Procedure: Facility Maintenance

|  |  |  |  |
| --- | --- | --- | --- |
| Document information, authorship and approvals | | | |
| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

Table of Contents

[1. Purpose 3](#_Toc407011842)

[2. Scope 3](#_Toc407011843)

[3. Responsibilities 3](#_Toc407011844)

[4. Procedure 3](#_Toc407011845)

[4.1. General 3](#_Toc407011846)

[4.2. Risk management 3](#_Toc407011847)

[4.3. Maintenance schedule 4](#_Toc407011848)

[4.4. Facility condition monitoring 4](#_Toc407011849)

[4.5. Maintenance records 4](#_Toc407011850)

[4.6. Buildings and grounds 5](#_Toc407011851)

[4.7. Site security 5](#_Toc407011852)

[4.8. Heating ventilation and air conditioning 5](#_Toc407011853)

[4.9. Waste management 6](#_Toc407011854)

[4.10. Environmental management 6](#_Toc407011855)

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for maintenance of the manufacturing facility and support systems needed to meet production requirements.

# Scope

* The scope of this procedure includes the following areas of the GMP (TGA PIC/S Guide for Good Manufacturing Practice for Medicinal Products, PE009-13 2017 as of Jan 2018.

<https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products>)

facility at the [Company] site at <Company Address> Insert the appropriate address(es):

* buildings and grounds,
* facility services, including HVAC
* site security
* environmental management systems,
* site waste systems

# Responsibilities

Amend to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Facilities Manager (could be the Engineering Manager) | Define maintenance requirements for the site buildings, grounds and facilities.  Ensure the facilities maintenance schedule is written and followed.  Train staff and contractors to perform the maintenance tasks.  Manage contract staff. |
| Security Staff | Maintain the facility security.  Manage visitors. |
| Cleaning, Waste Disposal and HVAC Contractors | Perform tasks in accordance with site procedures. |

# Procedure

## General

It is important to maintain the facility in good condition to ensure that product is not manufactured under conditions that could compromise product quality, potency, purity, or integrity.

## Risk management

The Facilities Manager must undertake a risk assessment on each of the areas within the facility so that maintenance tasks and changes to the facility are performed under the appropriate compliance oversight.

Establishing baseline requirements is the key to this exercise, from which risks can be assigned. If there are unacceptable risks posed on the site by deficiencies observed between the requirements and the actual facility, then the Facilities Manager must allocate resources to mitigate the risks associated with these deficiencies. The outputs of the risk assessment can act as inputs to the maintenance regime and have a direct bearing on the maintenance frequencies.

The site facilities must be included in the scope of internal audits. Compliance with the baseline requirements should ensure GMP compliance.

## Maintenance schedule

A written maintenance schedule must be created to cover each area of the facility. This defines the scope and frequency of inspections, routine maintenance and repairs. Such activities may include but not be limited to inspection of floor, ceiling and wall surfaces, light fittings, HVAC filter inspection and cleaning, HVAC motor servicing and testing to Australian standards.

Maintenance schedules are based on:

* Good engineering practice
* the manufacturer's recommendations
* previous experience and service history.

## Facility condition monitoring

Operators should note the condition of the facility at the time of use and report any deficiencies, deterioration, faults or breakages to the supervisor for resolution. Any issues that could impact product quality or operator safety should be reported as soon as possible after detection. Manufacture should not occur if a serious maintenance deficiency exists in the manufacturing facility. Work should also cease if operator or plant safety is at risk.

## Maintenance records

Inspection, maintenance and repair activities are recorded in the maintenance and calibration log. The log should include the following maintenance information:

* date and time the maintenance activity was performed
* name of the person performing the maintenance/repair, including the company name if carried out by a contractor
* classification of the activity (inspection, maintenance, repair etc.)
* description of the work performed
* a record of replaced parts and/or supplies used and
* reports (checklists, etc.) of equipment inspection/testing after the maintenance or repair (if appropriate).

## Buildings and grounds

It is a GMP requirement that the buildings are maintained to suit the operations carried out therein. Maintenance activities must focus on the protection of the manufacturing process, materials and goods from contamination.

The facilities manager in collaboration with the engineering manager must ensure that the maintenance activities are carried out in a manner that does not present any hazard to the quality of products. To this end, management of maintenance staff and contractors must be performed so that entry to unauthorised manufacturing areas, messy work areas and ignoring manufacturing dress codes are avoided. Maintenance work must be coordinated with production and cleaners to ensure that the affected area is returned to a suitably clean state and that the orderly storage of equipment and product is not disrupted.

Consideration must be made to decommissioning areas before work is to commence. Where building works require opening up areas to the outside, consideration must be given to reducing the risk of ingress of insects and other animals during maintenance works as well as routine inspection of gaps and seals between building materials.

Buildings must comply with local building and fire regulations, as must any additions or alterations. Maintenance activities must be undertaken in compliance with these regulations.

## Site security

Access to the site and buildings must be controlled. Access restrictions must be commensurate with the risks identified.

Entry into the grounds must be controlled, with steps taken to prevent unauthorised entry. Surveillance systems must be used where the risk of interference to operations, tampering or theft of product is deemed to be at risk.

Entry into the manufacturing areas must also be controlled, so that only trained operators may enter areas where product and raw materials are stored.

Areas where IT infrastructure equipment is located must be secure from unauthorised entry.

There must be procedures in place for the management (granting revocation and changing access) of staff access to the site and also for production and storage areas.

## Heating ventilation and air conditioning

HVAC systems are critical GMP systems and must be on the preventative maintenance program. These systems must also be revalidated regularly, according to Australian standards, usually by specialist contractors.

The facilities manager must coordinate the validation work with production.

It is the responsibility of the facilities manager to monitor the performance of the HVAC system, preferably in real time. Alarms and alert limits must be set logically in order that the deteriorating performance can be detected before the monitored trends are out of specification.

Ventilation of hazardous areas must also be monitored for the safety of staff. Deteriorating conditions must be addressed.

## Waste management

Waste management must be carefully managed in consideration to the risk of contamination to staff, the public and the environment.

Careful planning is required and the following considerations must be taken into account.

* Assess and categorise/classify the waste in accordance with the relevant EPA regulations
* Dispose of each waste type according to regulations.
* Contracts with waste transport and disposal contractors must be in writing. Waste volumes / weights must be documented along with details.

Due to environmental considerations, waste management must also incorporate waste minimisation.

Procedures must be in place for waste handling by staff, spill management, waste holding and transport (and disposal if performed on site) especially where there are active pharmaceutical chemicals involved. These chemicals must be identified and handled and disposed of correctly.

## Environmental management

Manufacturers must comply with local council regulations with respect to liquids sent to storm-water drain. The constituents of the liquid waste sent to drain must be monitored to ensure that no pollutants are returned to the drain outflows.

Lighting, office air conditioning and other non-critical consumption of electricity can be monitored and steps taken to reduce electrical supply to the site when not needed.

Steps can be taken to reduce the amount of water consumed by the plant by harvesting water from building roofs and undertaking water efficiency programs.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
| EPA | Environmental Protection Agency |
| GMP | Good Manufacturing Practice |
| HVAC | Heating Ventilation Air Conditioning |
| IT | Information Technology |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END