Regulatory Affairs- Dossier/ANDA compilation program:-

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: 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 3: Hands on experience in dossier compilation activity.

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

HR-Interview Etiquettes:-

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

E-Mail ID; contact@covalenttrainings.com **Phone:** +91-9848733309/+91-9676828080
www.covalenttrainings.com