Regulatory Affairs Drug Substance (API):-

Class Room:	Online
Training Fee & Duration : 15K & 1 Month	Training Fee & Duration : 15K & 1 Month

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: CMC of API

- API development, polymorphism, impurities, deficiencies and how to respond effectively.

Topic 3: CTD – eCTD

- Introduction about CTD/eCTD, origin of CTD and brief description about Module 3 – Quality Part- S (drug substance)

Topic 4: Drug substance submissionin US

- US(FDA) Introduction, Patents and their types, GDUFA, Post approval changes (Annual reports, CB-30 and prior approval supplements) and Types of DMF's.

Topic 5: Drug substance submissionin 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).

HR-Interview Etiquettes:-

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