The Company

Quality Manual

ISO 13485 2003
ISO 9001 2008
FDA 21 CFR 820 QSR

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1 General

1.1 Purpose and scope

This Quality Manual documents 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 or ISO 9001 2008, 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)

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.

Phone:	(123) 123-4567
Fax:	(123) 123-4568
Web site:	www.qwmedical.com.

3 Definitions and Conventions

Applicable standards
- Where the term '*applicable standards and regulations'* 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 italicized text
- *Blue italicized text defines specific requirements of ISO 13486 2003.*

Red text - Red text identifies specific requirements of 21 CFR 820 QSR. If a requirement of the QSR is addressed through ISO 13485 2003 or ISO 9001 2008, it is not repeated.

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:

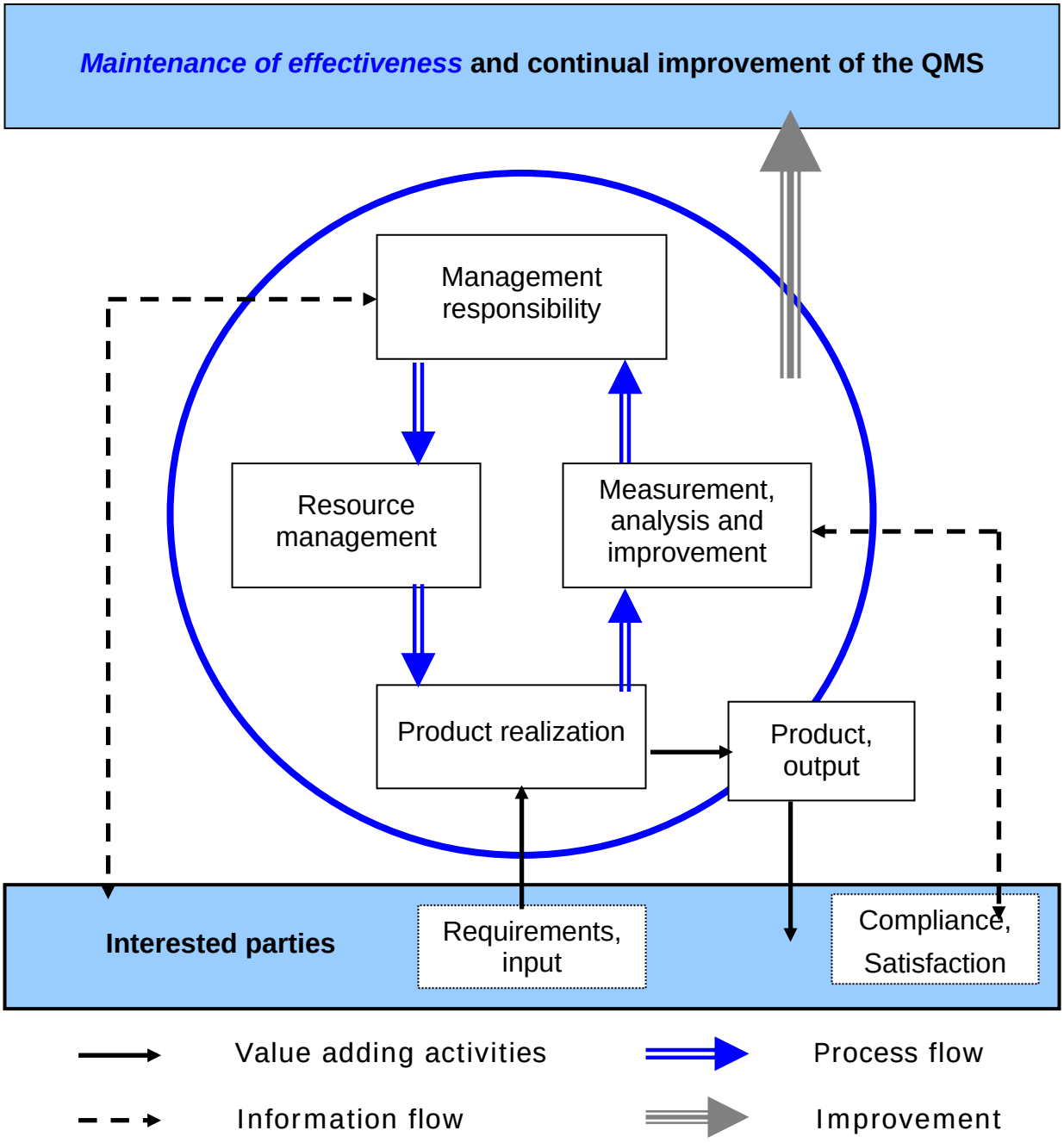
a) Identifies the processes needed for its operations and their application throughout the organization,
b) Determines the sequence and interaction of these primary processes per Figure 1, Interaction of main processes,
c) Determines criteria and methods needed to ensure that both the operation and management 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 the applicable standards and regulations.

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 and regulations,
d) Documents needed by the organization to ensure the effective planning, operation and management of its processes,
e) Records required by applicable standards and regulations 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.

QSR 820.186 The Company maintains this Quality manual that includes, or refers to the location of procedures and the documentation of activities required by the QSR that are not specific to a particular type of device(s), including, but not limited to, the records required by the quality management system. The Company ensures that the Quality Manual is prepared and approved in accordance with the Documentation Management Procedure.

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

9 21 CFR 820 v. this manual

21 CFR 820		This manual
Section	**Description**	**Clause**
Subpart A	**General provisions**	**Title**
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820.20 (d)	Quality planning	5.4.2
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10 Revision history and master verification

Rev.	DCR	Description of change	Master verified	Date
01		Initial release		