QUALITY SYSTEM OVERVIEW

Ecolab Inc. manufactures its cleaning and sanitizing products at a number of chemical manufacturing facilities throughout the US and Canada. The facilities range in size and number of employees from 45,000 to 610,000 square feet and from 15 to 400 employees. The facilities are located near major metropolitan areas with the goal of providing excellent service to customers.

The Ecolab Quality System is structured such that the manufacturing facilities follow the same set of standards. The Ecolab quality policy is stated as "Quality Matters Everywhere We Work" At the highest level, the Ecolab Quality Manual defines the policies of the Ecolab Quality System. This is followed at the second level with the basic quality standards that all manufacturing facilities follow. The third level includes the procedures and work instructions which are specific to each manufacturing site that set forth Ecolab Quality System requirements.

Ecolab's Chemical and Mechanical plants are certified to the requirements of ISO 9001 – 2008 through a multi-site third party audit program administered by NQA (National Quality Assurance). The effort to maintain ISO certification is supported by the structure of the Quality System defined above that provides for all Ecolab plants to meet the same quality objectives.

In addition to the ISO 9001 certification, Ecolab has 3 facilities in the US that are registered with the FDA as drug manufacturing facilities. These are the Eagan, MN (Reg. # 2127269), Huntington, IN (Reg. # 1810414) and City of Industry, CA (Reg. # 2030831) plants.

The Quality Organization at Ecolab ultimately reports to the Senior Vice President of Global Operations. Local plant Quality Managers and their organizations have dual reporting to their respective Plant Managers and the Vice President of Quality, North America.

The Ecolab Quality System is reviewed at least quarterly by individual Quality Management Review Boards (QMRB) at each of the manufacturing facilities. In addition, quality review monthly meetings are conducted by Ecolab's Corporate Quality group with participation from each North American plant as well as corporate functional management. The Quality Management Review Board agenda covers such items as:

- Customer Complaints (Key Performance Indicator for Quality System)
- Corrective and Preventive Actions
- Internal Audit Results (Internal Audit Schedule Status)
- External Audit Results
- Training Schedule Status and Training Status
- Action Items from Prior Meetings
- Action Items from the Current Meeting

A document management system is used to manage and control the documentation for the Quality System. It is carried on the Ecolab Intranet. Any person with a personal computer in the manufacturing facilities can freely access this documentation but additions and changes are under the control of the quality unit.

Purchasing component requirements (chemical raw materials, packaging supplies and labels) are defined through component specifications issued by Ecolab Research and Development. An approved vendor listing is provided for Purchasing. This list is managed through an Approved Vendor Process that involves vendor evaluation of material quality, service capability, and financial stability. Ecolab R&D divisions that will be using the material must approve the quality of the material for their use before a vendor's material is approved for purchase.

When a vendor has been approved for a material purchase, they are mailed a copy of the Ecolab component specification for the material they will be supplying. Vendors are asked to sign and return confirming their commitment to meet the specification.

Ecolab has a documented supplier management program that includes procedures pertaining to selection, approval, monitoring, development and communication of Ecolab requirements.

Materials used in the manufacturing process are assigned a raw material code number. A material is not allowed into a manufacturing facility without an Ecolab raw material code number. This includes chemical raw materials, packaging supplies, labels, formulas, and finished products. For purchased items, the code number is applied by the suppliers and verification that the code is present is part of the receiving process.

Chemical raw materials are inspected by receiving personnel for verification of supplier, Ecolab code number, quantity received, and any damage. Materials are selected for sampling and testing against the chemical raw material specifications based on certain criteria such as new materials, materials with any changes, materials that will be used to produce FDA regulated products, materials that are stored in bulk (due to risk of contamination), and materials that may have been a problem in the manufacturing process. Certificates of analysis may accompany shipments or may be mailed or faxed to the QC department.

Packaging supplies are inspected by receiving personnel for verification of supplier, Ecolab code number, quantity received and any damage. Certificates of conformance may accompany some shipments and are forwarded to the QC department.

Products are manufactured according to production specifications that are issued to manufacturing and distribution by the Ecolab Research and Development. The production specifications define the manufacturing process requirements (equipment requirements, safety precautions, formula, and mix instructions), QC analytical testing requirements, QC analytical testing methodologies, package assembly procedures, and packaging QC requirements.

Each chemical manufacturing facility has a Quality Control laboratory managed by a Quality Manager and supporting staff. Their responsibilities include:

- Set up and accuracy of bills of material based on product specifications to drive material requirements.
- Set up and accuracy of production paperwork based on product specifications.
- Maintenance of laboratory equipment, analytical methods, analytical reagents, equipment calibrations, method assurance procedures, reagent standardization and validation of new analytical methods as needed.
- Analytical testing of production samples based on product specifications and documentation of results.
- Creation and maintenance of product retain samples.
- Control and disposition of nonconforming material.
- Conformance to standards for housekeeping and safety in the laboratory.
- Management of complaint handling process.

Product quality is confirmed by analytical testing at several stages in the manufacturing process: at the batch completion point, at the start up of package assembly and again at the completion of package assembly. During the package assembly process, quality checks are performed to assure quality control requirements are met.

Products are identified by an item code that defines the product description and package size. Packages also carry a date code (lot number) which links the package back to production records, quality testing and inspection completed on that product.

During the manufacturing process, additional process quality controls are performed. These include but are not limited to such things as:

- Washout/cleanout procedures for processing equipment.
- Weighing and measuring procedures for chemical material additions.
- Line clearance between packaging runs.
- Yield calculation (material balance as well as material variation) on every manufacturing job.

Lot numbers of chemical raw materials used in the production of FDA regulated products or as active ingredients for EPA registered products are tracked/documented.

There is a control, calibration and maintenance program for inspection, measuring and test equipment. Standard tolerances for component additions and process variables are listed in the product specifications. Calibration procedures and schedules are maintained as well as calibration records. Inspection, measurement and test equipment used to verify product conformance to specification requirements are calibrated to rated accuracy using standards traceable to the National Institute of Standards and Technology (NIST) or other appropriate standards as documented. Preventive maintenance procedures and schedules are maintained as well as preventive maintenance records.

The Ecolab Quality System is supported by a training program that defines and documents the training requirements for each position and the training given.

There is a complaint handling process. Complaints can be received from any source but normally come in through the Technical Service function for each Ecolab division. The complaints are logged into a database and then sent to the responsible party for investigation and resolution as required. Feedback on the results of the investigation is documented in the database and used to respond to the complainant as needed.

Plant personnel maintain a corrective/preventive action process. Corrective actions are completed using a corrective action form on customer complaints (external nonconformances), internal nonconformances and vendor nonconformances. Corrective actions are assigned completion dates and the actions are monitored for completion and effectiveness. The plant Quality Management Review Boards monitor their corrective/preventative action process.

The Ecolab Quality System has a recall procedure which is managed by an implementation team that consists of the following or their designee(s):

- The Vice President of Quality, North America
- The Technical Director/Vice President of the R&D division for the affected product(s)
- The Marketing Manager for the affected product(s)
- The Regulatory Affairs Department, if a regulated product is involved.

The Ecolab Quality System is routinely audited as follows:

- Each plant location has an internal auditing program that is structured to audit all elements of the Quality System on an annual basis.
- At least once every two years, each plant location quality system is audited by the Ecolab Corporate Quality function or its designee.
- Once every two years, each plant location Quality System is audited by the ISO Registrar.
- Critical suppliers are audited based on the supplier management program.

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