Regulatory Affairs Course-Entry Level:-

Class Room:	**Online**
Training Fee & Duration : 20K & 45 Days	Training Fee & Duration : 23K & 45 Days

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 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 overview of each module.
  - 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 approval procedure in US

- US(FDA) Introduction, overview on 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.

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Topic 5: Drug approval procedure in Europe

- Overview on 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).

HR-Interview Etiquettes:-

- Communication Skill
- Office etiquettes
- E-mail etiquettes
- Presentation skills and Public speaking
- Interview preparation
- CV preparation
- Mock interviews
- Assessments

ENTRY Level – This programme is best for beginners who want to start up their carrier in Regulatory Affairs