



Design and Validation of Critical Utility Systems

Course Objective: To provide an understanding of the right approach to engineering practices and strategies needed to comply with regulatory requirements while optimizing the cost and efficiency of facilities and their utility systems. Minimal requirements for design and validation of critical utility systems are defined by cGMP and federal regulations for all drug, biologic and medical device manufacturing.

Course Description: This course is designed to provide knowledge needed for pharmaceutical professionals for the process of developing and completing a cGMP facility while identifying specific areas for saving, ensuring that facility will provide its intended function to optimize its operation and comply with cGMP requirements.

The requirements for the pharmaceutical and biotechnology facility are providing a controlled environment, purified water system, clean steam system, and HVAC system in accordance to cGMP. Overdesign of the utility systems result in high facility construction and equipment cost will be discussed.

The course will address the rules, tools, and techniques to develop and implement a validation process, validate a single system and to conduct validation projects.

Course Outline:

- Design and Construction Projects (Step by Step)
- Pharmaceutical and Biotechnology Facility and Utility Systems Engineering and Compliance Factor
- Manufacturing Standards, Engineering Codes and Legislations
- Equipment/Systems Construction Materials Requirements
- Facility and Utility Systems Commissioning and Validation Requirements
- Pharmaceutical HVAC Systems vs. Ordinary Building HVAC Systems
- WFI and USP Purified Water Systems vs. Potable Water Systems
- Pure Steam System vs. Plant Steam System
- Pharmaceutical/Medical Compressed Air/Gas System Requirements
- CIP and SIP Systems

- Waste Disposal and Neutralization Systems and Environmental Control Factors
- Process Chilled Water System vs. Building Chilled Water System
- Electrical Systems
- Process PLC System and Building Computerized Control Systems