REGULATORY AFFAIRS

(MPH 104T)

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PREFACE

A Regulatory Affair is a one-of-a-kind collaboration between internal departments of an industry and regulatory bodies that begins with the conceptualization of the product to be developed by that industry and ends with the marketing of that product. It is a crucial and noticeable aspect of pharmaceutical product development. This chapter discusses the regulatory affairs, regulatory requirements for product approval, and documentation in the pharmaceutical industry, with a focus on the master formula record, drug master file, and distribution records.

The book's chapters provide an overview of the regulatory affairs field, information about different regulatory authorities, how these professionals work, and the various roles and responsibilities of regulatory affairs professionals. This book also discusses the various skills required for a career in regulatory affairs, as well as the employment opportunities available in various sectors. We go over typical tasks, required skills, the ins and outs of the submission process, critical knowledge, and much more. Are you drowning in acronyms? We've got your back. Not sure how regulatory plays a role in pharmaceutical development? We describe the procedure.

Following Chapters are including:

1. Documentation in Pharmaceutical industry
2. Regulatory requirement for product approval
3. CMC, post approval regulatory affairs
4. Nonclinical drug development
5. Clinical trials

SCOPE:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

Abbreviations

Abbreviated New Drug Application (ANDA)

Absorption, Distribution, Metabolism, and Excretion (ADME)

Active Implantable Medical Device Category (AIMD)

Active Pharmaceutical Ingredient (API)

Active Pharmaceutical Ingredients (APIs)

Advance Notice of Proposed Rule Making (ANPRM)

Advanced Therapy Medicinal Products (ATMPs)

Agência Nacional de VigilânciaSanitária (ANVISA)

Association of Pharmaceutical Scientists (AAPS)

Australian Register of Therapeutic Goods (ARTG)

Batch Manufacturing Records (BMR)

British Pharmacopoeia (BP)

Carboxymethylcellulose (CMC)

Center for Biologics Evaluation and Research (CBER)

Center for Devices and Radiologic Health (CDER) (CDRH)

Center for Drug Evaluation and Research (CDER)

Central Drugs Standard Control Organization (CDSCO)

central nervous system (CNS)

Change Being Effected (CBE)

chemistry, manufacturing, and control (CMC)

Clinical Trial Applications (CTAs)

Code of Federal Regulations (CFR)

Committee on Genetic Manipulation (RCGM)

Common Good Manufacturing Practise (GMP)

Common Technical Document (CTD)

Common Technical Document (CTD)

Contract Research Organizations (CRO)

Council for International Organizations of Medical Sciences (CIOMS)

Degree of Substitution (DS)

Department of Health and Human Services (DHHS)

Development and Reproductive Toxicology (DART)

Drug Controller General of India (DCGI)

Drug Master File (DMF)

Drug Regulatory Authority (DRA)

Drugs and Health products (DHP)

Electronic Submissions Gateway (ESG)

European Union (EU)

Federal Food, Drug, and Cosmetic Act (FDCA)

Food and Drug Administration (FDA)

General Practice Research Database (GPRD)

Global Harmonization Task Force (GHTF)

Good Clinical Practices (GCP)

Good Laboratory Practice principles (GLP)

Good Laboratory Practices (GLP)

Good Manufacturing Practise (GMP)

Government Publishing Office (GPO)

Health Authority (HA)

Human Factor (HF)

Human Research Ethics Committee (HREC)

Institutional Review Board (IRB)

International Conference of Harmonization (ICH)

International Conference on Harmonization (ICH)

International Conference on Harmonization Good Clinical Practice (ICH-GCP)

Investigational Medicinal Product (IMP)

Investigational Medicinal Product (IMP)

Investigational Medicinal Product Dossier (IMPD)

Investigational Medicinal Products (IMPs)

Investigational New Drug Application (IND)

Investigator's Brochure (IB)

Market Authorization Group (MAG)

Marketing Authorization Applications (MAA)

Marketing Authorization Applications (MAA)

Master Formula Record (MFN)

Material of Construction (MOC)

Monitoring and Compliance Group (MCG)

Mutual Recognition Agreement (MRA)

National Archives and Records Administration's (NARA)

National Institutes of Health (NIH)

New Drug Application (NDA)

Non-Observed Adverse Effect (NOAEL)

Novel Drug Delivery System (NDDS)

Office of Combination Products (OCP)

Office of Regulatory Integrity (ORI)

Office of the Federal Register (OFR)

Pan American Health Organization (PAHO)

Pan American Health Organization (PAHO)

Patient Information Leaflets (PILs)

Pharmaceuticals and Medical Devices Agency (PMDA)

Pharmacodynamics (PD)

Pharmacokinetic/Toxicokinetic (PK/TK)

Pharmacokinetics (PK)

Pharmacovigilance (PV)

Pharmacovigilance Risk Assessment Committee, or PRAC

Post-Marketing Surveillance (PMS)

Prior Approval Supplement (PAS)

Proposed Primary Mode of Action (PMOA)

Public Health Services Act (PHS Act)

Quality Control (QC)

Request-for-Designation (RFD)

Roszdravnadzor (RZN)

Scaleup and Post-Approval Change (SUPAC)

Scale-Up and Post-Approval Changes (SUPAC)

Standard Operating Procedures (SOPS)

United States Pharmacopeia-National Formulary (USP-NF)

US Pharmacopeia (USP)

World Health Organization (WHO)

World Intellectual Property Organization (WIPO)

World Trade Organization (WTO)

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He is presently working as Asst. Professor at Navsahyadri Institute of Pharmacy, Nasarapur, Pune. He has completed M.Pharm in Pharmaceutics from Savitribai Phule Pune University, Pune. He has completed PhD in Naturopathy (Diabetes Reversal) & another PhD (HC) in subject healthcare from Commonwealth University, kingdom of Tonga for his contribution to healthcare sector. He also Completed Certificate and Diploma courses in Naturopathy, Medical Astrology (International Medical Astrologer), Cupping Therapy (TCM – China), Code Blue Trainer (Lincoln University, Malaysia), Nutrition & Diet Planning (FAB Academy, USA) and Regulatory Affairs (IADL, UK approved) from various national & international Universities. He received 1 Indian Patent Grant (Designs) & 4 international Germany utility patent grants. His research works under patent grant process in India and South Africa country. His research interest includes GRDDS, Nanoparticles, Herbal formulations, Type 1 & 2 diabetes reversal. He received 3 copyrights for his value added courses designs. He published review as well as research papers in various UGC Care, Scopus journals. He is a founder of Intellect Institute of Education and Research, Pune. He is also founder of Suvijaya Natural Cure, Satara. He is also working as consultant for Hospitals and Pharma giants. In 2021 he is appointed and upgraded as ILI Paramedic at Hospital & Institute of Integrated Medical Sciences, Chandigarh. He is a fellow member of Screenwriters Association, Mumbai. He is a certified Psychological Counselor. He is also member of Indo-Vietnam medical board and appointed as Network of Influenza Care Expert.

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