Quality Manual

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This Quality Manual has been formatted on the requirements of ISO 13485:2003, ISO 9001:2008, ICH Q10, PIC/S and 21 CFR Part 820. Where differences arise, these have been noted in the text. Compliance with ISO 13485 does not infer compliance with ISO 9001, and vice versa. Each standard has some specific requirements which must all be addressed to comply with both international standards.

References to clauses or sections of standards are to parts of ISO 13485:2003, unless specified otherwise.

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

## Introduction

Provide a general description of the company, its location, operations and the products it produces. Describe which quality systems apply and identify any exclusion from ISO 13485.

[Company] develops and manufactures medical devices that are sold in [Australia, the United States of America and the European Union].

This quality manual, which is based on AS/NZS ISO 13485:2003, FDA 21 CFR Part 820 quality system standards and regulation clauses, addresses the requirements for a QMS (Quality Management System) for the development and manufacture of these products. It addresses the quality standards used to comply with regulatory requirements where the products are developed, manufactured and distributed. It references relevant policies, procedures and other documentation that form the QMS. This quality manual also defines the authorities and responsibilities of management and personnel involved in operation of the QMS.

This manual presents the QMS to customers, suppliers, regulators and other external interested parties, informing them what specific controls are in place to assure quality.

Amend the following standards as appropriate.

This QMS complies with the following Australian and international standards:

* AS/NZS ISO 13485:2003: Medical devices–Quality management systems–Requirements for regulatory purposes
* AS/NZS ISO 9001:2008: Quality management systems–Requirements
* US FDA Code of Federal Regulations, Part 820, Quality System Regulation.

Education in the elements that make up the Quality Management System (QMS) shall be managed via a training program and compliance to the QMS via an internal audit schedule.

## Quality policy

Write the company’s quality policy here. It should embody both the process and the required outcome(s).

[Company] is committed to consistently meeting customer requirements and expectations and regulatory requirements by delivering products that meet or exceed relevant quality standards through continual improvement of its products, services and the QMS. It is the responsibility of Senior Management to ensure that the Quality Policy is implemented.

The Senior Management team will:

* implement and maintain a formal QMS
* ensure these requirements are always met
* review this quality manual at least annually to ensure the objectives are appropriate and that it is effective and suitable
* ensure this quality manual is communicated and understood by all employees, contractors and suppliers to ensure a culture committed to quality

## Application

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

Identify the products (devices) and services which are to be covered by this quality system. As appropriate, include manufacture, delivery, design, development, distribution, installation, servicing, etc. Also identify those products (or groups or types of products) to which the system does not apply. Any exclusion should be justified in this manual

## Exclusions

Organisations may claim exclusions from various requirements that do not apply to their operations (e.g. design requirements, customer property). Any exclusion must be explained and justified in writing and identify who made the decision and by who it was approved. The QMS described in this quality manual relates to [Company], its products, customer requirements and regulatory obligations.

The 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 only

The quality assurance manager is responsible for identifying requirements that do not apply and proposing to high-level management that they be excluded from the scope of the QMS.

Processes which are applicable to the product but are performed by outside contractors, do not qualify for exclusion. They are accounted for in this quality manual to ensure adequate controls are in place.

Any exclusion should be documented in this section of the manual. Excluded requirements must be precisely identified with reference to specific clauses and/or statements in ISO 13485:2003. Provide a brief justification as to why the exclusion is taken and why it is appropriate.

Following are two examples of exclusions and their justification:

Example 1

Exclusion: ISO 13485:2003, Section 7.3, Design and Development (including all subsections)

Justification: [Company] does not design or develop products. All principal product characteristics are specified by the customers or their consultants. Our engineering activities are limited to developing methods and means of production, fabrication, or installation.

Example 2

Exclusion: ISO 13484–2003, Section 7.5.4, Customer Property

Justification: [Company] does not receive from customers any tangible or intellectual property that is intended for incorporation into, or in any way associated with the medical device(s).

The next paragraph is not mandatory and may be deleted.

High-level management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions is conducted within the frame-work of management reviews of the QMS.

Refer to *Procedure QP501: Management Review*.

# References

List any relevant international, national, regulatory or industry, quality system related regulations, standards or guidelines. Add to or delete from the following list as appropriate.

## Regulatory codes and guidelines

Table 1: Regulatory codes and guidelines

|  |  |
| --- | --- |
| Reference | Title |
| US FDA 21CFR Part 820 | Quality System Regulation |
| United States Food and Drug Administration, Title 21 of the Code of Federal Regulations (US FDA 21CFR) Part 11 | Electronic Records; Electronic Signatures |
|  |  |

Add/delete as appropriate

## Standards

Table 2: Standards

|  |  |
| --- | --- |
| Reference | Title |
| ANSI/ASQC M1–1996 | American National Standard for Calibration Systems |
| AS/NZS ISO 10006:1997 | Quality Management–Guidelines to Quality in Project Management |
| AS/NZS ISO 10007:1995 | Quality Management–Guidelines for Configuration Management |
| AS/NZS ISO 10013:1995 | Guidelines for Quality Manuals |
| AS/NZS ISO 9000:2000 | Quality Management Systems–Fundamentals and Vocabulary |
| AS/NZS ISO 9001:2000 | Quality Management Systems–Requirements |
| AS/NZS ISO 9004:2000 | Quality Management Systems–Guidelines for Performance Improvements |
| AS/NZS ISO 13485:2003 | Medical devices–Quality management systems–Requirements for regulatory purposes |
| AS/NZS ISO 14971:2007 | Medical Devices – Application of Risk Management to Medical Devices |
|  |  |
|  |  |

Add/delete as appropriate

# Terms and definitions

Add or delete definitions as appropriate. Define company or Industry specific abbreviations and acronyms.

The following definitions are from ISO 13485 and may be changed to comply with national regulations, if necessary. Delete those definitions that do not apply.

To comply with 21 CFR 820, include relevant definitions from 21 CFR 820.3, Definitions.

Any additional requirements that are over and above ISO 13485 should be added here, for example, items from ISO 9001 such as quality, non-conformity, process, etc.

Define company specific abbreviations and acronyms.

Table 3: Terms and definitions

| Term | Definition |
| --- | --- |
| Active implantable medical device | An active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice and which is intended to remain after the procedure |
| Active medical device | A medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity |
| Advisory notice | notice issued by the organisation, subsequent to delivery of the medical device, to provide supplementary information and/or to advise on corrective or preventive action to be taken:   * in the use of a medical device, * modification of a medical device, * return of the medical device to the organisation that supplied it or * destruction of a medical device |
| Customer complaint | A written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market |
| Implantable medical device | A medical device intended to be totally or partially introduced into the human body or a natural orifice, or to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention  **NOTE:** This definition applies to implantable medical devices other than active implantable medical devices |
| Labelling | A written, printed or graphic matter affixed to a medical device, or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description and use of the medical device but excluding shipping documents |
| Medical device | Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:   * diagnosis, prevention, monitoring, treatment or alleviation of disease * diagnosis, monitoring, treatment, alleviation of or compensation for an injury * investigation, replacement, modification, or support of the anatomy or of a physiological process * supporting or sustaining life * control of conception * disinfection of medical devices   Providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. |
| Sterile medical device | A category of medical device intended to meet the requirements for sterility |
|  |  |
|  |  |

# Quality management system

To satisfy ISO 13485 it is common to include a “Plan-Do-Check-Act” diagram in the QMS (refer Fig. 1). This depicts the quality system process, sequence and interrelations.

## General requirements

This QMS is designed as a system of interrelated processes. It sets out the processes and procedures that together provide the mechanisms required to implement the Quality Policy. The systems’ main activities are defined as Quality System Processes (QSPs) and are grouped into six categories, as listed in

Figure 1:

A – Customer requirements

B – Product realisation

C – Measurement, analysis and improvement

D – Management responsibility

E – Resource management

F – Continual improvement

Figure 1: QSP Map

Customer Communication

1. Production Product info, quotes & orders

CUSTOMERS

A. CUSTOMER REQUIREMENTS

10 Management policies, planning & commitments

11 Management review

C. MEASUREMENT, ANALYSIS & IMPROVEMENT

E. RESOURCE MANAGEMENT

12 Human Resources

13 Plant, facility & equipment

14 Information resources (document control)

15 Measuring/monitoring devices

B. PRODUCT REALISATION

D. MANAGEMENT RESPONSIBILITY

F. (16) CONTINUAL IMPROVEMENT -Corrective & Preventive Action

6 Labelling, packaging, shipping, distribution

7 Monitoring of manufacturing processes measurement of product

8. Monitoring/measurement of QMS (internal audits)

9 Monitoring customer satisfaction

CUSTOMERS

Note: Detailed process descriptions are provided in the Quality System Process Matrix.

2 Product development

3. Production & quality planning

4. Purchasing & receiving

5 Production

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

This section describes the scope of the quality system and related documentation, sets out general policies regarding this manual and references operational procedures for document control and quality records.

### General

The last three types of documents are similar to those in the Device Master Record (DMR). However, the list identifies documents that need to be controlled rather than those that should be in the DMR. All DMR documents must be controlled but not all controlled documents are in the DMR

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

### Quality Manual

This Quality Manual details the:

* quality policy of [Company]
* process by which the policy will be implemented
* the scope of the quality system, including details and justification for any exclusion(s)
* the organisational structure of [Company]
* procedures for the QMS
* the overall quality system, its processes, sequence and interaction
* high-level management responsibilities to achieve compliance

Secondary documentation details the QMS processes and procedures.

| Secondary documents | Description |
| --- | --- |
| Procedures | describe and explain processes and define what records must be maintained to document the results |
| Forms, templates or matrices | recording raw data or information  If templates are not used at the company then delete from above bullet point. |
| Work instructions | Details specific tasks, such production processes (process operator instructions), handling products, calibrating measuring equipment, conducting tests or inspections |
| Device, labelling and packaging specifications | * Component, subassembly, assembly and packaging drawings and specifications * Bills of materials (or lists of ingredients); compositions * Formulations * Wiring and piping diagrams * Software specifications * User manual, packaging artwork * Other such documents defining the medical device and its packaging.   All of these documents shall be included in the DMR. Refer to these documents as is customary in the company. For example, specifications may be called data sheets and they may be drawings, not diagrams. Whatever the format and names, this clause refers to documents defining the company’s medical devices. If such documents are not received from the customer, delete the last sentence (above). |
| manufacturing, installation and servicing specifications | * Process flow charts * Process/assembly lines diagrams * Specifications for equipment, tools and molds * Manufacturing environment specifications * Setup procedures * Operator instructions * Machine maintenance procedures * Blank work orders (job travellers), non-conforming product / process forms and other reporting forms * Other such documents defining the manufacturing processes and the manner of production.   Delete items that are not applicable. For example, if process flowcharts are not used, delete references to flowcharts. |
| Quality Assurance/Control procedures and specifications | * Process control specifications / charts * Control plans, instructions and acceptance criteria for incoming, in-process and finished device inspection and testing * Procedures and acceptance criteria for the verification of packaging, labelling, installation and servicing activities * Blank forms for inspection/testing reports and other device history records * Release document review list * Other such documents defining how products and manufacturing processes are controlled and verified.   Delete items that are not applicable. For example, if SPC is not used, delete references to process control. |
| Standards and codes | * International, national and local regulations * Standards and codes that define operational, quality and product requirements. |

The DMR is not an additional category but a compilation of device-specific documents. Relevant document from any category may be included in the DMR.

For simple devices, the DMR may be a collection of engineering and production documents specific to that device. For more complex devices, the DMR may be an index or reference list of relevant documents, including their revision status and location.

In this QMS, the DMR is treated as an index and there is a procedure for establishing and maintaining DMRs. Modify this section to reflect the company’s procedures.

The Device Master Record (DMR) includes engineering, manufacturing, quality specifications, production methods and other specific documentation. The DMR may be actual documents or an index referencing these documents, their revision status and location.

When a DMR document is withdrawn or superseded a copy of the old document is retained (archived) for at least the life of the medical device and no less than two years from product release. In the event of conflict, local regulatory requirements shall take precedence. Refer to *Procedure QP402: Device Master Record*.

### Control of documents

This section will vary depending on whether documents are distributed and controlled as hard copies or electronically. Requirements are the same for both systems but the means of control will differ. The text in this section assumes the company has both hard and electronic systems.

Modify this section, and Procedure QP401 to reflect the company’s systems and practices.

All documents required by the QMS are controlled. [Company] uses both hard copies and electronic copies of documents. 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 (including revision and change status)
* a review and approval (and if necessary a re-approval) process to ensure documents are adequate and approved prior to release
* 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 the company in GxP
* maintenance of a master file of all current and superseded controlled documents (whether internal or external)

Refer to *Procedure QP401: Control of Documents*.

### Control of records

ISO 13485 discusses records and documents in the same section, however, they differ in some important respects. Records are not reviewed and approved and should not be revised. Documents instruct or inform; records are a statement of facts or events and provide complete evidence of product and process conformity and of the conformity and effectiveness of a quality system.

Records can be paper or electronic and methods for control will depend on the media. This section relates to paper records. Modify to reflect company conditions.

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. All records that give evidence of conformity to product quality requirements are retained. These are retrievable in human readable form, uniquely identifiable and legible. A procedure is defined for the identification, storage, protection, retrieval, retention and deposition of records.

Records are organised into the following five categories:

* Design History File (DHF)
* Device Master Record (DMR)
* Device History Record (DHR)
* Quality System Record (QSR)
* Complaint Files

ISO 13485 is quite general in its requirements and allows companies to tailor to their needs. However, the above five groups are explicitly required in 21 CFR Part 820 Subpart M.

Refer to *Procedure QP403: Control of Records*.

Table 4: Documentation

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 |
| --- | --- |
| Product information, quotations and orders | QP702 Order Processing and Review |
| Product development | QP703 Design Control |
| Production and quality planning | QP401 Control of Documents  QP402 Device Master Record  QP703 Design Control  QP704 Control of Design and Process Changes |
| Purchasing and receiving | QP701 Production Planning and Risk Management  QP702 Order Processing and Review  QP703 Design Control  QP707 Verification of Purchased Product  QP708 Production Work Order and History Record  QP803 In-Process Inspections  QP804 Final Acceptance Inspection |
| Production | QP705 Supplier Evaluation and Monitoring  QP706 Purchasing  QP707 Verification of Purchased Product  QP712 Product Identification and Traceability  QP810 Corrective and Preventative Action |
| Labelling, packaging, shipping and distribution | QP403 Control of Records  QP702 Order Processing and Review  QP713 Labelling and Packaging  QP714 Storage and Distribution |
| Monitoring and measurement of products | QP707 Verification of Purchased Product  QP712 Product Identification and Traceability  QP803 In-Process Inspections  QP804 Final Acceptance Inspection  QP805 Control of Nonconforming Product |
| Monitoring and measurement of quality management systems (internal audits) | QP501 Management Review  QP801 Feedback and Customer Satisfaction  QP802 Internal Quality Audits  QP806 Analysis of Data |
| Monitoring customer feedback and satisfaction | QP501 Management Review  QP801 Feedback and Customer Satisfaction  QP808 Device Recall and Advisory Notices  QP809 Customer Complaints |
| Management policies, planning and commitments | QM 5.3 Quality Policy  QM 5.4 Quality System Planning  QM 5.5 Organisation and Communication  QP501 Management Review |
| Management review | QP501 Management Review |
| Human resources | QP601 Competence, Awareness and Training |
| Plant, facility and equipment | QM 6.3 Infrastructure  QP602 Equipment Maintenance  QP603 Production and Work Environment  QP701Production Planning and Risk Management |
| Information resources (document control) | QP401 Control of Documents  QP402 Device Master Record  QP403 Control of Records |
| Measuring and monitoring devices | QP715 Measuring and Monitoring Equipment |
| Continual improvement (Corrective and preventative action) | QP501 Management Review  QP806 Analysis of Data  QP807 Continual Improvement  QP809 Customer Complaints  QP810 Corrective and Preventative Action |

# Management responsibility

This section follows ISO 13485 Clause 5.1 requirements a) through e). It demonstrates management commitment and points to those sections of the manual and procedures where corresponding activities are defined and explained

## Management commitment

[Company] high-level management 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
* promoting awareness of the QMS
* establishing and maintaining the QMS
* ensuring the availability of resources
* conducting regulatory quality audits and management reviews

High-level management periodically review the QMS to ensure its continuing appropriateness, adequacy and effectives. The status and performance of the system is evaluated, and actions for improvement initiated.

Refer to *Procedure QP501: Management Review*.

## Customer focus

Determination of customer requirements is addressed more specifically and in more detail in ISO 13485 Clause 7.2.1.

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.

High-level management ensures that customer requirements are determined and are well understood. This is done through the process of order and contract review.

High-level management ensures that customer requirements are met by inspecting and testing products at various stages of production and upon completion.

## Quality policy

This section describes requirements for the quality policy and the process for its formulation and review. The quality policy itself is documented at the beginning of this manual.

[Company]’s quality policy is described in Section 1.2*.* The quality policy is established by the CEO and:

* is appropriate to the purpose of the company
* is committed to complying with requirements
* is continually improving the effectiveness of the QMS
* provides a framework for establishing specific quality objectives
* provides direction for the continual improvement effort

The use of the quality policy to set quality objectives and facilitate continual improvement is addressed in this manual. The quality policy is:

* periodically reviewed as part of management review of the QMS. This ensures its continual relevance and suitability
* posted throughout the company and its role is explained and discussed at general orientation training provided to all employees
* communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on the [Company] internet site

External communication of the quality policy is not required. Delete the last two bullet points of this clause if not appropriate.

Refer to *Procedure QP501: Management Review* and *Procedure QP807: Continual Improvement*.

## Planning

ISO 13484 addresses quality planning in several clauses. This section relates to Clauses 5.4.1 and 5.4.2 and addresses planning of the quality system and achievement of quality objectives. Clause 7.1 addresses requirements for planning of manufacturing processes, product verification and validation.

### Quality objectives

This documentation includes a specific system for establishing, documenting and implementing quality objectives.

Quality objectives are established throughout the organisation to:

* implement the quality policy
* meet requirements for products and processes
* improve quality system 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.

Refer to *Procedure QP501: Management Review*.

### 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 requirements of ISO 13485 standard and applicable regulatory requirements

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 product, process, capacity, operational or organisational changes and are made to improve the effectiveness and efficiency of the QMS. Changes are discussed during management reviews of the QMS.

Refer to *Procedure QP501: Management Review*.

## Responsibility, authority and communication

### Responsibility and authority

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

Figure 2: Organisational structure

Insert organisational structure

High level management ensures that personnel have sufficient independence and authority to perform their allotted tasks, in particular, internal auditors and personnel responsible for monitoring and reporting adverse events.

For the purpose of the QMS, high level management includes the CEO, quality manager, chief engineer, production manager, marketing manager and accounting/finance manager. Every employee within [Company] has a responsibility to meet the intent of the Quality System by following approved procedures and accurately documenting their activities.

All departments and functions in the company are responsible for implementing, maintaining and improving the QMS.

Authorities and responsibilities for specific processes of the QMS are defined:

* throughout this quality manual
* in operational procedures
* where the specific quality system processes or activities are documented
* in job descriptions

### Management representative

The regulatory affairs and/or Quality Assurance manager is typically the management representative. However, anyone from the management team may be appointed, irrespective of responsibilities. It is not necessary that the representative be involved in daily operation of the QMS.

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

Table 5: Roles and responsibilities

| Role | Responsibilities |
| --- | --- |
| High-level management | Ensuring all personnel are nominated to manage, perform and to supervise activities within the quality system  Ensuring that responsibilities of personnel are clearly defined  Nominating a quality management representative  Review of the quality system at planned intervals  Assessing opportunities for improvement of the quality system  Identifying the need to change the quality system |
| Quality manager | Establishing, developing, implementing and maintaining the quality management system  Managing the quality process  Reporting to high-level management on the performance of the QMS  Promoting awareness of the customer’s requirements and this QMS throughout the organisation  Approving quality related documentation  Verifying the implementation of corrective and preventative processes  Identifying deficiencies relating to the quality system  Initiating preventative and corrective actions to prevent re-occurrence of non-conformances |
| Departmental managers | Identifying training requirements  Training personnel, visitors, contractors and if necessary suppliers, including induction of new staff in the requirements of the QMS  Developing and approving controlled documentation  Implementing preventative and corrective actions  Addressing and resolving technical problems  Managing equipment and product related issues  Updating personnel training plans and registers to reflect current procedures and policies |

### Internal communication

ISO 13485:2003 Clause 5.5.3 requires that "Top management shall ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality system". The standard outlines methods for communicating this information and references appropriate procedures, in particular those pertaining to document control, training and management reviews.

Although an operational procedure for internal communication is not explicitly required, such procedures are useful and sometimes expected in a larger organisation, i.e. refer to more specific communication methods such as weekly production meetings, monthly newsletters or a bulletin board or intranet site where appropriate.

Internal communication regarding the quality system flows two ways:

* management communicates to the organisation:
* the quality policy and objectives
* customer and regulatory requirements
* product and process specifications
* verification and validation requirements
* instructions on how to implement and use the quality system
* the organisation communicates to management:
* information and data regarding quality performance
* effectiveness of the quality system

Note that there is no requirement for customer satisfaction or continual improvement in ISO 13485.

The information is communicated through:

Edit the following list to remove those methods that are not used in [Company].

* paper or electronic documents such as manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.
* emails, memos and meetings
* bulletin boards, the intranet site and newsletters
* training and awareness programs
* employee suggestions, surveys and feedback

Management review meetings have a special role in ensuring proper communication between high-level management and the organisation. The meeting provides the framework for the organisation to report on the status of quality-related issues and activities and for management to formulate and communicate policies and directives to change and/or improve the quality system.

The quality assurance manager has the overall responsibility for ensuring that pertinent documents, reports and records are distributed to appropriate departments and that information and data about quality performance and the effectiveness of the quality system are reported to high-level management.

Refer to *Procedure QP501: Management Review*.

## Management reviews

### General

Managers will review the effectiveness of the QMS and advise high-level management of recommended improvements to the system. These reviews are performed at least annually. More frequent reviews are scheduled in periods when organisational, technological, product or other changes require increased attention and input from the high-level management.

The purpose of management reviews is to:

* evaluate the suitability, adequacy and effectiveness of the QMS
* consider changes to the QMS, quality policy and quality objectives

Modify the following and QP501 Section 3 to suite the structure of [Company].

Management reviews are chaired by the CEO and are attended by managers representing quality assurance, marketing, sales, engineering, production, purchasing and human resources.

Refer to *Procedure QP501: Management Review*.

### Review input

The QMS review takes into account:

* findings of audits carried out since the last management review
* customer feedback and complaints
* changes in policy and standards
* changes in work practices and organisational structures
* status of corrective and preventative actions
* follow up on previous management review actions
* new or revised regulatory requirements
* recommendations for improvement
* other changes that could affect the QMS

### Review output

This section of the manual summarises procedure QP501, Management Review. It can be further abbreviated if required.

The output from management reviews include:

* Improvements needed to maintain effectiveness of the quality management system
* Initiating actions for improvement of product relating to customer requirements
* Resource requirements to maintain QMS effectiveness and continuous improvement of product

Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions and assign responsibilities and allocate resources for implementation of these actions.

# Resource management

## Provision of resources

The high-level management of [Company] ensures that adequate resources are available to implement and maintain and improve the quality systems and to meet regulatory and customer requirements. Resources required for implementing, maintaining and improving the QMS include personnel, infrastructure, work environment, equipment, materials, information and financial resources.

Determination of resource needs for specific activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

Depending on the type and nature of the operation or activity, resource requirements are defined in:

* the quality manual, operational procedures and work instructions
* product and process drawings and specifications
* production plans
* job descriptions, competence matrixes and training programs
* minutes of management reviews
* quality objective records
* corrective and preventive action requests

High-level management has the responsibility and authority for provision of resources.

Management reviews of the QMS are the principal forum for determining and providing adequate resources for maintaining and improving the quality system.

References to "improvement" and "customer satisfaction" are not required for ISO 13485:2003.

## Human resources

### General

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

Human Resources are responsible for training and awareness programs for company-wide participation, such as general orientation, rules and regulations, quality systems, safety and other company-wide systems and issues.

Departmental managers are responsible for identifying competency requirements and for providing specific training in their departments. Departmental training is primarily focused on increasing skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques and other such skills as appropriate for particular positions and jobs.

Refer to *Procedure QP601: Training, Awareness and Competency*.

### Competence, awareness and training

The company:

* assesses resource needs
* employs personnel (including consultants and contractors) with appropriate qualifications, skills and experience
* provides on-going training to ensure that personnel retain a high level of expertise in their fields
* maintains up-to-date training plans for all personnel
* maintains records of training received

Senior staff 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.

Refer to *Procedure QP601: Training, Awareness and Competency*.

## Infrastructure

ISO 13485 Clause 6.3 applies only to those facilities, equipment and supporting services having direct impact on product conformity, for example, production equipment or processes.

This documentation takes a minimalist approach and does not cover buildings, infrastructure and services, etc., that do not impact product quality.

The facilities are located at [insert address] and includes premises, services and equipment that has been designed to support the QMS.

### Buildings, workspace and associated utilities

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 submitted to the high-level management for review and approval.

External contractors perform maintenance of buildings and facilities. This includes regular scheduled maintenance of lighting systems, air conditioning, heating systems, landscaping and cleaning (modify as appropriate). Repairs to buildings and other such facilities are contracted as needed.

Purchasing is responsible for coordinating and managing maintenance contracts.

Refer to the following procedures:

* *Procedure* QP705: Purchasing

### Process equipment

Procurement of new and/or modification of existing process equipment (including hardware and software) is planned in conjunction with development of manufacturing processes, as defined in Section 7.1.

### Supporting services

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

* 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

### Equipment maintenance

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.

Refer to *Procedure QP602: Equipment Maintenance.*

## Work environment

### Human factors

This section addresses general requirements for the work environment as applied to an ISO 9001 system. ISO 13485 emphasises controlling the physical environment of production areas rather than the "workplace" environment. This section can be deleted if compliance with ISO 9001 is not required.

Human resources and departmental managers are responsible for ensuring suitable physical, social and psychological conditions in the workplace including temperature, lighting, cleanliness and interaction between employees.

Production and quality assurance are responsible for identifying operations where extreme environmental conditions could impact product quality. Where appropriate, limits of exposure and/or mitigating measures are defined and implemented for these operations.

For legal reasons, it is preferable to keep Health and Safety management systems separate from quality management. Edit this section to reflect how H&S is administrated in [Company].

The health and safety management system is independent from the QMS. It is administrated by human resources and is documented in the Health and Safety manual.

### Work environment in production and storage areas

This section is based on ISO 13485 clauses 6.4 a) through d). Delete any that don't apply. However, issues such as general cleanliness, clothing and contamination control apply to most workplaces. Coordinate this section with procedure QP603.

The work environment is properly controlled in areas where environmental conditions could adversely affect product quality. The following are controlled:

* Health, cleanliness and clothing of personnel where contact between personnel and product or the work environment could adversely affect product quality. Requirements for health, cleanliness and clothing of personnel are established and documented.
* Conditions where the work environment can adversely affect product quality. Requirements for environmental conditions and monitoring are defined and documented. Environmental control systems are periodically inspected to verify that the systems and equipment are adequate and functioning properly.

The last sentence is from CFR 820.70(c).

* Contaminated product where special arrangements are established and documented for control of contaminated or potentially contaminated product in order to prevent contamination of other products, the work environment and/or personnel.
* Training where personnel who work under special environmental conditions are appropriately trained. Personnel who work or temporarily enter controlled areas are trained in appropriate procedures or are supervised by a trained person.

Refer to *Procedure QP603: Production and Work Environment*.

# Product realisation

## Planning for product realisation

The term "design transfer" is used in this heading to establish a link to CFR 820.30(h) Design Transfer. However, this is actually used in CFR 820 Subpart C - Design Controls.

ISO 13485 is not specific about how the manufacturing and inspection/testing program is planned and documented but it does require that it is planned and documented is some form.

Planning for production processes and product verification activities include the determination of:

* requirements and quality objectives for products and processes
* the need to develop production processes; establish process specifications, operator instructions and other such documentation; and provide training to process operators
* required product verification, inspection and test activities, and the criteria for product acceptance
* records needed to provide evidence of product and process conformity

This manual uses the Work Order (a job traveller) to define the manufacturing processes and inspection/ testing activities necessary to produce and verify product. If Work Orders are not used, develop an alternative system, for example, process flow charts, control plans, etc. for each product (or family of products).

### Risk Management

Risk management is a new requirement of ISO 13485. Procedure QP701 describes this activity.

Risk analysis studies are conducted for key manufacturing and product realisation processes. This identifies high-risk activities and focuses controls on those higher risk areas to reduce the risk.

Refer to *Procedure QP708: Production Work Order and History Record* and *Procedure QP701: Production Planning and Risk Management*.

## Customer-related processes

### Determination of requirements related to the product

The company determines customer requirements by identifying the following:

* requirements specified by the customer
* requirements not stated by the customer but necessary for intended use
* statutory and regulatory requirements
* any additional requirements determined by [Company]

Refer to *Procedure QP702: Order Processing and Review*.

### Review of requirements related to the product

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

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

The confirmation would typically be by e-mail or fax or by repeating the order requirements back to the customer (refer to procedure). Delete below if verbal orders are not taken.

When the customer provides no documented statement of requirements (e.g. verbal orders), the customer requirements are confirmed before acceptance.

Changes or amendments to orders are processed and reviewed using the same procedures as for initial orders. Changes to orders are communicated to all functions within the company that may be affected.

Refer to *Procedure QP702: Order Processing and Review*.

### Customer communication

There are no specific requirements for personnel communicating product information to customers. Modify this clause to reflect the practices of [Company].

Marketing is responsible for developing and controlling the [Company] brochures, catalogues, internet site and other forms of promotional and product information. These communications are based on technical specifications developed by design engineering. Only designated personnel from marketing, sales, customer service and engineering are authorised to communicate with customers regarding product information. The customer service manager is responsible for designating which personnel are authorised and for supporting them with training and current product information.

Refer to the following documents:

* *Procedure QP702: Order Processing and Review*
* *Procedure QP801 Feedback and Customer Satisfaction*
* *Procedure* QP809 Customer Complaints.

## Design and development

### Design and development planning

If [Company] does not design products, an exemption can be claimed from ISO 13485 Clause 7.3. Remove this section and document reasons in the exclusions section of this manual.

Each product is designed by the chief engineer to an agreed development plan. The plan determines:

* the design and development stages
* the review, verification and validation appropriate to each stage
* personnel responsible for each stage

### Design and development inputs

Design input requirements are developed by design engineering from product concepts and include:

* product briefs
* sketches
* models
* prototypes

Design inputs are reviewed and approved before they are used in design.

### Design and development outputs

Design outputs include:

* documents
* samples
* models
* mathematical data
* software

Products are considered developed when they:

* meet the input requirements
* 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

Developed products are registered by the regulatory agency in the country or territory in which they are to be sold. The information required to register the product will be documented (and such documentation approved) by suitably trained and experienced product development and regulatory affairs staff.

Design output documents are approved before release to production. Design output documents are organised in a DMR.

Refer to *Procedure QP401: Document Control* and *Procedure QP402: Device Master Record*.

### Design and development review

Design reviews are performed at appropriate development stages in accordance with the design project plan. The purpose of the design reviews is to evaluate the ability of the design to meet design input requirements and to identify any problems and propose necessary corrective actions.

Participants in design reviews include representatives of functions concerned with the design stage being reviewed, and other specialist personnel as appropriate. All design reviews are documented.

### Design and development verification

Transfer of product manufacture to production includes technology transfer, validation, 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.

### Design and development validation

Validation of each product is performed using approved test plans, test protocols and checklists as described in the [Company] validation policy. Validation activities are performed prior to delivery or implementation of the product and records are maintained.

Records of the results of device design verification and validation, and any necessary actions are maintained.

Refer to *Procedure QP710: Validation of Processes and Software*.

### 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. Design changes are reviewed, verified and validated, as appropriate, before implementation.

Refer to *Procedure QP703: Design Control*.

## Purchasing

This selection details evaluation and monitoring of suppliers, purchasing and verification of purchased product. These elements are covered by procedures QP705, Supplier Evaluation and Monitoring, QP706, Purchasing and QP707 Verification of Purchased Product. Modify the procedures as required and then ensure this section matches.

### Purchasing process

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

Purchasing and quality assurance conduct supplier evaluations and those who meet requirements are added to the approved supplier list.

Quality assurance monitors supplier quality performance. Suppliers with inadequate performance are requested to implement corrective actions. If corrective actions are not implemented and/or are not effective, the supplier may be removed from the approved supplier list.

Purchasing maintains the approved supplier list. Orders for materials, components and subcontracted services are only placed with vendors on the list.

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.

Refer to the following documents:

* *Procedure QP705: Supplier Evaluation and Monitoring*
* *Procedure QP706: Purchasing*

An approved supplier list is not explicitly required by ISO 13485 but communicating supplier status within the organisation is required. Refer procedure QP705.

### Purchasing information

Review and approval of purchasing documents is not explicitly required in ISO 13485 but there is a requirement to ensure adequacy of specified requirements contained in purchase orders. Refer procedure QP706.

The purchasing department prepares purchasing documents. [Company] ensures that the purchased product conforms by providing relevant documentation to the supplier including relevant specifications, procedures and processes to determine conformance.

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

Refer to *Procedure QP706: Purchasing*.

### Verification of purchased product

Purchased products are inspected prior to use in production and/or dispatch. Quality assurance is responsible for selecting appropriate methods for purchased product verification and acceptance. Testing and inspection are performed to approved specifications and procedures.

Delete below if not applicable.

When verification of purchased product is to be performed at a supplier's premises, purchasing documents specify the intended verification arrangements and method of product release.

Refer to *Procedure QP707: Verification of Purchased Product*.

## Production and service operations

### Control of production and service provision

Device manufacturing and provision of associated services are carried out under controlled conditions. The specific requirements and controls are identified below.

The following clauses correspond to ISO 13485 Clause 7.5.1.1 a) through g). Control of each item is demonstrated by referencing activities and related procedures. Retain the format of this section to ensure all sections are covered. Ensure this also reflects the company’s activities and any changes.

#### General Requirements

1. Product and process information and work instructions - information and instructions specifying product characteristics and manufacturing processes are communicated to process operators in the form of work orders, drawings, specifications, samples, work instructions and/or product-specific templates and tooling. Information is developed during product design and in production and quality planning.
2. Process equipment - process equipment, machines, hardware and software are selected on their ability to consistently produce products and provide services that meet specified requirements. Selection and maintenance of process equipment is documented. Refer to *Procedure QP701: Production Planning and Risk Management* and *Procedure QP602: Equipment Maintenance*.
3. Monitoring and measuring devices - requirements for measuring and monitoring devices are determined in accordance with product and process monitoring and measurement programs defined in product realisation planning. The system for managing and controlling measuring and monitoring devices is documented. Refer to Procedure QP715: Measuring and Monitoring Equipment.
4. Monitoring and measurement activities - monitoring and measurement of product is implemented through receiving, in-process and final inspection, as defined in procedures. Refer to *Procedure QP707: Verification of Purchased Product*, *Procedure QP803: In-process Inspection* and *Procedure QP804: Final Acceptance Inspection*.
5. Product release and delivery - products are released for delivery only after all specified production activities have been satisfactorily completed and conformity of the product and associated Device History Record has been verified. Refer to *Procedure QP804: Final Acceptance Inspection* and *Procedure QP714: Storage and Delivery*.

If installation and servicing do not apply, delete or edit clause f. (following) accordingly and delete and/or edit the associated procedure.

1. Installation and servicing - device installation and servicing specifications and instructions are developed as part of the device design project, subject to applicable controls specified. The system for controlling installation and servicing operations is defined in a procedure. Refer to *Procedure QP711: Installation and Servici*ng and *Procedure QP703: Design Control*.
2. Labelling and packaging - labelling and packaging are considered to be part of the device itself. All components, processes and activities related to labelling and packaging meet the same requirements that apply to the design and manufacturing of the device. Application of quality system controls to labelling and packaging are documented. Refer to *Procedure QP713: Labelling and Packaging*.

#### Cleanliness of product and contamination control

Documented requirements for cleanliness of product are established when product cleanliness is of significance, and when the product is to be cleaned for any reason and at any time prior to use. A procedure is in place to define who is responsible for defining these requirements, and how cleaning processes are developed, validated and implemented.

Devices that may have been biologically contaminated are labelled ‘BIO HAZARD’ and are immediately moved to a special decontamination area. A procedure defines how to identify, handle, segregate and decontaminate such devices.

This applies to devices that have been used by customers or in trials or demonstrations, and may be contaminated (typically with blood or other bodily fluids). Delete this clause if it does not apply.

For other types of contaminants that do not create a bio-hazard, products that are suspected of being contaminated are handled, identified and processed accordingly.

Refer to *Procedure QP80: Control of Non-Conforming Product* and *Procedure QP709: Cleanliness and Contamination of Product*.

#### Installation activities

Installation may be not applicable, performed by [Company] or agent prior to "delivery" or performed by customer/user after delivery. This section describes the third case (refer QP711). However, modify to reflect [Company] practices.

Product installation instructions are developed as part of the product design project, subject to applicable controls and published in a booklet enclosed with the product.

Development, validation and control of installation instructions are documented.

Refer to *Procedure QP711: Installation and Servicing* and *Procedure QP703: Design Control*.

#### Servicing activities

If servicing (either directly or indirectly) of products is not performed, state that servicing of products is not performed by [Company].

If servicing is subcontracted, explain the procedures, selection of sub-contractors and controls (including customer feedback and corrective actions).

Servicing is concluded by verifying that the servicing meets specified requirements. Checklists, inspection instructions and test procedures are documented and servicing personnel are trained in their use.

Servicing diagnosis, repairs and verification results are recorded in a service report. As a minimum, the report includes the:

This list is from CFR 820.200, delete or edit as applicable.

* name of the product serviced
* product serial or batch number
* date of service
* technician servicing the device
* service performed
* test and inspection data

Service reports are analysed with appropriate statistical methods to identify any systematic failures and quality problems that need to be addressed.

Service requests associated with allegations of serious injury or death are automatically considered as complaints and recorded and investigated, in accordance with, to determine whether the complaint represents an event which must be reported to the TGA.

Refer to *Procedure QP711: Installation and Servicing* and *Procedure QP809: Customer Complaints*.

#### Particular requirements for sterile medical devices

Insert as appropriate or delete.

### Validation of processes for production and service provision

Production, engineering and quality assurance are responsible for identifying, validating and documenting processes for production and services.

Examples of special processes are: joining of materials by welding, soldering, splicing, gluing; moulding and casing of metals, plastics or cements; coating with paints, epoxies, metals, plastics or other materials; heat, radiation or chemical treatment of materials; etc.

Delete if sterilisation does not apply.

The sterilisation process is validated and qualified using a documented validation protocol and records maintained.

Computer software is validated prior to use if it controls production processes or if its malfunction could result in product non-conformity. This also applies to software used in quality control (equipment or instruments).

Refer to *Procedure QP710: Validation of Processes and Software*.

#### Particular requirements for sterile medical devices

Insert as required or delete.

### Identification and traceability

#### Identification

Materials, components and finished devices are identified throughout all stages of production and in storage.

Refer to the following documents:

* *Procedure QP712: Product Identification and Traceability*
* *Procedure QP708: Production Work Order and History Record*
* *Procedure* QP713: Labelling and Packaging

#### Traceability

Traceability is maintained when required by applicable laws and regulations or when specified internally to facilitate corrective actions. Traceability is based on identifying the finished devices or batches with unique numbers. Activities related to maintaining and recording traceability are documented.

Refer to *Procedure QP712: Product Identification and Traceability* and *Procedure QP708: Production Work Order and History Record*.

If traceability is not applicable, a claim for exemption from this clause can be made. However, if traceability is a requirement, refer procedures QP712 and QP708. Ensure these procedures and this section match.

In this documentation, detailed instructions for identification of inspection status are provided directly in the referenced inspection and product verification procedures.

Include particular requirements for active implantable medical devices and implantable medical devices

#### Status identification

Amend as required or delete

### Customer property

If products are not received from customers, an exemption may be claimed (then delete this section).

Customer property includes samples, materials, components and parts intended for production, returnable packaging materials, manufacturing equipment and tooling, special gauges, templates, measuring and testing equipment or software and engineering drawings and specifications.

Customer-supplied products are received and inspected following the same procedure that applies to purchased products. In the event the supplied products fail inspection or are not suitable for any other reason, the customer is contacted.

Marking, storage, handling and preservation of customer-supplied products follow the same procedures that apply to the purchased products.

Refer to the following documents:

* *Procedure QP712: Product Identification and Traceability*
* *Procedure QP714: Storage and Distribution*
* *Procedure QP707: Verification of Purchased Product*

Refer to any other procedures that would apply to customer's products.

Customer-owned tooling, gauges and returnable packaging are permanently marked so that ownership of each item is apparent.

Customer's software, documents and other intellectual property are protected to the same extent, as would internal documents of similar content. Additional measures may be required if there are contractual requirements for special measures to protect the customer's intellectual property.

When specified in a contract, special handling instructions from customers will take precedent over [Company]'s standard procedures.

For example, customers may require that their products be segregated and identified in a special way.

Customers are immediately informed in the event of loss, damage, deterioration, or unsuitability of their products.

### Preservation of product

During internal processing and final delivery to the customer, the 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

Production is responsible for product handling and preservation and in particular:

* for ensuring that containers holding products are suitable and are in good condition
* that equipment used for internal transportation of products is well maintained and is properly operated
* that products are adequately protected during production and storage

Refer to *Procedure QP709: Cleanliness and Contamination of Product* and *Procedure QP714: Storage and Distribution.*

Storage, stockrooms and storage, staging and holding areas:

* are controlled by the department that brings in new stock or uses the area
* are appropriate to ensure adequate preservation and protection of product

Procedures and/or work instructions are established for control of product with limited shelf-life or requiring special storage conditions (*Procedure QP714: Storage and Distribution).*

Primary packaging includes boxes, bags or other packaging in which products are presented to the customers and patients. Primary packaging and labelling are considered to be part of production processes and are controlled as defined in a procedure (*Procedure QP713: Labelling and Packaging).*

Secondary packaging includes cardboard boxes, crates or additional packaging intended to contain and protect products for shipping and transportation.

Modify clause to accurately identify the nature of primary and secondary packaging, as used at [Company].

## Control of monitoring and measuring devices

This section is a brief summary of procedure QP715. Review and modify QP715, as required, then adjust this section accordingly.

Appropriate measuring and monitoring devices are selected to ensure that their measurement capability is consistent with the measurement requirements. Devices used for ensuring and verifying product conformity are calibrated against an appropriate, traceable standard. Refer to *Procedure QP715: Measuring and Monitoring Equipment*.

### Measuring and monitoring devices calibration and maintenance

The scope of calibration control extends to measuring and test equipment, comparative reference hardware (e.g. gauges, templates) and software used for:

* setup and monitoring of production processes
* monitoring of environmental conditions
* verification of product conformity
* operations where defined accuracy of a measurement is required to assure product conformity

Quality assurance is responsible for calibrating and maintaining measuring and monitoring devices. All active devices are inventoried in a controlled list, indicating their calibration status and location.

Measuring devices are checked, adjusted and re-adjusted as necessary and are calibrated at specified intervals (or prior to use) against measurement standards traceable to international or national standards.

Calibration is recorded in a calibration certificate and the calibrated devices are labelled with a calibration sticker to identify their calibration status.

Measuring and monitoring devices are safeguarded from adjustments that would invalidate the measurement result.

Measuring and monitoring devices are protected from damage and deterioration during handling, maintenance and storage.

### Validity of measurements made with non-conforming devices

When measuring equipment is found not to conform to requirements, previous measuring results are reassessed and appropriate action taken on the equipment and any product affected.

### Validation of software

Inspection, test, and monitoring software developed in-house is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

# Measurement, analysis and improvement

## General

Measurement and monitoring activities to ensure and verify product conformity are defined in engineering specifications and drawings, production work orders, inspection and testing procedures and process control procedures.

Refer to the following documents:

* *Procedure QP707: Verification of Purchased Product*
* *Procedure QP803: In-process inspections*
* *Procedure QP804: Final inspection*

Edit to reflect the types of activities at [Company]. Delete references to QP803 if not relevant.

The conformity and effectiveness of the QMS is monitored by internal audits and measuring quality performance. Results of these activities are reported to high-level management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are defined in procedures.

Refer to *Procedure QP802: Internal Quality Audits* and *Procedure QP801: Feedback and Customer Satisfaction.*

### Statistical analysis

As applicable, statistical techniques may be applied to the following types of activities:

Add or delete as applicable.

* testing and validation of designs
* set up of process equipment
* testing and validation of processes
* control of process stability and performance
* establishment of sampling plans for inspections and testing
* evaluation of measurement systems
* analysis of quality performance and other company-level data

Departmental managers are responsible for identifying the need for using statistical techniques in their departments and in other activities for which they are responsible. Quality assurance may be called upon to assist other departments in selecting and documenting specific techniques.

This clause reflects CFR 820.250 Statistical Techniques. The regulation requires that sampling plans be documented and be based on valid statistical rationale. Procedures must exist to control the establishment, use and changes to sampling plans.

This documentation does not have a specific procedure for controlling sampling plans but rather considers them as part of inspection/testing procedures.

### Sampling plans

Sampling plans for inspections, testing and other product and process acceptance activities are documented. Sampling plans are reviewed and approved by quality assurance to ensure they are based on valid statistical rationale and are appropriate.

Sampling plans are issued and controlled as work instructions and are either included with the inspection/testing instructions to which they pertain or are issued as independent documents.

Sampling plans are reviewed and re-evaluated when there is a significant change in reject rates or when a non-conforming product is shipped or otherwise identified after passing its acceptance inspection. Re-evaluation of a sampling plan is carried out within the framework of the pertinent corrective action and the plan is revised and reissued.

## Monitoring and measurement

### Feedback

Some regulators require companies to gain experience from the post-production phase. If appropriate, expand on this section and the associated procedure to define the use of post-production feedback.

Customer satisfaction is a requirement of ISO 9001 only. To comply with ISO 13485 only, simplify the second part of this section to focus on collecting information about customer requirements rather than the broader customer satisfaction.

The post-production feedback system provides early warning of quality problems and input into the corrective and preventive action processes. The following sources of information are used:

Edit to coordinate with Procedure QP801.

* customer, user and patient complaints
* defective or otherwise non-conforming product returned by customers
* servicing records
* monitoring orders for spare parts
* clinical evaluations
* reviews and articles in trade and professional publications

Information and data pertaining to customer satisfaction is collected from several sources, including:

* customer complaints and other feedback
* customer satisfaction surveys
* product returns and warranty claims
* repeat customer rates
* market share

Coordinate this list with Procedure QP801

Refer to Procedure *QP801: Feedback and Customer Satisfaction* and *Procedure QP809: Customer Complaints*.

### Internal audit

Quality assurance is responsible for conducting internal audits to determine whether the QMS:

* conforms to quality plans
* conforms to management system requirements as defined in this quality manual and operational procedures
* conforms to the requirements of the ISO 9001, ISO 13485 and 21 CFR 820
* is effectively implemented and maintained

Internal 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.

Appropriate corrective actions are taken by management personnel responsible for the areas where non-conforming processes and/or practices are identified. Auditors follow up to ensure that actions taken are implemented and effective.

Refer to *Procedure QP802: Internal Audits*.

### Monitoring and measurement of processes

ISO 13485 Clause 8.2.3 applies to "QMS processes". Some include product realisation processes in this. ISO 9001 Clause 3.2.3 defines a QMS as "management system to direct and control an organisation with regard to quality." On this basis product realisation processes are not considered in this section.

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

Items in this list are mandatory as they are specified elsewhere in the standard. Further, process specific items may be added.

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

To meet ISO 13485 only, the following dot-point may be changed to "monitoring information related to meeting customer requirements."

* monitoring information related to meeting customer requirements

When a quality system process does not conform to requirements, quality assurance initiates a corrective action request to address the problem.

Refer to *Procedure QP810: Corrective and Preventative Actions*.

### Monitoring and measurement of product

This section summarises the three inspection procedures QP707 Verification of Purchased Product, QP803 In-process Inspections and QP804 Final Acceptance Inspection. Edit these procedures to reflect [Company] practices then modify this section appropriately.

Products are defined in drawings and specifications, work orders, purchasing documents and inspection and testing procedures. Documents defining the inspection and testing program are collectively referred to as control plans.

Modify to include the types of documents relevant to [Company]. Ensure coordination of this with Section 7.6.

All purchased products are subjected to a visual inspection. Some designated products are subjected to a detailed and technical quality control inspection. Processes for performing these inspections are documented.

Refer to *Procedure QP707: Verification of Purchased Product*.

Coordinate with Procedure QP707.

In-process inspections are in the form of first article inspections, operator and quality control inspections, continuous product verification by automated inspection equipment and SPC [Statistical Process Control]. The focus is on defect prevention rather than detection. Systems for performing in-process inspections are documented.

Refer to *Procedure QP803: In-process Inspections* and *Procedure QP803: Statistical Process Control*.

List only the types of in-process inspections that apply. If statistical process control is not use, delete references to SPC. A procedure for in-process inspections is not explicitly required in the standard and may not be necessary or relevant. Refer QP803.

Finished products are subjected to the final quality control inspection. Inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily. Remaining inspections and tests necessary to complete the evidence of product conformity are then performed. Only devices that pass final inspection are distributed. Results of inspections and tests are recorded and filed.

Devices are released for distribution when all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorising product release is recorded.

Refer to the following documents:

* *Procedure QP804: Final Acceptance Inspection*
* *Procedure QP708: Production Work Order and History Record*
* *Procedure QP403: Control of Records*

## Control of non-conforming product

The review and disposition of non-conforming product is the responsibility of quality assurance. When non-conforming product is identified, it is evaluated to determine whether it should be reworked, accepted or rejected. To prevent non-conforming products being shipped, they are labelled appropriately.

If reworking is required, this is documented in written rework instructions that undergo the same authorisation and approval as the original work. Reworked products are re-inspected to demonstrate conformity to original requirements. These verification activities are carried out in accordance with applicable inspection instructions and procedures.

To prevent a re-occurrence of a problem, an investigation into the cause of the non-conformance 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:

Modify this list to reflect what is used in [Company].

* evaluation and pre-qualification of suppliers
* assessment of subcontractor's manufacturing processes
* assessment of subcontractor'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.

Refer to the following documents:

* *Procedure QP803: In-process Inspections*
* *Procedure QP 805: Control of Non-Conforming Product*
* *Procedure QP810: Corrective and Preventative Actions*

## Analysis of data

Quality Assurance coordinates the collection and analysis of appropriate data to demonstrate the suitability and effectiveness of the QMS and to identify opportunities for improvement. Refer to *Procedure QP806: Analysis of Data*.

The quality performance data focuses on providing information relating to:

* customer feedback
* conformity to product requirements
* characteristics of processes and products
* supplier quality performance

## Improvement

Continuous improvement of the QMS is a requirement of ISO 9001 only. ISO 13485 only requires that its suitability is maintained. The minimalist approach is to edit this section and the associated procedure to reflect this difference. In practice, maintenance is not very different from improvement.

The following clause explain how the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews are used to implement continual improvement and to reference relevant operational procedures.

### General

Continual improvements are identified via the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review. All changes are managed via the change control procedure.

Internal audit results and quality performance data are analysed by management to assess the effectiveness of the QMS and current organisational performance. Opportunities and priorities for improvement are identified by comparing present quality performance to goals defined in the quality policy.

Refer to *Procedure QP501: Management Review*.

### Device recall and advisory notices

The recall committee, including the CEO, quality assurance manager and production manager, is responsible for decisions regarding device recalls and issuing of advisory notices. In an emergency, and when there is no time to assemble the full committee, the CEO or quality manager is authorised to initiate a recall.

Planning of the recall, receipt of the recalled devices, communication with regulatory authorities and other activities related to recall and to issuing of advisory notices are documented.

Refer to *Procedure QP808: Device Recall and Advisory Notices*.

### Customer complaints

Customer complaints that allege deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a distributed device are logged and documented.

Complaints that involve a possible failure of a device, labelling or packaging to meet specifications and/or complaints representing an event which must be reported to regulatory authorities are always investigated and the results of the investigation documented.

Refer to *Procedure QP809: Customer Complaints*.

### Corrective action

In this manual, corrective actions and preventive actions are addressed in one section and there is only one operational procedure covering both. This is appropriate provided there are different procedures for identifying the need for corrective action and the need for preventive action. The difference between the two lies in the criteria for identifying the need, not in the implementation.

Corrective actions are taken to eliminate causes of actual non-conformities in order to prevent their recurrence.

The process for taking corrective actions includes:

* reviewing non-conformities and potential non-conformities
* determining causes for actual and potential non-conformities
* evaluating the need for action to ensure that non-conformities do not recur and that potential non-conformities are prevented
* determining and implementing actions needed, including, updating documentation
* recording results of any investigations and of actions taken
* reviewing corrective actions taken and their effectiveness

Refer to *Procedure QP810: Procedure Corrective and Preventative Actions*.

### Preventative action

Preventive actions are implemented to eliminate causes of potential non-conformities in order to prevent their occurrence.

Refer to *QP810: Procedure Corrective and Preventative Actions*.

Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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| Associated forms and procedures | |
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| Associated records | |
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