



Maintaining the Validated State

**Expert
Compliance
Consulting &
Program
Development**

**Engineering,
Maintenance, &
Calibration
Programs**

Maintaining the Validated State

Validating a modern pharmaceutical, biopharmaceutical, API, or device facility can use as much as 20% of the total project cost. It is good business to control that cost and to ensure that the investment in validation is not wasted.

One area that can effectively control the costs is the engineering program of a project. If adequate controls and reviews are not incorporated in the process from User Requirement Specifications through commissioning and qualification of equipment, the validation costs can move to the high end of the spectrum unnecessarily.

After a site or project is validated and operational, it is necessary to maintain that validation through continuing maintenance and calibration programs.

The Principal of PTS draws upon extensive experience, as both an owner and consultant, to develop ongoing systems that will enable your site to more effectively maintain the validated state. PTS specializes in developing Engineering, Maintenance and Calibration programs



Engineering Program

A new process, facility, or even a simple equipment addition or replacement must be based on sound, *compliant* engineering systems. Long gone are the days when the engineering effort can be done apart from compliance requirements. CFR 211 Part C and the new System Inspection Guidelines make this clear. Starting with the URS (User Requirement Specifications) provided by the process owner, Functional



Requirement Specifications, preliminary and detail design, factory and site acceptance

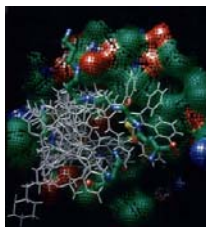
testing, and commissioning and qualification of equipment, engineering must be ever aware of the final use and validation requirements of the project.

PTS can help develop an engineering program that works with both large and small projects and incorporates appropriate compliance reviews to make sure regulatory issues are identified and addressed early in the process – on paper, and not after the brick and mortar are in place.

See: www.PTSGMP.com/PTSLifeCycle.pdf, for a simple Engineering Life Cycle Process Map

Maintenance and Calibration Programs

The Second Law of Thermodynamics tells us that things wear out. All things wear out. 21CFR 211.67 and 211.68 show us that this universal law is recognized by the regulators. They expect you to be aware of this “wearing out” and NOT let it impact the validated state of your equipment or facility.



PTS can work with you and develop maintenance and calibration programs that meet regulatory requirements and are manageable.

Maintenance

Maintenance programs need to address the requirements for:

- Equipment identification
- Preventive Maintenance regimen development
- Executing PMs and corrective work
- Parts program
- Reporting PM and corrective work status

See www.PTSGMP.com/PTSMntReq.PDF, for an outline of a Compliant Maintenance Program.

Calibration

Calibration programs need to address the requirements for:

- Classification of instruments and rationale for the same
- Setting calibration limits and Process Calibration Tolerances
- Calibration procedures and requirements
- Out-of-Tolerance procedures
- Parts program

See www.PTSGMP.com/PTSCalReq.PDF, for an outline of a Compliant Calibration Program

Maintenance and Calibration

Both programs need to address the requirements for:

- Technician and contractor qualification
- Change control and Quality involvement
- Training
- Computerized control systems

PTS can draw upon extensive experience in establishing engineering, maintenance and calibration programs for organizations under the burden of a Consent Decree (six sites) or Warning Letter/483 citations. Additionally, PTS has helped clients ensure they avoid issues in these critical areas. We have helped clients in the U.S. and in Europe.

Let PTS help you counter the Second Law of Thermodynamics and maintain the validated state!



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