M.PHARM-PHARMACEUTICAL REGULATORY AFFAIRS

PROGRAM OUTCOMES

1. Implement Good Regulatory practices for Pharmaceuticals, cosmetics, Food and Nutraceuticals, Medical devices, IVDs and biological products.
2. Explain the rationale behind regulatory requirements and ways and means of complying with them.
3. Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
4. Handle documentation and general principles involved in regulatory writing and submission to agencies.
5. Assist in clinical development process of drugs, pharmaceuticals and Medical Devices.
6. Demonstrate knowledge of regulations and guidelines for conducting clinical research in India, USA and EU.
7. Demonstrate knowledge about various laws, legislation and guidance related to safety, efficacy ethical conduct and regulatory approval of clinical research.
8. Discuss the regulations and legislation in India and other major egulated countries with respect to drugs and cosmetics, Medical Devices, Biologicals Herbals and Food and Nutraceuticals.
9. Demonstrate knowledge about licensing and registration, regulation on labelling of biological in India, USA and Europe.

COURSEOUTCOMES:

Name of the course: Good Regulatory Practices (17S11101)

1. Prepare checklists and SOPs for various good regulatory practices.
2. Develop good regulatory practices in the healthcare and related industries
3. Demonstrate a plan for the readiness and conduct of audits and inspections.
4. Categorize the key regulatory and compliance elements with respect to GMP.
5. Categorize the key regulatory and compliance elements with respect to GLP.
6. Categorize the key regulatory and compliance elements with respect to GALP.
7. Categorize the key regulatory and compliance elements with respect to GDP.
8. Describe the quality management system in the Pharmaceutical Industry.

Name of the Course: Documentation & Regulatory Writing (17S11102)

1. Discuss the basic Documentation in Pharmaceutical industry
2. Discuss on dossier preparation and CTD submission
3. Learn about eCTD and technologies available
4. The basics of CTD submission in India through Sugam system
5. Learn the basics of internal and external audits
6. Learn ISO standards and guidelines on audits
7. Understand inspection systems in pharmaceutical companies and follow up actions
8. Learn the regulatory aspects of product life-cycle management and product recalls

Name of the Course: Clinical Research Regulations (17S11103)

1. Understand the History, origin and ethics of clinical and biomedical research and evaluation
2. Know Clinical drug, medical device development process, different types and phases of clinical trials
3. Know the regulatory requirements and guidance for conduct of clinical trials and research.
4. Understand the European union guidance for clinical evaluation and safety for medicinal products and medical devices.
5. Understand the clinical, ethical principles, informed consent form, process and documentation.
6. Know the General biostatic principles applied in clinical research.
7. Understand FDA guidance for bioavailability and bioequivalence requirements for medicinal products
8. Understand Indian GCP, CDSCO and ICMR guidelines for biomedical research.

Name of the course: Drug Regulations & other regulations in India &Intellectual Property Rights (17S11104)

1. Assess the approval process and regulatory requirements for drugs & cosmetics, medical devices, biological & herbals, and food & nutraceuticals
2. Examine the Indian Pharmacopoeial and BIS standards
3. Review and validate the guidelines for drug testing in animals
4. Practice the concept of Intellectual Property Rights
5. Describe the different acts and guidelines that regulate drugs & cosmetics, medical devices, biological & herbals, and food & nutraceuticals industry in India
6. Categorize the guidelines for drug testing in animals
7. Assess the regulatory requirements for bioequivalence study
8. Describe the role of IPR in regulatory affairs.

Name of the Course: Regulatory Aspect of Drugs &Cosmetics (17S11201)

1. Study the regulatory approval process and registration procedures for API and drug products in USA and Canada
2. Explain the role of various committees across the globe (APEC, EAC, GCC, PANDRH, SADC)
3. Know the legislation and regulations for import, manufacture, distribution and sale of drugs and cosmetics in EU and Australia
4. Understand the cosmetics regulations in regulated and semi-regulated countries
5. Understand the legislation and regulations for manufacturing, packaging and labelling of pharmaceuticals in Japan
6. Describe the requirements for registration of drugs and post approval requirements in ASEAN countries
7. Study the regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries
8. Understand the concept of Certificate of Pharmaceutical Product(CoPP) in General and Country Specific

Name of the course: Regulatory aspect of Herbals &Biologicals (17S11202)

1. Recognize the regulation for newly developed biologics and biosimilars.
2. Explain the pre-clinical and clinical development considerations of biologics.
3. Discuss the regulatory requirements of blood and/or its components including blood products and label requirements.
4. Set up the quality and safety of herbal products.
5. Describe the regulatory requirements for biologics and vaccines.
6. Describe the regulatory requirements for the herbal products.
7. Set up the quality and safety of herbal products.
8. Set up the legislation for herbal products.

Name of the Course: Regulatory aspect of Medical Devices (17S11203)

1. Know the basics of medical devices and IVDs, process of development, ethical and quality considerations.
2. Know the quality system regulations and quality risk management of medical devices.
3. Know the medical devices and IVDs directives in European Union and USA.
4. Understand organizational structure, regulatory guidelines and functions of IMDRF/GHTF.
5. Know Harmonization initiatives for approval and marketing of medical devices and IVDs.
6. Understand regulatory approval process for medical devices and IVDs in India, US, and Europe.
7. Know clinical evaluation and investigation of medical devices and IVDs.
8. Understand regulatory approval process for medical devices and IVDs in China, Japan and ASEAN countries.

Name of the Course: Regulatory Aspect of Food &Neutraceuticals(17S11204)

1. Define and differentiate nutraceuticals, functional foods, dietary supplements, and medical foods
2. Discuss the scope and opportunities in nutraceutical market
3. Learn the history of neutraceuticals and their regulations
4. Learn the global aspects of regulations in food and nutraceutical markets
5. Understand the nutraceutical regulations in India
6. Learn the nutraceutical regulations in USA
7. Study the nutraceutical regulations in European Union
8. Understand and compare the Recommended Dietary Allowance in various regulated countries

Name of the Course: Research Methodology and Biostatistics* (17S01301)

1. Learn general research methodology
2. Understand the basic concepts of biostatistics
3. Learn different parametric and non-parametric tests
4. Understand the functions of ethics committees in medical research
5. Learn the guidelines for developing animal facilities
6. Explain the guidelines and importance of medical research
7. Learn the guidelines for the experimentation on animals
8. Understand the genesis of bioethics with special reference to Helsinki declaration