TULIP Course Modules

Pharmaceutical Regulatory Affairs (Drugs and Medical Devices)

Module 1: Registration of Drug and Dossier Preparation (CTD and eCTD submissions)
Module 2: Drug Registration (European market, GCC, African, India)
Module 3: Drug Registration (US Market-ANDA, NDA etc)
Module 4: Preparation and Submission of Drug Master File (DMF)
Module 5: Intellectual Property Rights
Module 6: Medical Devices Directive CE Marking for Europe (93/42/EEC)
Module 7: In Vitro Diagnostic Medical Device Directive – CE Marking for Europe (98/79/EC)
Module 8: EU IVD Medical Device Regulation
Module 9: EU Medical Devices Regulation
Module 10: Medical Device Quality Auditor
Module 11: Food Regulatory Affairs

Clinical Trial (Clinical Research)

Module 1: Introduction to Clinical Research Industry and Clinical Trial Phases
Module 2: Pharmacological Principles and Application in Clinical Trial
Module 3: Drug Development Process, Role of Pharmacovigilance, NDA Application
Module 4: Ethical Guidelines for Clinical Trials and Good Clinical Practice (GCP)
Module 5: Regulations guiding the Clinical Research Industry - History and Basics of National and International Regulatory bodies.
a) ICH
b) ICMR
c) Schedule Y
Module 6: Outsourcing Clinical Trials, Functioning of Clinical Research Organisations
Module 7: Biostatistics - Concepts and Application in Drug Development and Clinical Research
Module 8: Clinical Trial Phases and Trial designs
Module 9: Documentation and Data Management in Clinical Trial
Module 10: Safety Reporting Techniques in Pharmacovigilance
Module 11: Quality Control and Clinical Trial Management
a) 21 CFR Part II
Module 12: Protocol Writing and Designing

Pharmacovigilance

Module 1: Introduction, History and Overview of Pharmacovigilance.
Module 2: Adverse Events and its Types, Adverse Drug Reactions and Safety Reports in Pharmacovigilance including Herbal and Medical Devices. Different types of A Reporting Forms.
Module 3: Methodologies and management systems in Pharmacovigilance
Module 4: Pharmacovigilance Programme in India (PVPI)
Module 5: Different dictionaries in drug coding and various Database
Module 6: Assessment of safety reports based on Seriousness, Expectedness & Causality (Relatedness)
Module 7: Signal Detection and Data Mining
Module 8: Aggregate Safety Reports, Expedited reporting and its timelines.
a) DSUR

b) PBRER
c) PADER

Module 9: Pharmacovigilance Regulations in India and around the globe
Module 10: Pharmacovigilance Laws, Compliance, and Inspections
a) Regulatory Guidelines and Laws in PV
b) SOPs in PV
c) Risk Management Plan (RMP)
Module 11: Pharmacovigilance process /Case study on ICSR in training environment (Argus, ArisGlobal, ABcube like software platforms)
a) Global perspective of Pharmacovigilance
b) Seriousness criteria, Roles and responsibilities of Case Receipt and Triage Unit
c) Case Narrative Writing
d) Case Quality Check, Medical Review, and its Submissions.

Certificate in Medical Coding and ICD-10-CM
Module 1 : Introduction to Medical Coding
Module 2 : Basics of Anatomy and Physiology
Module 3 : Medical Coding and terminologies in association with Diseases
Module 4 : Introduction to International Classification of Diseases (ICD)
Module 5 : Certain Infectious and Parasitic Diseases (A00-B99)
Module 6 : Neoplasms (C00-D49)
Module 7 : Diseases of the Blood and Blood-forming Organs and Certain Disorders Involving the Immune Mechanism (D50-D89)
Module 8 : Endocrine, Nutritional, and Metabolic Diseases (E00-E89)
Module 9 : Mental, Behavioural and Neurodevelopmental Disorders (F01-F99)
Module 10 : Diseases of Nervous System (G00-G99)
Module 11 : Diseases of Eye and Adnexa (H00-H59)
Module 12 : Diseases of Ear and Mastoid Process (H60-H95)
Module 13 : Diseases of Circulatory System (I00-I99)
Module 14 : Diseases of Respiratory System (J00-J99)
Module 15 : Diseases of Digestive System (K00-K94)
Module 16 : Diseases of Skin and Subcutaneous Tissue (L00-L99)
Module 17 : Diseases of the Musculoskeletal System and Connective Tissue (M00-M99)
Module 18 : Diseases of Genitourinary System (N00-N99)
Module 19 : Pregnancy, Childbirth, and the Puerperium (O00-O9A)
Module 20 : Newborn (Perinatal) Guidelines (P00-P96)
Module 21 : Congenital Malformations, Deformations, and Chromosomal Abnormalities (Q00-Q99)
Module 22 : Symptoms, Signs, and Abnormal Clinical and Laboratory Findings, Not Elsewhere Classified (R00-R99)
Module 23 : Injury, Poisoning, and Certain Other Consequences of External Causes (S00-T88)
Module 24 : External Causes of Morbidity (V00-Y99)
Module 25 : Factors Influencing Health Status and Contact with Health Services (Z00-Z99)
Module 26 : Healthcare Common Procedure Coding System (HCPCS)
Module 27 : Current Procedural Terminology (CPT)
Module 28 : Modifiers
Module 29 : Evaluation and Management Guidelines for Medical coding professionals
Module 30 : Radiology and Anaesthesia Guidelines for Medical coding professionals

Module 31 : Surgery Guidelines for Medical coding professionals
Module 32 : Pathology and Laboratory and Medicine Services and Procedures Guidelines for Medical coding professionals
Module 33 : Health Insurance Portability and Accountability Act (HIPAA)
Module 34: Case Studies

Pharmaceutical Production Management
Module 1: Introduction to Pharmaceutical Production
Module 2: Good Manufacturing Practices (GMP)
Module 3: Pharmaceutical Quality Assurance
Module 4: Production Planning and Scheduling
Module 5: Pharmaceutical Process Engineering
Module 6: Equipment and Facility Management
Module 7: Supply Chain Management
Module 8: Regulatory Compliance
Module 9: Risk Management in Production
Module 10: Lean Manufacturing and Six Sigma
Module 11: Technology and Automation in Production
Module 12: Environmental and Safety Considerations
Module 13: Human Resources and Team Management
Module 14: Product Lifecycle Management
Module 14: Case Studies and Practical Applications

Pharmaceutical Quality Control and Quality Assurance
Module 1: Quality, Quality Assurance and Quality Control in Pharmaceutical Industry (International perspective of USA, WHO, ICH & Europe/ Australia & New Zealand / Gulf Countries (GCC)/ Canada/ Africa / India etc).
Module 2: Qualification and Validation
Module 3: Quality Assurance and Quality Control - Possible problems and Solutions
Module 4: Types of Quality Testing (models, types, procedures etc)
Module 5: Quality Testing Tools and Techniques
Module 6: Quality Certifications, Govt regulations, ICH Guidelines and ISO 9000
Module 7: Total Quality Management and GMP: Quality Risk Management, Assessing Quality Concerns at different work units or areas
Module 8: Setting up Quality Control Checks
Module 9: Documentations, Good Documentation Practice, SOPs, Protocols etc
Module 10: Addressing Internal and External Quality Issues - Complying with Govt Regulations
Module 11: Computer System Validation (CSV)
Module 12: Demonstration of Instrument handing used in Pharmaceutical Laboratory

Pharmaceutical Sales and Marketing Management
Module 1: Introduction to Pharmaceutical Industry
Module 2: Principles of Management
Module 3: Pharmaceutical Marketing Management
Module 4: Pharmaceutical Sales Management
Module 5: Advertising and Promotion in Pharmaceuticals

Module 6: Visual Aids and Input Designing
Module 7: Pharmaceutical Logistics Management
Module 8: Fundamentals of Drug Discovery
Module 9: Healthcare Systems
Module 10: Market Research in Pharmaceuticals
Module 11: Pharmacoeconomics
Module 12: Legal and Regulatory Framework
Module 13: Digital Marketing in Pharmaceuticals
Module 14: Relationship Marketing and KOL Management
Module 15: E-Commerce Management
Module 16: Entrepreneurship Development
Module 17: Industry-Based Case Studies

Clinical Data Management

Module 1: Introduction to Clinical Research, .Rules and responsibilities of stake holders
Module 2: Preparation, planning for clinical trials and essential documentation in Clinical Research and Regulatory admissions.
Module 3: Introduction to Data Management
Module 4: CRF design Considerations
Module 5: Data entry, remote Data Entry
Module 6: Identifying and Managing Discrepancies
Module 7: Data Management Plan
Module 8: Electronic Data Capture
Module 9: Tracking CRF Data
Module 10: Managing Lab Data
Module 11: Collecting Adverse Event Data
Module 12: Creating Reports and Transferring Data

Retail Pharmacy: Regulated and Business Operations with Store Management

Module 1: Introduction to Drug Store Management
Module 2: Regulatory Framework for Drug Store Operations
Module 3: Inventory and Supply Chain Management
Module 4: Pharmacological Essentials for Drug Store Management
Module 5: Good Pharmacy Practice (GPP) and Customer Service
Module 6: Storage and Distribution of Medicines
Module 7: Financial Management in Drug Stores
Module 8: Documentation and Record-Keeping
Module 9: Digital Transformation in Drug Store Management
Module 10: Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting
Module 11: Ethical and Legal Considerations in Drug Store Management
Module 12: Career and Business Development in Drug Store Management

Upcoming Courses:

Certified Good Clinical Practice Professional
Module 1: Introduction to Clinical Research Industry and Basics of Clinical Trials
Module 2: Drug Development Process
Module 3: Ethics and Ethical Guidelines for Clinical Trials and Good Clinical Practice (GCP): ICH Good Clinical Practice E6 (R2)
Module 4: Indian GCP and Schedule Y
Module 5: Regulations Guiding the Clinical Research Industry- History and Basics of National and International Regulatory Bodies
Module 6: Essential Documents in Clinical Trials: Protocol, CRF, Inform Consent, Investigator's Brochure, Study Progress Report
Module 7: Clinical Trials -Latest updates : New Drugs and Clinical Trials Rules, 2019
Module 8: Industry Based Case Studies

Certified in Good Laboratory Practice
Module 1: Introduction to Good Laboratory Practice
Module 2: All about GLP documentations
Module 3: GLP compliance & preparation for certification; ISO / IEC 17025: 2005 & Laboratory accreditation
Module 4: About GLP audits and Quality Management Systems (QMS)
Module 5: Computer based record keeping in laboratory
Module 6: General Good Testing Conduct, Inspection of a testing facility
Module 7: GLP as given by OECD, FDA etc (International perspective)
Module 8: Management, Personnel, Buildings & Equipment
Module 9: GLP for Quality Assurance, Method Validation
Module 10: Case studies

Certified Pharmaceutical GMP Professional
Module 1: Good Manufacturing Practices: Regulations and guidance (PIC/S, ICH, ISO, WHO, FDA, EMA, India)
Module 2: Quality Systems (TQM, QMS, CAPA)
Module 3: Laboratory Systems
Module 4: Infrastructure: Facilities, Utilities, and Equipment Qualification and Validation
Module 5: Material Flow and Supply Chain Management (FIFO,FEFO)
Module 6: Sterile and Nonsterile Manufacturing Systems
Module 7: Filling, Packaging, and Labeling Controls
Module 8: Product Development and Technology Transfer (ICH Q11,Q12,Q13)
Module 9: Documentation and Records Management (SOP, Protocol, MPCR, BPCR, VMP, SMF, etc.)
Module 10: Case Studies

Medical Writing
Module 1: Introduction to Medical Writing (Types and Requirements)
Module 2: Writer's Role Need or basis of Medical Writing

Module 3: Tools used for Medical Writing references and writing style.
Module 4: Medical writing for Clinical Research Industry (Designing and Preparation of Protocols, ICDs etc)
Module 5: Writing for Regulatory Submissions and Drug Promotion Activities (IND, NDA, ANDA)
Module 6: Dossier preparation in CTD format, eCTD Submissions
Module 7: Scientific Writing (Manuscript, Abstract Writing, review articles)
Module 8: Documents in Medical Marketing
Module 9: Achieving Flow and Cohesiveness
Module 10: Managing the Review Process (Quality Control Check / Proof reading process)
Module 11: Judicial / Copyright issues in Medical Writing and unethical practice
Module 12: Ethics and Ethical Guidelines for Clinical Trials and Good Clinical Practice (GCP)
Module 13: Clinical Trials - Latest updates: New Drugs and Clinical Trials rules