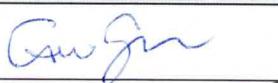
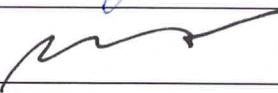


**Document Authorization:**

	Name	Date	Signature
Owner	Sijin Guo	15Dec2025	
Operation Management	Baozhong Zhao	15Dec2025	
Quality Assurance	Xibo Li	15Dec2025	

**Changes from previous version:**

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ALL	1. New document	

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**1. PURPOSE**

The purpose of this procedure is to provide definition and description of the Management Review process

**2. SCOPE**

This procedure applies to all Management Reviews conducted by Synoligo

**3. INTERNAL REFERENCES**

Document ID	Title
QUA004	Quality Policy

**4. EXTERNAL REFERENCES**

Document ID	Title

**5. RESPONSIBILITIES**

Job Function and/or Department	Responsibility
All Personnel	

**6. DEFINITION**

Term	Definition
Management	<ul style="list-style-type: none"><li>Ensures that the system and resources are adequate and appropriate for the company's needs.</li><li>Ensures the systems continue to meet the requirements of applicable</li></ul>
Management Representative	<ul style="list-style-type: none"><li>Scheduling Management Review Meetings.</li><li>Preparing the Management Review presentation.</li><li>Recording the findings of the meetings.</li><li>Distributing minutes to attendees.</li><li>Ensuring action items assigned by management are executed.</li></ul>
Quality Assurance	<ul style="list-style-type: none"><li>Recording meeting minutes.</li><li>Ensuring the procedure is followed.</li><li>Compile information for review.</li></ul>

**7. EXPOSURE DETERMINATION****7.1. Scheduling**

- Management Reviews are scheduled to be held annually.
- Site Management will be updated with standard quality metrics quarterly

**7.2. Attendance**

7.2.1. The minimum attendance required for Management Review meetings shall include the Management Representative and management from Manufacturing, Quality Control, and Quality Assurance, or their designees. In addition, Department Managers shall be invited to attend and present at the meeting.

7.2.2. Attendance at the Management Review meeting shall be documented by means of a sign-in record. If members participate via telephone, such attendance must also be recorded.

**7.3. Review input**

7.3.1. The input for the Management Review should include but is not limited to trending data obtained from the following areas:

7.3.1.1. Quality Objectives

7.3.1.2. Audits (Internal/External):

- Number of audits (critical, major, minor findings)
- Length of closing

7.3.1.3. Customer Complaints

7.3.1.4. Monitoring and Measurement of Processes:

- Deviations (total numbers and category)
- Non-Conformances
- OOS (open and closed, confirmed and non-confirmed and open length)

7.3.1.5. Employee Training

- On-time training rate

7.3.1.6. Document Control

7.3.1.7. Stability Monitoring Program

- Cycle time (from sample pull to test finish to report issued)

7.3.1.8. Process Performance and Product Conformity

7.3.1.9. Monitoring and Measurement of Product (number of orders, category)

7.3.1.10. Corrective and Preventive Actions:

- Number of CAPA closed and open
- Status of open CAPAs
- Extensions requested / granted.
- Length of time open
- On time closure rate of Corrective Actions.
- On time closure rate of Effectiveness Checks.

7.3.1.11. Supplier Performance

- Supplier Corrective Action Reports (SCAR) issued

7.3.1.12. Resources

- Facilities, Equipment, Personnel

7.3.1.13. Follow up actions from previous management reviews.

7.3.1.14. Changes that could affect the Quality Management System.

7.3.1.15. Recommendations for Improvements.

7.3.1.16. Applicable new or revised regulatory requirements.

7.3.2. The trending data presented shall, at a minimum, cover the timeframe from the last management review meeting to the present.

7.3.3. The presenter of the trending data shall be a member of management from the relevant functional area.

**7.4. Review output**

7.4.1. The output from the management review shall include decisions and actions related to:

7.4.1.1. A review of the quality policy and objective to maintain suitability, adequacy and effectiveness of the quality management system and its processes.

7.4.1.2. Resources and training needs.

7.4.1.3. Changes needed to respond to applicable new or revised regulatory requirements.

7.4.2. The review should make the conclusion regarding the suitability and effectiveness of the quality system in satisfying quality regulation requirements.

7.4.3. The output date of the review and any resulting items must be documented.

**7.5. Action items**

7.5.1. Action items identified during the management review shall be the responsibility of the relevant quality system element owners for implementation.

7.5.2. Corrective actions taken as part of action items must have both implementation and verification documented.

7.5.3. Top management must provide a written justification for any action items not pursued.

7.5.4. Quality Assurance shall track action plans and report progress to top management.