pts Pharmaceutical Technical Services

PO Box 219
Warrington, PA 18976
(215) 882-3816 (m)
JTBusfield@PTSGMP.com

cGMP ENGINEEERING COMPLIANCE - PROGRAM CONSIDERATIONS

General: There shall be written procedures and programs that define the conceptualization, design, specification, procurement, installation, commissioning, validation, operation, deactivation and retirement of all GMP facilities and GMP equipment. The requirements delineated in this policy are to be applied to all GMP facilities and GMP equipment projects regardless of the capital level of the project.

Evaluations: All projects, installations and changes to facilities, process equipment, utility equipment, and laboratory facilities and equipment used in the manufacturing, processing, packaging, holding or testing of products, shall be evaluated from the inception by relevant personnel regarding the applicable GMP requirements.

Project Phases: There shall be written programs and procedures to define the activities that are appropriate for particular facilities and equipment. These shall address the size and complexity of the engineering activity and facility and/or equipment, and the degree of validation activity required.

User Input: The programs and procedures shall include defined steps to obtain the appropriate input from the end users, maintenance and calibration groups, validation group, purchasing, and QA at the onset of an engineering activity or a project. The procedure shall have provisions for continuing the input and review by the named groups as appropriate, throughout the life of the activity. The level of this input may be determined based on the evaluation and the requirements of each phase of the project.

Approvals: The programs and procedures shall clearly define those junctures and activities in the chronology of the project phases, where formal approvals are required by QA and other appropriate functional disciplines. Such approvals shall be obtained in a timely manner.

Critical Parameters: The program and procedure shall include steps to identify the critical parameters of the facility and/or equipment.

Other Provisions: There shall be written procedures to address the following additional elements of a well managed facilities and equipment program: (These requirements shall be considered throughout the engineering activities.)

- Developing specifications and periodic verification that they are consistent with GMPs
- Assuring that any necessary validation requirements are adequately addressed
- Defining the type, detail and general quantity of drawings required for a particular engineering activity
- Specifying commissioning requirements
- Defining the requirements for technology transfer or turnover of facility and/or equipment from the contractor/installer to the disciplines responsible for validation, maintenance, calibration and the ultimate user (including the disposition of operating manuals and instructions)
- Change control system to assure proper controls and documentation during deactivation, re-activation and disposal of facilities and equipment.

Record Keeping: There shall be written procedures to address the following documents of record keeping requirements:

pts Pharmaceutical Technical Services

PO Box 219
Warrington, PA 18976
(215) 882-3816 (m)
JTBusfield@PTSGMP.com

- To retain and secure intermediate drawings and specifications and to clearly note significant changes to concept, design or specification for an engineering activity and the reasons for those changes
- To file and control other records, such as design drawings, record sets, manufacturer manuals, specifications and commissioning documents
- To assure that notation by engineering personnel or personnel working on their behalf must be completed in clear, understandable terms and must include the signature or identifiable initials.
- To assure final as-built drawings are prepared and secured for each project.

Contracted Services: There shall be adequate controls and procedures in place to assure that the contracted companies and their personnel performing the engineering services are qualified. Their qualification shall be documented. The sites using their services shall assure that the work performed by them is under the supervision of designated person(s) and that the procedures used and the work are approved by such person(s)

Laboratory Equipment: Laboratory management shall assume a leadership role during the selection, procurement qualification and use of the equipment; supported by other functional disciplines (e.g., engineering, information systems, calibration and maintenance) as warranted.

Validation, Change Control, Documentation and Training: Since programs related to facilities, equipment and instruments are inter-linked with Validation, Change Control, Documentation and Training, ensure all activities are consistent with requirements in these areas.

This guide is offered as a basis for a Compliant Project Engineering Program and do not pretend to cover all the aspects thereof.

Pharmaceutical Technical Services is ready to assist in your efforts to establish a compliant Engineering (or Maintenance or Calibration) Programs. Please contact us at:

Pharmaceutical Technical Services
Warrington, PA 18976 USA
Mobile Phone: 2315.882.3816
JTBusfield@PTSGMP.com
www.PTSGMP.com