

cGMP MAINTENANCE COMPLIANCE - PROGRAM CONSIDERATIONS

The terms used in this paper are examples and are used throughout this document as points of reference.

CHARACTERIZATION AND CLASSIFICATION

- All facility, process, utility, and laboratory equipment used in the manufacturing, processing, packing, holding, or testing of drug products, biological products, or medical devices must be characterized as GMP or Non-GMP according to their use in the GMP environment. This characterization must recognize that in a pharmaceutical, biological, diagnostic or related industry the majority of equipment exists to monitor or control some aspect of the manufacturing operation and are therefore GMP.

Note: GMP filling and packaging equipment and systems shall be maintained by a system incorporating the same characteristics as the maintenance system for GMP process, facility and utilities.

- There should be procedures defining the rationale and approach for classifying equipment as GMP or non-GMP.

GENERAL PROGRAM ELEMENTS

Maintenance in a GMP environment is part of the overall *compliance* effort of the site, instituted to not only maintain equipment correctly to ensure availability and proper operation, but also to maintain the validated state of equipment used in the manufacturing, processing, packing, holding, or testing of a regulated product. As such the program should consider the following components.

- There should be maintenance program administrative procedures outlining the roles and responsibilities to prepare and approve preventive maintenance regimens, execute preventive and corrective maintenance, review and approve work orders, report late preventive maintenance and open corrective maintenance procedures, etc.
- There should be individual procedures prepared for the preventive maintenance of specific GMP equipment and these procedures should be reviewed and approved by Quality, Operations, and Technical personnel.
- The preventive maintenance procedures must specify tasks and frequency for each task.
- There should be a procedure for tracking scheduled maintenance activities.
- The Quality Unit should review all systems and procedures, including procedures entered into a computerized maintenance management system (CMMS).
- Where a computerized maintenance management system (CMMS) is employed, it must be qualified for its intended use.
- Equipment should be clearly identified by an unique number.
- Any maintenance that can possibly be understood as a change to a piece of validated equipment – especially parts changes - must be processed through Change Control.
- Maintenance records should be reviewed regularly to identify any trends.
- Records of non-completed and/or late preventive maintenance must be generated and reviewed by appropriate management personnel and corrective action plans developed.
- Spare parts and consumables will be maintained and controlled to ensure correct replacement parts and consumables are used.
- Like-for-like (functional equivalent or replacement-in-kind) parts should be subject to review and approval prior to use in validated equipment.
- Equipment logbooks should be completed in clear, understandable terms by any maintenance personnel working on equipment.

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- The Maintenance department may be responsible for generation and maintenance of logbooks for facility and utility equipment.

RECORD KEEPING

- Maintenance records (work orders) – preventive, corrective, and changes – shall be completed by the person fulfilling the work order.
- Records of all maintenance – preventive, corrective, and changes – shall be maintained for a specified period beyond the longest expiration date of any product produced using the equipment.
- A chronological Equipment History File for each Instrument shall be established. Information required to maintain and repair equipment (manufacturer's manuals, drawings, etc.) must be maintained in an Equipment Information File.
- Notations in equipment logbooks by any maintenance personnel shall be completed in clear, understandable terms.

PERSONNEL QUALIFICATIONS

- There must be a system for ensuring the qualification and technical training of technicians and mechanics employed in the maintenance and repair of GMP equipment, including technical training on the specific requirements of preventive maintenance procedures.
- There must be a written procedure for the qualification and training of contracted mechanics and technicians used to supplement facility resources.
- There must be regular training sessions for all maintenance personnel covering both cGMP's and job-specific issues.

These guides are offered as a basis for a Compliant Maintenance Program and do not pretend to cover all the aspects of, e.g., how to qualify a maintenance contractor, details on reporting Out-of-Frequency events for preventive maintenance, review of open corrective work orders, a system for reviewing/approving like-for-like parts, etc. Developing a maintenance program is a significant undertaking, best done as comprehensively as possible in the early stages of a facility's life to avoid redoing procedures, etc., at later dates.

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

Pharmaceutical Technical Services

P.O. Box 219
Warrington, PA 18976 USA
Office Phone: 215.491.9355
Mobile Phone: 2315.882.3816
JTBusfield@PTSGMP.com
www.PTSGMP.com