

The Company

Quality Manual

ISO 13485:2003
ISO 9001:2008

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1 General

1.1 Purpose and scope

This Quality Manual documents QW Enterprises, LLP (the Company)'s Quality Management System to demonstrate its ability to consistently provide product that meets customer and regulatory requirements *applicable to medical devices and related services*. This manual establishes compliance with those standards and regulations listed in the [Applicable standards and regulations](#) section of this Manual. This Manual applies to research and development, production, sales, marketing, installation and servicing activities conducted by the Company. This Manual follows the format of ISO 13485:2003 standard.

1.2 Application

Where any requirements of ISO 13485:2003, Clause 7, cannot be applied due to the nature of the Company's activities and its products, they will be considered for exclusion.

The Company's Quality Management System satisfies the full range of requirements of ISO 13485:2003 and ISO 9001:2000 standards.

1.3 Applicable standards and regulations

1.3.1 [ISO 13485:2003 – Medical devices – Quality management systems – Requirements for regulatory purposes](#)

1.3.2 [ISO 9001:2008, Quality management system – Requirements](#)

1.3.3 [FDA 21 CFR 820, Quality System Regulation \(QSR\)](#)

1.3.4 [Council Directive 93/42/EEC of 14 June 1993 concerning medical devices](#)

1.3.5 [Medical Device Regulations \(Canada\)](#)

2 Company information

The Company is located at 123 Innovation Drive, Sun City, AS, 123456, USA. The Company designs, manufactures, distributes and services XY products.

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3 Definitions and Conventions

Applicable standards

- Where the term *applicable standards* is used in the Manual, documents listed in the [Applicable standards and regulations](#) section of this Manual apply.

NC-CAPA - Non-conformity and Corrective & Preventive Action.

Management Team

- President and Directors form the Management Team. The Management Team has executive responsibility for performance of all business systems, including Quality Management System.

QMS - Quality Management System.

[XYZ Procedure](#) - Underlined procedures and standards in the body of the Manual identify reference documents supporting a particular element of the manual. These hyperlinks lead to the corresponding documents within the Company's QMS structure, sections of the Manual, or to the [Documentation Master List](#) for external documents.

Blue italic text - *Blue italic text identifies specific requirements of ISO 13486:2003.*

4 Quality management system

4.1 General requirements

the Company has established, documented, implemented, and maintains a QMS in accordance with the requirements of [Applicable standards and regulations](#). The Company continually *maintains* and improves the effectiveness of its QMS. The Company's QMS:

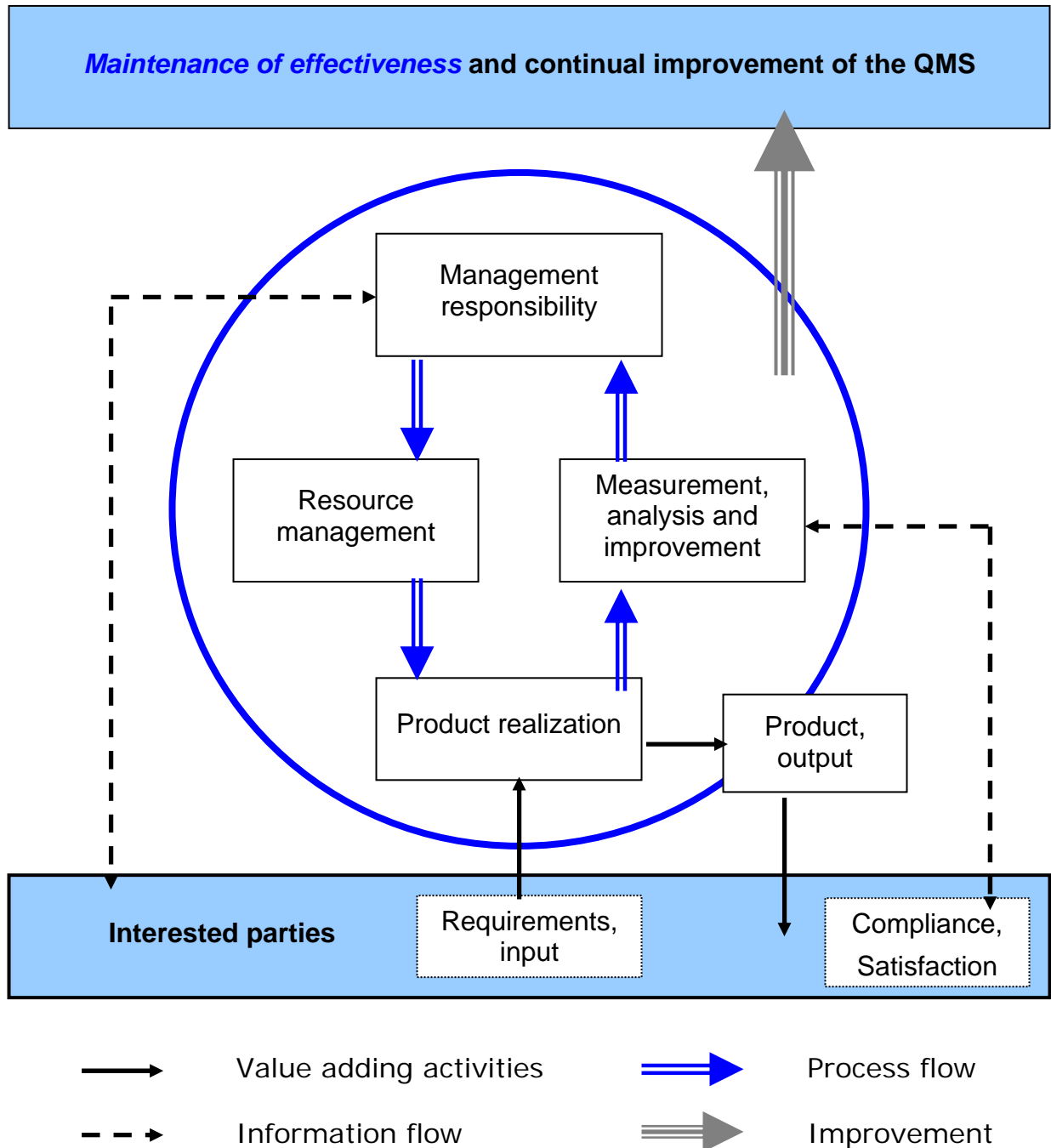
- a) Identifies the processes needed for its operations and their application throughout the organization,
- b) Determines the sequence and interaction of these primary processes per Figure 1, Interaction of main processes,
- c) Determines criteria and methods needed to ensure that both the operation and management of these processes are effective,
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Ensures monitoring, measurement and analyses of these processes, and
- f) Ensures implementation of actions necessary to achieve planned results, *maintain the effectiveness* and continual improvement of these processes.

The Company manages these processes in accordance with the requirements of [applicable standards](#).

Where any process that affects product conformity with requirements is outsourced, the Company ensures management of such processes. Methods of management of outsourced processes are identified per the [Purchasing Procedure](#).

Processes needed for the QMS referred to above include processes for management activities, provision of resources, product realization and measurement.

4.1.1 Figure 1, Interaction of main processes



4.2 Documentation requirements

4.2.1 General

The Company's QMS documentation includes:

- a) Documented statements of the [Quality Policy](#) and quality objectives per the [Quality Objectives](#) matrix,
- b) This Quality Manual,
- c) Documented procedures required by [applicable standards](#),
- d) Documents needed by the organization to ensure the effective planning, operation and management of its processes,
- e) Records required by [applicable standards](#) per the [Records Procedure](#), and
- f) *Any other documentation specified by national or regional regulations*

Where the term *documented procedure* appears within this Manual, the procedure is established, documented, implemented and maintained.

For each type or model of medical device, the Company has established and maintains a Technical File per the [Technical File ToC](#). This file either contains or references documents defining product specifications and QMS requirements. The Technical File includes the complete manufacturing process including installation and servicing.

The extent of the Company's QMS is based on:

- a) The size of the organization and type of its activities,
- b) The complexity of processes and their interactions per the [Process Interaction Matrix](#), and
- c) The competence of personnel per the [Resource Management Procedure](#) and [Training Procedure](#).

The Company maintains its documents on various media such as paper, electronic, magnetic, optical, etc.

4.2.2 Quality Manual

The Company has established and maintains this Manual that includes:

- a) The scope of the QMS, including details of and justification for any exclusions *and or non-application* per the [Application](#) section of this Manual,
- b) Reference to the documented procedures established for the QMS,
- c) A description of the interaction between the processes of the QMS, and
- d) *Outlines the structure of the documentation used in the QMS.*

4.2.3 Management of documents

Documents required by the QMS are managed per the [Documentation Management Procedure](#). Records are a special type of document and are managed per the [Records Procedure](#).

The [Documentation Management Procedure](#) is established to define the means needed to:

- a) Approve documents for adequacy prior to issue,
- b) Review and update as necessary and re-approve documents,
- c) Ensure that changes and the current revision status of documents are identified,
- d) Ensure that relevant versions of applicable documents are available at points of use,
- e) Ensure that documents remain legible and readily identifiable,
- f) Ensure that documents of external origin are identified and their distribution managed using the [Documentation Master List](#), and
- f) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The [Documentation Management Procedure](#) *ensures that changes to documents are reviewed and approved either by the original approving function or another designated function, which has access to pertinent*

background information.

The [Records Procedure](#) defines the period for which at least one copy of obsolete controlled documents are retained. This period ensures that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record, or as specified by relevant regulatory requirements.

4.2.4 Management of records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Mechanisms are established for records to remain legible, readily identifiable and retrievable. A documented [Records Procedure](#) is established to define the means needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The Company retains the records for a period of time at least equivalent to the lifetime of the medical device as defined by product Technical Files, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements per the [Records Procedure](#).

5 Management responsibility

5.1 Management commitment

The Company's Management Team provides its commitment to the development and implementation of the QMS and *maintaining* and continually improving its effectiveness by:

- a) Communicating to the personnel the importance of meeting customer as well as statutory and regulatory requirements per the [Communication Procedure](#),
- b) Establishing the [Quality Policy](#).