



Master Plan – Roadmap To Compliance

Course Objective: The Master Plan contains all the programs necessary to certify the pharmaceutical facility, it may be used as an instrument to define areas of responsibility and accountability to validation team members. The objective of this course is to give guidance in the development of a Master Plan document that communicates to the FDA/HPFBI understanding of a company's philosophy concerning the validation. Also, to help create a document that will serve as a guide to those administering and performing validation activities and as a road map to successful project completion.

Course Description: This course provides a comprehensive plan outlining all necessary validation and engineering activities and relevant GMP programs so that compliance requirements will be met.

Course Outline:

- Scope of the Mater Plan
- Validation / Compliance Plan
- Facility Design / Compliance
- Purchased Materials Qualification
- Process Description
- Room and Area Control Classifications
- Description of Utilities
- Cleaning Validation / Compliance
- Description of Process Equipment / Equipment History Files
- Computerized Systems Validation / Compliance
- List of Standard Operating Procedures
- GMP and Regulatory Perspectives
- Environmental Monitoring Program
- Analytical Testing Procedures
- Calibration Program
- Training Program
- Stability Program
- Preventive Maintenance Program
- Change Control Program
- Document Control Program

- Manpower Requirements
- Key Personnel
- Project Responsibilities
- Validation / Compliance Schedule