How to Get Into (and Out of) Trouble with FDA

Course Description

Analytical laboratories involved in the validation of analytical methods and the Quality Control release testing of excipients, Active Pharmaceutical Ingredients (APIs), finished drug products and the analysis of developmental and annual stability samples are required to operate under the Current Good Manufacturing Practice (CGMP) regulations 21 CFR Parts 210 and 211. Despite the fact that the CGMPs were formally adopted in the late 1970's, many companies continue to struggle with their proper implementation. In addition, the Laboratory Control System, a sub-element of the regulations, is one of the areas where significant challenges arise with respect to compliance. This course, which is divided into two parts, is designed to assist laboratories comply with the letter and the intent of the regulations. In the first half, the instructor will present real world FDA observations related to the Laboratory Control System. These observations are extracted from more recent Warning Letters and Form 483 observations. In the second half of the course, students will break into small-groups and brainstorm to determine the root or most probable cause of the observations and draft potential Corrective and Preventive Actions (CAPAs). These offerings will then be shared at large with the entire class with following full-group discussion and input from the instructor based on his recent consulting experiences with companies who have run into trouble with FDA.

Target Audience

All Laboratory and Quality Assurance personnel involved in the validation of analytical methods and the Quality Control release testing of excipients, APIs, finished drug products and stability samples in CGMPs environments.

Course Outline

1. Background and Approach
2. Introduction to the Systems Based Approach to Laboratory CGMPs.
3. Example FDA Observations: Laboratory Managerial and Administrative Systems
4. Example FDA Observations: Laboratory Documentation Practices and Standard Operating Procedures
5. Example FDA Observations: Laboratory Equipment Qualification and Calibration
6. Example FDA Observations: Laboratory Facilities
7. Example FDA Observations: Methods Validation and Verification
8. Example FDA Observations: Laboratory Computer Systems
9. Example FDA Observations: Laboratory Investigations
10. Example FDA Observations: General Laboratory Compliance Practices
11. Example FDA Observations: Stability Program

12. Observation Analysis and CAPAs: Laboratory Managerial and Administrative Systems (with group discussions)
13. Observation Analysis and CAPAs: Laboratory Documentation Practices and Standard Operating Procedures (with group discussions)
14. Observation Analysis and CAPAs: Laboratory Equipment Qualification and Calibration (with group discussions)
15. Observation Analysis and CAPAs: Laboratory Facilities (with group discussions)
16. Observation Analysis and CAPAs: Methods Validation and Verification (with group discussions)
17. Observation Analysis and CAPAs: Laboratory Computer Systems (with group discussions)
18. Observation Analysis and CAPAs: Laboratory Investigations (with group discussions)
19. Observation Analysis and CAPAs: General Laboratory Compliance Practices (with group discussions)
20. Observation Analysis and CAPAs: Stability Program (with group discussions)
21. Where to Get Help
22. Questions and Answers