



Good Documentation Practices

Course Objective: This workshop is designed to provide an overview of the various aspects of Good Documentation Practices (GDP).

Course Description: This one-day workshop will focus on the principles and application of GDP as they apply to GLP/GMP regulations in the pharmaceutical industry.

Participants will learn about documentation objectives, life cycle and control, various types of documentation, electronic and online documentation as well as document related technologies.

The program will consist of lectures, case studies, FDA 483 observations and warning letters. The course will cover the objective purpose of GDP concepts and key requirements for the proper documentation of a GLP/GMP program in a pharmaceutical or biotechnology facility. Also covered will be the KISS principle.

Course Outline:

- Documentation Objectives
- Document Lifecycle
- Format
- Version Control
- Master Document File
- Changes
- KISS Principle
- Online Documents
- Validation Documents
- SOPs
- Document Related Technologies