QW Medical, LLP

Aeronautics Division

Quality Manual

SAE AS9100:2004

Revision D1

0 Table of contents

1 General

1.1 Purpose and scope

This Quality Manual documents QW Medical, LLP's quality management system to demonstrate the company's ability to consistently provide product that meets customer and regulatory requirements. This manual establishes compliance with those standards and regulations listed in the Applicable standards and regulations section of this manual. This Quality Manual applies to design and development, production, sales, marketing, installation and servicing activities conducted by QW Medical, LLP. This manual follows the format of SAE AS9100 Standard for quality management systems for aerospace industry.

1.2 Application

Where any requirements of SAE AS9100 Revision B Standard cannot be applied due to the nature of QW Medical, LLP's activities and its products, they will be considered for exclusion. QW Medical, LLP's QMS satisfies the full range of the requirements of SAE AS9100 Revision B Standard.

1.3 Applicable standards and regulations

1.3.1 SAE AS9100 Revision B, Quality management Systems – Aerospace – Requirements
1.3.2 FAA, Department of Transportation Part 145 – Repair Station
1.3.3 PMA reference

2 Company information

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

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

3 Definitions and Conventions

All applicable standards

- Where the term *all applicable standards* is used in the Quality Manual, all documents listed in the Applicable standards and regulations section of this document apply.

BPI Matrix - Business Performance Indicator Matrix.

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

Management Team

- President and Directors form the Management Team. The Management Team has executive responsibility for performance of the business and quality system.

QMS - Quality Management System.

XYZ Procedure - Underlined procedures and standards in the body of the Quality Manual identify reference documents supporting a particular element of the manual. These hyperlinks lead to the corresponding sections of the Quality Manual, documents or to the Documentation Master List for external documents.

Blue italic text - ***Blue bold italic text identifies the additional aerospace requirements.***

Key Characteristics - The features of a material, process or part whose variation has a significant influence on product for performance, service life or manufacturability.

4 Quality management system

4.1 General requirements

QW Medical, LLP has established, documented, implemented, and maintains a QMS in accordance with the requirements of all Applicable standards and regulations. QW Medical, LLP continually improves the effectiveness of its QMS. QW Medical, LLP's QMS:

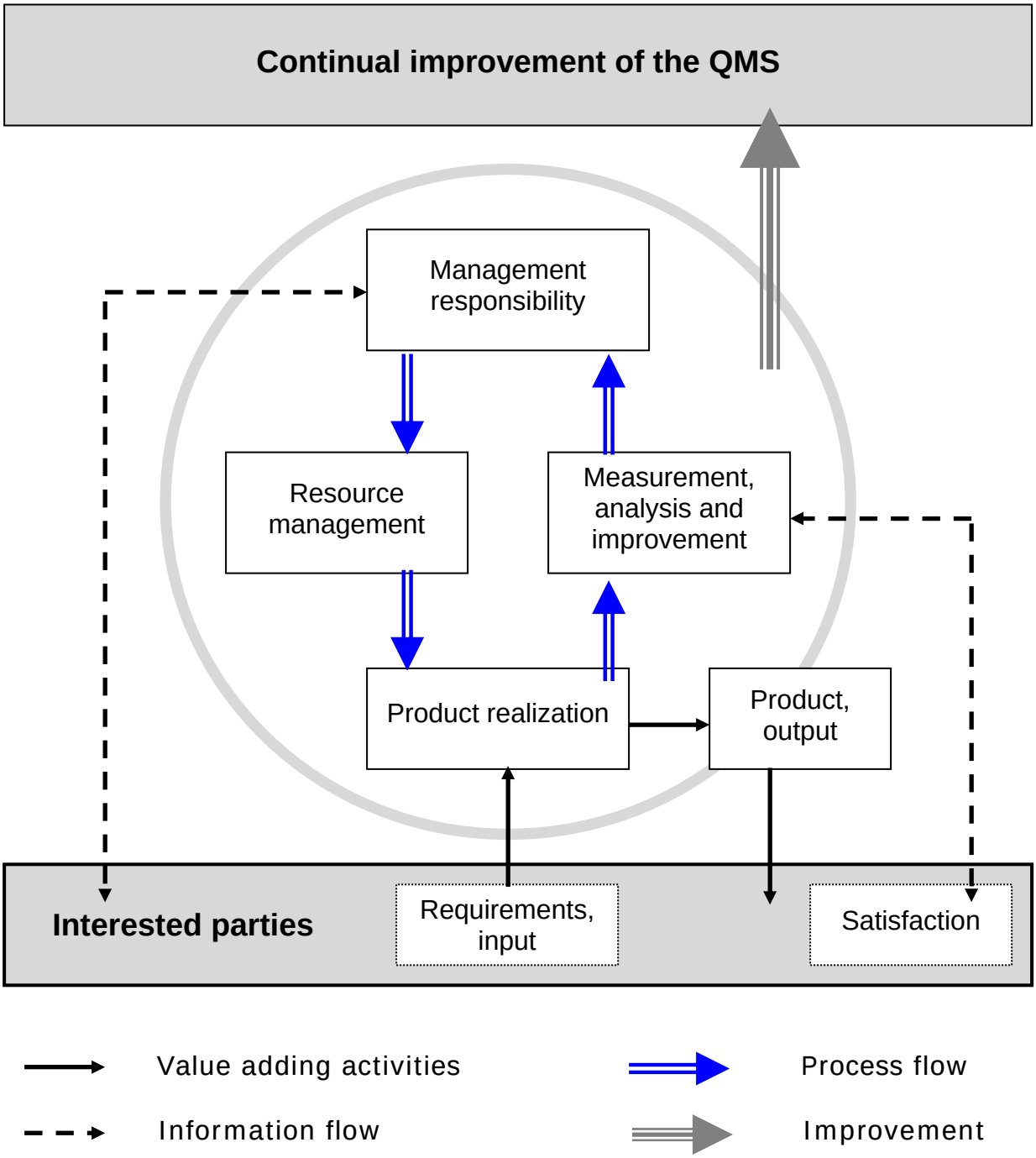
a) Identifies the processes needed for its operations and their application throughout the organization,
b) Determines the sequence and interaction of these primary processes per Figure 1, Interaction of Processes, and the Process Interaction Matrix.
c) Determines criteria and methods needed to ensure 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 and continual improvement of these processes.

QW Medical, LLP manages these processes in accordance with the requirements of all Applicable standards and regulations.

Where any process that affects product conformity with requirements is outsourced, QW Medical, LLP ensures management of such processes. Methods of management of such outsourced processes are identified within the QMS per the Supplier Partnership Program.

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, Model of a process-based QMS



4.2 Documentation requirements

4.2.1 General

QW Medical, LLP's QMS documentation includes:

a) Documented statements of the Quality Policy and quality objectives per the BPI Matrix,
b) This Quality Manual,
c) Documented procedures required by all Applicable standards and regulations,
d) Documents needed by the organization to ensure the effective planning, operation and management of its processes, and
e) Records required by all Applicable standards and regulations per the Records Procedure.
f) Quality system requirements imposed by the applicable regulatory authorities

QW Medical, LLP ensures that personnel have access to quality management system documentation and are aware of relevant procedures per the Training Procedure***. Customer and/or regulatory authorities' representatives are allowed access to relevant quality management system documentation per the*** Communication Procedure***.***

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

The extent of the QW Medical, LLP's QMS is based on:

a) The size of the organization and type of activities,
b) The complexity of processes and their interactions, and
c) The competence of personnel per the Training Procedure.

QW Medical, LLP maintains its documents on various media such as paper, electronic, magnetic, optical, etc.

specification may be dispositioned by QW Medical, LLP as use-as-is or repair, provided the non-conformity does not result in a departure from customer-specified requirements.

Product dispositioned for scrap is clearly and permanently identified and controlled, until physically rendered unusable.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, are maintained per the Records Procedure.

When non-conforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements per the Inspection Procedure.

When non-conforming product is detected after delivery or use has started, QW Medical, LLP takes action appropriate to the effects, or potential effects, of the non-conformity per the NC-CAPA Procedure.

In addition to any contract or regulatory authority reporting requirements, QW Medical, LLP's system provides for timely reporting of delivered non-conforming product that may affect reliability or safety. Notification includes a clear description of the non-conformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and daters) delivered per the NC-CAPA Procedure***.***

8.4 Analysis of data

QW Medical, LLP has established and maintains documented Management Review Procedure and the Data Analysis Procedure to determine, collect an analyze appropriate data to determine the suitability and effectiveness of the QMS to evaluate areas where continual improvements of the effectiveness of the QMS can be made. This includes data generated by monitoring and measurement and other relevant sources.

QW Medical, LLP analyzes these data to provide information related to:

a) Customer satisfaction per the Post Market Surveillance Procedure and the NC-CAPA Procedure,
b) Conformity to product requirements per the Product Realization Procedure and the NC-CAPA Procedure,
c) Characteristics and trends of process and products including opportunities for preventive action per the CAPA Procedure, and
d) Suppliers per the Supplier Partnership Program.

8.5 Improvement

8.5.1 Continual improvement

QW Medical, LLP has established and maintains documented procedures to continually improve its QMS through the use of the:

a) Quality Policy.
b) Quality objectives,
c) Audit results per the Audit Procedure,
d) Analysis of data per the Data Analysis Procedure,
e) Corrective and preventive actions per the CAPA Procedure, and
f) Management Review Procedure.

8.5.2 Corrective action

QW Medical, LLP has established and maintains a documented CAPA Procedure to eliminate the causes of non-conformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered. The NC-CAPA Procedure defines requirements for:

a) Reviewing non-conformities, including customer complaints,
b) Determining the causes of non-conformities,
c) Evaluating of the need for action to ensure that non-conformities do not recur,
d) Determining and implementing action needed,
e) Records of the results of action taken, and

f) Reviewing corrective action taken,
g) Flow-down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and
h) Specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive action

QW Medical, LLP has established and maintains documented quality plans, a Design Management Procedure and a NC-CAPA Procedure to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. Quality plans and the NC-CAPA Procedure define requirements for:

a) Determining potential non-conformities and their causes,
b) Evaluating the need for action to prevent occurrence of non-conformities,
c) Determining and implementing action needed,
d) Records of results of action taken, and
e) Reviewing preventive action taken.

9 Revision history and master verification

Rev	DCR	Description of change	Master verified	Date
D1	1007	Initial release	*Mark Wright*	1/7/09