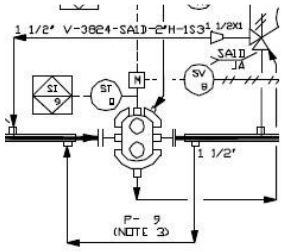
Change Management



Change is the only thing that stays the same in our business world today. Manufacturing organizations must not only accept change as a necessity for survival but embrace it as a competitive advantage. A comprehensive, yet streamlined Change Management process will insure that product quality is not diminished by the proposed change and assure FDA inspectors that the process is being maintained in a state of control. It will also reduce design and installation errors and will therefore save time and money.

Who Should Attend: Production, Quality, R&D, Maintenance, Engineering personnel working in the manufacturing environment, and anyone else who is involved in manufacturing changes.

Class Length: Half day

Maximum Class Size: 20

Course Prerequisites: A basic knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will be able to:

- Find and use the relevant regulatory requirements/expectations and industry standards for change control
- Develop a Change Management process within their organization
- Insure that the documentation for any change includes all the needed information
- Delineate the criteria that determines the level or degree of change
- Understand the difference between a major and minor change
- Perform a risk analysis to determine what degree of verification or validation that needs to be done to assure that quality is not affected by the change
- Develop the type of study data or information that must be generated to support changes at each level
- Evaluate the impact of process changes on stability, retest dates and expiry dates
- Describe the necessary components of a change control record
- Define the communication and training requirements generated by any change
- Consider the regulatory submissions that may be required by the change

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