Supplier Quality Requirements Manual

Table of Contents

1.0 Welcome to Amway

Amway is one of the world's largest direct selling companies. Founded in 1959, and headquartered in Ada, Michigan, USA, Amway offers consumer products and business opportunities in more than 80 countries and territories worldwide. The company also provides product development, manufacturing and logistics services through its Amway Operations and Alticor Corporate Enterprises divisions.

Amway and its family of companies have more than 17,000 employees globally, and help more than 3 million people own and operate their own independent businesses in more than 80 countries and territories around the world. Some 450 unique, high-quality products carry the Amway name in the areas of nutrition, wellness, beauty and home care. Nutrilite™ supplements and Artistry™ skin care and cosmetics are the company's flagship brands.

With facilities in Michigan, California, Washington, Brazil, Mexico, Vietnam, Europe, China and India. Amway Operations serves the market with sourcing, quality assurance, product development, manufacturing, and logistics services through a diverse portfolio of leading wellness, body & beauty, and home care products. Amway Operations also operates farms in Washington, as well as international farms in Mexico and Brazil.

As an existing or new supplier to Amway, you play a critical role in our quality processes. This manual contains information to assist your company in establishing a successful partnership with us by identifying our quality requirements and expectations. We value each of our suppliers as part of our team. Thank you for your support in providing safe, high-quality products to our customers and consumers.

2.0 Scope

The requirements and expectations contained herein are applicable for those distributors and manufacturers supplying Amway/Nutrilite.

3.0 Communication

We encourage and expect open and active communication with our suppliers. By working together and establishing open lines of communication, we can achieve our mutual goals.

3.1 Supplier Portal

The supplier portal, located at http://supplier.amway.com is a dedicated supplier website designed to provide up-to-date requirements, guidelines and business intelligence reporting for Amway/Nutrilite. Throughout this manual, you will see references to the portal, which will provide you with more specific information regarding our requirements. If at any time you have questions, please contact your Amway Procurement Representative or Supplier Quality Development (SQD) Engineer. Non-Critical Quality Issues for Nutrilite email NutriliteSQD@Amway.com

3.2 Supplier Contacts

To maintain current contact information for our suppliers, we request you submit to your Amway SQD Engineer and Technical Regulatory Analyst a name, phone number, and email address for the Primary Quality contact and Technical/Regulatory contact for each applicable manufacturing site supplying products or materials to Amway. Supplier Order/Sales/Customer Service contact information should be submitted to your Amway Procurement Representative. If you are unsure of who to contact, please reference the Item Buyer in Supplier Analytics, our business intelligence system (under the Item Information tab).

3.3 Supplier Analytics

Supplier performance information is available through Supplier Analytics. Suppliers are expected to monitor their own performance information and discuss performance data with their Amway Procurement Representative. Contact your Amway Procurement Representative for access to this system.

4.0 General Supplier Quality Requirements/Expectations

Amway desires to partner with you to provide world class quality products to our consumers. We expect all suppliers to actively and continuously drive quality improvements that will support the prevention of non-conforming material. In order for us to assist suppliers in meeting these goals, we expect you to engage in the process and meet certain requirements and expectations, as outlined in the pages that follow.

4.1 Product Requirements

- Provide products manufactured from statistically stable processes, and which meet product and shipping specifications for Amway.
- Adhere to all Business Requirements located at http://supplier.amway.com including specific shipping, quality, technical regulatory, accounts payable, engineering, specification, EBusiness, and procurement requirements.

4.2 Specification Requirements

- Possess the latest specifications from Amway and distribute those specifications to the proper departments. Every purchase order (PO) contains reference to the proper specification to be utilized. If the SKU or the specification revision date on the P0 is not aligned with the Amway specifications in your possession, or you cannot locate them on the P,O. contact your Amway Procurement Representative.
- Ensure specification range alignment between Amway and supplier specifications. Contact your Amway procurement representative if not in alignment (or if additional information is needed to ensure alignment).
- Reference Amway conformance checklists and applicable standards for finished goods and components.
- Adhere to agreed upon standards and specifications.

4.3 Document Requirements

As a global company, we require our suppliers to provide us with certain documents. Specific document requirements can be found on the supplier portal under Supplier Requirements > Technical Regulatory as well as within Amway specifications.

When Providing documentation for finished goods, please include the Amway SKU number if possible.

1. Document Types

Depending on the line of product, including, but not limited to, the following:

a. Questionnaires – ex. FORM 1294

b. Statements – ex. Statement of non-irradiation, Non GMO

c. Certifications – ex. 3rd Party Quality System Audit Certificate

d. Certificates – ex. Certificate of Analysis (COA), Certificate of Conformance (COC),

Halal, Kosher

e. Process Documents – ex. PPAPs, Manufacturing Flow Charts

2. Documentation Compliance

- To remain in compliance with our requirements, certificate updates should be sent to the appropriate SQD Engineer when certification status changes occur. Documents are required to be udated every three years in accordance with Amway's record keeping practices for Quality Assurance.
- When indicated as a requirement on the Amway specification, COA's and COC's are required to accompany every lot shipped to Amway, and should be attached to the shipping documents. These COA's and COC's are also required to be emailed to the appropriate Quality Assurance (QA) department prior to shipment. Reference SOP SRM-SW-0002.

4.4 Regulatory Requirements

As a global company with products in over 80 countries and territories, we must adhere to the rules and regulations for each market. Please refer to Amway product and material specifications for details regarding additional requirements including, but not limited to, the following:

1. Nutrition Raw Material and Regulatory Requirements

- **FDA Food Safety Modernization Act**

  All food products, dietary supplement ingredients and packaging materials to be consumed in the USA and territories must meet the regulations and requirements of the FDA Food Safety Modernization Act. Amway's domestic suppliers are expected to develop and follow their own Food Safety Plan and or HARPC/HACCP. Foreign suppliers fall under FDA FSVP and will be required to provide a more in-depth documentation than domestic suppliers. Be prepared to submit all necessary documentation for review by Amway corporate or Amway affiliates.

- **Restricted and Disallowed Ingredients**

  All products and materials supplied into Amway NA Operations must meet current regulations/requirements for Restricted and Disallowed Ingredients per Amway specifications. Contact your Amway Procurement Representative if you have questions. Reference Form 1294.

- **CGMP for Dietary Supplements**

  Distributors and Raw Material Manufacturers who provide raw materials to our Nutrilite™ division must comply with Food cGMPs; however, Dietary Supplement cGMP compliance is strongly recommended. Additional dietary supplement guidance may be found on the Standardized Information on Dietary Ingredients (SIDI) website: http://www.sidiworkgroup,com/ As part of Amway's Risk Minimization Program, an Amway Procurement Representative or SQD Engineer may request Technical Regulatory records to support your compliance level.

- **NutriCert Auditing Program**

  Amway desires to use functional botanicals from organically farmed and socially sustainable sources. For those sources purchased from suppliers (and not our own certified farms), we have developed the NutriCert Auditing program. The NutriCert Auditing program ensures our global agricultural suppliers meet Nutrilite's triple-bottom-line standards. Nutrilite's founder, Carl Rehnborg, set the bar high for quality farming with his Nutrilite Sustainable Farming System (NSFS) practices. It was

precisely those quality farming practices that led to the development of quality nutrients and supplements. NutriCert has been founded as the vehicle to ensure Carl's legacy. The guiding principles of our NutriCert standards are based on common NSFS elements familiar to all sustainable and certified organic farms: Encourage Diversity, Build Soil, Don't Contaminate, Ensure Traceability and Build a Healthy Social Environment.

Suppliers of botanical ingredients may be subject to the NutriCert Auditing program at the farm (source) location. Discussions regarding the complete botanical supply chain and the NutriCert policy, standards and auditing procedures - are the first steps of cooperation with our program. Farms are scored based upon compliance to NutriCert standards, and are certified accordingly. NutriCert certification status is integral to Amway Global Procurement sourcing strategies and considerations. Now, more than ever, trusted botanical suppliers who demonstrate a willingness to provide organically grown raw materials are of great value.

- **Non-Irradiation Policy**

  Raw materials or products that have been irradiated or treated with ethylene oxide are prohibited. The following statement is required on CoA's or on signed company letterhead and must accompany incoming shipments, Reference SRM-POL-0002.

  "This raw material (including all sub components such as additives or excipients, and the origin feed stock) has not been subjected to irradiation or ethylene oxide treatment."

- **Residual Solvents**

  Suppliers must adhere to ICH and USP guidelines for residual solvents.

  Amway requires reporting of any/all solvents (including water) used in the processing of any finished Botanical/material that Amway Nutrilite purchases (from origin feed stock to finished material).

  Amway requires reporting of any/all solvents (including water) in any process step (including, but not limited to: preparation, actual extraction, and clean-up of the material produced).

  To describe each process step, Amway requires the provision of a Process Flow Diagram, describing all process steps from Feed Stock through Finished Product.

  Process Flow Diagrams must be descriptive enough to include any Resin Technology, Chemical Stripping, and/or special Clean-Up processes utilized.

  For solvent disclosures provided, the order of listing shall be chronological (by process step), and must clearly define the full Chain of Custody.

- **Non-GMO Policy**

  All ingredients for Amway branded products will be non-GMO or Identity Preserved (IP)/PCR-negative with a recombinant DNA threshold of 0.9%.

  Suppliers of ingredients where GMO crops exist will be required to provide chain of custody to substantiate GMO status.

- **Japan Food Additives Regulations**

  Materials or products destined for the Japanese market will need to abide by these regulations, and may be subject to Japan Import Testing (JIT). If prohibited materials are naturally occurring, please provide documentation. Contact your Amway Procurement Representative or SQD Engineer for specific information, and refer to Amway product specifications for requirement status.

- **CIQ (China Import and Quarantine)**

  Materials or products destined for the Chinese market may be subject to CIQ (China Import and Quarantine). Regulations may include, but are not limited to, the following:

  - Raw materials must meet National Standard requirements or receive pre-approval prior to import.
  - Full disclosure of the manufacturing process, including process flow diagrams, is required.
  - Specific requirements related to resin extraction technology must be met.

- **DSHEA:** Materials must be compliant with the Dietary Supplement Health and Education Act of 1994 and properly categorized (with supporting documentation) as stated on the 1294 form.
- **Nagoya Protocol**: Material must comply with the Nagoya Protocol with supporting documentation or statement on company letterhead.

2. Durable Goods Regulatory Requirements

- **RESTRICTED SUBSTANCES: RoHS/REACH**

  Materials, products or components for use in electrical/ energy using appliances must meet the current requirements for RoHS compliance. While subject to expansion, the current list of RoHS includes limits for lead (Pb), cadmium (Cd), mercury (Hg), chromium (Cr), PBBs, and PBDEs. In terms of REACH, the materials, products or components must be in accordance with Annex XVII in terms of Substances of Very High Concern (SVHC).

- **ELECTRICAL SAFETY**

  Where applicable, products and/or components must meet and/or be certified and/or recognized in accordance with electrical safety standards. This includes the appropriate IEC and/or UL standards. Appropriate documentation in the form of test reports or certificates from authorized test houses or certifiers is an expectation.

- **ELECTROMAGNETIC COMPATIBILITY (EMC)**

  Products and/or components must meet the appropriate EMC limits in accordance with current FCC, IEC, EN, VCCI standards, where applicable. Appropriate documentation in the form of test reports or certificates from authorized test houses or certifiers is an expectation.

- **MATERIAL SAFETY**

  Where applicable, materials, products or components intended for use in drinking water treatment applications must meet current NSF/ANSI requirements for material safety. Suppliers should be prepared to disclose material formulation information directly to NSF International Toxicology Services. Additionally, products must meet current Japan MHLW requirements for articles in contact with foods and the EU requirements for materials in contact with foods.

3. Home Care Regulatory Requirements

The supplier shall provide documentation, where applicable, such as listing of their material on inventories/lists to include, but not limited to: TSCA, CERCLA, SARA, REACH, Domestic Substances List (Canada), and Inventory of Existing Chemical Substances (China).

4. Cosmetic/Beauty/Personal Care Regulatory Requirements

The supplier shall provide documentation, where applicable, citing compliance with the US Code of Federal Regulations, the European Cosmetics Directive (76/768/EEC) and the Hygienic Standard for Cosmetics published by the Ministry of Health of the People's Republic of China. As applicable, state where the material may appear on a published list/inventory including, but not limited to: REACH, Domestic Substances List (Canada), and Inventory of Existing Chemical Substances (China).

5. REACH Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals)

Amway routinely ships products and raw materials into the European Union. In 2013, certain specified materials which are imported into the European Union (above a designated volume) will be considered reportable under this chemical inventory regulation. The Amway Regulatory Affairs Department may contact you for more information in regards to the status of your materials and compliance with REACH requirements.

4.5 Packaging & Package Security Requirements

Provide properly packaged materials and products per Amway specifications.

- **Tamper-Evident Packaging Requirement**

  To ensure product integrity and guard against the possibility of adulteration, Amway requires TAMPER-EVIDENT seals and features on all raw material, chemical, and component packaging forms.

  Examples of Compliance:

  - ❖ Components – Boxes properly and securely sealed with tape or glue (no metal staples)
  - ❖ Raw Materials and Chemicals (liquids, resins) – Super sacks are tied up, and then zip-tied. Seal integrity (for paper sacks) is self-evident by its very nature.
  - ❖ Raw Materials and Chemicals (liquids, resins) – Drums and totes are secured with bung covers, zip-ties, etc. Pails are fitted with lids having tamper-evident tear tabs (and/or zip- ties). Tankers and Rail Cars have C-TPAT-compliant safety seals at each opening.
  - ❖ This Amway requirement has been traditionally enforced for all API's (active pharmaceutical ingredients), excipients, and NMI's (non-medicinal ingredients), as well as tankers and rail cars subject to the US Government's C-TPAT program.

4.6 Labeling & Lot Traceability Requirements

Provide properly labeled materials and products per Amway specifications and shipping requirements (including manufacturing trade names for raw materials and chemicals).

4.7 Shelf Life and Inventory Control Requirements

Amway seeks to provide our consumers products of the highest possible quality. As such, product age and freshness are an important part of that commitment. Reference Raw Material Specifications.

- Materials received by Amway/Nutrilite will have at least 50% of their Shelf Life remaining at

time of receipt.

- In some situations, Amway may have the ability to quickly schedule and process materials when remaining Shelf Life is less than 50%. In cases where suppliers cannot meet this guideline to fulfill open orders, we expect suppliers to gain the Prior Approval of their Item Planner and/or Item Buyer and document this agreement on the Supplier's Certificate of Analysis (to avoid rejection at Incoming Inspection).

4.8 Change Control/Agreement

Suppliers are required to maintain and demonstrate change control through documentation. Reference the following categories:

1. Changes in sub-suppliers
2. Design/Formulation: Any change in materials used or composition of raw material(s)
3. Processes: Any change to the manufacturing processes or equipment
4. Facilities: Moving to a different facility, or adding lines to or changing lines within a current facility
5. Trade Name or INCI (International Nomenclature of Cosmetic Ingredients) name changes
6. Test Method changes

All such changes shall be communicated to Amway, with advance notice given to allow for any necessary analytical/reliability/market registration/stability performed.

Written approval of all changes (per above) must be obtained from Amway prior to implementation. When required, a Quality Assurance Change Control Agreement (QACCA) will be issued by Amway.

4.9 Shipping Requirements

Ship materials produced at approved manufacturing facilities only.

4.10 Supplier Material Recall Requirements

In the event of a Supplier Raw Material/Component recall situation, it is the supplier's responsibility to email notification of the recall to: NutriliteSQD@amway.com, your Supplier Quality Engineer and/or Procurement Representative with affected purchase order and lot information. Notifications are critical in order for Global Amway/Nutrilite Quality Assurance to take immediate action on any Raw Material/Components that are being transported or have been delivered to Amway sites.

5.0 Non-Conforming Products and Materials

Our Incoming Quality Assurance labs perform product and material inspections per ANSI/ASQ Z1.4. Your control plan directed sampling (for Incoming, In-Process, and Finished Good inspections) should fully align with all significant characteristics listed on the Amway specification, per the following examples of Acceptable Quality Levels (AQL):

- 0.65% for Critical Non-Conformances
- 1.0% for Major Non-Conformances
- 4.0% for Minor Non-Conformances

Should your product or material fail to pass incoming inspection, we will issue an NCM. NCM's are typically communicated via email from either the Incoming Quality Assurance group or your Supplier Quality Development (SQD) Group.

5.1 Quality Incident

Amway defines non-conforming product as any Amway purchased product or raw material that fails to meet specifications and agreed upon standards. NCM's that can be issued to a supplier are:

- External Incoming and In-process: raw materials/components found to be not in compliance with Amway requirements.
- Arrival Defect Report (ADR): issued for inbound shipments that are not in compliance with Amway's Supplier Shipping, Transportation, Quality, and Packaging Requirements.
- OS&D (Over, Short, and Damaged): initiated by receiving personnel whenever a shipment is received damaged or the actual quantity received does not match the supplier's (and/or carrier's) shipping documents or master shipper/case label quantities.

5.2 Corrective Action/Preventive Action (CAPA)

A Corrective Action/Preventive Action (CAPA) is a supplier created action plan focused on preventing a non-conformance from recurring. The CAPA is created in response to a Quality Incident issued to communicate non-conforming material (NCM) or an ADR (Arrival Defect Report) issued to communicate shipping, packaging, identification, or paperwork errors that lead to a delay in material or product receipt. CAPAs may be required for all NCM's.

Acknowledge Receipt and Define Issue - The supplier is expected to acknowledge receipt of the Amway NCM/ADR notification and CAPA request within 48 hours.

6.0 Performance Measures/Metrics

Amway has a team of Supplier Quality Development (SQD) Engineers focused on partnering with key suppliers to drive mutually beneficial improvements in quality, consistency, and service. This is accomplished through:

- Clearly defined Specifications and quality expectations for materials.
- Measurement and analysis of supplier performance against expectations.
- Development of continuous improvement plans.
- Implementation of effective corrective and preventive action processes.
- Verification of capable quality control systems and processes.

6.1 Measures

Our SQD program measures supplier quality performance and continuous improvement as follows:

- Quality of Incoming Shipments (Right First Time score from Supplier Analytics Scorecard)
- Quality of Systems (audit score)
- Effectiveness of Corrective and Preventive Actions

6.2 Metrics

1. Supplier Scorecard

The Supplier Scorecard measures supplier performance using key supply chain metrics. Scorecards are available on the supplier portal in the Supplier Analytics section. Contact your Procurement Representative to set up access, as this section is password protected.

2. RFT (Right First Time)

   The RFT metric measures a supplier's ability to meet agreed-upon specifications and requirements. Each incoming Purchase Order Line is assigned a score of 100% or 0%. Any Purchase Order Line assigned a Supplier-related DMDO or ADR will be assigned a score of 0%. Suppliers are expected to maintain or exceed an overall RFT score of 98%. In addition to CAPA requests for individual failures, SQD Representatives may require a Supplier Quality Improvement Plan from suppliers with RFT scores < 98%.

$$RFT\ Score = 1 - (\frac{Total\ PO\ lines\ with\ at\ least\ one\ Supplier\ Releated\ NCM\ or\ ADR}{PO\ lines\ recieved})$$

3. Quality Systems Audit Checklist

   Amway utilizes Supplier Quality Audit Checklist to:

   - Help suppliers develop and implement adequate Quality Management Systems.
   - Help Amway resources assess the risk to Amway of using material from a supplier.
   - Improve Amway decision making relative to supplier qualification, certification, and improvement.

7.0 Glossary

- ADR - Arrival Defect Report; issued for inbound shipments not in compliance with Amway supplier shipping, transportation, quality, and packaging requirements.
- AQL - Acceptable Quality Levels
- cGMP - Current Good Manufacturing Practices
- CAPA - Corrective Action Preventive Action
- CDA - Confidentiality Disclosure Agreement
- CERCLA - Comprehensive Environmental Response, Compensation, and Reliability Act
- CIQ - China Import and Quarantine
- C of A - Certificate of Analysis; summarizes testing performed on referenced product/material demonstrating its acceptance against the specifications.
- C of C - Certificate of Compliance; a declaration from a non-consumable item supplier stating the referenced product/material meets all requirements, standards, and/or specifications.
- Corrective Action - Supplier created action plan focused on containing non-conforming material and determining root cause and immediate resolution of issue.
- NCM - Materials that are non-conformance to meet specifications.
- External Incoming NCM - Issued for products found out of specification at time of receipt.
- External In-Process NCM - Issued for products found defective or out of specification after passing incoming inspection; may be discovered at any point during or after the manufacturing process.
- FSMA - Food Safety Modernization Act, 21 CFR 117
- FSVP - Foreign Supplier Verification Program

- GMO - Genetically Modified Organisms
- IP - Identity Preservation is the practice of tracking the details of agricultural shipments so that the specific characteristics of each shipment is known.
- INCI - International Nomenclature of Cosmetic Ingredients
- JIT - Japanese Import Testing
- OS&D - Over, Short, and Damage; issued by receiving personnel for shipment received damaged or for quantity discrepancies between the actual quantity received and what is documented on the shipping papers or master shipper/case labels.
- PO - Purchase Order
- Preventive Action - Supplier created action plan focused on preventing a non-conformance from recurring.
- QACCA - Quality Assurance Change Control Agreement
- Quality Incident - Quality issue that results in not meeting specifications or requirements for ADR/NCM/OS&D
- REACH - Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals
- RFT - Right First Time
- RUD - Release Under Deviation; products/materials that do not meet Amway specifications but are accepted “as-is” due to minimum impact.
- RTV - Return to Vendor; disposition notice issued for rejected products/materials that will be returned to the supplier.
- RVE - Rework Vendor Expense; disposition notice issued for rejected products/materials that will be reworked at Amway but charges will be forwarded to the supplier.
- Root Cause - Fundamental deficiency that caused the non-conformance to occur
- SARA - Superfund Amendments and Reauthorization Act
- SIDI - Standardized Information on Dietary Ingredients
- SQD - Supplier Quality Development
- SVE - Scrap Vendor Expense; disposition notice issued for products/materials that will be scrapped at Amway and charged back to the supplier for payment.
- TSCA - Toxic Substances Control Act
- WADA - World Anti-Doping Agency

8.0 Amway's Contacts and Documents

8.1 Amway Contacts

COA's to be sent by hardcopy and Email according to the following:

- Raw Materials (Ada, MI) INCCHM@Amway.com
- Packaging Components (Ada, MI) INCPKG@Amway.com
- Durables Components (Ada, MI) INCHT@Amway.com

- Finished Goods (Ada, MI) INCBO@Amway.com
- Nutrilite Components, Raw Materials (Buena Park, CA, Trout Lake, WA, Quincy, WA, Spaulding, Ada, MI) RMCOA@Amway.com
- Nutrilite Finished Goods/Buy Outs (Buena Park, CA, Ada, MI) ContractLab@Amway.com

8.2 Documents

- CC-SOP-0003 - Supplier Requirements-Change control
- CC-SOP-0004 - Durables Engineering Change Procedure,
- SRM-SW-0002 - Supplier Requirements-Certificates of Analysis,
- SRM-SOP-0004 - Supplier Requirements-Remaining Shelf Life,
- 1294 Form - Raw Material Questionnaire (Nutrition) Form
- SRM-FRM-0001 - Supplier CAPA Form,
- SRM-POL-0002 – Global Irradiation Policy
- SRM-FRM-0003 - Amway Global Supplier Quality Development GSQD, Quality Audit Checklist

Approvals

Title	Name	Signature
Group Mgr. QE	Sam Kilgore	Reference document system.
DIR QA	Brandon Goodyke	Reference document system.
Author	Kevin Homrich	Reference document system.