Good Documentation Practices

If you didn't document it, you didn't do it! This course guides the participant through the process of setting up a documentation system that meets regulatory requirements <u>and</u> serve its business purpose. Participants will learn which systems require documentary coverage; how to flowchart operations to identify what type of documentation is required; and how to set up, implement and manage the maintenance of such documentation systems to ensure continuous compliance.

Who Should Attend: Anyone who is responsible for writing, using, or managing documentation in any FDA regulated industry. The course will benefit personnel in Quality Assurance, Manufacturing, Engineering, Maintenance, and R&D.

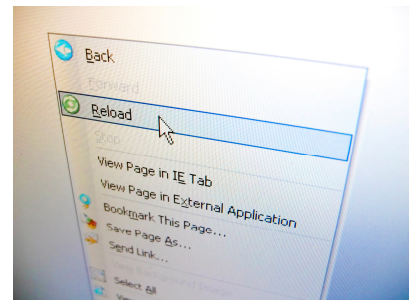**Class Length**: One day

Maximum Class Size: 20

Course Prerequisites: Participants must have a working knowledge of cGMP's.

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

- The regulatory requirements and draft guidelines

- The purpose of documentation

- Definition of Standard Operating Procedures (SOP's)

- The purpose of Signatures and Initials of individuals

- The definition of a documentation system -critical parameters

- The design of a documentation system- Electronic and Paper

    o FDA Requirements for electronic signatures & Records (Part 11)

    o Storage

    o End User requirements

- The key aspects of an SOP

- Training requirements

- Documents that must be controlled-

    o Records and reports: Logs, Deviation Reports, Batch Production and Packaging Records, work instructions, Laboratory Records, Failure Investigations, Out of Specification reports, Change Control reports, Calibration and Maintenance Records

    o Protocols

    o Quality Manuals, Policy Manuals

    o Piping and Instrument Diagrams

    o Equipment specifications and drawings

- How to manage and maintain the document system so that it stays current and compliant