Procedure: Quality System Management

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# Purpose

This procedure describes how the QMS (quality management system) at [Company] is managed so it is suitable and effective.

# Scope

The scope of this procedure includes all processes used by [Company] to meet current Good Manufacturing Practice (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>

customer requirements and other applicable regulatory requirements.

# Responsibilities

Names of personnel responsible should reflect the company structure. This is maintained in the quality manual or as a separate organisation chart referred to in the manual and version controlled. Amend as required.

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| Role | Responsibility |
| Quality Manager | Manages the QMS, ensures the Company complies with it and maintains compliance with GMP, other applicable standards, codes and guidelines.  Issues and keeps up-to-date the quality system documents that manage the QMS (see Section 4) and conducts regular management reviews and compliance audits. |
| Departmental managers and specified staff | Manage and/or implement changes to ensure continued compliance with the QMS. |
| Managing Director | Ensures that annual reviews are conducted, resources are made available and resulting actions are completed in a timely manner. |
| All employees, contractors and consultants of the company | Comply with the requirements of the Quality Management System. |

# Documentation of the Quality Management System

The Company QMS is documented in the QM001 Quality Manual. The Quality Manual, together with all associated controlled documents such as standards, procedures and forms, embodies the Company QMS.

These are controlled documents and are managed according to Procedure QP401: Document Control.

# Management of the QMS

Internal QMS review and compliance audits are carried out to ensure the ongoing effectiveness and suitability of the QMS and confirm compliance with it as documented. These are carried out according to Procedure QP501: Management Review and Procedure and QP802: Procedure: Internal Quality Audit, respectively.

## Management review

These are carried out according to Procedure QP501: Management Review. These consider QMS audits are undertaken since the last review.

Reviews and the action plan are written down and resulting documents controlled.

## Internal audit

Internal audits are completed according to Procedure QP802: Internal Quality Audit and are carried out at the frequency prescribed and additionally when there are:

* major changes in the company’s structure
* changes in the type of work carried out
* regulatory changes.

## Delivery of Quality Management System improvements

If necessary, after an audit or management review, a QMS Improvement Plan will be developed.

The plan will include:

* activities to be undertaken to correct issues
* suitable staff to complete the job and agreed deadlines.

Progress will be managed by a suitably experienced and trained manager and reviewed regularly.

Department managers are responsible for delivering the actions assigned to their area of responsibility.

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. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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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 | |
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| Doc. No. | Document Title |
| QM001 | Quality Manual |
| QP401 | Document Control |
| QP501 | Management Review |
| QP802 | Internal Quality Audit |

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.

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