



# Supplier Quality Manual

## Suppliers of Non-GMP Materials

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## **Scope and Purpose**

The purpose of this Supplier Quality Manual is to communicate the minimum expectations and requirements for all new and existing suppliers to Ecolab, its subsidiaries, or its affiliates – hereafter referred to as Ecolab. A supplier is any company or organization independent from Ecolab’s Quality Management System that provides a good or service to Ecolab, inclusive contract manufacturers and service providers.

Suppliers must ensure that all products and services provided to Ecolab meet applicable specification requirements and quality agreements. This manual establishes general policies and requirements. In some cases, certain business units may at their discretion add additional requirements based upon their market needs. Suppliers are expected to comply with these additional requirements and the requirements in this manual.

Suppliers are critical to Ecolab’s success in delivering superior quality products and services to its customers. Preference will be given to suppliers who consistently exceed the expectations defined in this manual. If there are questions or concerns regarding the content of this manual please direct them to your procurement representative, who will get you in contact with the Ecolab Supplier Quality function.

## **Ecolab Supplier Quality Program**

### **Supplier Evaluation, Selection, and Approval**

Ecolab follows a systemic approach for supplier evaluation, selection, and approval. Supplier evaluation is the process followed to add or maintain a supplier on the Approved Supplier List. Suppliers need to be on the Approved Supplier List before supplier selection and component qualification are complete.

Ecolab must follow a common approach for the evaluation of suppliers, to ensure quality, performance, and compliance of received materials and services meet the needs of the business. Supplier audits are an integral part of the supplier evaluation process.

Suppliers will be evaluated per the standards for the specific materials or services to be provided. This may include Ecolab Supplier Quality Standards documented in this manual, as well as any relevant quality certifications the supplier holds. Ecolab may choose to audit new or existing suppliers to these standards. To ensure compliance, it is expected during these audits that Ecolab shall have reasonable access to supplier processes, quality systems, and records.

The approval of one supplier location may not be sufficient to qualify all supplier locations; each location may be evaluated on its own merits. Ecolab may review specific elements of the quality system at each location and grant a site-by-site approval.

## Supplier Quality Issue Management

Supplier quality issue management is the process followed to address non-conformances related to purchased materials or services. A non-conformance is any material or process that does not meet Ecolab and/or supplier specifications. A non-conformance may be identified in receiving, during use, or during review of a finished good complaint.

Ecolab may notify suppliers of non-conformances. For some non-conformances where the supplier is at fault, a full root cause investigation and corrective action will be required, and a Supplier Corrective Action Request (SCAR) form will be sent via email. The expectation is that all SCAR fields will be completed and returned within 30 days unless an extension request is granted by Ecolab. The intent of the SCAR process is to prevent recurrence of a particular non-conformance.

## Supplier Performance Monitoring

Ecolab monitors supplier performance on a continuous basis, to ensure suppliers and supplied materials are meeting the needs of the organization. Suppliers not meeting organizational needs will be addressed through supplier action plans. Failure to act upon action plans may result in loss of business.

## Minimum Supplier Quality Standards

Ecolab has established minimum acceptable standards for suppliers by category of material or service. All suppliers of direct materials shall comply with the minimum standards documented here. Suppliers of GMP materials shall comply with GMP minimum standards.

### Quality Management System

Suppliers must develop and maintain a quality management system to manage their business.

Supplier Type	Minimum Standard	GMP Minimum Standard
Contract Manufacturer or OEM - Medical Device	ISO 13485 compliant	ISO 13485 certified
All other contract manufacturer or OEM	ISO 9001 compliant	ISO 9001 certified
Chemical, packaging, equipment	ISO 9001 compliant	ISO 9001 certified
Indirect materials	Competency evidence	
Services - calibration	ISO 17025 compliant	ISO 17025 certified
Services - testing laboratory (including microbiology)	ISO 17025 compliant	ISO 17025 certified
Services - sterilization	ISO 13485 certified	ISO 13485 certified
Services - external designer	Competency evidence	ISO 13485 certified
Services - translation	Competency evidence	ISO 17100 certified
Services - other	Competency evidence	Competency evidence

In addition, suppliers must at minimum:

- Have an operating quality manual that covers all sections of the quality system OR relevant procedures that cover all areas of the quality system.
- Have an internal audit program. All audits must be part of an internal audit plan, with audit findings closed prior to due dates.
- Hold annual management reviews with their leadership teams.
- Track quality metrics monthly (one being customer complaints), with results cascaded to employees at least once per year.
- Have a quality policy that is communicated to employees.

### **Facility, People, and Infrastructure**

Suppliers must maintain facilities and empower employees to a level consistent with the material being produced. Suppliers must at minimum:

- Provide appropriate temperature and humidity controls in pertinent areas.
- Have active pest control.
- Have an organization chart in place, with the Top-Quality role reporting to a plant manager or corporate quality function.
- Have stop work and shipment authority for all line supervisors.
- Have a control plan or Quality signoff for resumption of production after a non-conformance was reported.

### **Process Control**

Suppliers must ensure process controls in manufacturing, to minimize variation and ensure form, fit, and function continue to meet all specifications over time. Suppliers must at minimum:

- Maintain standard operating procedures (SOP), work instruction (WI), and/or process management plans (PMP) for relevant operation processes. Edit access must be limited while allowing most employees to view.
- Have secondary verification at point of raw material addition.
- Have a system to monitor and control raw material expiration/shelf life, with justification and documentation to use materials past shelf life.
- Identify critical process parameters and establish targets and control limits, with regular checks to ensure they remain in control.
- Develop in-process sampling plans/quality checks for key product properties, acting when properties drift out of control.
- Have a documented validation process with quality signoff for the qualification of production equipment.
- Ensure processes do not run out of specifications without Ecolab approval AND a temporary deviation from specification (TDS) in place.
- Keep retains of all lots of finished goods for a set amount of time.

- Maintain a preventative maintenance program for all critical equipment, with critical parts inventoried.
- Document and follow cleaning and/or sanitizing SOPs as necessary.

### **Product Identification and Traceability**

Suppliers must ensure that the correct specifications and testing requirements are being followed and maintain an appropriate level of traceability throughout the manufacturing process. Suppliers must at minimum:

- Check incoming purchase orders to ensure building to correct specification revisions.
- Have a system in place to track material through the workflow, including raw material lots, operators, and equipment used. Merged and split lots can be tracked.
- Maintain records of material lots shipped to customers with yearly mock recalls to test the system.
- Clearly label and identify product for shipping and receiving.

### **Metrology and Testing**

Suppliers must use appropriate tools and methods to measure processes and materials. This includes incoming, in-process, and outgoing quality control and assurance. Suppliers must at minimum:

- Ensure measurement tools are qualified through a documented procedure and calibrated annually to international or national measurement standards.
- Document calibrations and tag equipment critical to the creation and testing of finished goods.
- Maintain tools on-site to measure all critical dimensions to appropriate resolution.
- Maintain visual or reference standards as needed. Standards cannot be expired.

### **Incoming and Outgoing Quality Assurance**

Suppliers must ensure received materials meet internal and vendor specifications. Suppliers must ensure outgoing materials meet internal and Ecolab specifications. Suppliers must at minimum:

- Approve incoming critical materials through COA or COC review.
- Ensure internal and vendor specifications are met before received material is released for production. Specifications and any testing methods must be up to date.
- Release outgoing material only after properties are measured to a sampling plan, confirmed to fall within specifications by a quality representative, and entered in a quality system.
- Generate COA or COC at Ecolab request.

## **Control of Non-Conforming Material**

Suppliers must quarantine and disposition all materials that do not meet product and/or process specifications. Suppliers must at minimum:

- Block and clearly label non-conforming material.
- Have deviation and rework procedures if those processes are allowed. Deviations require signoff, and rework requires testing comparable to original finished good testing.
- Follow return material authorization (RMA) procedure with returns tied to shipping records and customer complaint systems.

## **Safety**

Suppliers must maintain a safe work environment, in compliance with all applicable laws and regulations. Suppliers must at minimum:

- Determine appropriate personal protective equipment (PPE) for employees and visitors and develop and communicate an Emergency Action Plan.
- Track all safety metrics required by law or regulation.
- Control access to the location.
- Address unsafe conditions.

## **Training**

Suppliers must ensure employees are competent to perform the duties they have been assigned. Suppliers must at minimum:

- Have a documented training program that ensures training required by role has been completed.
- Provide training for new processes and/or equipment startups, and on quality and safety SOPs.
- Qualify any laboratory testers for each method to be run through hands on training and demonstration of competence, with refresher training when a method is updated.

## **Control of Documents and Records**

Suppliers must maintain an appropriate level of control of documents and records, either on paper or in an electronic document management system. Suppliers must at minimum:

- Have a record retention procedure with periodic reviews, limited edit access, and defined lengths of retention for all document and record types.
- Be willing to enter into a non-disclosure agreement (NDA) to protect customer IP upon request.

## **Supplier and Resource Management**

Suppliers must manage their suppliers of materials and services as applicable. Suppliers must at minimum:

- Have a supplier qualification plan and follow an approved supplier list OR use an approved supplier list provided by Ecolab.
- Monitor supplier performance and take action (including audits) on repeat quality issues.
- Require notification for any changes to form/fit/function of supplied material.

## **Change Control**

Suppliers must have a documented change control process for all changes that impact form, fit, function, or manufacturing location. Suppliers must at minimum:

- Identify and address quality risks before changes are completed.
- Notify Ecolab of any changes that impact form, fit, function, or manufacturing location.
- When notified by Ecolab of a specification revision, update internal specifications within the specified transition period.

## **Continuous Improvement Activities**

Suppliers must practice continuous improvement. Suppliers must at minimum:

- Use a corrective and preventative action (CAPA) program to drive improvements.
- Acknowledge Ecolab complaints and provide resolution or action plans, including responding to supplier corrective action requests (SCAR) when applicable.
- Establish metrics and targets for both CAPA and SCAR closure.