Validation Trainer

Validation Trainer Course Content:-

- Introduction to Pharma industry.
- What is Regulatory Affairs? And its role.
- Importance of RA department, Roles and their functions, worldwide regulatory agencies and their roles.
- Notes on clinical trials, Drug development, Pre-formulation studies, API characterization, Generics and Innovator drugs,
- ICH guidelines: Stability Testing of New Drug Substances and Drug Products, Photo stability 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, Impurities in New Drug Substances, Impurities in New Drug Products, Impurities: Guideline for Residual Solvents, good manufacturing practise and Pharmaceutical Development,.
- Discussion in details on Common Technical Document CTD (Module 1 to 5)
- USFDA Introduction, ANDA Regulatory Approval Process (US), Hatch-Waxman act, Patents and their types, Post approval changes (Annual reports, CB-30 and prior approval supplements), Types of DMF's, Rules and guidelines.
- 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), approval procedures for drug substance (DMF and CEP), rules and regulations
- Quality Assurance (QA) general concepts and SOP preparation & maintenance.
- Introduction to validations and their types (concurrent, prospective, retrospective and revalidation).
- Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) Procedures and Validation master plan (VMP)
- Validation of Analytical Methods and process validation
- Sterilization basics, selection of sterilization method and its overview

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