Regulatory Affairs Course-Expert Level:-

Topic 1: Introduction to RA

- What is Regulatory Affairs, Importance of RA department, Roles and their functions, and Worldwide regulatory agencies
- General overview of the Pharmaceutical Industry, role of various departments and their functioning.

Topic 2: ICH guidelines

- What are ICH guidelines and their importance.
- Overview and understanding of following ICH guidelines
  - Stability Testing of New Drug Substances and Products.
  - Photostability Testing of New Drug Substances and Products.
  - Stability Testing for New Dosage Forms.
  - Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products.
  - Evaluation of Stability Data.
  - Analytical Method Validation.
  - Impurities in New Drug Substances, Impurities in New Drug Products, and Guideline for Residual Solvents.
  - Specifications.
  - Pharmaceutical Development.

Topic 3: CTD – eCTD

- Introduction about CTD/eCTD, origin of CTD and brief description about each section in the modules along with Hands on experience in CTD dossier compilation.
  - Module 1 - Administrative and Prescribing Information
  - Module 2 – Common Technical Document Summaries
  - Module 3 – Quality Part-CMC
  - Module 4 - Nonclinical Study Reports
  - Module 5 - Clinical Study Reports

Topic 4: Drug Development Process and Product development.

- Newdrug development process, QSAR, pre-clinical and clinical studies, Basics of formulation development, Importance of pre-formulation studies and demonstration of product development with live project

Topic 5: Generic Drugs

- What are generic drugs, how are they equal with innovator drugs, their development process, dissolution study comparisons and overview on concept of bioequivalence studies.

Topic 6: Drug approval procedure in US

- US(FDA) Introduction, 21CFR, INDA, NDA, ANDA drug applications, Patents and their types, GDUFA, Post approval changes (Annual reports, CB-30 and prior approval supplements) and Types of DMF's.

Topic 7: Drug approval procedure in Europe

- Drug regulatory authorities in European Union (EU), different types of approval procedures (MRP, DCP, National and Centralized Procedures), brief study on post approval changes (variations and extensions) and approval procedures for drug substance (DMF and CEP).

Topic 8: Discussion on deficiencies received from authorities and how to address the quires effectively.

- Deficiencies received from various health agencies will be discussed along with best remedial action plan. This programme helps to boost up technical skills and knowledge enhancement.

Topic 9: Project work with hands on experience in dossier compilation activity.

- Brief description and extensive discussion about each section in the modules along with project and compilation activity will taught.

Topic 10: Resume preparation and interview questions.

- Resume meeting the latest trends with notified key words will be prepared. Interview questions shall be discussed.