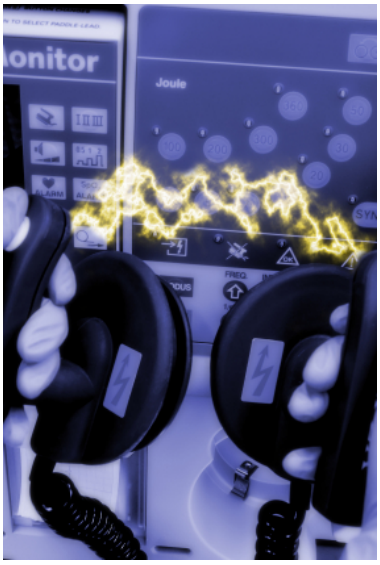
Introduction to Basic QSR's



This course provides the understanding of Quality System Regulations that everyone supporting manufacturing needs. It reinforces the concept that quality is everyone's responsibility and provides them with the tools to maintain compliance. Participants will find out that compliance not only enhances quality but productivity as well. They will learn the 'why' behind cGMP's and how to apply its principles to specific situations.

Who Should Attend: production & laboratory technicians, managers, scientists, and engineers.

Class Length: one day

Maximum Class Size: 25

Course Prerequisites: None

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

- History of cGMP's
- The Code of Federal Regulations, 21CFR 820, and Guidance Documents as source information
- Who is the FDA and what power do they have?
- How employees should act during an FDA inspection
- How FDA communicates with the company
- Why FDA considers all products not made by cGMP's to be adulterated
- Roles and responsibilities of Manufacturing, Quality Assurance, Management and Employees
- Buildings and facilities
    - Cleaning & maintenance
    - Specialized systems & clean rooms
    - Facility Records
- Manufacturing.
    - Equipment selection, calibration & maintenance
    - Production and process control
    - Shipping and Receiving.
- Device History Record, Design History File, Device Master Record.
- Quality Control and Quality Assurance
    - Sampling
    - Testing
    - Out-of-Specification results
    - Laboratory records
- Holding and distribution
- Packaging and labeling
- Complaint files.
- Requirements for employee training.
- The responsibilities of employees in a GMP environment
- The responsibilities of managers in a GMP environment

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