JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Regulatory Affairs
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S11101	Good Regulatory Practices	4	-	-	4
2	17S11102	Documentation and Regulatory Writing	4	-	-	4
3	17S11103	Clinical Research Regulations	4	-	-	4
4	17S11104	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	-	-	4
5	17S11105	Regulatory Affairs Practical I	-	-	6	3
6	17S11106	Regulatory Affairs Practical II	-	-	6	3
7	17S11107	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S11201	Regulatory Aspects of Drugs& Cosmetics	4	-	-	4
2	17S11202	Regulatory Aspects of Herbal& Biologicals	4	-	-	4
3	17S11203	Regulatory Aspects of Medical Devices	4	-	-	4
4	17S11204	Regulatory Aspects of Food & Nutraceuticals	4	-	-	4
5	17S11205	Regulatory Affairs Practical III	-	-	6	3
6	17S11206	Regulatory Affairs Practical IV	-	-	6	3
7	17S11207	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S11301	Journal Club	1	-	-	1
3.	17S11302	Teaching Assignment	10	-	-	2
4.	17S11303	Comprehensive viva voce	-	-	-	2
5.	17S11304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S11305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S11401	Journal Club	1	-	-	1
2.	17S11402	Research work	31	-	-	16
3.	17S11403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

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M. Pharm – I year I Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11101) GOOD REGULATORY PRACTICES

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. 12Hrs

Current Good Manufacturing Practices: Introduction, US cGMPPart 210 and Part 211.EC Principles of GMP (Directive91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelinesGAMP-5; Medical device and IVDs Global Harmonization TaskForce(GHTF) Guidance docs.

2

12HrsGood Laboratory Practices: Introduction, USFDA GLPRegulations (Subpart A to Subpart K), Controlling the GLPinspection process, Documentation, Audit, goals of LaboratoryQuality Audit, Audit tools, Future of GLP regulations, relevant ISOand Quality Council of India(QCI) Standards

3 12Hrs

Good Automated Laboratory Practices: 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 andQCI Standards.

4 12Hrs

Good Distribution Practices: Introduction to GDP, Legal GDPrequirements put worldwide, Principles, Personnel,Documentation, Premises and Equipment, Deliveries toCustomers, Returns, Self-Inspection, Provision of information,Stability testing principles, WHO GDP, USP GDP (Supply chainintegrity), relevant CDSCO guidance and ISO standards

5 12Hrs

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

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 DavidM.Bleisner, Wiley Publication.

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

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

6. Drugs & Cosmetics Act, Rules & Amendments

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M. Pharm – I year I Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11102) DOCUMENTATION AND REGULATORY WRITING

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 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

THEORY 60 Hrs

1. 12Hrs

Documentation in pharmaceutical industry: ExploratoryProduct Development Brief (EPDB) for Drug substance and Drugproduct, Product Development Plan (PDP), Product DevelopmentReport (PDR), Master Formula Record, Batch ManufacturingRecord and its calculations, Batch Reconciliation, BatchPackaging Records, Print pack specifications, Distributionrecords, Certificate of Analysis (CoA), Site Master File and DrugMaster Files (DMF).

2 12Hrs

Dossier preparation and submission: Introduction andoverview of dossiers, contents and organization of dossier,binders and sections, compilation and review of dossier. Papersubmissions, overview and modules of CTD, electronic CTDsubmissions; Electronic submission: Planning electronicsubmission, requirements for submission, regulatory bindingsandrequirements, Tool and Technologies, electronic dossiersubmission process and validating the submission, ElectronicSubmission Gateway (ESG). Non eCTD electronic submissions(NeeS), Asian CTD formats (ACTD) submission. Organizing,process and validation of submission. Submission in Sugamsystem of CDSCO.

3 12Hrs

Audits: Introduction, Definition, Summary, Types of audits, GMPcompliance audit, Audit policy, Internal and External Audits,Second Party Audits, External third party audits,

Auditingstrategies, Preparation and conducting audit, Auditing strategies,audit analysis, audit report, audit follow up. Auditing/inspection ofmanufacturing facilities by regulatory agencies. Timelines foraudits/inspection. GHTF study group 4 guidance document.ISO 13485.

4 12Hrs

Inspections: Pre-approval inspections, Inspection ofpharmaceutical manufacturers, Inspection of drug distributionchannels, Quality systems requirements for national goodmanufacturing practice inspectorates, inspection report, modelcertificate of good manufacturing practices, Root cause analysis,Corrective and Preventive action (CAPA).

5 12Hrs

Product life cycle management: Prior Approval Supplement(PAS), Post Approval Changes [SUPAC], Changes BeingEffected in 30 Days (CBE-30), Annual Report, Post marketingReporting 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. KarenGinsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London NewYork, Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality byShayne 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 andFrancis (2005).

5. Implementing Juran's Road Map for Quality Leadership: Benchmarksand 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: TheCEO Report By Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson, 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 toMaterials and Resources By Christine Avery; Diane Zabel, Routledge,1997

10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQPublications

11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and JosephA. De Feo, ASQ Publications

12. Root Cause Analysis, The Core of Problem Solving and CorrectiveAction, Duke Okes, 2009, ASQ Publications

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

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M. Pharm – I year I Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11103) CLINICAL RESEARCH REGULATIONS

Scope

This course is designed to impart the fundamental knowledge on the clinicaldevelopment process of drugs, pharmaceuticals and Medical Devices, phasesand conduct of clinical trials and research, regulations and guidance governingthe conduct of clinical research in India, USA and EU. It prepares the studentsto 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 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

Theory 60 Hrs

1. 12Hrs

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

2 12Hrs

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

3 12Hrs

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)

4 12Hrs

ClinicalResearch Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance’s

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
  - E10 – Choice of Control Groups and Related Issues in Clinical Trials,
  - E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population
  - General biostatics principle applied in clinical research

5 USA & EU Guidance

USA: FDA Guidance

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

European Union: EMA Guidance

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

1. Clinical Trials and Human Research: A Practical Guide to RegulatoryComplianceBy Fay A. Rozovsky and Rodney K. Adams

2. HIPAA and Human Subjects Research: A Question and AnswerReference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD,PhD

3. Principles and Practices of Clinical Research, Second Edition Edited byJohn I. Gallin and Frederick P. Ognibene

4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PEKarlberg and Marjorie A Speers; Karlberg, Johan PetterEinar, HongKong.

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, RichardA; 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

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M. Pharm – I year I Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11104) REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS,MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD &NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTYRIGHTS

Scope

This course is designed to impart fundamental knowledge on regulations andlegislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals &Herbals, and Food &Nutraceuticals. It prepares the students for basicregulatory requirements in India of Drugs & Cosmetics, Medical Devices,Biologicals& Herbals, and Food &Nutraceuticals. for manufacture, import &registration, export, sale, marketing authorization, clinical trials and intellectualproperty 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. 12Hrs

Biologicals & Herbals, and Food &NutraceuticalsActs and Rules (with latest amendments):

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCOand NPPA

2. Other relevant provisions (rules schedules andguidelines for approval of Drugs & Cosmetics, MedicalDevices, Biologicals & Herbals, and Food &Nutraceuticals in IndiaOther relevant Acts: Narcotics Drugs and PsychotropicSubstances Act; Medicinal and Toilet Preparations (ExciseDuties) Act, 1955; Pharmacy Act, 1948; Drugs and MagicRemedies (Objectionable Advertisements) Act, 1955; Preventionof Cruelty to Animals Act.

2 12Hrs

Regulatory requirements and approval procedures for Drugs& Cosmetics Medical Devices, Biologicals & Herbals, andFood&NutraceuticalsCDSCO (Central Drug Standard Control Organization) and StateLicensing 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 12Hrs

Indian Pharmacopoeial Standards, BIS standards and ISO andother relevant standards

4 12Hrs

Bioavailability and Bioequivalence data (BA &BE), BCSClassification of Drugs, Regulatory Requirements forBioequivalencestudyStability requirements: ICH and WHOGuidelines for Drug testing in animals/Preclinical StudiesAnimal testing: Rationale for conducting studies, CPCSEAGuidelines

Ethical guidelines for human participants

ICMR-DBT Guidelines for Stem Cell Research

5 12Hrs

Intellectual Property Rights: Patent, Trademark, Copyright,Industrial Designs and Geographical Indications, Indian PatentScenario. 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 forEvaluating Safety and Efficacy by CDSCO (Central Drug Standard ControlOrganisation)

8. Guidance for Industry on Requirement of Chemical &PharmaceuticalInformation 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

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M. Pharm – I year I Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S11105) REGULATORY AFFAIRS PRACTICAL - I

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests forSolid, 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.

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M. Pharm – I year I Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S11106) REGULATORY AFFAIRS PRACTICAL - II

1. Preparation of checklist for registration of NDA as per ICH CTD format.
2. Preparation of checklist for registration of ANDA as per ICH CTD format.
3. Case studies on response with scientific rationale to USFDA Warning Letter
4. Preparation of submission checklist of IMPD for EU submission.
5. Comparison study of marketing authorization procedures in EU.
6. Comparative study of DMF system in US, EU and Japan
7. Preparation of regulatory submission using eCTD software
8. Preparation of Clinical Trial Application (CTA) for US submission
9. Preparation of Clinical Trial Application (CTA) for EU submission
10. Comparison of Clinical Trial Application requirements of US, EU and Japanof a dosage form.
11. Regulatory requirements checklist for conducting clinical trials in India.
12. Regulatory requirements checklist for conducting clinical trials in Europe.
13. Regulatory requirements checklist for conducting clinical trials in USA

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M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11201) REGULATORY ASPECTS OF DRUGS & COSMETICS

Scope

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

Theory 60 Hrs

1. 12Hrs

USA & CANADA: Organization structure and functions of FDA.Federal register and Code of Federal Regulations (CFR), Historyand evolution of United States Federal, Food, Drug and CosmeticAct (FFDCA), Hatch Waxman act and Orange book, Purple book,Drug Master Files (DMF) system in US, Regulatory ApprovalProcess for Investigational New Drug (IND), New DrugApplication (NDA), Abbreviated New Drug Application (ANDA),Supplemental New Drug Application (SNDA); Regulatoryrequirements for Orphan drugs and Combination Products,Changes to an approved NDA / ANDA. Regulatory considerationsfor manufacturing, packaging and labeling of pharmaceuticals inUSA. Legislation and regulations for import, manufacture,distribution and sale of cosmetics in USA and Canada.

2 12Hrs

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 andNational Procedure). Regulatory considerations for manufacturing,packaging and labeling of pharmaceuticals in EU, Eudralexdirectives for human medicines, Variations &extensions,Compliance of European Pharmacopoeia (CEP)/ Certificate

ofSuitability (CoS), Marketing Authorization (MA) transfers, QualifiedPerson (QP) in EU. Legislation and regulations for import,manufacture, distribution and sale of cosmetics in EuropeanUnion& Australia.

3 12Hrs

Japan: Organization of the PMDA, Pharmaceutical Laws andregulations, types of registration applications, DMF system inJapan, drug regulatory approval process, Regulatoryconsiderations for manufacturing, packaging and labeling ofpharmaceuticals in Japan, Post marketing surveillance in Japan.Legislation and regulations for import, manufacture, distributionand sale of cosmetics in Japan

4 12Hrs

Emerging Market: Introduction, Countries covered, Study of theworldmap,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

WHO: WHO, GMP, Regulatory Requirements for registration ofdrugs and post approval requirements in WHO throughprequalification programme, Certificate of Pharmaceutical Product(CoPP) - General and Country Specific (South Africa, Egypt,Algeria and Morocco, Nigeria, Kenya and Botswana)

5 12Hrs

Brazil, ASEAN, CIS and GCC Countries:ASIAN Countries: Introduction to ACTD, RegulatoryRequirements for registration of drugs and post approvalrequirements in China and South Korea & Association ofSoutheast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia,Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory prerequisitesrelated to Marketing authorization requirements fordrugs 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 Marketingauthorization requirements for drugs and post approvalrequirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distributionand sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, LeonShargel and IsaderKaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry MarcelDekker 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.185Informa Health care Publishers.

4. New Drug Approval Process: Accelerating Global Registrations ByRichardAGuarino, MD, 5th edition, Drugs and the Pharmaceutical

Sciences, 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 ByMarkMathieu

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, MarkKobayashi-Hillary, Springer

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

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

17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's WorldByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes

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

19. Doing Business in the Asean Countries, BalbirBhasin, Business ExpertPress ISBN:13:978-1-60649-108-9

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

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M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11202) REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Scope

This course is designed to impart fundamental knowledge on RegulatoryRequirements, Licensing and Registration, Regulation on Labelling of Biologicsin India, USA and EuropeIt prepares the students to learn in detail on Regulatory Requirements forbiologics, 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. 12Hrs

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

2 12Hrs

USA: Introduction to Biologics; biologics, biological andbiosimilars, different biological products, difference betweengeneric drug and biosimilars, laws, regulations and guidance onbiologics/ biosimilars, development and approval of biologics andbiosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinicaldevelopment considerations, advertising, labelling and packing ofbiologics

3 12Hrs

European Union: Introduction to Biologics; directives, scientificguidelines and guidance related to biologics in EU, comparability/biosimilarity assessment, Plasma master file, TSE/ BSEevaluation, development and regulatory approval of biologics(Investigational medicinal

products and biosimilars), pre-clinicaland clinical development considerations; stability, safety,advertising, labelling and packing of biologics in EU

4 12Hrs

Vaccine regulations in India, US and European Union: Clinicalevaluation, Marketing authorisation, Registration or licensing,Quality assessment, Pharmacovigilance, Additional requirementsBlood and Blood Products Regulations in India, US and EuropeanUnion: Regulatory Requirements of Blood and/or Its ComponentsIncluding Blood Products, Label Requirements, ISBT(International Society of Blood Transfusion) and IHN (InternationalHaemovigilence Network)

5 12Hrs

Herbal Products: 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 RegulatoryInformation (Biologics)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11203) REGULATORY ASPECTS OF MEDICAL DEVICES

Scope

This course is designed to impart the fundamental knowledge on the medicaldevices and in vitro diagnostics, basis of classification and product life cycle ofmedical devices, regulatory requirements for approval of medical devices inregulated countries like US, EU and Asian countries along with WHOregulations. It prepares the students to learn in detail on the harmonizationinitiatives, quality and ethical considerations, regulatory and documentationrequirements 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

Theory 60 Hrs

1. 12Hrs

Medical Devices: Introduction, Definition, Risk basedclassification and Essential Principles of Medical Devices andIVDs. Differentiating medical devices IVDs and CombinationProducts from that of pharmaceuticals, History of Medical DeviceRegulation, Product Lifecycle of Medical Devices andClassification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purposeand Functions, Regulatory Guidelines, Working Groups,Summary Technical Document (STED), Global Medical DeviceNomenclature (GMDN).

2 12Hrs

Ethics: Clinical Investigation of Medical Devices, ClinicalInvestigation Plan for Medical Devices, Good Clinical Practice forClinical 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 12Hrs

USA: Introduction, Classification, Regulatory approval process forMedical Devices (510k) Premarket Notification, Pre-MarketApproval (PMA), Investigational Device Exemption (IDE) and Invitro Diagnostics, Quality System Requirements 21 CFR Part 820,Labeling requirements 21 CFR Part 801, Post marketingsurveillance of MD and Unique Device Identification (UDI). Basicsof In vitro diagnostics, classification and approval process.

4 12Hrs

European Union: Introduction, Classification, Regulatoryapproval process for Medical Devices(Medical Device Directive, Active Implantable Medical DeviceDirective) and In vitro Diagnostics (In Vitro Diagnostics Directive),CE certification process.Basics of In vitro diagnostics, classification and approval process.

5 12Hrs

ASEAN, China & Japan: Medical Devices and IVDs, Regulatoryregistration procedures, Quality System requirements and clinicalevaluation 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, MedicalDevices 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S11204) REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Scope

This course is designed to impart the fundamental knowledge on RegulatoryRequirements, Registration and Labeling Regulations of Nutraceuticals in India,USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects fornutraceuticals 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 nutraceuticals and food supplements in India, USA and Europe.

Theory 60 Hrs

1. 12Hrs

Nutraceuticals: Introduction, History of Food and NutraceuticalRegulations, Meaning of Nutraceuticals, Dietary Supplements,Functional Foods, Medical Foods, Scope and Opportunities inNutraceutical Market.

2 12Hrs

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

3 12Hrs

India : Food Safety and Standards Act, Food Safety andStandards Authority of India: Organization and Functions,Regulations for import, manufacture and sale of nutraceuticalproducts in India, Recommended Dietary Allowances (RDA) inIndia.

4 12Hrs

USA: US FDA Food Safety Modernization Act, DietarySupplement Health and Education Act. U.S. regulations formanufacture and sale of nutraceuticals and dietary supplements,Labelling

Requirements and Label Claims for DietarySupplements, Recommended Dietary Allowances (RDA) in theU.S

5 12Hrs

European Union: European Food Safety Authority (EFSA):Organization and Functions. EU Directives and regulations formanufacture and sale of nutraceuticals and dietary supplements.

Nutrition labelling. European Regulation on Novel Foods andNovel 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 DebasisBagchi (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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S11205) REGULATORY AFFAIRS PRACTICAL - III

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S11206) REGULATORY AFFAIRS PRACTICAL - IV

1. Preparation of Checklist for Registration of Blood and Blood Products
2. Registration requirement comparison study in 5 emerging markets(WHO) and preparing check list for market authorization
3. Registration requirement comparison study in emerging markets(BRICS) and preparing check list for market authorization
4. Registration requirement comparison study in emerging markets(China and South Korea) and preparing check list for marketauthorization
5. Registration requirement comparison study in emerging markets(ASEAN) and preparing check list for market authorization
6. Registration requirement comparison study in emerging markets (GCC)and preparing check list for market authorization
7. Checklists for 510k and PMA for US market
8. Checklist for CE marking for various classes of devices for EU
9. STED Application for Class III Devices
10. Audit Checklist for Medical Device Facility
11. Clinical Investigation Plan for Medical Devices

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlationcoefficient, 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 – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

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