M.Pharm Syllabus

Semester 02

Pharmaceutical Regulatory Affairs

Subjects

Subject	PDF page	Open
Regulatory Aspects of Drugs and Cosmetics	2	Click here
Regulatory Aspects of Herbal and Biologicals	4	Click here
Regulatory Aspects of Medical Devices	5	Click here
Regulatory Aspects of Food and Nutraceuticals	6	Click here
Regulatory Affairs II	7	Click here

MRA201T - Regulatory Aspects of Drugs and Cosmetics

Theory

Unit 1

- USA & 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

Unit 2

- 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 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

Unit 3

- 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.
- Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan

Unit 4

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

Unit 5

- Brazil, ASEAN, CIS and GCC Countries: 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.

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

MRA202T - Regulatory Aspects of Herbal and Biologicals

Theory

Unit 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.

Unit 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, labelling and packing of biologics

Unit 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

Unit 4

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

Unit 5

- Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

MRA203T - Regulatory Aspects of Medical Devices

Theory

Unit 1

- Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and 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 2

- 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 3

- 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 4

- 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 5

- ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.
- IMDRF study groups and guidance documents.

MRA204T - Regulatory Aspects of Food and Nutraceuticals

Theory

Unit 1

- Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

Unit 2

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

Unit 3

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

Unit 4

- USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the
- S

Unit 5

- European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.
- Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

MRA205P - Regulatory Affairs II

Practical

- Case studies on
- Change Management/ Change control. Deviations
- Corrective & Preventive Actions (CAPA)
- Documentation of raw materials analysis as per official monographs
- Preparation of audit checklist for various agencies
- Preparation of submission to FDA using eCTD software
- Preparation of submission to EMA using eCTD software
- Preparation of submission to MHRA using eCTD software
- Preparation of Biologics License Applications (BLA)
- Preparation of documents required for Vaccine Product Approval
- Comparison of clinical trial application requirements of US, EU and India of Biologics
- Preparation of Checklist for Registration of Blood and Blood Products
- Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
- Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
- Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
- Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
- Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
- Checklists for 510k and PMA for US market
- Checklist for CE marking for various classes of devices for EU
- STED Application for Class III Devices
- Audit Checklist for Medical Device Facility
- Clinical Investigation Plan for Medical Devices

Continue Learning with FirstHope

Complete Notes on the FirstHope App

Complete subject and semesters are available on FirstHope app only.

- Get complete subject and semester notes in the FirstHope app.
- Available for B.Pharm, D.Pharm, M.Pharm and Pharm.D students.

Click here to get the FirstHope app

Join the FirstHope Telegram Channel

Join FirstHope Notes and keep up with channel updates.

Click here to join Telegram

Instagram

@firsthope.official

Click here to follow Instagram

YouTube Channel

FirstHope-Pharmacy / Live streams

Click here to watch the YouTube channel

WhatsApp Channel

Follow FirstHope on WhatsApp.

Click here to join the WhatsApp channel

FirstHope Website

firsthopenotes.com

Click here to visit the website