	10	15	1 Hr	25	75	3 Hrs	100
DRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table- Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER III								
MRM101T	Research Methodology and Biostatistics	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work	-	-	-	-	350	1 Hr	350
							Total	**525**
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
							Total	**500**

SYLLABUS

SEMESTER-1

GOOD PHARMACEUTICAL PRACTICES (DRA 101T)

Course outcomes

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

CO1 The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices

CO2 The check lists for various Good Regulatory Practices and

CO3 Prepare SOPs for Good Pharmaceutical Practices

CO4 Implement Good Regulatory Practices in the Health care Industries and

CO5 Prepare for the Audit of the Pharmaceutical Industries.

THEORY **60Hrs**

1. **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical devices, GHTF guidance docts

12Hrs

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

12Hrs

3. **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP

Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11,General check list of 21CFR Part 11, Software Evaluation checklist, ISO.

12Hrs

4. **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP(Supply chain integrity), GHTF guidance/IMDRF/CDSCO

12Hrs

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

12Hrs

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition,Drugs and the Pharmaceutical Sciences, Vol.168

2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press

3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.

4. How to practice GLP by PP Sharma, Vandana Publications.

5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

PHARMACEUTICAL REGULATIONS IN INDIA (DRA 102T)

Course outcomes

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

CO1 Know different Acts and guidelines that regulate PMBC industry in India.

CO2 Understand the approval process and regulatory requirements for drugs and medical devices

CO3 Demands of the pharmaceutical industries in the area of the drug development.

THEORY 60 HOURS

UNIT I

 Study of Relevant provisions of FPMBC

 Acts and Rules (with latest amendments):

 Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC , Rules 1945: DPCO and NPPA

 Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs& Packing of drugs & other related Acts-Narcotic etc Central Drug Standard Control Organization and State Licensing Authority:

1. Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations

2. Fomat and contents of Regulatory dossier filling

3. Clinical trials /Investigations

 Clinical Trials

 New Drugs

 Medical Devices

 Fixed Dose Combinations

12 Hrs

UNIT II

Regulatory requirements FNPCMB and approval procedures for:

12 Hrs

UNIT III

Indian Pharmacopoeial standards

 BIS Standards & ISO and other relevant standards

UNIT IV

BA/ BE: Bioavailability and Bioequivalence data, 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

12 Hrs

UNIT V

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

12 Hrs

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

INTERNATIONAL PHARMACEUTICAL REGULATIONS-I (DRA103T)

Course outcomes

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

CO1 Regulatory registration and landscape

CO2 International standards related to the drug development.

CO3 Process of the new drug approval process in different parts of the world.

THEORY **60 Hours**

Unit-I

12 Hours

USA and 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

Unit-II

12 Hours

EUROPEAN UNION and 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

Unit-III

12 Hours

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

UNIT IV

BRAZIL and CHINA

UNIT V

ASEAN and SOUTH ASIA

REFERENCES:

Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer,

Marcel Dekker series, Vol.143Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel

Dekker Series,Vol.144

1. 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.

2. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

3. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

4. Drugs: From Discovery to Approval, Second Edition By Rick Ng

5. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu

6. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko

7. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema

8. Country Specific Guidelines from official websites.

CLINICAL RESEARCH REGULATIONS (DRA 104T)

Course outcomes

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

CO1 Clinical drug development process and different phases of clinical trials, investigations

CO2 History, origin and ethics of clinical research

CO3 Regulatory requirements for conducting clinical trials investigations and research

CO4 Regulations and guidance governing the conduct of clinical research,

THEORY **60 Hours**

Unit-I

12 Hours

Basics for Clinical trials for drug development process

 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 authorization studies; pits and practices)

 Ethical principles governing informed consent process

 Patient Information Sheet and Informed Consent Form

 The informed consent process and documentation

Unit-II

12 Hours

Basic CT for MD 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

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 Data safety monitoring boards.

 Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Unit-III

12 Hours

Regulations governing Clinical Trials

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)

India: Clinical Research regulations in India – Schedule Y

Unit-IV

Clinical Research Related Guidelines **12 Hours**

 Good Clinical Practice Guidelines (ICH GCP E6)

 Indian GCP Guidelines

 ICMR Ethical Guidelines for Biomedical Research

 CDSCO guidelines

Regulatory Guidance on Efficacy and Safety

ICH Guidance's

 E4 – Dose Response Information to support Drug Registration

 E7 – Studies in support of General Population: Geriatrics

 E8 – General Considerations of Clinical Trials

 E10 – Choice of Control Groups and Related Issues in Clinical Trials,

 E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

Unit-V 12 Hours

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 213

 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

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.

RECOMMENDED WEBSITES:

1. 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/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm

6. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk 214

7. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCOGuidanceForIndustry. pdf

8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

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PHARMACEUTICAL REGULATORY AFFAIRS PRACTICAL-I (MRA105P)

Course outcomes

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

CO1 SOPs and Analytical reports

CO2 Case studies in the area of the regulatory affairs

CO3 Clinical study, clinical research and clinical trials

Practicals

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

10. Registering for different Intellectual Property Rights in India

11. GMP Audit Requirements as per CDSCO

12. Preparation and documentation for Indian Patent application.

13. Preparation of checklist for registration of IND as per ICH CTD format.

14. Preparation of checklist for registration of NDA as per ICH CTD format.

15. Preparation of checklist for registration of ANDA as per ICH CTD format.

16. Case studies on response with scientific rationale to USFDA Warning Letter

17. Preparation of submission checklist of IMPD for EU submission.

18. Comparison study of marketing authorization procedures in EU.

19. Comparative study of DMF system in US, EU and Japan

20. Preparation of regulatory submission using eCTD software

21. Preparation of Clinical Trial Application (CTA) for US submission

22. Preparation of Clinical Trial Application (CTA) for EU submission

23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.

24. Regulatory requirements checklist for conducting clinical trials in India.

25. Regulatory requirements checklist for conducting clinical trials in Europe.

26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER-II

DOCUMENTATION AND REGULATORY WRITING (DRA 201T)

Course outcomes

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

CO1 Know the various documents pertaining to drugs in pharmaceutical industry

CO2 Understand the basics of regulatory compilation

CO3 Create and assemble the regulation submission as per the requirements of agencies

CO4 Follow up the submissions and post approval document requirements

1. ***Documentation in pharmaceutical industry***: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development

Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch

Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2. ***Dossier preparation and submission:*** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions

Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic

submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission

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

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

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

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

BIOLOGICALS REGULATIONS (DRA 202T)

Course outcomes

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

CO1 Know the regulatory Requirements for Biologics and Vaccines

CO2 Understand the regulation for newly developed biologics and biosimilars

CO3 Know the pre-clinical and clinical development considerations of biologics

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

Theory **60 Hrs**

Unit I

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

12 Hrs

Unit II

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

12 Hrs

Unit III

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

12 Hrs

Unit IV

4. **Vaccine regulations in India, US and European Union**: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V

5**. Blood and Blood Products Regulations in India, US and European Union**: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

12 Hrs

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)

INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (DRA 203T)

Course Outcomes

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

CO1 Know the regulatory Requirements for drug and medical device registration in emerging market;

CO2 Understand the registration requirements of emerging market by comparison; and

CO3 Prepare dossiers for the registration of the products in emerging market.

THEORY **60 HOURS**

1. **Emerging Market:** Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

12Hrs

2. **WHO:** WHO GMP,Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical

Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

12Hrs

3. **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.

12Hrs

4. **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

12Hrs

5. **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

12Hrs

REFERENCES

1.http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf

2. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2

3. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7

4. Building a Future With Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer

5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,

6. The world Bank, Washington, DC, ISBN: 0-8212-5896-0

7. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139

8. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)

9. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9

10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

MEDICAL DEVICE REGULATIONS (DRA 204T)

Course outcomes

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

CO1 Basics of medical devices, process of development, ethical and quality considerations

CO2 Harmonization initiatives for approval and marketing medical devices

CO3 Regulatory approval process for medical devices in US, EU and Asia

CO4 Clinical aspects of medical devices

THEORY 60 Hours

Unit-I

12 Hours

Medical Devices: Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, 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-II

12 Hours

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-III

12 Hours

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-IV

12 Hours

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-V

12 Hours

Medical Device Regulations in World Health Organization (WHO): Registration Procedures,

Quality System requirements and Regulatory requirements **Asia:** Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

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.

PHARMACEUTICAL REGULATORY AFFAIRS PRACTICAL-II (DRA 205P)

Course outcomes

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

CO1 Requirements for the approval of the medical devices in the different parts of the world.

CO2 Regulatory guidelines for the new drug approval.

CO3 Quality system in the different parts of the world.

Number of Practicals based on above mentioned Theory.