An Overview of the Current Good Manufacturing Practice (CGMP) Regulations: Annual Training Course

Course Description

An Overview of the Current Good Manufacturing Practice (CGMP) Regulations is a solid, one-day, introductory level or yearly CGMP refresher course. Unlike most annual CGMP training this course is based on FDA's newly adopted quality systems based approach for auditing CGMP facilities. The course materials are based on internal FDA guidance documents and current best practices of the pharmaceutical industry. Presented in a "real world" format it starts with an overview of the pharmaceutical industry and progresses to specific examples of how companies end up getting in trouble with FDA. This is an excellent means to introduce and re-fresh your knowledge of the concepts of current good manufacturing practices.

Target Audience

All personnel involved in the manufacture, packaging, testing and hold of drugs and drug product governed by 21 CFR Parts 210 and 211, the Current Good Manufacturing Practices (CGMP) regulations.

Course Outline

1. How Drugs are Developed and Get to Market
2. An Overview of the Pharmaceutical Market
3. The Law Governing Drug Development, Manufacture and Distribution: The Current
4. Good Manufacturing Practice (CGMP) Regulations
5. Complying with the Law and Your Responsibilities: A Scheme of Systems for Manufacture of Drugs/Drug Products
6. Enforcing the Law: The Food and Drug Administration's (FDA) Responsibilities and
7. Roles
8. The Consequences of Not Complying with the Law
9. Summary-The Least You Need to Know