

M.Pharm Syllabus

Semester 01

Pharmaceutical Regulatory Affairs

Subjects

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MRA101T - Good Regulatory Practices

Theory

Unit 1

- Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211. EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

Unit 2

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

Unit 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 21 CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

Unit 4

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

Unit 5

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

MRA102T - Documentation and Regulatory Writing

Theory

Unit 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).

Unit 2

- Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

Unit 3

- Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document.
- ISO 13485.

Unit 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).

Unit 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. ISO Risk Management Standard

MRA103T - Clinical Research Regulations

Theory

Unit 1

- Clinical Drug Development Process
- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug - drug interaction, PK end points)
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR) Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation

Unit 2

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

Unit 3

- Regulations governing Clinical Trials India: Clinical Research regulations in India - Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA)
- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)

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

Unit 4

- Clinical Research Related Guidelines
- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines GHTF study group 5 guidance documents Regulatory Guidance on Efficacy and Safety ICH Guidance's
- E4 - Dose Response Information to support Drug Registration
- E7 - Studies in support of General Population: Geriatrics
- E8 - General Considerations of Clinical Trials
- E10 - Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 - Clinical Investigation of Medicinal Products in the Pediatric Population
- General biostatistics principle applied in clinical research

Unit 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 (EMA) 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

MRA104T - Regulations and Legislation for Drugs, Cosmetics, Medical Devices, Biologicals, Herbals, Food and Nutraceuticals in India, and Intellectual Property Rights

Theory

Unit 1

- Biologicals & Herbals, and Food & Nutraceuticals
- Acts and Rules (with latest amendments):
- Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
- Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

Unit 2

- Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities
- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

Unit 3

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

Unit 4

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

Unit 5

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

MRA105P - Regulatory Affairs I

Practical

- Case studies of each of Good Pharmaceutical Practices.
- Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
- Preparation of SOPs, Analytical reports (Stability and validation)
- Protocol preparation for documentation of various types of records (BMR, MFR, DR)
- Labeling comparison between brand & generics.
- Preparation of clinical trial protocol for registering trial in India
- Registration for conducting BA/ BE studies in India
- Import of drugs for research and developmental activities
- Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
- Registering for different Intellectual Property Rights in India
- GMP Audit Requirements as per CDSCO
- Preparation and documentation for Indian Patent application.
- Preparation of checklist for registration of IND as per ICH CTD format.
- Preparation of checklist for registration of NDA as per ICH CTD format.
- Preparation of checklist for registration of ANDA as per ICH CTD format.
- Case studies on response with scientific rationale to USFDA Warning Letter
- Preparation of submission checklist of IMPD for EU submission.
- Comparison study of marketing authorization procedures in EU.
- Comparative study of DMF system in US, EU and Japan
- Preparation of regulatory submission using eCTD software
- Preparation of Clinical Trial Application (CTA) for US submission
- Preparation of Clinical Trial Application (CTA) for EU submission
- Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
- Regulatory requirements checklist for conducting clinical trials in India.
- Regulatory requirements checklist for conducting clinical trials in Europe.
- Regulatory requirements checklist for conducting clinical trials in USA

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