The History of Current Good Manufacturing Practices

Photo courtesy of FDA.

This class is designed to provide participants with a description of the events prior to and leading up to creation of the various food and drug regulations. Participants will gain an understanding of the tragedies that occurred as a result of an unregulated food and drug industry. This understanding will help participates answer the question, "Why are the current food and drug regulation so important"? It will also provide them with foundation for the concepts introduced during a cGMP Basics class.

Who Should Attend: Employees working in a FDA regulated environment

Class Length: 2 hours

Maximum Class Size: 20

Course Prerequisites: None

Course Objectives: At the conclusion of the class a participant should have a basic understanding of the following:

- A description of the "good old days" prior to Food and drug regulations
- How the transition to an industrialized society prompted the need for food and drug regulation
- The events leading up to the Food and Drug Act of 1906
- The leaders in the fight to establish regulations
- A explanation of the "Sulfanilamide tragedy"
- The Federal Food Drug and Cosmetics Act of 1938
- A discussion of three amendments that fundamentally changed the character of the U.S. food and drug law
- The role of the Kefauver-Harris Drug Amendments in assuring drug safety
- Medical Device Amendments of 1976 and their role in further strengthening device regulations
- The transition to the preventative regulations that are in place today

VALIDATION & COMPLIANCE INSTITUTE
537 Fort Dearborn St.
Dearborn, MI 48124
734-274-4680