Document Authorization:

	Name	Date	Signature
Owner	**Sijin Guo**	**15Dec2025**	
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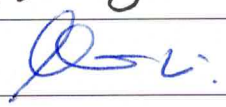
Quality Assurance	**Xibo Li**	**15Dec2025**	

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 document is to provide guidance for the selection, assessment, qualification, requalification and/or disqualification/inactivation of suppliers and service providers.

2. SCOPE

- Suppliers of intermediate / raw materials, packaging, or parts which are incorporated within final products.
- Suppliers of critical equipment and instruments used to prepare or test these products.
- Services that directly impact production, testing, delivery or support of Synoligo products.
- Services that have direct impact on the Synoligo Quality Management System.

3. INTERNAL REFERENCES

Document ID	Title
QUA004	Quality Policy
QUA016	Supplier Corrective Action Request (SCAR) Procedure

4. qEXTERNAL REFERENCES

Document ID	Title
21 CFR Part 820	Medical Device; Current Good Manufacturing Practice (cGMP) Final Rule; Quality System Regulation, Food and Drug Administration, Federal Register
21 CFR Part 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
ISO 9001	Quality management systems -Requirements, International Organization for Standardization
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes, International Organization for Standardization
ISO/IEC 17025:2017	General Requirements for the Competence of Testing and Calibration Laboratories
ICH Q7	Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
QA	• Leading the Supplier Management Team including qualifying new suppliers or service providers. • Monitoring the performance of currently qualified suppliers and leading supplier performance monitoring meetings. • Re-qualifying approved suppliers and service providers every three years, or every year for conditionally qualified suppliers and service providers. • Initiating and conducting supplier audits, as necessary. • Initiation and tracking of SCARs. • Determining final specific qualification requirements when necessary for certain suppliers (e.g. requirements for onsite supplier audits versus a desk audit of selected documents and records). • Conducting DPL checks for new suppliers and for those suppliers that have moved to a new address.
Purchasing	• Procuring goods and services for product and non-product applications using the Approved Supplier List.

	• Serving as the primary business contact for Synoligo suppliers. • Amending expected delivery dates in the Purchase Order system when updates are received from suppliers to provide an accurate history of delivery performance at a later date. • Participating as part of the Supplier Management Team to assess and qualify suppliers. • Responsible for working with all departments to identify suppliers, negotiate terms and agreements to ensure cost-effective and timely delivery of goods and services • Assisting with pulling metrics for Supplier Performance Monitoring meetings.
Receiving	• Recording accurate receiving information in the Purchasing database including date of receipt, whether a delivery is partial or full, and any damages or other quality issues associated with a delivery.

6. DEFINITION

Term	Definition
Approved	Suppliers who are considered acceptable as goods or service providers based upon the satisfactory completion of the supplier qualification process or based upon satisfactory supplier performance during the requalification cycle.
Approved Supplier List (ASL)	The list maintained by Quality Assurance in the supplier qualification database defines all suppliers who have satisfactorily completed the supplier approval process during initial qualification or have demonstrated acceptable performance reporting data during the requalification cycle.
Conditionally Approved	Suppliers who are considered marginally acceptable as goods or service providers based upon the completion of the supplier qualification process. To mediate a conditional approval, satisfactory supplier performance is required and a future site or desk audit may be required. Suppliers who achieve ISO 9001 certification while classified as Conditionally Approved may transition to Approved as a result.
Inactive/Disqualified/Retired Supplier	Supplier that is deemed inactive/disqualified/Retired. These suppliers are not considered acceptable as goods or service providers due to previously unacceptable quality or service levels, regulatory/legal actions or for other business reasons as they are no longer in business. Suppliers who have been problematic due to delivery or quality issues, or are otherwise receiving scrutiny due to performance issues will be issued a SCAR and may be inactivated per SCAR procedure.
Critical Supplier	Refers to materials, or service providers that have the potential to adversely impact final product if the quality or functioning does not meet prescribed requirements (i.e. specifications).
CSM	Customer Supplied Material
Supplier Management Team	Minimally comprised of Purchasing and Quality Assurance
SCAR	Supplier Corrective Action Request
DPL	Denied Persons List. Denied/Restricted Party checks to be conducted on new suppliers or if the supplier's address has changed.
Master Supplier Details Spreadsheet	Tool that is used to keep track of the qualification and requalification due dates by the Supplier Quality department. This list contains all the suppliers that are in the ASL, as well as any suppliers that have been disqualified.

7. PROCEDURE

7.1. All critical suppliers and service providers involved technically or intellectually in our production processes are qualified according to the requirements of this procedure.

7.2. At a minimum, each supplier subject to this procedure has a supplier qualification file containing a New

Supplier Requestor Form, Supplier Qualification Form, and a completed Supplier Quality Assessment Questionnaire. These documents identify the supplier, the goods or services they provide and a description of the Quality System or level of process control within their company.

7.3. Synoligo categorizes its suppliers based on certain aspects related to the material or services they provide. These aspects include:

7.3.1. Material suppliers of commercially available items are subdivided into the following tiers (A, B, C, D, and CSM). Criticality is based on the type of item the vendor provides, its intended use, and the potential for it to impact the safety, identity, strength, quality, and purity of the finished product.

7.3.1.1. Tier A (Most Critical): These suppliers provide items that have the highest potential to impact finished product safety, identity, strength, purity and quality. Example: materials that are incorporated into final products and can impact product form, fit, or function

7.3.1.2. Tier B (Moderate Criticality): These suppliers provide items that have a moderate risk of impacting the safety, identity, strength, purity and quality of the finished product. Items provided by these suppliers include: Primary packaging components, components, and production consumables with direct product contact

7.3.1.3. Tier C (Less Critical): These suppliers provide items that have little impact on the finished product quality. Items provided by these suppliers include: Secondary packaging materials and production consumables that have indirect product contact and specialized quality control items.

7.3.1.4. Tier D (Non-Critical): These items have little to no impact on the finished product quality. This tier includes the following: Production consumables that are non-product contact, but could impact the production environment or personnel, etc and Exempt items: General Quality Control items and supplies.

7.3.1.5. Tier CSM: These items are customer supplied materials and the risk associated is absorbed by the supplier and handled in their own qualification program.

7.3.1.6. Service providers are classified as Tier E, with further categorization based on criticality. Criticality is based on the type of service provided (contract manufacturer, cleaning service, etc.), and the potential for that service to impact the safety, identity, strength, quality, and purity of the finished product.

This category includes service providers with criticality ranging from most critical to non-critical.

- (E1) Most Critical: Includes contract service providers whose services, products, or components have the highest potential to impact finished product safety, identity, strength, purity and quality.
- (E2) Moderate Criticality: Includes key support service providers (e.g., calibration, cleaning and environmental monitoring). Includes suppliers of test articles or materials, as needed and based on risk.
- (E3) Less Critical: Includes other support services with indirect impact on finished product quality.
- (E4) Non-Critical: Includes services provided that have no impact to product quality.
- (E5) Risk Based: Includes services provided that don't fall into the categories defined above, and are therefore evaluated for risk level based on use of a quality risk management tool.

7.3.2. The regulatory standards with which they are required to comply: ISO 9001, ISO 13485, ISO 17025, 21 CFR Part 820, CFR 210-211 or similar certification generally assures the suitability of a supplier for full approval.

7.3.3. Quality Assurance retains the authority to add or delete qualification requirements for individual suppliers. These decisions are documented in the supplier qualification file.

7.4. Initial Qualification of a Supplier or Service Provider

7.4.1. The individual requesting a supplier to be added to the Approved Supplier List in order to place an order with that supplier must initiate Requesting New Supplier for the Qualification Process and send to Quality Assurance.

7.4.2. Quality Assurance must perform a DPL Check as part of the Supplier Qualification procedure. The new supplier must pass DPL Check for new suppliers.

7.4.2.1. If the DPL Check comes up as failed, send the report to DPL review team.

- If the DPL team advises us to proceed, attach the email communication as objective evidence. Proceed with supplier qualification.
- If the DPL team advises not to proceed, the supplier will not be qualified, and the notes will be added to the supplier file.

7.4.3. For customer supplied materials where the customer qualifies the supplier via their own procedures, it is filled out with notes explaining this workflow to describe that these qualification activities occur at the customer site and no further action is required. The notes are also added in the database and the master supplier spreadsheet so the team knows that these suppliers are differentiated. For customer supplied materials or services where the customer is supplying their own materials/services, Synoligo can qualify them via the procedures described below.

7.4.3.1. These suppliers should not be added to the existing Approved Suppliers Lists.

7.4.4. Quality Assurance e-mails the contact and attaches Supplier Quality Assessment Questionnaire for critical suppliers in tier A through C and E1 through E3.

7.4.5. Upon return of the completed questionnaire, the Supplier Management Team will consider the company's qualifications for full approval.

7.4.6. General approval criteria during initial supplier qualification are based on the following:

7.4.6.1. Supplier indicates certification to ISO – Supplier is approved.

- Suppliers who have achieved certification to an ISO standard have the requisite Quality Management System elements in place to proceed with supplier approval. Supplier performance will be monitored over time to assure these suppliers continue to meet our requirements. Expiration date of supplier ISO certification will be tracked and suppliers will be notified to send their recent ISO certification before their other certification expires, or websites may be reviewed for a current copy of the ISO certification. If they don't send or post their updated certification within 45 days from notification, they will be removed from the Approved Supplier List and will have to go through requalification when they send their updated certification.
- When ISO certification is not applicable, a supplier who is able to demonstrate proficiency in their field by other certification (e.g. CLIA) or registration with a governmental regulatory authority (e.g. CA Structural Pest Board) may also be approved. Their performance will be monitored over time to assure our requirements are being met.

7.4.6.2. In lieu of ISO certification, certain point values will be applied to each question and the total assessed during the evaluation of the Supplier Quality Assessment Questionnaire:

- A supplier's qualification status will be established according to the rubric indicated.

7.4.7. Critical and Non-Critical suppliers undergoing initial assessment that fall into Approved status will be approved by Purchasing and Quality Assurance prior to closure of the supplier file. Critical and Non-Critical suppliers undergoing initial assessment who fall into the Qualification Levels of Conditionally Approved or Rejected/Disqualified shall be sent Desk Audit Form. Critical suppliers falling under tier A or E1 should be Desk Audit Form upon initial assessment.

7.4.7.1. These suppliers have the opportunity to be moved up one Qualification Level based upon the satisfactory completion of the Desk Audit (e.g. a supplier initially falling in the Conditionally Approved Qualification Level may be moved to the Approved level based upon a review of the Desk Audit). This evaluation is performed by Quality Assurance and the final Qualification Status determination will be documented on Supplier Qualification Form. This will be approved by Purchasing and Quality Assurance prior to closure of the supplier file.

7.4.8. For critical suppliers, as needed, after sending the questionnaire, a non-disclosure agreement (NDA) will be created by using the most recent template from the corporate site. NDAs will be created whenever proprietary information or documentation is shared. The NDAs will be filed within the individual supplier folders and tracked in a master supplier database.

7.4.9. If suppliers indicate that their facility has products of animal origin, send them Material Sourcing Survey.

7.4.10. Maintain a log and update the (re) qualification progress in the supplier qualification QA network file.

7.5. Ongoing Supplier Performance Monitoring

7.5.1. Supplier Performance Monitoring Meetings will be held at a minimum frequency of twice per year.

7.5.2. Stakeholders from different cross functional groups will track supplier performance and discuss during

the meetings.

7.5.3. Purchasing team and Incoming QC team and area SMEs will provide requested data to Quality Assurance to compile or the meetings.

7.5.4. These meetings will specifically target critical suppliers and suppliers requiring further evaluation.

7.5.4.1. For critical suppliers falling under Tier A and E1, metrics will be evaluated like supplier defect rate and return rate, PO vs invoice accuracy, # of SCARs and SCAR response rate, and response time on PO confirmation.

7.5.4.2. For suppliers requiring further evaluation, metrics will be evaluated like incoming QC failures, the supplier performance monitoring spreadsheet, and # of SCARs/SCAR response rate.

7.5.4.3. Trends will be assessed to determine what additional actions need to be taken to assess the supplier (i.e. SCAR, desk audit, audit, etc)

7.6. Requalification of a Supplier

7.6.1. Fully Approved Suppliers (including consultant and non-technical service providers) are re-qualified every three (3) years at a minimum. This cycle may be accelerated as a result of unsatisfactory supplier performance monitoring data. Conditionally Approved suppliers are re-qualified annually.

7.6.2. At the time of supplier re-qualification, the supplier will be sent Supplier Quality Assessment Questionnaire for completion with purchasing copied on the notification for visibility. They will have 45 days to send the completed form needed for re-qualification. At the 30-day mark, they will be sent another notification requiring them to send the completed form and Purchasing will be copied on the notification for visibility. If they do not send the completed form within this time frame, they will be removed from the Approved Supplier List.

7.6.2.1. For orders for bulk amounts of material delivered over a period of time, the delivery date for some of the line items on the order may fall after the requalification due date. If the supplier does not complete all items for requalification prior to the due date and if the supplier has had acceptable levels of performance during the last year, Supplier Quality and Purchasing will sign a memo to justify the low level of risk involved with receiving items from the blanket PO after the requalification due date. Then, Supplier Quality will authorize the order to come in. Purchasing will work with Supplier Quality to proactively get these suppliers requalified prior to the due date for minimal disruption to these blanket POs.

7.6.2.2. When Supplier Quality determines that a supplier will be inactivated, they will send a memo for inactivation to be signed by Purchasing and Quality Assurance Management. Before signing, Purchasing will run an open PO line report specific to the supplier. If there are any open lines, they will communicate to both supplier and Supplier Quality a revised purchase order cancelling these open lines due to failed requalification.

7.6.3. Approval criteria for supplier requalification are the same as the criteria for initial supplier qualification.

7.6.4. Maintain a log and update the (re) qualification progress in the supplier qualification QA network file.

7.7. Timeframe for Supplier Qualification

7.7.1. Suppliers of materials or services, which may be used or needed as part of new product development, should be identified as early as possible in the development process.

7.7.2. It is recognized that multiple suppliers may be evaluated initially as part of development activities. After the initial technical screening of suppliers has been completed and one or more potentially viable suppliers is/are identified, the supplier(s) must be formally qualified and approved.

7.8. Supplier Communication

7.8.1. Notification shall be sent via email to inform a supplier and internal stakeholder (s) (as needed) of qualification disposition. If the Qualification Level is classified as Conditional or Rejected/Disqualified, an explanation must be included.

7.9. Supplier Changes and Ongoing Supplier Performance

7.9.1. Suppliers falling under Tier A/E1 are required to notify Purchasing in writing of any process changes or changes in raw materials that may affect the form, fit or function of the material(s) being purchased. Note Synoligo will not move forward with qualifying/re-qualifying suppliers falling in Tier A/E1 that will not agree to the change notification requirement.

7.9.1.1. When Purchasing is notified of these changes, they will provide this notification to Quality Assurance.

7.9.1.2. All employees are responsible for sending change notification to QA

7.9.1.3. Quality Assurance will assess the criticality of the material supplied using criteria from section and the critical suppliers will be recorded on Critical Suppliers / Service Providers

7.9.1.4. The change will also be recorded on Vendor Change Notification Assessment Form where the risk of the change can be assessed to determine if further actions are required and if the change can be implemented.

7.10. Supplier Corrective Action Requests (SCARs)

7.10.1. SCARs shall be handled according to the procedure defined in Supplier Corrective Action Request (SCAR) Procedure.

7.10.2. Quality Assurance will review the nonconformance and Supplier history/ trends to determine if a SCAR will be initiated. Quality Assurance shall initiate Supplier Corrective Action Request (SCAR) Form if a SCAR is determined to be required.

7.10.3. SCARs shall be saved in the supplier qualification QA network file.

7.11. Supplier Monitoring by Audit

7.11.1. Suppliers and Service Providers identified as being the most Critical and requiring an audit will be placed on an audit schedule or will be sent a desk audit form. Critical suppliers falling under tier A or E1 should be sent Desk Audit Form upon initial assessment. Then, the team will assess if an on-site or virtual audit is required.

7.11.1.1. Criticality of Suppliers are determined by production management and will provide Quality Assurance a list of those suppliers falling under tier A or tier E1 and any other tier as applicable.

7.11.1.2. Criticality of Service Providers are determined by production management and will provide Quality Assurance a list of those suppliers falling under tier A or tier E1 and any other tier as applicable.

7.11.2. QA will complete audit schedule for Supplier Monitoring and differentiates desk audit from on-site audit as required.

7.12. Metrics

7.12.1. Metrics associated with supplier qualification are presented as part of Management Review meetings.