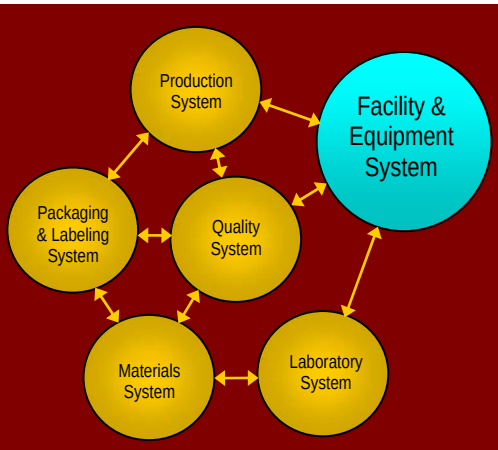
Facility & Equipment Component of the Quality System



An overview of the Facility & Equipment Quality System
"Maintaining the Validated State"

The FDA has put forth the concept of the over all Quality System, with six separate components all linked together to ensure to manufacture of a product meeting all of its predetermined quality attributes. The six components are:

Production System

Packaging and Labeling System

Materials System

Laboratory System

Facility and Equipment System

Quality System

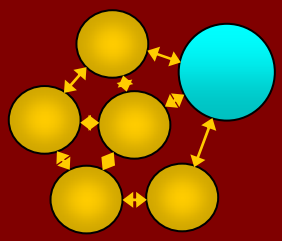
The Facilities & Equipment component of the FDA's Quality System approach is as important as the other components – even if it has less attention paid to it. Throughout the lifecycle of a facility or equipment train, every action has to be taken with an eye towards compliance to insure "validatability" and the ongoing sustainability of the validated state. Beginning with project conception, through design, implementation, commissioning, qualification, operation (maintenance, calibration, change control, pest control, cleaning, etc.) and decommissioning, the validated state must be sustained via constant diligence to GMP engineering and operations concepts.

This **two day** seminar will present requirements for Compliant Engineering, Maintenance, Calibration and associated systems as part of an overall Quality System. It will demonstrate how these functions as the Facilities and Equipment System of the FDA Quality Systems Approach to inspections, are major, though often unheralded, parts of the overall compliance effort.

Course topics include:

- Regulatory basis for the Facilities & Equipment component of the Quality System
- The *appropriate* role for the Quality Unit throughout the Facilities & Equipment Component
- The Role of Project Engineering in Compliance – the Engineering Life Cycle Model
- Facility Auxiliary Programs Basics:
  - Pest Control
  - Cleaning
  - Drawing Control
  - Engineering Change Control
  - Spare Parts (& Lubricants)
  - Technician/Contractor Qualification and Training
- A Compliant Maintenance Program
  - Work Order Management
  - PM System Control
  - Metrics
- A Compliant Calibration Program
  - Classifications
  - SOPs
  - Out-of-Tolerance
  - Limits and Tolerances

Facility & Equipment Component of the Quality System



An overview of the Facility & Equipment Quality System
"Maintaining the Validated State"

At Your Site, On Your Schedule

By presenting the two day Facility & Equipment 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 four 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 Decree 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.

Proudly offered by:

pts
Pharmaceutical
Technical
Services

Warrington, PA 18976 USA
215.882.3816 (mobile)

Focused consulting for the FDA regulated industry:

- Engineering
- Maintenance
- Calibration
- Engineering Change Control
- Pest Control
- Facilities Cleaning
- Equipment Qualification

www.PTSGMP.com
Training@ptsgmp.com