Documents are in Microsoft Word for ease of editing

4.1 General requirements

Your company has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 13485:2003 and ISO 9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

You can search and replace "your company" with your own

To design and implement the QMS *Your Company* has:

Blue text throughout the manual highlight areas for customization

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, *and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table*
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation Requirements

4.2.1 General

Requirements of the standard are all addressed

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Any other documentation specified by national or regional regulations.
- Each procedure, activity or special arrangement that has been documented is also implemented and maintained.
- For each type or model of medical device, a file is maintained containing or identifying documents defining product specifications and quality management system requirements.
- These documents define the complete manufacturing process and, if applicable, installation and servicing.

Documents are all numbered to comply with document control requirements

1.0 Purpose

1.1 This procedure describes Management Responsibilities for the Quality Management System (QMS) at *Your Company*.

2.0 Responsibilities

2.1 Top Management is responsible for Establishing the Quality Policy, and reviewing it for continuing suitability.

2.2 Top Management is responsible for Communicating the Quality Policy, the importance of meeting regulatory and statutory and customer requirements.

2.3 Top Management is responsible for identifying the Key Processes to be included in the QMS.

2.4 Top Management is responsible for identifying the data required for effective review of the QMS.

2.5 Top Management is responsible for identifying the management review team.

2.6 It is the responsibility of the management review team to schedule and conduct management review meetings in compliance with this procedure.

2.7 The Management Representative is responsible for collecting summary reports and data from the responsible functions and for ensuring adequate employee awareness of the company's QMS.

2.8 The management review team members are responsible for bringing information and progress reports on action items assigned to them at previous management review meetings, information on planned changes that could affect the QMS, quality planning needs and activities and recommendations for improvements to the QMS.

3.0 Definitions

3.1 Top Management: *put your definition of top management here*

3.2 Management Review Team: *identify who will be on the management review team. By title of function, not individual names.*

3.3 Product realization processes: the processes that contribute or result in the product being produced or the product being provided.

3.4 Key Processes: product realization processes, customer related processes and quality management system processes that are included in the QMS.

4.0 Equipment/Software

4.1 Not Applicable

5.0 Instructions

5.1 Top Management has established a Quality Policy, and reviews it for continuing suitability during Management Review meetings.

5.2 Top Management communicates the Quality Policy and the importance of meeting regulatory, statutory and customer requirements in employee orientation training and during company and department meetings and functions.

5.3 Top Management identifies the Key Processes included in the QMS.

5.3.1 Top Management identifies the Key QMS Processes and documents them on the Key Process Master List (F-500-002)

5.3.2 Top Management identifies the Key Product Realization Processes and documents them on the Product Realization Monitoring, Measuring and Analysis Table. (F-824-001)

5.4 Identifying data required for review of the QMS Processes

5.4.1 Top Management will complete the QMS Monitoring, Measuring and Analysis Table (F-500-001)

5.4.2 The table identifies:

a) The process requiring measurement

b) The planned measurement

c) Measurement frequency

d) Function responsible for measurement

e) Function responsible for analysis

f) Analyses methodology

g) Quality Objective to measure against

h) Improvement goals

5.5 Identifying data required for review of Product Realization Processes

5.5.1 Top Management will identify what summaries are required from data generated by measuring and monitoring of product and realization processes.

a) Management will review the Product Realization Monitoring, Measuring and Analysis Table, and assign responsibility for preparing summary reports. (F-824-001) *Management will not need to review all inspection and test results, but will need to identify what data they need to see to make improvements in product realization processes. Identify the data you would like to review. This data may be in the form of summaries prepared by production management. Add these summaries to the table (F-824-001); identify the frequency that they need to be prepared.*

b) The required summaries will be added to the Product Realization Monitoring, Measuring and Analysis Table.

5.6 Identifying data required for review of customer feedback

5.6.1 Management identifies customer feedback projects during management review. Management assigns responsibility for the projects. Projects may include:

a) Focus group meetings
b) Direct client communication
c) Customer satisfaction studies
d) Return customer studies
e) Other methods identified by management.

Requirements of the standard are all addressed

5.7 Management Review

5.7.1 The management review team performs quarterly reviews to evaluate the continuing suitability and effectiveness of the QMS in satisfying the requirements of ISO 13485, the Quality Policy and Quality Objectives.

5.7.2 The Management Representative schedules the meeting and notifies team members.

5.7.3 The Management Representative collects data and summary reports and provides copies to the members of the management review team one week before the scheduled meeting.

5.7.4 The Management Representative prepares an agenda for each meeting that includes:

a) Data from the QMS
    - § Review of QMS Monitoring, Measuring and Analysis Table and related data and summaries
b) Follow-up actions from previous management reviews,
c) Planned changes that could affect the quality management system,
d) An evaluation of the continuing suitability of the Quality Policy and Objectives.

5.7.5 Management analyzes the data, identifies improvement opportunities and assigns action items, preventive actions and corrective actions as appropriate.

5.7.6 Management updates the table with new quality objectives and improvement goals as appropriate to achieve continual improvement.

5.7.7 Minutes are taken at each meeting, recording discussions, decisions and actions and due dates assigned. Data and reports that are reviewed are attached to the minutes of the management review meeting.

5.7.8 The minutes, with attached data and reports, are maintained as a record of management review.

6.0 Forms and Records

6.1 Minutes of management review meetings

6.2 F-500-001 QMS Monitoring, Measuring and Analysis Table

6.3 F-500-002 Key Process Master List

6.4 F-824-001 Product Realization Monitoring, Measuring and Analysis Table

7.0 Attachments

7.1 None

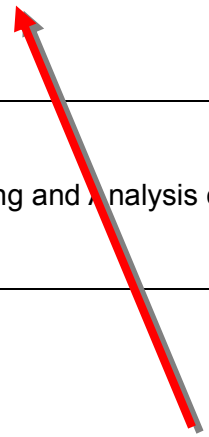
8.0 Related Documents

8.1 Quality Manual

8.2 P-821 Measuring, Monitoring and Analysis of Customer Satisfaction

9.0 References

9.1 None



Related forms, records and documents are referenced to comply with document control requirements

Program Manager:

Program Team:

Roles and responsibilities

Risk management approach:

Include:

- Methods to organize the risks
- Risk and numbering methodology
- Risk identification techniques
- Assessment scales, criteria, equations, prioritization techniques, thresholds for risk levels
- Risk analysis to be performed, cost impact analysis and schedule risk analysis
- Criteria for determining which risks require mitigation plans
- Frequency for updating the date
- Risk data change approval process and the use of a risk review board
- Required vs. optional data to be collected for program use
- Methods for team members to provide data inputs
- Minimum reporting requirements

APPROVALS:

Plan approved by:

Appropriate function: _____ Date:_____

Appropriate function: _____ Date:_____