

EFFECTIVE AND PRAGMATIC COMPLIANCE PROGRAMS

Pharmaceutical Technical Services is a focused consulting organization specializing in servicing the facility and equipment operations of healthcare industries regulated by the FDA and overseas equivalent agencies. PTS offers effective and pragmatic compliance services based on years of successful operating and consulting experience. Our efforts cover such areas as:

Project Engineering Programs

The early steps of a new facility or equipment installation can determine the effort required later to qualify and validate the project and maintain that validation. PTS has developed the compliance aspects of Project Engineering Programs to ensure projects will be compliant, capable of being readily validated, and will be able to maintain that validation throughout its life-cycle.

Equipment Qualification

New and changed equipment needs to be commissioned and qualified. The goal of that effort should be to ensure product quality. PTS has developed Master Plans, protocols, and executed protocols, bringing to this effort the same practical approach while maintaining the rigor needed for compliance.

Compliant Maintenance Programming

Once equipment is qualified and running – it wears out! Thus the state of the facility and equipment is different than it was when it was qualified. Its qualification may rightly be called into question if a robust, compliant maintenance program is not in place to ensure the validated state of the equipment. PTS has worked with many clients to design and install compliant maintenance systems. Clients in start-up situations where they wanted to demonstrate ongoing control of the equipment and clients under regulatory duress because their maintenance system could not ensure maintaining the validated state.

Compliant Calibration Programming

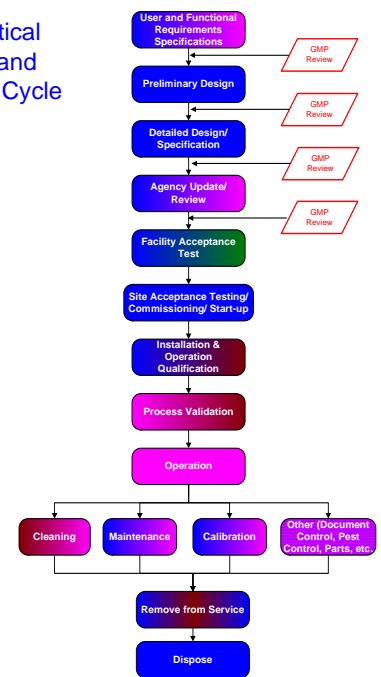
Calibration can be considered a specialized subset of maintenance, but there are differences. When equipment fails, that failure is often very evident. If an instrument is out of calibration, that may not be evident. Thus there are additional safeguards necessary to ensure product is made with instruments that will maintain the quality of that product. These additional safeguards should be applied cautiously to avoid unnecessary costs and “gridlock” in a calibration program. PTS has again worked with many clients to develop rigorous, pragmatic, and compliant calibration programs.

Compliance Training

Even the best of programs will fail if not understood or made part of the understanding of the folks implementing them. PTS has regularly trained people in the preceding compliance areas at three distinct times in a program life-cycle:

General knowledge while considering compliance requirements for a facility

Pharmaceutical Equipment and Facility Life Cycle Model



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Before the effort to develop a program, so there is an understanding of the logic of the program

After a program has been installed to insure ongoing adherence to the program

These training programs are presented in an interesting, interactive, and informative manner to ensure a meaningful training experience.

Other Programming

PTS has worked with clients to establish various facility related programs that maintain the validated state. These efforts include:

Pest Control programs

HEPA filter testing programs

Contractor Qualification

Training

EXAMPLES OF PROJECTS:

Engineering Programming

Wyeth (Corp, PA, NJ, NY, PR, CN), Schering Plough (NJ, PR), and GlaxoSmithKline (PR) – development of corporate policies and standards for project engineering¹

Aventis (PA) - Prepared URS and FRS for Purified Water system and Computerized Calibration Management System

Equipment Qualification

Merck (PA) - Packaging line IQ/OQ, insert inspection machines, labeler FAT, etc.

Chiron (MA) – New HIV test kit facility equipment ranging from HVAC, Compressors, Hoods, walk-in boxes, etc.

Accucorp (PA) – New oral dose manufacturing equipment, including mills, dryers, sieves, etc.

Johnson & Johnson (NJ), Molecular Circuitry (PA), Centocor (PA), Regeneration Technologies (FL) – Prepared Purified Water and WFI qualification protocols.

Maintenance and Calibration Programming

Wyeth (Corp, PA, NJ, NY, PR, CN), Schering Plough (NJ, PR), Glaxo SmithKline (PR), Leiner Health Products (CA) – development of new maintenance and calibration programming, including corporate guidelines, systems SOP, device SOPS, qualification and training of technicians¹

Aviron and Bristol-Myers Squibb (NY) - developed compliant maintenance programs in anticipation of Pre-license Inspections by the FDA

Ortho-Diagnostics(NJ), SmithKline Beecham (PA) - Developed complaint Maintenance Programs.

¹ Working within the Quantic Group, LLC.