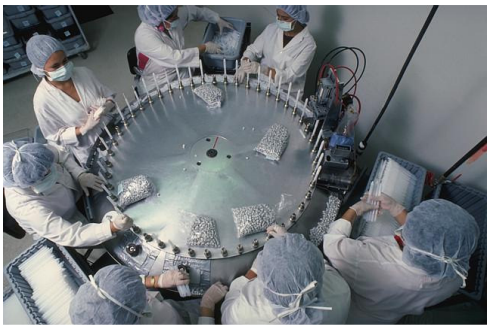
cGMP Review



This class reviews the basics of the Current Good Manufacturing Practices. Participants learn the regulations that are relevant to their industry in an interactive format. The course material emphasizes that assuring quality is the responsibility of all employees not just the quality control unit. Participants are provided with the background knowledge necessary to understand what cGMPs are and why they are important. Employees leave with an understanding of their role in assuring compliance in an FDA regulated environment.

Who Should Attend: All employees working in a FDA regulated environment

Class Length: half day

Maximum Class Size: 20

Course Prerequisites: cGMP History

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- What the FDA is and its role in the regulated industries
- Where the cGMPs are written and which ones apply to them
- How the relevant cGMPs relate to employee's actual everyday activities
- Examples of how employees can directly affect their facilities' regulatory compliance.
- How the decisions employees make each day can affect the quality of the products they produce
- The roles of the different functional units such as Quality, Manufacturing, etc as defined in the Code of Federal Regulations
- What to expect during an FDA inspection
- How to act during a FDA inspection
- The FDA's options for enforcing compliance with regulations
- Training requirements

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