



Preparing and Maintaining Laboratory Notebooks and Records

Course description

Preparing and Maintaining Laboratory Notebooks and Records is a one-half day, introductory level course designed for recent graduates or individuals transitioning into jobs in regulated industries such as the pharmaceutical, biopharmaceutical, or contract analytical laboratories. The course is designed to help personnel appreciate the types of records they will be keeping, the skills required to keep good laboratory records, recognizing the value of keeping good notebooks and records and understanding the different types of people who may be reviewing their records. It also examines the level and type of details which need to be recorded, as well as some suggestions for formatting and techniques for keeping records consistent from individual to individual within the same laboratory. Examples of common mistakes will also be shown. The course is augmented with real world examples and practical exercises which will be performed by the students.

Target Audience

Newly hired analytical chemists preparing to work in a CGMP laboratory environment, and QA personnel who review data and audit laboratories, will benefit from this course. Laboratory managers desiring to evaluate the current status of their compliance with CGMPs will also find this course very useful.

Course Outline

1. The Importance of Preparing and Maintaining Good Laboratory Notebooks and Records
2. Types of Laboratory Data and Records
3. The Flow of Laboratory Data and Records
4. Proper Documentation Techniques and Required Skills
5. A Notebook Review Checklist: What Needs to Be Documented
6. Reviewing Laboratory Notebooks and Records: An External Reviewer's Perspective
7. Examples of Some Common Deficiencies (with practical exercise)
8. Questions and Answers