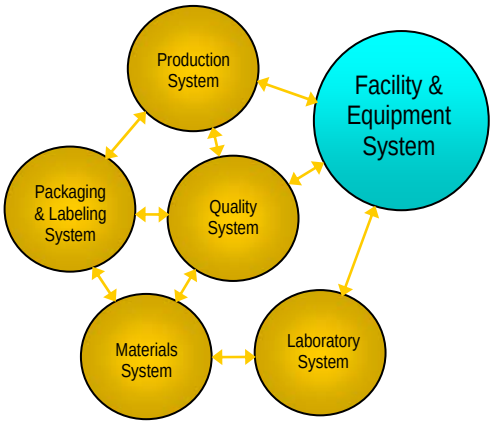
Compliant Maintenance
in the
FDA Regulated Industry

An Overview of the Maintenance System requirements in a Regulated Environment
"Maintaining the Validated State"

In order for a company regulated by the FDA to maintain the validated state of its equipment and facilities, it must maintain its equipment and facilities properly. Equipment that is not maintained is soon driven to a "state of greater disorder" by the laws of nature into conditions not covered by the original equipment qualification. They wear out!

This "wearing out" should be counteracted by a compliant maintenance system, consistent with regulatory requirements, to sustain the validated state of the equipment. A maintenance system that encompasses procedures, practices, and paperwork designed to ensure the equipment will manufacture product meeting predetermine quality attributes.

This **one day** seminar will present requirements for a Compliant Maintenance as part of an overall Quality System. It will demonstrate how maintenance, as a component of the Facilities and Equipment System of the FDA Quality Systems Approach to inspections, is a major, though often unheralded, part of the overall compliance effort.



Course topics include:

- Regulatory basis for maintenance and relationship to the validation effort
- The *appropriate* role for the Quality Unit
- Overview of Compliant Maintenance Activities
- The Preventive Maintenance Program – requirements for developing and approving PMs
- Executing PMs
- Reviewing PM Out-of-Frequency tasks
- Corrective Work Order requests – How they should be generated and reviewed
- Executing, reviewing, and approving Corrective Work Orders
- Maintenance Metrics – how to avoid the numbers racket!
- Controlling spare parts and evaluating Functionally Equivalent Parts
- Equipment identification
- Equipment files
- Qualification and training of in-house and contracted personnel and companies

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At Your Site, On Your Schedule

By presenting the two day Compliant Maintenance Seminar at your site, you can avoid the travel and costs associated with that travel for multiple personnel. Plus you can have more people trained on the concepts of the Facility & Equipment Quality System Component than you may normally have the budget to send to an off-site course. For example if you sent four participants to an off site seminar at $1800 per person plus expenses and unnecessary lost time, the total cost could exceed $10,000! That is much more than an on-site presentation without limits on the number of attendees.

This seminar would be of value to:

- Maintenance Management
- Maintenance and Facilities Technicians
- Operations Management
- Quality Unit Personnel
- Validation Personnel
- Technical Support Personnel

This session has been presented twice at a single site over a two day period, dividing the interested personnel into two groups to allow for coverage of ongoing operations.

This seminar is relevant, interesting, and at times, humorous. It has always been well received by the attendees and thought well worth the expense.

The Course Leader

Joseph T. Busfield is the Principal of Pharmaceutical Technical Services and has over 30 years experience in the pharmaceutical and related industries. His responsibilities have included: maintenance, instrumentation, utilities, project engineering, and validation for both oral dose and parenteral pharmaceutical manufacturing facilities and engineering companies. His experience in operating plants includes design, start up, validation and operation.

Joe has worked with clients under consent degree or other regulatory burdens and others trying to avoid such problems. He always works to develop sustainable, pragmatic programs that will withstand regulatory scrutiny. His major emphases are in maintenance, calibration, engineering, and general facilities related programs in the pharmaceutical, biotech, device and dietary supplement industries. His activities have been conducted throughout the US and Europe. He holds a B.S., (Mechanical Engineering) from Drexel University, and a M.B.A., (Management), from LaSalle University. Joe has served as an adjunct professor at several colleges teaching management and math courses and is a frequent speaker at seminars on Facility, Maintenance, and Calibration programs in the regulated industry.

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