PHARMA ANALYTICA

Regulatory Affairs Curriculum

Course : Online /Offline

Duration : 2 months

Course contents/Topics

MODULE - I

- ✓ Introduction to Pharmaceutical Regulatory Affairs
- ✓ Life Cycle of a Medicinal Product from Lab to Launch
- ✓ Pharmaceutical Regulations in India
  - Overview of Pharmaceutical Regulations in India
  - Drug & Cosmetics Act
  - D & C Act Schedule-Y

MODULE - II

- ✓ International Pharmaceutical Regulatory Affairs-Part-I
  - ➢ Introduction to ICH guidelines (QSEM)
  - ➢ US FDA, Health Canada and EMA
    - a Registration of Medicinal Products in USA
      - Food and Drug Regulations in USA
      - Navigating through the US FDA site
      - Generic Drug Development & ANDA Approval Pathway
      - NDA and 505 (b) (2) approval pathway
      - Drug Master Files
      - Post-approval/post-marketing life cycle management
    - b Registration of Medicinal Products in Europe
      - MAA pathways in Europe
      - EDQM-CEP
    - c Registration of Medicinal Product in Canada
      - NDS and ANDS
      - Post Approval Management

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MODULE - III

- ✓ International Pharmaceutical Regulatory Affairs-Part-II
  - Pharmaceutical Regulations-Australia and New Zealand.
  - Pharmaceutical Regulations-African Markets
  - Pharmaceutical Regulations-Asian Markets
  - Pharmaceutical Regulations-GCC & LATAM
  - WHO Prequalification
- ✓ Regulatory Affairs-Clinical Trails
  - IMPD-Europe
  - CTA-Health Canada
  - IND-US FDA

MODULE - IV

- ✓ Miscellaneous Scientific Topics
  - Fundamentals of Dissolution and In-vivo Bioequivalence studies
  - BCS Classification and Bio-waivers
  - ICH Stability (Q1) and Impurities (Q3)
  - GMP, GLP and Quality Management
  - Food Supplements
  - Pharmacopoeias (USP/Ph.Eur/BP)
  - Medical Device Regulatory Affairs
  - Biologics Regulatory Affairs
  - Introduction to e-Publishing (eCTD & Non e-CTD) and organization of the dossier (ICH M4Q)
  - ICH Q6A and Q6B-Specifications-Test Procedure and Acceptance Criteria for New Drug Products and Biologics
  - Regulatory Strategies (Case Studies) & Regulatory Intelligence.