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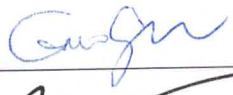
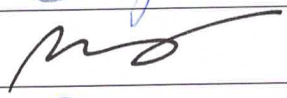
Owner	**Sijin Guo**	**15Dec2025**	
Operation Management	**Baozhong Zhao**	**15Dec2025**	
Quality Assurance	**Xibo Li**	**15Dec2025**	

Changes from previous version:

Section	Summary of Changes	Change Control Number
ALL	1. New document	

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1. PURPOSE

The purpose of this SOP is to describe the process for collection, identification, investigation communication and documentation of Customer Feedback and Complaints.

2. SCOPE

This procedure applies to all products manufactured and services provided by Synoligo.

3. INTERNAL REFERENCES

Document ID	Title
QA001	Quality Policy

4. EXTERNAL REFERENCES

Document ID	Title

5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
All Personnel	Inform their Operational Management and QA when receiving a customer feedback or complaint.
Operational Management	• Evaluating customer's feedback for escalation to a customer complaint. • Assign an investigator to a customer complaint.
Quality Assurance	• Evaluating all Customer complaint. • Issuing a deviation number. • Working with Operational teams and Management to determine root cause, any corrective and/or preventative actions resulting from the customer complaint to ensure timely completion of the complaint.
Investigator	• Facilitating a thorough root cause analysis.

6. DEFINITION

Term	Definition
Complaint	When a customer contacts Synoligo to complain about any aspect of work performed or the quality of service provided, the complaint may include alleged deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product after release for distribution. Complaints may also involve administrative or service-related issues such as, but not limited to, data errors, report quality, timeliness, or quantity
Feedback	General inquiries about services or results can be positive, neutral or negative. Not all negative feedback is a complaint.
Corrective Action and Preventive Action (CAPA)	Corrective Action and Preventive Action (CAPA)

7. PROCEDURE

7.1. Receiving Customer Feedback

7.1.1. Feedback and Complaints

7.1.1.1. Feedback may be received verbally, by phone, email, or in writing. All feedback must be

recorded.

7.1.1.2. Positive or neutral feedback may be forwarded to management and/or included in the management review.

7.1.2. QA shall review feedback and determine if it should be converted into a complaint. Complaints are classified per the deviation procedure.

7.1.3. Complaints shall be logged by initiating a deviation.

7.1.4. Record the complaint route (e.g., letter, email, phone, verbal at meeting). Attach related paperwork or note its location (e.g., “email received 03-Dec-20, saved in ABC\123”).

7.1.5. Record the date raised and any mitigation actions taken.

7.1.6. Record the identity of the person/company raising the complaint. If different from the recorder, also document the recipient.

7.1.7. Assess each complaint and assign an investigator.

7.1.8. Operational Management shall notify the customer of complaint initiation.

7.1.9. Inform the customer of the investigation outcome. Record details with investigation.

7.2. Investigation

7.2.1. The assigned investigator will lead the investigation and facilitate the root cause analysis meeting.

7.2.2. The assigned investigator will identify and assemble an investigation team. The most suitable individuals to report and support the investigation of quality incidents are those directly involved with the relevant procedure and considered subject matter experts. A QA representative must be included in the investigation team.

7.2.3. The assigned investigator will determine the most appropriate tool(s) and format to document the investigation in the root cause analysis report.

7.2.4. The investigation should be completed within 30 days of the event being reported to QA. If additional time is required, the investigator must request an extension, providing justification. The extension must be approved by QA and operational management.

7.2.5. The investigation should include the following:

7.2.5.1. A background section providing context, basic information on the customer complaint, and an accurate, detailed chronology of events.

7.2.5.2. Identification of all potentially affected materials, including batches beyond those initially identified.

7.2.5.3. A trend analysis of all deviations over a minimum of 12 months (or a justified time period) to identify recurring issues. If the deviation has occurred two or more times within the defined period, this may indicate that previous corrective actions were incomplete, ineffective, or that the root cause was not adequately identified.

7.2.5.4. A proposed CAPA plan described in the deviation report. All probable root causes identified must be appropriately evaluated for CAPA implementation.

7.2.5.5. Supporting documentation attached to the deviation report, clearly referencing the deviation number.

7.2.5.6. The investigation section signed by the investigator and approved by operational management and QA.

7.3. Inform Customer

7.3.1. The investigator and management prepare an appropriate summary of the investigation and inform the customer of the investigation outcome.

7.4. Actions

7.4.1. Once a root cause has been identified, corrective and preventive actions must be determined to address the root cause and/or mitigate the associated risk. Before assigning each action, the investigator must inform the actionee and agree upon an appropriate timescale for completion. This agreed timescale must be documented in the CAPA system when the action is raised.

7.5. Effectiveness and Trending

7.5.1. An effectiveness check must be assigned as a follow-up action to the investigation to verify that all corrective and preventive actions have been effective. The suggested timeframe for conducting the effectiveness check is six months after the investigation completion date