



How to Manage a CGMP Compliant Laboratory

Course Description

Very few people, including the best laboratory managers, have a true appreciation for the complexity of running an analytical laboratory in a regulated environment. To make things worse, each laboratory has its own unique set of challenges and operates differently. Therefore, whether the lab is run well or poorly comes down to the individual skills of the laboratory managers or supervisors. These facts obviously do not bid well for the long term compliant operation of the laboratory. Although standard operating procedures (SOPs) are required by the Current Good Manufacturing Practice Regulations (CGMPs) in most circumstances there is no "operations manual" for the laboratory: that is a coherent set of "how to" instructions which tie all documented and undocumented procedures together. Therefore, many of the daily, weekly, monthly, quarterly and yearly tasks reside in "someone's head". In this course you will learn how to construct an operations manual for your laboratory through instructor-guided small group brainstorming and open forum discussions and knowledge sharing. This manual will allow you to withstand the rigors of an inspection by a regulatory agency and make your life easier by helping you to better organize and execute your work functions.

Target Audience

New laboratory managers and supervisors. More senior managers and supervisors looking to become more compliant and efficient.

Course Outline

1. Overview of Quality Control Laboratory Operations in a CGMP Environment
2. How to Create Your Operations Manual: Instructor-Guided Small Group Brainstorming and Open Forum Discussions
 - a. Laboratory Managerial and Administrative Systems
 - b. Laboratory Documentation Practices and Standard Operating Procedures
 - c. Laboratory Equipment Qualification and Calibration
 - d. Laboratory Facilities
 - e. Methods Validation and Technology Transfer
 - f. Laboratory Computer Systems
 - g. Laboratory Investigations
 - h. General Laboratory Compliance Practices
3. Additional Questions and Answers
4. Selected References