# Purpose

The purpose of this procedure is to define [Company Name]’s requirements for conducting Management Reviews.

# Scope

This procedure is the primary document meeting the applicable regulatory requirements for conducting Management Reviews as defined in [Company Name]’s Quality System Manual (POL-001).

# References and Relationships

* ISO 13485
* 21 CFR 820.20



# Definitions

# Deputy Management Representative – a back-up to the Management Representative for when this Management Representative position is vacant or for when the Management Representative is not available (e.g., due to illness or vacation).

# Management Representative – The person given the responsibility and authority by Top Management to schedule Management Reviews, conduct the reviews and to finalize the meeting minutes. This person also is a liaison between [Company Name] and Regulatory Authorities and/or Certification Bodies.

# Quality Objectives – something sought, or aimed for, related to quality (ISO 9000, Clause 3.2.5).

# Quality Policy – overall intentions and direction of an organization related to quality as formally expressed by top management (ISO 9000, Clause 3.2.4).

# Top Management – Members of the senior management of the company that are required to participate in Management Reviews—including the Management Representative and Deputy Management Representative.

# Document Approval

Changes to this procedure document and associated forms and templates are to be approved by:

* Quality Management / Management Representative
* Executive Management / Back-up Management Representative

# Revision History

| *Rev* | *Date mm/dd/yy* | *DCN* | *What changed?* | *Why did it change?* | *Author* |
| --- | --- | --- | --- | --- | --- |
| A | mm/dd/yy | YY-nnn | Initial release | Establishing Initial QMS, updated for ISO 13485:2016 | R Packard |

# Responsibilities and Authorities

| *Role* | *Responsibilities and Authorities* |
| --- | --- |
| Quality Management / Management Representative | Primary responsibility for maintaining this process and ensuring that Management Review meetings are scheduled, conducted and the minutes are recorded. |
| Deputy Management Representative | When the Management Representative is not available, but a Management Review needs to be conducted, the Deputy Management Representative shall assume the responsibilities of the Management Representative. At least one person must be identified as a Deputy Management Representative, and that person shall be a member of the Executive Management. |
| Top Management | The Management responsible for attending Management Review Meetings as identified in [Company Name]’s organization chart (FRM-022). These managers are responsible for participating in Management Reviews—including the preparation of inputs to the Management Review and completion of action items resulting from Management Reviews. The organization chart should also identify the following personnel:   * Management Representative * Deputy Management Representative * Most Senior Executive Manager * Second Most Senior Executive Manager   It is not recommended to have the same person hold two of the above four positions. |

# Procedure

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| --- | --- |
| 1 | Management Review meetings shall be scheduled at least once a year, but Top Management has established a quality objective of conducting at least three Management Reviews per year. The date of the next management review shall be set during the previous Management Review meeting and the date should be 2-4 months from the date of the previous Management Review. The date shall be documented in the meeting minutes as an output. |
| 2 | All Top Management is expected to participate in the Management Review, however, absence is allowed for illness and vacations—with the exception of the Management Representative and the most senior Executive Manager of [Company Name]. If the Management Representative is not present, the Deputy Management Representative must be present. If the Most senior Executive Manager is not present, the second most senior Executive Manager must be present. |
| 3 | The following inputs are required to the Management Review meeting for discussion:   1. Quality policy (Clause 5.3) 2. Quality objectives (Clause 5.4.1) 3. Results of audits – including internal, supplier, certification audits and FDA inspections (Clause 5.6.2a) 4. Customer feedback – including complaints and post-market surveillance (Clause 5.6.2b) 5. Process performance (Clause 5.6.2c) 6. Product conformity (Clause 5.6.2c) 7. Supplier quality performance (Clause 8.4) 8. Status of corrective and preventive actions (Clause 5.6.2d) 9. Follow-up of action items from the previous Management Review(s) (Clause 5.6.2e) 10. Changes that could affect the quality system (Clause 5.6.2f) 11. Recommendations for improvement (Clause 5.6.2g) 12. New and revised regulatory requirements (Clause 5.6.2h) 13. Risk management process (ISO 14971) 14. Overall quality system effectiveness (Clause 5.1) |
| 4 | Management Review inputs shall be documented in a presentation slide deck using a controlled template (FRM-023). The Management Representative shall assign responsibility for completing each slide of the presentation as an action item in the previous Management Review. These assignments shall be documented in the meeting minutes. Each input slide shall be provided to the Management Representative at least 10 calendar days prior to the planned review date, and the Management Representative shall combine the slides into a draft presentation and electronically deliver the draft presentation to Top Management at least 7 calendar days prior to the planned review date. Any necessary corrections to slides should be communicated to the Management Representative as soon as possible so that corrections can be communicated to Top Management prior to the planned review date. |
| 5 | During the Management Review, Top Management shall review the Quality Policy to ensure it:   1. is appropriate to [Company Name]’s purpose, 2. includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system, 3. provides a framework for establishing and reviewing quality objectives, 4. is communicated and understood within the organization, and 5. is reviewed for continuing suitability during at least one Management Review meeting each year. |
| 6 | During the Management Review meeting, the Management Representative is assigned the role of scribe to record notes about the discussions. Notes shall be recorded in the notes section of the slides, while another electronic version of the presentation is displayed for attendees to view. Remote attendees should make every effort to provide feedback to the Management Representative prior to the meeting to facilitate their remote participation. Attendance of Top Management shall be recorded by the Management Representative—including remote attendance. Each member of Top Management shall present the slide(s) they prepared—unless they are not able to participate. |
| 7 | Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established for all functions (i.e., departments) and all levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. The status of quality objectives shall be reviewed during management reviews and when one objective is met, Top Management shall determine if the objective shall be maintained or if a new objective shall be set. |
| 8 | The risk management process should be reviewed by Top Management for effectiveness during reviews, but it is allowed to schedule the review of the risk management process at another time. The risk management review should include a review of risk management plans during design projects and as part of past-market data collection. Compliance with the risk management plans should be reviewed, and any corrective actions taken to improve risk controls and/or update a risk analysis should be reviewed as a possible opportunity to improve the risk management process or the risk management training of personnel. |
| 9 | The following items shall be documented as outputs from Management Review meetings in the meeting minutes:   1. the date of the next scheduled Management Review Meeting and the rationale for the interval between reviews, 2. actual attendance of Top Management, 3. any changes to the quality policy required, 4. any new quality objectives, 5. any corrective actions recommended for initiation, 6. improvements needed to maintain the effectiveness of the quality management system and its processes, 7. improvement of product related to customer requirements, 8. changes needed to respond to applicable new or revised regulatory requirements, 9. resource needs, 10. assignments to Top Management for preparing the Management Review meeting inputs for the next meeting, and 11. any additional action items identified during the review.   Improvement required to maintain the effectiveness of the quality system may include changes to the following:   1. the monitoring and measurement of processes, and 2. the auditing schedule. |
| 10 | The draft meeting minutes shall be distributed to Top Management within 7 calendar days of the review, and Top Management shall provide corrections and additional comments within 14 calendar days of the review. The Management Representative shall distribute the final version of the meeting minutes to Top Management with 21 calendar days and the minutes shall be maintained as a quality system record. |

# Monitoring and Measurement

Top management should consider scheduling an audit of the Management Review process approximately 6 months after 3rd party certification audits. Therefore, there will be time to implement any corrective actions and verify effectiveness prior to the next 3rd party certification audit. The following variables are recommended for monitoring and measurement for the management review process and should be maintained over time:

* Number of management reviews conducted in one year (quality objective is 3/year to ensure that trend data is acted upon in a timely manner)
* Management review participation (quality objective is >75% of invited attendees)
* Management review is completed on-time (i.e., does not finish after the scheduled meeting stop time)

# Training/Retraining

| *Role* | *Training or Retraining Required* |
| --- | --- |
| Quality Management / Management Representative | Shall be trained and be competent in all aspects of this procedure. |
| Deputy Management Representative | Shall be trained and be competent in all aspects of this procedure. |
| Top Management | Shall be trained on all aspects of the procedure with the exception of the Management Representatives responsibilities. |

# Risk Management

| *Hazard* | *Risk control measures* |
| --- | --- |
| 1. Reviews are not conducted frequently enough | The number of Management Reviews per year is set as a quality objective for Top Management and the date of the next review is an output of the previous meeting. |
| 1. A required input or output of the meeting is accidentally skipped. | Top Management uses a controlled template for the presentation that includes a cross reference to the requirements of the procedure and applicable Standards. |

# Records

The Management Review meeting minutes are a quality system record that is regulatory requirement, but this record is excluded from the records that shall be made available to FDA inspectors as per 21 CFR 820.180(c). FDA inspectors shall be allowed to see the following documentation:

1. the schedule for and the rationale for when Management Reviews shall be conducted (a required output documented in the Management Review Action Items; ISO 13485:2016, Clause 5.6.1);
2. the agenda for the Management Review including the date, time and location (one of the slides in the Management Review slide deck);
3. the attendees of the Management Review (one of the slides in the Management Review slide deck that is updated in the meeting minutes to reflect actual attendance);
4. corrective actions resulting from the Management Review (an output documented in the Management Review Action Items, and also available as part of the CAPA process records);
5. the organization chart (FRM-022) defining the members of Top Management that are required to participate in Management Reviews; and
6. this procedure (SYS-003).