28-08-2012

RAJIV GANDHI PROUDHYOGIKI VISHWAVIDYALAYA

M. Pharm (Drug Regulatory Affairs)

III Semester Elective Course Contents

ELECTIVE I

MPY- 301 DRA : REGULATIONS IN CLINICAL STUDIES

Unit I

Introduction Regulatory guidelines used for clinical trials in India and other regulated countries. Terminologies, Principles of good clinical practices, role of clinical trials in new drug developments. Study of relevant regulatory requirements prescribed by USFDA and D&C Act 1940 for IND and NDA.

Unit II

Ethics in clinical trials, Principles of ICH GCP, ICMR guidelines on Clinical Research, Patient's rights and safety, conduct of illegal / unethical trials. The Nuremberg Code of 1946, Thalidomide disaster of 1962, Declaration of Helsinki– Ethical Principles for Medical Research Involving Human Subjects (current version)., 1964, ICH-Good Clinical Practice of 1997, Ethical Guidelines for Biomedical Research on Human Subjects, ICMR, 2000, Good Clinical Practices, 2001(Indian GCP)The Principles of ICH GCP.

Unit III

Organization: Institutional Review Board/Independent Ethics Committee (IRB/IEC): Its role and responsibilities in clinical trials, organization of IRB, their functions and operations. Procedures and documentations. Investigator: Qualifications and agreements, role of investigators regarding resources development, medical care of subjects, Communication with IRB/IEC, Compliance with Protocol, Responsibility and accountability for investigational products, information of consent to trial subjects. Maintenance of records and reports by investigator. Sponsor: role and responsibility, maintenance of quality assurance and quality control system in clinical trials. Contract Research Organization (CRO): Role and responsibility. Medical expert.

Unit IV

Clinical trial design: Trial management, data handling, and record keeping. Investigator selection, preparation of SOPs, auditing procedures, non compliance, premature termination, ICH guideline for structure and content of clinical study reports. Multicentre trials,

Unit IV

Clinical Trial Protocol: Procedure for preparation of protocol. Relevant components of protocol, objectives, design, criteria for selection and withdrawal of subjects. Statistical data handling methods and their significance. Records & reports. Investigator's Brochure: Contents of the Investigator's Brochure.

Books and References Recommended:

1. http://www.stanford.edu/group/psylawseminar/The%20Nuremburg%20Code.htm.
2. http://www.pnc.com.au/~cafmr/online/research/thalid2.html.
3. ICH Guidelines. www.ich.org.
4. Code of Federal Regulation. www.fda.gov
5. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
6. World Medical Organization. Declaration of Helsinki. *British Medical Journal* (7 December) 1996;313(7070):1448-1449.
7. Guideline for Good Clinical Practice, www.ema.europa.eu/pdfs/human/ich/013595en.pdf
8. Good clinical practices for clinical research in India, http://cdsco.nic.in/html/GCP.htm

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III Semester Elective Course Contents

ELECTIVE II

MPY- 302 DRA : GENERIC DRUG APPROVAL

Unit I

USFDA: Regulations. Effects of patent and trademark laws. Patent certification in drug approvals. Para filings.

Unit II

FDA's Product Approval Processes

A. New Drug Approval Process.
B. Generic Drug Approval Process .
C. Biologics Approval Process.

Unit III

Special Innovation Incentives and Disincentives for FDA-Regulated Products

A. Approval of duplicates and variants based on innovator data – ANDAs, "Hybrid" NDAs, Follow-on Medical Devices, Follow-on Biologics
B. Infringement Safe Harbor for FDA Submission-Related Acts
C. Patent Term Extensions
D. Non-Patent Exclusive Marketing Rights - Orphan Drugs, New Compounds and Uses, Pediatric Studies.

Unit IV

Eligibility for ANDA Approval

A. The "Same"-ness Requirement – Active and Inactive Ingredients, Bioavailability, Conditions of Use, and Labeling.
B. Approval Based on Discontinued Innovator Drug.

Unit V

The role of patents in the approval process

i. The Patent Listing ("Orange Book") Requirement
ii. The "Paragraph IV" Certification and Notice Requirement
iii. ANDA Filing As An Act of Infringement
iv. The Automatic 30-Month Stay of ANDA Approval
v. 180-Day Exclusivity for first paragraph IV filers
vi. Antitrust issues in pharmaceutical patent litigation settlements

Books and References Recommended:

1. Code of federal regulation. www.fda.gov.
2. I. R. Berry, *The pharmaceutical regulatory process*, Marcel dekker.
3. L. Shargel, I. Kanfer, *Generic drug product development solid oral dosage forms*, Marcel dekker.

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III Semester Elective Course Contents
ELECTIVE III
MPY- 303 DRA : INTELLECTUAL PROPERTY RIGHTS

Unit I

Intellectual property: Trade related intellectual property rights: Patent, Industrial Designs, Trade Mark, Copyright, Geographical Indication, Layout Designs of Integrated Circuit, Protection of Undisclosed Information/Trade Secrets. Types of patent applications.

Unit II

Patents Act (Indian Legislation): Inventions, Inventions not patentable, forms of application, Information and undertaking regarding foreign applications, Provisional and complete specifications, Contents of specifications, Priority dates of claims of a complete specification, Publication and examination of application, withdrawal of an application. Grant of patent: Grant and sealing of patent, Opposition to grant of patent, post grant opposition, Amendment of patent granted to deceased applicant, Important dates of patent, Rights of patentee, Rights of co-owners of patents, Term of patent, Patents of addition, Amendment of application and specification, restoration of lapsed patents, surrender and revocation of patents, Register of patents, use of inventions for purposes of government and acquisition of inventions by central government, Suits concerning infringement of patents. Offences and penalties. Forms and fees structure used in filing of patent.

Unit III

Patent Officials: Controller Generally; Power of controller, time frame, acceptance. Exclusive marketing rights: Application for grant of exclusive rights, Grant of exclusive rights, Compulsory licenses, Suits relating to infringements, Opposition to grant of patent, Refusal of patent without opposition, Anticipations, provisions for secrecy of certain inventions, Patent agents: Register of patent agents, Qualifications for registration as patent agents, Rights of patent agents, Subscription and verification of certain documents by patent agents, Restrictions on practice as patent agents, Removal from register of patent agents and restoration.

Unit IV

International Arrangements: Notification as to convention countries, Notification as to countries not providing for reciprocity, Patent Cooperation treaty, Overview of PCT process, Convention applications, Special provisions relating to convention applications, Multiple priorities, Supplementary provisions as to convention applications, Other provisions of Act to apply to convention applications

Unit V

Patent Drafting: Case study for proper drafting of complete specification relating to: title of invention, Field of invention, Background of invention with regard to the drawback associated with known art, Object of invention, Statement of invention, summary of invention, brief description of the accompanying drawing, detailed description of the invention with reference to drawing/examples, claim(s), Abstract.

Books and References Recommended:

1. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
2. J. L. Rogers, *The complete patent book: Everything you need to know to obtain your patent.* Sphinx Publishing.
3. www.uspto.gov.in
4. www.ep.espace.net

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III Semester Elective Course Contents
ELECTIVE IV
MPY- 304 DRA : REGULATIONS OF GOOD LABORATORY PRACTICES

Unit I

Introduction : GLP regulation of WHO, USFDA and D&C Act 1940, Organization and Personnel: Staffing laboratories. Personal health and hygiene for staff. laboratory test facility management's role in staffing the laboratory to ensure work is performed effectively and efficiently. The role of study director in conducting non clinical studies, managing study data and controlling conditions of the study. Quality Assurance Unit

Unit II

Facilities: Facilities required for non clinical studies: Animal care facilities, Separation and isolation of animals, Animal supply facilities, Facilities to handle test articles and control articles, Specimen / data storage. Regulation of Computer systems, Equipment: Equipment installation, operation, and performance qualifications. Equipment maintenance and calibration, Documentation of procedures and results of equipment maintenance and calibration.

Unit III

Testing Facilities Operation: Documenting SOPs, Labelling reagents and solutions, Methodologies for test system handling, Quarantine, separation, isolation, and disease control, Clean cages and adequate food and water for test systems.

Unit IV

Test and Control Articles: Stability testing of test and control articles, Labelling containers for test and control articles, Handling test and control article, Mixing test and control articles with carriers, Implementing tests on test or control articles mixed with a carrier.

Unit V

Protocol for and Conduct of a Nonclinical Laboratory Study: The study protocol and its uses. Correct methods of amending protocols and dealing with deviations. Correct conduct of non-clinical studies, Records and Reports: Writing final reports, Data storage, retention, retrieval, and archival procedures, The amount of time the study component must be kept. Disqualification of testing facilities, appeal and reinstatement process.

Books and References Recommended:

1. Good Laboratory Practice Regulations, fourth edition, Sandy Weinberg, Informa healthcare.
2. Good laboratory practice (GLP): quality practices for regulated non-clinical research and development -2nd ed. World health organization.
3. Food and Drug Administration (1999). Non-clinical Laboratory Studies, Good Laboratory Practice Regulations, U. S. Federal Register 43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999.4.
4. Good laboratory practice: guidance on archiving, MHRA guidelines.