



Insert your company's name and logo

AP-500-A  
Management Responsibility

Documents are all numbered to comply with document control requirements

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## 1.0 Purpose

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

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## 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.

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## 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.

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## 4.0 Equipment/Software

- 4.1 Not Applicable

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## 5.0 Instructions



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- 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

Recommendations for customization are included



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**

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- 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**

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- 7.1 None

**8.0 Related Documents**

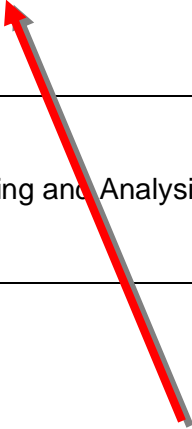
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- 8.1 Quality Manual
- 8.2 AP-821 Measuring, Monitoring and Analysis of Customer Satisfaction

**9.0 References**

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- 9.1 None



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