Quality Manual

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A quality manual is a comprehensive description of your company’s quality management system (QMS) which ensures the conformity of your products to the regulatory requirements you are required to meet.

This quality manual template has a structure that complies with **ISO9001:2015 – published Sept 2015,** previously 2008

ISO 9001:2015 significantly differs from the 2008 edition, with:

* A stronger focus on risk management and customer satisfaction
* A new structure to align management systems Standards
* More emphasis on leadership and commitment
* Fewer prescriptive requirements
* More requirements on communication and strategic alignment
* Formal introduction of ‘interested parties’.

and content that will prepare for compliance to CFR 210 and 211, and ICH Q10 Pharmaceutical Quality System. While populating this manual with your information, reference these regulatory/compliance documents and others such as the Australian Code of Good Manufacturing Practice (GMP). Ensure that your QMS is compliant to these regulations and is detailed in the quality manual.

Additional detail not included in this template may need to be included for unique, company-specific requirements.

# Scope

## General

### Introduction

[Company] develops and manufactures fine chemicals and intermediate products used in the manufacture of pharmaceutical (drug substances for human and veterinary use), materials and electronics industries. [Company] products are sold ...

Insert product details above as appropriate. Insert your company name in the field above to populate the remainder of the document.

This quality manual:

* Addresses the requirements for a QMS (Quality Management System) for the development and manufacture of these products, incorporating management of the life cycle of each product.
* Addresses the quality standards used to comply with regulatory requirements where the products are developed, manufactured and distributed.
* References relevant policies, procedures and other documents that make up the QMS.
* Presents the QMS to customers, suppliers, regulators and other external interested parties, informing them what specific controls are in place to assure quality.

This manual is structured on ISO 9001:2008 with eight sections divided into subsections relating to the main QMS processes. The subsections define general policies and principles of the relevant quality system.

### Quality policy

[Company] is committed to meeting customer requirements and enhancing customer satisfaction by delivering products that meet or exceed relevant quality standards through continual improvement of its products, services and the QMS.

The management team will:

* Implement and maintain a formal QMS that conforms to ISO 9001:2008
* Ensure the QMS requirements are always met
* Review this policy at least every two years to ensure the objectives are appropriate and that it is effective and suitable
* Ensure that this policy is communicated and understood by all employees, contractors and suppliers.

## Application

The QMS described in this quality manual applies to the development, manufacture and distribution of products supplied by [Company].

The QMS described in this quality manual relates to [Company], its products, customer requirements and regulatory obligations.

[Company] excludes QMS requirements only if the exclusion:

* Does not affect the company’s ability nor remove its responsibility to provide product that meets specified requirements
* Does not affect the company’s ability to carry out corrective action
* Applies to quality requirements in Section 7 (inclusive) because of its nature, customer requirements and applicable regulatory requirements.

The Quality Manager is responsible for identifying exclusions and proposing these to the Managing Director for exclusion from the scope of the quality system. The evaluation and approval of exclusions is conducted within the framework of management reviews of the QMS.

### Identified exclusion

There are no exclusions to the QMS... or

The following exclusions have been identified:

List relevant procedures that are excluded.

# Normative references

## Regulatory codes and guidelines

Table 1: Regulatory codes and guidelines for this QMS

|  |  |
| --- | --- |
| Reference | Title |
| Pharmaceutical Inspection Convention / Pharmaceutical Inspection Cooperation Scheme (PIC/S) PE 009-13 | 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> |
| US FDA 21CFR Part 210 | Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs, General |
| US FDA 21CFR Part 211 | Current Good Manufacturing Practice for Finished Pharmaceuticals |
| ICH of Technical Requirements for Registration of Pharmaceuticals for Human Use | Pharmaceutical Quality System Q10, Step 4 version |
| Therapeutic Good Administration | Australian Code of Good Manufacturing Practice for Medicinal Products, 16 August 2002 |
|  |  |
|  |  |

Add/delete as appropriate

## Standards

Table 2: Standard requirements for this QMS

|  |  |
| --- | --- |
| Reference | Title |
| AS/NZS ISO 9000:2008 | Quality Management Systems–Fundamentals and Vocabulary |
| AS/NZS ISO 9001:2008 | Quality Management Systems–Requirements |

Add/delete as required.

# Terms and definitions

Table 3: Terms and definitions used in this Quality Manual

| Term | Definition |
| --- | --- |
| Customer complaint | Written, electronic or oral communication that alleges deficiencies related to the identity, quality, safety or performance of a drug product |
| Pharmaceutical drug substance | An active drug ingredient or precursor of an active drug ingredient which is used - sometimes after further chemical reaction – in association with inactive ingredients to form a finished dosage form. |
| FDA (Food and Drug Administration) | The government agency that administers the registration of medicinal (and other) products for sale in the United States |
| GMP (Good Manufacturing Practices) | Accepted manufacturing practices in the pharmaceutical industry. The FDA refers to cGMP; the ‘c’ meaning current |
| ICH (International Conference on Harmonisation) | The international body set up to harmonise legislation and regulations governing the International Pharmaceutical industry |
| ISO (International Organisation for Standardisation) | The international body that sets and manages a range of international benchmark standards, including the one to which this manual is written |
| TGA (Therapeutic Goods Administration) | The government agency that administers the registration of medicinal (and other) products in Australia |
| Conformity | Meets standards or specifications |
|  |  |
|  |  |

Add/delete as required.

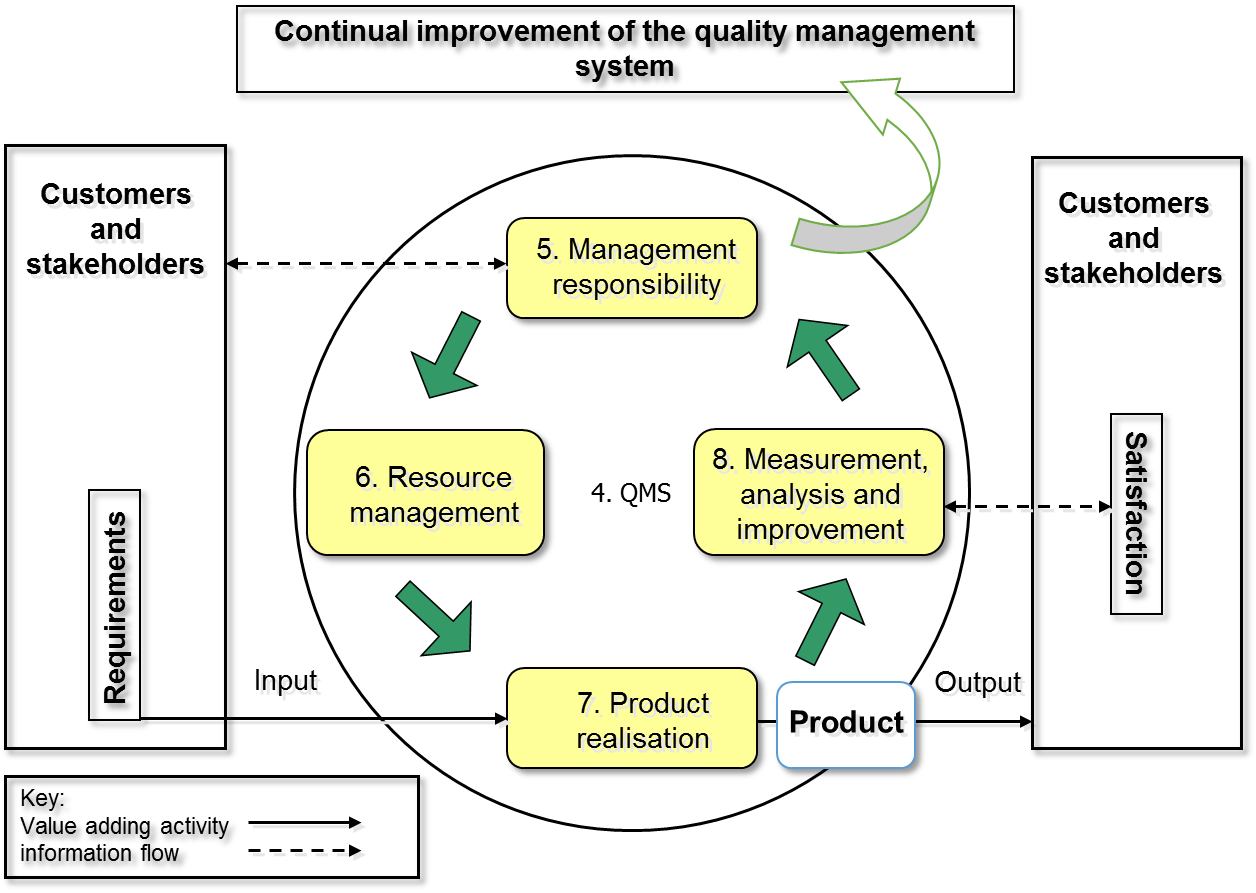
# Quality management system

## General requirements

This QMS is designed as a system of interrelated processes (Figure 1). It sets out the processes and procedures that together will provide the mechanisms required to implement the Quality Policy (refer to Section 1.1.2).

A separate Quality Policy may be generated if required, although typically this is incorporated into the Quality Manual in Section 1.1.2.

Figure : QSP map



Where applicable, delete the contents of Figure 1 and insert a customised diagram for your company.

The Quality System Process Matrix may be a separate document listing the relationship of key compliance processes and sub-processes. This could be controlled documentation of the document map generated during the drafting stage of the QMS (refer to the How to Prepare QMS Documents guide supplied by PharmOut with the QMS templates). However, a QMS could also use the documents tabled in Section 4.2.4.

Ensure accurate cross referencing of names and locations for the Quality System Process Matrix used by your company.

## Documentation requirements

### General

Each quality system sub-process is controlled by documentation (refer to Table 4). The QMS at [Company] contains appropriate documents that ensure effective operation and control of processes and record keeping, and include this quality manual and the quality policy.

The documentation describes:

* what, when and how it is to be done
* the resources required
* who is responsible.

Table 4: Documentation controlling each sub-process

Confirm documents listed are in use for your system. Include additional document references that you have generated to describe unique, company-specific procedures.

| Sub-processes | Related document no. and title |
| --- | --- |
| Quality Management System (QMS) | QM001 Procedure: Quality manual  QP401 Procedure: Document control  QP402 Procedure: Quality system management  QP403 Procedure: Control of records |
| Management responsibility | QP501 Procedure: Management review |
| Resource management | QP601 Procedure: Training, awareness and competency  QP602 Procedure: Equipment maintenance  QP603 Procedure: Pest management  QP604 Procedure: Facility maintenance  QP605 Procedure: Recruitment and selection of personnel |
| Product realisation | QP701 Procedure: Environmental monitoring  QP702 Procedure: Order processing and review  QP703 Procedure: Change control  QP704 Procedure: Supplier evaluation and monitoring  QP705 Procedure: Sampling  QP706 Procedure: Procurement  QP707 Procedure: Verification of purchased materials  QP708 Procedure: Batch processing instruction and recording  QP709 Procedure: Manufacture of product  QP710 Procedure: Validation of processes and equipment  QP711 Procedure: Status labelling  QP712 Procedure: Materials identification and traceability  QP713 Procedure: Labelling and packaging  QP714 Procedure: Measuring and monitoring equipment  QP715 Procedure: Analytical method validation  QP716 Procedure: Reprocessing of drug product and API  QP717 Procedure: Sample handling in the QC laboratory  QP718 Procedure: Computer system validation  QP719 Procedure: Storage and distribution |
| Measurement, analysis and improvement | QP801 Procedure: Feedback and customer satisfaction  QP802 Procedure: Internal quality audit  QP803 Procedure: Product returns  QP804 Procedure: Product batch release  QP805 Procedure: Managing deviations  QP806 Procedure: Continual improvement  QP807 Procedure: Product recall  QP808 Procedure: Customer complaints  QP809 Procedure: Corrective and preventative action  QP810 Procedure: Calibration of balances  QP811 Procedure: Annual review of drug products  QP812 Procedure: Quality risk management |

### Quality manual

This quality manual details the:

* quality policy of [Company]
* process by which the policy will be implemented
* organisational structure of [Company]
* procedures for the QMS
* management’s responsibilities to achieve compliance.

### Control of documents

All documents required by the QMS are controlled. Approval of, and changes to, these documents is the responsibility of the Quality Manager.

The following processes are in place:

* unique identification of controlled documents
* a review and approval (and if necessary a re-approval) process
* identification of personnel to approve, issue and register controlled documents
* allocation and distribution of controlled documents
* control of changes to controlled documents
* control, removal and archival of obsolete documents, including a system to prevent their unintended use
* identification and management of documents produced by external organisations used by [Company] during GxP procedures
* maintenance of a master file of all current and superseded controlled documents (whether internal or external)

All superseded controlled documents must be clearly marked ‘superseded’ to avoid confusion.

Copies of master documents are created only when specifically required. Uncontrolled copies may be made provided these are clearly marked ‘Uncontrolled’.

The following procedure(s) manage this process:

* *Procedure QP401: Document control*

List relevant procedures related to the document control function.

### Control of records

All records containing compliance evidence of product quality requirements are retained. These are retrievable in a readable form, uniquely identifiable and legible. A procedure is defined for the identification, storage, protection, retrieval, retention and deposition of records.

The following procedure(s) manage this process:

* *Procedure QP403: Control of records*

List relevant procedures related to the control of quality records such as forms, logs, batch records etc. or other quality records.

# Management responsibility

## Management commitment

[Company]’s Managing Director will ensure the company is continually striving to meet its quality objectives by:

* communicating formally and regularly to the organisation the importance of meeting customer, legal and regulatory commitments
* establishing and maintaining this QMS
* ensuring the availability of resources
* conducting regular quality audits and management reviews.

## Customer focus

The principal objective of the QMS is to focus the organisation on the customer. The key to achieving high customer satisfaction is an accurate determination of customer requirements and an effective verification that the requirements are met.

Customer requirements will be determined as per Section 7.2 and monitored as per Section 8.2 of this manual.

Ensure that section numbering is correct prior to approving this document.

## Quality policy

The Managing Director will ensure that the quality policy:

* is appropriate to the purpose of [Company]
* commits the organisation to meeting these quality requirements and to continual improvement
* has a suitable framework to establish and review quality objectives
* is communicated to, and understood by, appropriate parts of the company
* is reviewed for continued suitability.

## Planning

### Quality objectives

The quality objectives of [Company] are to:

* implement the quality policy
* meet requirements for products and processes
* improve the QMS and quality performance

Quality objectives are established during management reviews of the QMS. Management reviews can also initiate and monitor projects for achieving quality objectives.

### Quality management system planning

Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is to:

* comply with the quality policy
* ensure and demonstrate the company’s ability to provide products that consistently meet customer and applicable regulatory requirements
* ensure a high level of customer satisfaction
* facilitate continual improvement
* comply with the requirements of the ISO 9001:2008 standard and applicable regulatory requirements as listed in Section 2 of this manual.

The output of quality system planning comprises this quality manual, associated operational procedures and referenced documents.

Changes to the QMS may be in response to changes in product, process, capacity, operational or organisation and are made to improve the effectiveness and efficiency of the QMS. Changes are discussed during management reviews of the QMS.

The following procedure(s) manage this process:

* *Procedure QP402: Quality system management*

List relevant procedures as appropriate. Ensure table number is correct prior to approving this document.

## Responsibility, authority and communication

### Responsibility and authority

Refer to Figure 2 for the organisational structure that directs, manages and delivers the QMS.

Put organisation structure here, ensuring figure numbers are correct prior to approving this document.

Figure : Organisational structure

### Management representative

Table 5 details individual responsibilities responsible for the establishing, implementing and maintaining the QMS.

Table 5: Roles and responsibilities

|  |  |
| --- | --- |
| Role | Responsibilities |
| Leadership Team | * ensure all personnel are nominated to manage, perform and to supervise activities within the Quality Management System. * review the performance of the Quality Management System at planned intervals. * complete product reviews at planned intervals. * assess opportunities for improvement of the quality system or preventative actions (using a risk based approach). * identify the need to change the quality system. * ensure that responsibilities of staff are clearly defined. * appoint a member of the management responsible for the company’s quality management system * ensure compliance to legal and regulatory requirements |
| Managing Director | * overall responsibility for the Quality Management System * make the final management decisions * complete leadership team responsibilities |
| Quality Manager | * Management representative for Quality Management System * ensure the processes needed for the quality management system are established, implemented and maintained * report to the leadership team on the performance of the quality management system and any need for improvement * ensure the promotion of awareness of customer requirements throughout the company * approve or reject, as appropriate, starting materials, packing materials, and intermediate, bulk and finished products * evaluate batch records * ensure that all necessary testing is carried out * approve specifications, sampling instructions, test methods and other quality control procedures * approve and monitor any contract analysts * check the maintenance of quality department, premises and equipment * ensure that the appropriate validations are done * ensure the required initial and continuing training of quality department personnel is carries out and adapted according to need * complete leadership team responsibilities |
| Production Manager | * ensure products are produced and stored according to the appropriate documentation in order to obtain the required quality * approve the instructions relating to production operations and to ensure their strict implementation * ensure production records are evaluated and signed by an authorised person before they are sent to the quality control group * check the maintenance of the production department, premises and equipment * ensure that appropriate validations are done * ensure that the required initial and continuing training of production department personnel is carries out and adapted according to need * complete leadership team responsibilities |
| Staff | * Compliance with the quality management system. |

Amend as required.

### Internal communication

The Managing Director ensures that there is regular, scheduled and effective communication by all staff and contractors at [Company] regarding the quality system. This process is managed by the Quality Manager and comprises:

* Communication by managers to the organisation of:
* the company’s quality policy and objectives
* customer and regulatory requirements
* instructions on how to implement and use the quality system
* information on effectiveness of and any deviations from the quality system
* Communication by the organisation to managers of:
* information and data regarding quality performance
* effectiveness of the quality system

## Management review

### General

Management review provides the process for the organisation to report on the status of quality-related issues and activities and for the leadership team to formulate and communicate actions to change and/or improve the QMS. Records of management reviews are maintained.

These reviews are performed at planned intervals and cover each review input item listed in Section 5.6.2 of this manual at least once every year.

The following procedure(s) manage this process:

* *Procedure QP501: Management Review.*

List relevant procedures

### Review input

The QMS review takes into account:

* results of audits
* customer feedback
* process performance and product conformity
* status of corrective and preventative actions
* follow up from previous management reviews
* changes that could affect the quality management system
* recommendations for improvement

### Review output

The output of the QMS review details actions and decisions related to:

* improving the QMS and its associated processes
* improving product to meet customer requirements
* resources to implement any improvements.

QMS reviews are documented and logged within the quality system. Resulting changes to QMS systems are captured via the change control or corrective and preventative action process.

The following procedure(s) manage this process:

* *Procedure QP703: Change control*
* *Procedure QP809: Corrective and preventative action.*

List relevant procedures

# Resource management

## Provision of resources

The Managing Director of [Company] ensures that adequate resources are available to maintain and improve the quality systems, and enhance customer satisfaction by meeting customer requirements.

## Human resources

Add details about human resources with respect to the QMS.

### General

All personnel have the appropriate education, training, skills and experience to perform their duties.

### Competence, training and awareness

It is the company policy to:

* determine the necessary competence for personnel performing work affecting conformity to product requirements
* employ personnel (including consultants and contractors) with appropriate qualifications, skills, competency and experience
* provide ongoing training to ensure that personnel retain a high level of expertise in their field(s) and competency to perform their duties
* ensure personnel are aware of the relevance and importance of their activities and how they contribute to achieve the quality objectives
* maintain up-to-date training plans for all personnel
* maintain records of training received.

Departmental managers will assess and identify training requirements. Methods used will include on-the-job training, discussion groups and where required, formal in-house training or external courses.

Means of assessment may include interviews or supervisor evaluation of performance.

Appropriate records, resumes, job descriptions and training logs are maintained.

The following procedure(s) manage this process:

* *Procedure QP601: Training, awareness and competency*
* *Procedure QP605: Recruitment and selection of personnel.*

List relevant procedures

## Infrastructure

The facilities are located at [Company Address] and include premises, services and process equipment that has been designed and installed in accordance with applicable standards and is suitable to support the QMS.

Infrastructure and facilities, such as buildings, workspaces and associated utilities are appropriate and properly maintained to achieve conformity to product requirements.

Departmental managers are responsible for identifying the needs and requirements for new and/or modification/repair of existing infrastructure and facilities in their departments. Requests for changes and/or expansions of facilities are given to the Managing Director for review and approval.

Regular maintenance of buildings and facilities is performed and includes regular scheduled maintenance of systems, HVAC air conditioning, applicable services, and cleaning. Repairs to buildings and other such facilities are carried out as needed.

Ensure that section number is correct prior to approving this document.

Supporting services required by [Company] include transportation, communication and IT services. Specifically:

* Transportation services are purchased from parcel delivery, courier services and trucking or other approved transport companies
* Communication services are provided by telephone, wireless and internet access companies
* Installation, management and operation of IT systems, infrastructure and applications

Key process equipment, machines, hardware and software are regularly maintained in accordance with approved maintenance plans specified by equipment manufacturers, engineering or responsible departmental managers.

The Production Manager is responsible for coordinating and managing maintenance contracts.

The following procedure(s) manage this process:

* *Procedure QP602: Equipment maintenance*
* *Procedure QP603: Pest management*
* *Procedure QP604: Facility maintenance.*

List relevant procedures.

## Work environment

The company determines and manages the work environment to achieve product conformity by the application of appropriate environmental requirements and providing facilities that supply them. OHS&E requirements are managed by the Operations Manager.

# Product realisation

## Planning for product realisation

Before manufacture commences, planning of the product realisation is completed and includes:

* defining the quality objectives and requirements for the product
* establishing written batch process instructions
* training staff in production methods
* validation, verification, qualification, inspection, monitoring and testing activities
* detailing in-process tests required in the batch processing instructions
* documenting all of the above to demonstrate conformance to the QMS

Risk analysis studies are conducted for manufacturing and product realisation processes to assess, control, communicate and review risks to the quality of the product.

## Customer-related processes

### Determination of requirements related to the product

The company determines requirements by identifying the following:

* requirements specified by the customer, including requirements for delivery and post-delivery activities such as contractual obligations and warranty provisions,
* requirements not stated by the customer but necessary for intended use,
* statutory and regulatory requirements,
* any additional requirements determined by the company or customer.

### Review of requirements related to the product

The company reviews the requirements of the product prior to commitment to supply to ensure:

* the product requirements are defined
* differences in order requirements are resolved
* the product can be supplied to the time, budget and quality requirements

Where appropriate, customer requirements are confirmed by the leadership team before acceptance.

### Customer communication

The company has established and implemented arrangements for the communication with customers in relation to product information, enquiries, handling of contracts, customer feedback, complaints and recall. The following procedures manage this process:

* *Procedure QP801: Feedback and customer satisfaction*
* *Procedure QP807: Product recall*
* *Procedure QP808: Customer complaints*

List relevant procedures with respect to customer communication.

## Design and development

### Design and development planning

The company plans and controls the design and development of product. Each product is developed to an agreed design and development plan. The plan determines:

* the design and development stages
* the review, verification and validation appropriate to each design and development stage
* the responsibilities and authorities for design and development.

### Design and development inputs

Design and development inputs relating to product requirements are determined and records maintained by the company. Inputs include:

* functional, performance and safety requirements, according to the intended use,
* applicable statutory and regulatory requirements,
* information derived from previous similar designs,
* other requirements essential for design and development,
* output(s) of risk management as per Section 7.1 of this manual.

Design and development inputs are approved after being reviewed for adequacy by appropriate subject matter experts. Care is taken to ensure requirements are complete, unambiguous and not in conflict with each other.

List relevant procedures with respect to the design and development inputs. Ensure table number is correct prior to approving this document.

### Design and development outputs

Products are considered “developed” when they:

* meet the input requirements for design and development
* provide appropriate information for purchasing, production and service provision
* contain or reference product acceptance criteria
* specify the characteristics of the product for its safe and proper use
* use validated manufacturing processes
* have obtained regulatory approval to market from the relevant regulatory authorities.

### Design and development review

The company reviews the design and the development, at suitable stages, to evaluate the ability of the results of design and development to meet requirements, and to identify any problems and propose actions in accordance with planned arrangements.

A systematic review is conducted at each design and development stage to verify the product meets the requirements for that stage of development. Records of all reviews, results and necessary actions are documented and maintained.

### Design and development verification

Transfer of product manufacture to production includes technology transfer, verification and scale-up to production quantities of the final product.

Product and process acceptance criteria are set so that they can be measured to assure product quality and compliance with plans as per Section 7.3.1 of this manual. Records of verification activities are maintained.

### Design and development validation

Validation of selected product is performed using approved test plans, test protocols and checklists as described in the [Company] validation procedures. Validation activities are performed prior to delivery or implementation of the product and records are maintained. The following procedures manage this process:

* *Procedure QP710: Validation of processes and equipment*
* *Procedure QP715: Analytical method validation*
* *Procedure QP718: Computer system validation.*

List relevant procedures with respect to design/development validation.

Ensure that your QMS validation/verification covers all equipment, computer systems and parts of the facility that impact product quality (GxP) and/or safety, and describes a procedure to determine that impact (GxP versus non-GxP). PharmOut is able to assist your company in determining an appropriate validation approach suited to your company’s needs.

### Control of design and development changes

Design and development changes, including changes to the product specification, acceptance criteria or manufacturing process are captured using the change control process.

Before changes are implemented, the impact and risk of the change is evaluated and actions are taken to manage the risks associated with the change.

The following procedure(s) manage this process:

* *Procedure QP703: Change control*
* *Procedure QP812: Quality risk management*

List relevant procedures with respect to control of design/development changes.

## Purchasing

### Purchasing process

[Company] ensures that purchased product and materials conform to specified purchase requirements by internal and external inspections and/or qualification of goods and/or services received.

The ability of suppliers to meet the company’s requirements determines the level of control and supervision in place. Each supplier is evaluated and selected on their ability to meet the company’s requirements. Where necessary, a risk-based approach is used to determine the level of control.

The following procedure(s) manage this process:

* *Procedure QP706: Procurement*
* *Procedure QP707: Verification of purchased materials*
* *Procedure QP812: Quality risk management*

List relevant procedures with respect to the purchasing process.

### Purchasing information

[Company] ensures that the purchased product conforms preparing and providing relevant information to the supplier, including where appropriate:

* requirements for approval of product, procedures, processes and equipment,
* requirements for qualification of personnel,
* QMS requirements.

These documents are reviewed and approved by the company before release to the supplier.

To the extent required for traceability the organisation maintains relevant purchasing information such as documents as per Section 4.2.3 and records as per Section 4.2.4 of this manual.

### Verification of purchased product

[Company] ensures that purchased product meets specified purchase requirements by assessing purchased products for compliance to requirements. Tests, inspections and release of purchased product are performed using approved specifications and procedures. Verification arrangements and the method of release are stated in the purchasing information when performed at the supplier’s premises.

The following procedure(s) manage this process:

* *Procedure QP707: Verification of purchased materials*

List relevant procedures with respect to verifying the purchase product.

## Production and service provision

### Control of production and service provision

[Company] controls production and service operations through the provision of:

* Batch processing instructions
* Product specifications
* Suitable process equipment
* Monitoring and measuring devices for critical product parameters
* Release, delivery and post delivery activities.

The following procedure(s) manage this process:

* *Procedure QP701: Environmental monitoring*
* *Procedure QP702: Order processing and review*
* *Procedure QP703: Change control*
* *Procedure QP704: Supplier evaluation and monitoring*
* *Procedure QP705: Sampling*
* *Procedure QP706: Procurement*
* *Procedure QP707: Verification of purchased materials*
* *Procedure QP708: Batch processing instruction and recording*
* *Procedure QP709: Manufacture of product*
* *Procedure QP710: Validation of processes and equipment*
* *Procedure QP711: Status labelling*
* *Procedure QP712: Materials identification and traceability*
* *Procedure QP713: Labelling and packaging*
* *Procedure QP714: Measuring and monitoring equipment*
* *Procedure QP715: Analytical method validation*
* *Procedure QP716: Reprocessing of drug product and API*
* *Procedure QP717: Sample handling in the QC laboratory*
* *Procedure QP718: Computer system validation*
* *Procedure QP801: Feedback and customer satisfaction*
* *Procedure QP802: Internal quality audit*
* *Procedure QP803: Product returns*
* *Procedure QP804: Product batch release*
* *Procedure QP805: Managing deviations*
* *Procedure QP806: Continual improvement*
* *Procedure QP807: Product recall*
* *Procedure QP808: Customer complaints*
* *Procedure QP809: Corrective and preventative action*
* *Procedure QP810: Calibration of balances*
* *Procedure QP811: Annual review of drug products*
* *Procedure QP812: Quality risk management*

List relevant procedures with respect to controlling production/service provision.

### Validation of processes for production and service provision

Validation of processes is required to assure conformity of product to required specifications when this is not verified during the manufacture of each batch. Examples include mixing or stirring time or speed to assure homogeneity of product, heating time, filtration procedures to assure the sterility or clarity of product.

Products manufactured by [Company] will be manufactured using validated process when the resulting output of the process cannot be verified by subsequent measurement or monitoring.

The following procedure(s) manage this process:

* *Procedure QP710: Validation of processes and equipment*
* *Procedure QP715: Analytical method validation*
* *Procedure QP718: Computer system validation*

List relevant procedures detailing the validation approach of the QMS.

### Identification and traceability

The product, raw materials and equipment are uniquely identified and tracked through all stages of the process.

The following procedure(s) manage this process:

* *Procedure QP708: Batch processing instruction and recording*
* *Procedure QP711: Status labelling*
* *Procedure QP712: Materials identification and traceability*
* *Procedure QP713: Labelling and packaging*

List relevant procedures to identification and tracking of product, raw materials and equipment.

### Customer property

[Company] will exercise proper care with customer property, including intellectual property, while in use by or under the control of the company. Customer property is uniquely identified, protected and maintained as per customer requirements. Deviations, loss or damage is formally recorded and reported to the customer.

### Preservation of product

During internal processing and final delivery to the customer, [Company] will ensure adequate handling, storage, labelling and protection for all materials to:

* Preserve quality
* Safeguard from loss or theft
* Safeguard against damage or alteration

The following procedures manage this process:

* *Procedure QP602: Equipment maintenance*
* *Procedure QP603: Pest management*
* *Procedure QP604: Facility maintenance*
* *Procedure QP707: Verification of purchased materials*
* *Procedure QP713: Labelling and packaging*
* *Procedure QP716: Reprocessing of drug product and API*
* *Procedure QP719: Storage and distribution*
* *Procedure QP803: Product returns*

List relevant procedures to preserving the product

## Control of monitoring and measuring equipment

To provide evidence of conformity of the product, [Company] has installed monitoring and measuring devices. These monitoring and measuring devices are defined during the design, development and qualification of the facility, as shown in Section 7.2.1 of this manual.

To ensure continual compliance, these systems are:

* calibrated at specified intervals to traceable standards
* adjusted or re-adjusted as necessary,
* labelled with calibration status
* where possible, safeguarded from adjustments with tamper evident systems
* regularly maintained
* protected from deterioration and mishandling

Records of the results of calibration and verification are maintained. The following procedures manage this process:

* *Procedure QP602: Equipment maintenance*
* *Procedure QP710: Validation of processes and equipment*
* *Procedure QP711: Status labelling*
* *Procedure QP810: Calibration of balances*

List relevant procedures that detail the control of monitoring/measuring devices.

# Measurement, analysis and improvement

## General

In order to continually improve the effectiveness of the QMS, [Company] has implemented a review system to monitor, measure, analyse and improve the QMS.

## Monitoring and measurement

### Customer satisfaction

The company actively monitors customer satisfaction via product complaints and customer feedback. Customer satisfaction reports are assessed annually to determine if any actions are required.

The following procedures manage this process:

* *Procedure QP801: Feedback and customer satisfaction*
* *Procedure QP803: Product returns*
* *Procedure QP807: Product recall*
* *Procedure QP808: Customer complaints*
* *Procedure QP811: Annual review of drug products*

List relevant procedures with respect to customer satisfaction.

### Internal audit

The company conducts periodic internal audits on its quality system to confirm that it complies with the requirements and is operating effectively. Audits are conducted to seek objective evidence to provide this assurance.

Audits are performed according to the status and importance of the activities and areas, and take into consideration performance in previous audits. The audit scope, frequency, criteria and methods are defined and documented.

[Company] addresses any deficiencies in a timely manner.

The following procedure(s) manage this process:

* *Procedure QP802: Internal quality audit*
* *Procedure QP805: Managing deviations.*

List relevant procedures with respect to internal audits.

### Monitoring and measurement of processes

QMS processes are monitored by a variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

* conducting internal audits of the QMS
* monitoring trends in corrective and preventive action requests
* measuring product conformity
* monitoring other quality performance data and trends
* monitoring customer satisfaction.

The following procedure(s) manage this process:

* *Procedure QP501: Management review*
* *Procedure QP801: Feedback and customer satisfaction*
* *Procedure QP802: Internal quality audit*
* *Procedure QP806: Continual improvement.*

List relevant procedures detailing monitoring and measuring processes.

### Monitoring and measurement of product

[Company] measures the characteristics of a product to verify that product requirements and specifications have been met

The following procedure(s) manage this process:

* *Procedure QP501: Management review*
* *Procedure QP801: Feedback and customer satisfaction*
* *Procedure QP802: Internal quality audit*
* *Procedure QP803: Product returns*
* *Procedure QP805: Managing deviations*
* *Procedure QP806: Continual improvement*
* *Procedure QP807: Product recall*
* *Procedure QP808: Customer complaints*
* *Procedure QP809: Corrective and preventative action*
* *Procedure QP811: Annual review of drug products*
* *Procedure QP812: Quality risk management*

List relevant procedures detailing monitoring and measuring product.

## Control of non-conforming product

The review and disposition of non-conforming products and raw materials is the responsibility of the Quality Manager. When a non-conforming product is identified it is evaluated to determine whether it should be reworked, accepted or rejected.

To prevent a non-conformity reoccurring, an investigation into the cause is undertaken. This is documented via the corrective and preventative actions procedure and recommendations are followed up to ensure that action has been taken.

When processes affecting product conformity are outsourced, special controls are implemented to ensure these processes meet specified requirements. Such controls include, as appropriate:

* evaluation and pre-qualification of suppliers
* assessment of suppliers manufacturing processes
* assessment of contractor's quality system
* assessment of customer (contract) requirements
* monitoring of supplier quality performance
* requirements for process control, inspection, testing or other records demonstrating product conformity
* verification of the supplied product

The company takes full responsibility to ensure outsourced processes conform to all customer and regulatory requirements.

The following procedure(s) manage this process:

* *Procedure QP704: Supplier evaluation and monitoring*
* *Procedure QP805: Managing deviations*
* *Procedure QP809: Corrective and preventative action*

List relevant procedures with respect to the control of non-conformity.

## Analysis of data

Data is collected through quality reviews, non-conformances, risk assessments, manufacturing process trend data, customer complaints and customer satisfaction surveys to determine the conformance of the QMS.

## Improvement

### Continual improvement

Requests for improvements in product realisation are identified via the quality objectives, audit results, analysis of data, corrective and preventative actions and management review. All changes are managed via the change control procedure.

The following procedure(s) manage this process:

* *Procedure QP402: Quality system management*
* *Procedure QP501: Management review*
* *Procedure QP806: Continual improvement*
* *Procedure QP809: Corrective and preventative action*

List relevant procedures to implementing continual improvement.

### Corrective action

When a non-conformance is observed, an investigation is undertaken to determine the cause and identify the corrective action to ensure it does not re-occur.

The following procedures manage this process:

* *Procedure QP805: Managing deviations*
* *Procedure QP809: Corrective and preventative action*
* *Procedure QP812: Quality risk management*

List relevant procedures that detail the corrective action process.

### Preventative action

When a deviation is observed, an investigation is undertaken to determine the cause and identify the preventative action required to avoid product non-conformance.

The following procedures manage this process:

* *Procedure QP809: Corrective and preventative action*
* *Procedure QP812: Quality risk management*

List relevant procedures for implementing preventative action.

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 |
| 01 |  |  |  |
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