ACTIVE

Amway sQAC Audit Checklist (Cover Page)

(Non-Drug)

COMPANY NAME: _____

DATE(S) OF AUDIT: _____

LOCATION [ADDRESS]: _____

ESCORTS [NAME(S) AND TITLE(S)]: _____

AUDITOR(S) [NAME(S) AND TITLE(S)]: _____

NOTE:

THIS CHECKLIST IS DESIGNED AS AN AID OR TOOL TO BE USED BY EXPERIENCED AUDITORS IN CONDUCTING AUDITS. IT IS NOT NECESSARILY INTENDED TO BE ALL-INCLUSIVE OR TO LIMIT THE SCOPE OF THE AUDIT.

KEY ELEMENTS:

1. LEADERSHIP
2. TRAINING
3. BUILDINGS FACILITIES, EQUIPMENT DESIGN, INSTALLATION & MAINTENANCE
4. TECHNICAL STANDARDS
5. WRITTEN PROCEDURES
6. VALIDATION / VERIFICATION
7. HOUSEKEEPING, PEST CONTROL, SANITIZATION & HYGIENE
8. MATERIAL CONTROL
9. MANUFACTURING OPERATIONS
10. PACKAGING OPERATIONS
11. STORAGE & FINISHED PRODUCT HANDLING
12. LABORATORY CONTROL
13. PROCESS CONTROL
14. IN-PROCESS & FINISHED PRODUCT RELEASE & CONTROL
15. RECORDS
16. INTERNAL AUDITS
17. CUSTOMER LEARNING & RESPONSE
18. QUALITY METRICS TRACKING & IMPROVEMENT
19. ACCOUNTABILITY FOR SUPPLIERS
20. SAFETY & SECURITY

ACTIVE

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
1	**Leadership**	**Nap**									
1.1	**Quality Management Organization**										
1.1.1	The organization has established and maintained a quality management unit within the overall company, which includes a clearly documented quality policy. The quality policy is received & understood by all Staff.					X	X	X	X	X	
1.1.2	An organizational chart exists which reflects the current reporting structure & responsibilities. Evidence exists which indicates organizational freedom to exercise authority and responsibility.					X	X	X	X	X	
1.1.3	Supplier holds a quality system certificate, such as ISO 9001, ISO 14001, ISO 22000, TS16949, GMP, HACCP, GFSI-accepted certification, etc. GMP system must be reviewed by a competent 3rd party.					X	X	X	X	X	X
1.1.4	Quality Assurance has the prime responsibility for evaluating Manufacturing material. If manufacturing is responsible for quality within manufacturing operations, Quality Assurance has the prime responsibility for auditing quality system conformance.					X	X	X	X	X	
1.1.5	A Quality System Management Representative exists, with defined authority and responsibility for meeting customer compliance.					X	X	X	X	X	
1.1.6	Management proactively plans and implements effective quality and reliability programs.					X	X	X	X	X	
1.1.7	There is a system or program in place to identify future Quality System needs to improve overall capability (such as facility, machine, software, inspection equipment and training investments, etc.)					X	X	X	X	X	
	COMMENTS:										
1.2	**Quality System Policy Manual & Quality Objectives**										
1.2.1	A Quality Manual has been developed which details the quality system design, and structure of policies and procedures. Procedures (referenced in the Quality Manual) identify who is responsible for action, what has to be done, and when actions are required.					X	X	X	X	X	
1.2.2	Quality Objectives are reviewed and analyzed periodically, and an appropriate action plan is developed. Company Quality Objectives are documented, approved, dated, communicated, understood and maintained throughout the organization.					X	X	X	X	X	
1.2.3	Quality Objectives and goals exist for continuous improvement of quality systems. Key Performance Indicators (KPI's) and metrics are tracked against stated goals and objectives.					X	X	X	X	X	
1.2.4	Quality Objectives and goals include appropriate customer satisfaction measures.					X	X	X	X	X	

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1.2.5	Achievement of Quality Objectives is a high priority within individual employee performance reviews and reward programs.					X	X	X	X	X	
	COMMENTS:										
1.3	**Quality Planning**										
1.3.1	Formal Quality Planning processes and activities exist to ensure that customer requirements will be met. Quality Planning shall take place for all new products, and awarded customer business.					X	X	X	X	X	
1.3.2	Documented evidence exists that key customers are involved in Quality Planning activities, as appropriate.					X	X	X	X	X	
	COMMENTS:										
1.4	**Management Review**										
1.4.1	The Quality Management System is reviewed by top Management for suitability, effectiveness, and improvement opportunities, at defined intervals. This QMS review includes the Quality Manual, all Quality Systems components, and Internal Audit results.					X	X	X	X	X	
1.4.2	A system is in place to verify that Quality Policies and Quality Objectives are being met. Appropriate accountabilities are established.					X	X	X	X	X	
1.4.3	Management Reviews include data from key products and processes (from all major areas).					X	X	X	X	X	
	COMMENTS:										
2	**Training**		**Nap**								
2.1	**Qualifications and Experience**										
2.1.1	Management is responsible for ensuring qualified technical personnel are in place for key Quality System activities (i.e., design, process, product, service support, etc.).					X	X	X	X	X	
2.1.2	Management is responsible for ensuring that an adequate number of qualified personnel exist to perform critical functions (such as manufacturing, research/development, and Quality Assurance)					X	X	X	X	X	
2.1.3	Employee job descriptions (at every level within the organization) directly support Quality Objectives.					X	X	X	X	X	

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	COMMENTS:										
2.2	**Training Procedures**										
2.2.1	A Training Program exists for all levels of the organization (i.e. part-time, full-time, temporary staff, management, visitors, contract/construction personnel).					X	X	X	X	X	X
2.2.2	Training procedures define short and long-term training requirements, retraining, refresher training, as well as the qualification steps (and experience level needed) for Trainers.					X	X	X	X	X	
2.2.3	**Canadian market specific directive:** Where consultants are used for training purposes, they have the necessary qualifications/training/experience to advise on the subjects for which they are retained.					X	X	X	X	X	
2.2.4	Periodic evaluations of training procedures & requirements are performed as part of Management Review (to ensure effectiveness).					X	X	X	X	X	
2.2.5	Employees responsible for the manufacture and testing of products have been trained to a level appropriate to the task, and in conjunction with industry standards (i.e., HACCP, GMP, ISO, food safety, etc.)					X	X	X	X	X	X
2.2.6	All employees receive training on relevant general topics such as Quality System requirements, safety/hazard communication, sanitation, equipment use, environmental risks, critical control points, etc.					X	X	X	X	X	X
2.2.7	Personnel in Manufacturing and Quality Assurance are aware of (and can demonstrate training in) key process characteristics related to the achievement of customer requirements.					X	X	X	X	X	
	COMMENTS:										
2.3	**Training Records**										
2.3.1	Training and qualification records must be maintained for all personnel and should include: Date, Topic, Name of Instructor, Employee Signatures, Test/Quiz scores, etc.					X	X	X	X	X	X
	COMMENTS:										
3	**Building Facilities & Equipment Design, Installation and Maintenance**		**Nap**								
3.1	**Building Facilities - General**										
3.1.1	The building design, structure and construction materials are appropriate for necessary cleaning, sanitization and maintenance activities					X	X	X	X	X	X

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3.1.2	The building structure and condition is suitable to the nature of what is being produced (no cracks, visible gaps, loose bricks, leaks in roof, broken windows, etc).					X	X	X	X	X	X
	COMMENTS:										
3.2	**Building Facilities - Infrastructure**										
3.2.1	Manufacturing area lighting is sufficient to perform required operations. Shields and/or covers are used to protect plant lighting in manufacturing areas.					X	X	X	X	X	
3.2.2	Critical utilities (i.e., water, gas, air, electric) are supplied by reliable sources and are sufficient to handle facility demands.					X	X	X	X	X	
3.2.3	Back-up generators or other parallel systems are installed (and periodically tested) where power delivery is known to be inconsistent.					X	X	X	X	X	
	COMMENTS:										
3.3	**Building Facilities - Segregation**										
3.3.1	There is a system for control and segregation of genetically modified organisms (GMO) from non-GMO materials and allergens to prevent cross-contamination.								X	X	
	COMMENTS:										
3.4	**Building Facilities - Environmental Control**										
3.4.1	Floors and walls in the Manufacturing area are made of (or coated with) impervious materials. Floors, walls, ceilings, windows and doors and are free of cracks and open joints.							X	X	X	X
3.4.2	Loading dock doors are flush to the floor and sealed (from the outside environment) when closed.					X	X	X	X	X	X
3.4.3	The facility provides protection from possible outside pollutants, infestations and contaminants (i.e., proper installation and use of HVAC, positive air pressure in building to minimize outside air infiltration).					X	X	X	X	X	X
3.4.4	Drinking water sources are located outside the Manufacturing area.							X	X	X	X
3.4.5	Clean toilet and hand washing facilities are readily accessible, in good sanitary condition, and with self-closing doors that do not open into Manufacturing areas (or areas where materials can be exposed to airborne contaminants).							X	X	X	X
3.4.6	Appropriate indoor environmental controls exist and are properly maintained (i.e., controls for temperature, humidity, air filtration, lighting, etc.)					X	X	X	X	X	X

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3.4.7	Independent air handling and filtration systems are installed in high risk areas (i.e., micro labs, USP Packaging areas, etc.)						X	X	X	X	X
3.4.8	**Canadian market specific directive:** In all areas where raw material, primary packaging materials, in-process and finished NHP's (Natural Health Products) are exposed - floors, walls, ceilings and other surfaces are hard, smooth and free of sharp corners where extraneous material can collect. They permit cleaning and any porous materials (bricks, cement blocks) are sealed.								X	X	X
	COMMENTS:										
3.5	**Building Facilities - Water Quality**										
3.5.1	Process water/ice can be demonstrated to be safe and adequate (i.e., meets EPA 40 CFR part 141 for drinking water, or equivalent local standards), and analyzed as per documented plant schedule (minimum requirement is twice annually.)					X	X	X	X	X	X
3.5.2	Process water 'backflow preventers' and check valves are in place (where applicable) and identified.					X	X	X	X	X	X
	COMMENTS:										
3.6	**Equipment Design & Installation**										
3.6.1	There is adequate space provided for orderly placement of manufacturing lines, equipment, and materials. Placement is designed to prevent mix-ups and cross-contamination, and allows for effective cleaning.					X	X	X	X	X	X
3.6.2	Major equipment, piping, packaging lines, etc. are clearly labeled and identifiable to promote an orderly workplace.					X	X	X	X	X	X
3.6.3	Equipment is designed with cleaning and sanitization accessibility in mind.						X	X	X	X	X
3.6.4	Manufacturing equipment is constructed of materials appropriate for the application and environment (i.e. non-toxic, corrosion-resistant/stainless steel, fiberglass, etc.)					X	X	X	X	X	X
3.6.5	Manufacturing vessels and material handling equipment seams are well bonded and smooth to prevent material buildup and promote sanitary conditions.						X	X	X	X	X
3.6.6	Hoppers, tanks and similar receptacles are properly covered to avoid contamination.					X	X	X	X	X	
3.6.7	Manufacturing lines have appropriate metal detection equipment, as required							X	X	X	

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3.6.8	Material preservation equipment (refrigerators, freezers, cold rooms, etc.) and thermal processing equipment are fitted with working, accessible, and calibrated temperature gauges. Key environmental data is monitored and recorded.						X	X	X	X	
3.6.9	**Canadian market specific directive**: Equipment is maintained in a good state of repair and is protected from contamination when stored.					X	X	X	X	X	
3.6.10	**Canadian market specific directive:** Critical equipment is subject to installation and operational qualification and where required, calibrated and usage logs maintained.					X	X	X	X	X	
	COMMENTS:										
3.7	**Facility & Equipment Maintenance**										
3.7.1	Maintenance staff is appropriate to the size and complexity of the operation.					X	X	X	X	X	
3.7.2	Facility and equipment maintenance programs (both corrective and preventive) ensure the safe & reliable manufacture of materials.					X	X	X	X	X	X
3.7.3	Complete corrective and preventive maintenance records are readily available for all process equipment.					X	X	X	X	X	X
3.7.4	Maintenance Staff supports the reliable operation of critical equipment by holding stock of spare parts (or have expedite programs in place for their rapid supply).					X	X	X	X	X	
3.7.5	Lubricants and chemicals used for operation of equipment are approved for food grade applications.							X	X	X	
3.7.6	Preventive maintenance program is reviewed on a routine basis for effectiveness, and ensures that equipment (including returned equipment following maintenance) does not become a source of contamination.					X	X	X	X	X	X
	COMMENTS:										
4	**Technical Standards**		**Nap**								
4.1	**Specifications, Test Methods, and Inspection Standards - General**										
4.1.1	A Specification System exists for each product or material that is manufactured. Specifications are referenced in appropriate Quality System documents, and are traceable to Amway requirements.					X	X	X	X	X	
4.1.2	Specifications are aligned with the correct regulatory standard.					X	X	X	X	X	
4.1.3	Specifications, test methods, and inspection standards are validated, documented, properly stored, and maintained					X	X	X	X	X	

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4.1.4	Specifications, test methods, and inspection standards (including drawings and artwork) are controlled via a secured network (or equivalent means), and are readily accessible to all appropriate areas (including Sales, QA, and Manufacturing).					X	X	X	X	X	
4.1.5	Specifications, test methods, and inspection standards are routinely used to ensure that customer requirements will be met.					X	X	X	X	X	
4.1.6	Specifications, test methods, and inspection standards are routinely audited to confirm that the latest (most current) versions are being used throughout the facility					X	X	X	X	X	
4.1.7	Customer-specific inspection and qualification standards are identified and controlled by QA (including master samples, color standards, retains, and qualification samples)					X	X	X	X	X	
	COMMENTS:										
4.2	**Specifications, Test Methods, and Inspection Standards - Change Control**										
4.2.1	A system exists for necessary change control and maintenance of all pertinent (standards-oriented) documents related to the manufacturing, processing and control of finished products.					X	X	X	X	X	
4.2.2	A system exists for customer specification receipt, review and control.					X	X	X	X	X	
	COMMENTS:										
4.3	**Regulatory & Safety Standards**										
4.3.1	A qualified technical representative with responsibility for Regulatory Compliance is identified.					X	X	X	X	X	
4.3.2	Product Safety Evaluations and/or toxicology data are available for all items manufactured.							X	X	X	
4.3.3	Clinical data (to substantiate any product claims made on products) can be provided.							X	X	X	
4.3.4	Supplier has demonstrated the capability to register and supply finished products to countries where product registration is required.						X	X	X	X	
4.3.5	Certificates of Conformity, Health Certificates, etc. from recognized authorities can be supplied for finished products (and/or the manufacturing site) where required.						X	X	X	X	
	COMMENTS:										
4.4	**Local/National/Foreign Regulatory & Safety Requirements**										
4.4.1	Where required by local, national or foreign regulatory requirements, supplier has legal (governmental) permission to produce products/materials (for each intended market).					X	X	X	X	X	

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4.4.2	Where required by local, national or foreign regulatory requirements, supplier evaluates and verifies products and materials are safe for human use and/or consumption.					X	X	X	X	X	
4.4.3	Amway's Supplier Code of Conduct is followed (www.suppplier.amway.com, Business Requirements page).					X	X	X	X	X	
4.4.4	Applicable national standards, laws and regulations are identified, analyzed and followed.					X	X	X	X	X	
	COMMENTS:										
4.5	**European-Market Specific Directives**										
	PLASTICS & PACKAGING										
4.5.1	All individual batches are tested to EN1122 to comply with the Dangerous Substances and Preparations Directive 76/769/EEC (as amended) for total cadmium content.					X	X	X	X	X	
4.5.2	Packaging materials (intended for food contact use) are identified as such, and certified.					X			X		
4.5.3	All packaging used is tested for compliance to the European Packaging Directive 94/62/EC.					X					
	DETERGENTS										
4.5.4	Detergent Finished Product Dossiers meet the Dangerous Preparations Directive 1999/45/EC.						X				
4.5.5	All documentation (re:detergents regulation 648/2004/EC and its amendment 907/2006/EC), is available.						X				
	FOOD & FOOD SUPPLEMENT DOSSIERS										
4.5.6	Product complies with the hygienic requirements of Manufacturing, Shipping and Storage of Goods according to Regulation (EC) No 852/2004.								X	X	
4.5.7	Product complies with Regulation (EC) No 178/2002 General Food Law, Directive 2000/13/EC on Food Labeling, and Directive 1990/496 (and its amendment 2008/100/EC)vfor Nutrition Labeling								X	X	
4.5.8	Product complies with Directive 2002/46/EC on Food Supplements)and its amendment 2006/37/EC) regarding the inclusion of certain substances.								X	X	
4.5.9	Product complies with Regulation (EC) No 1925/2006 for the Addition of Vitamins, Minerals and certain other substances in foodstuffs.								X	X	
4.5.10	Product complies with Regulation (EC) No 258/1997 on Novel Foods and Novel Food Ingredients.								X	X	
	COSMETICS										
4.5.11	Cosmetics are manufactured to BS ISO 22716:2007 Cosmetic Good manufacturing practices (GMP) or other similar guidelines on good manufacturing practices.							X			

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4.5.12	A Safety Evaluation according to the Scientific Committee on Consumer Products (SCCP) guidelines for Cosmetic Products can be provided if needed.							X			
	COMMENTS:										
5	**Written Procedures**		**Nap**								
5.1	**Quality System Design**										
5.1.1	The design and structure of the Quality System is defined, and suitable to the type and complexity of the operations it covers.					X	X	X	X	X	
5.1.2	The inter-relationships between Quality Systems levels (policies, programs, procedures, work instructions, forms, etc) are defined, and are suitable and effective for the employees who use them.					X	X	X	X	X	
	COMMENTS:										
5.2	**Quality System Procedures - General**										
5.2.1	Current Quality System Procedures exist, for the direction and control of all Quality System activites referenced by these 20 Key Elements. *Example procedures include (but are not limited to):* Calibration Change Control Control of Non-Conforming Material (including identification and segregation) Corrective & Preventive Action (CAPA) Customer Requirements (establishment & verification) Customer Satisfaction (measurement & improvement) Detection Devices (testing & repair) Document Control First Piece Approvals & Line Clearance HACCP Hazardous Material Handling (including Pesticides) Inspection, Testing, and Product Acceptance/Release Inspection and Testing Status Laboratory Control Maintenance Manufacturing Operations Pollutant, Contamination, and Allergen Control Quality Control Quality Document & Information Systems Specifications Control (for products and packages) Test methods (creation, validation and use)					X	X	X	X	X	X
5.2.2	Responsibility for creation, approval, and revision of all Quality System documents is defined.					X	X	X	X	X	
5.2.3	Documented procedures clearly identify their scope (what processes and activities they cover)					X	X	X	X	X	

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5.2.4	Quality System documents are controlled by revision level, and show document ownership					X	X	X	X	X	
	COMMENTS:										
5.3	**Document Control - Creation, Approval, Revision & Distribution**										
5.3.1	A Document Control procedure exists describing the necessary steps for document creation, approval, revision & distribution					X	X	X	X	X	
5.3.2	Design changes are controlled by Engineering Change Notices or a similar process (SRN).					X	X	X	X	X	
5.3.3	For Food & Dietary Supplements - All applicable Quality System documents are approved and controlled by Quality Assurance								X	X	
5.3.4	A Master List referencing all controlled documents exists, including the Revision Level and Review Due Date (or Review Period).					X	X	X	X	X	
5.3.5	Where Controlled Documents are used in hard-copy form, a Document Distribution List is maintained					X	X	X	X	X	
	COMMENTS:										
5.4	**Document Control - Obsolete Documents**										
5.4.1	A written procedure exists for the removal and/or destruction of obsolete documents.					X	X	X	X	X	
5.4.2	Obsolete documents are removed and/or destroyed in a timely and confidential manner.					X	X	X	X	X	
5.4.3	Obsolete documents retained for legal (and/or knowledge-preservation purposes) are suitably identified.					X	X	X	X	X	
5.4.4	Obsolete document removal/destruction processes are audited for effectiveness (Internal Audits)					X	X	X	X	X	
	COMMENTS:										
6	**Validation/Verification**		**Nap**								
6.1	All key control inputs are validated (or verified) to ensure capability, compliance, and effectiveness. According to each unique supplier risk, some or all of the following validation/verification areas should be considered: *Products, processes, computerized systems, software, manufacturing systems, procedures, equipment and test methods*					X	X	X	X	X	
6.2	Written validation/verification procedures are documented and available, and is performed on all equipment and test methods. Systems are in place to provide review and revalidation/reverification if necessary.					X	X	X	X	X	
6.3	Verification testing is conducted and documented to assure detection devices are operating and effectively rejecting defective products/materials.					X	X	X	X	X	

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						Question Supports these Business Lines						
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6.4	Validation and verification activities, supporting HACCP program compliance and effectiveness, can be demonstrated.								X	X	X
6.5	A microbiology validation/verification program exists						X	X	X	X	
6.6	A documented Product Stability Program exists (for finished goods).						X	X	X	X	
	COMMENTS:										
7	**Housekeeping, Pest Control, Sanitization & Hygiene**	**Nap**									
7.1	**Housekeeping**										
7.1.1	The supplier practices good housekeeping. Work areas are neat and orderly (i.e. 5-S).					X	X	X	X	X	
7.1.2	A documented schedule for housekeeping exists.					X	X	X	X	X	
7.1.3	Facility grounds are well-maintained including roads, parking lots, grass and drain areas.					X	X	X	X	X	X
7.1.4	Cafeterias and break rooms are located away from Manufacturing area(s).					X	X	X	X	X	
7.1.5	Food and drink (for employee consumption) are not allowed outside the cafeteria or break room.					X	X	X	X	X	
7.1.6	Bathrooms contain antimicrobial soap products for washing and paper towels or blowers for drying hands.					X	X	X	X	X	
7.1.7	Wastes are disposed of properly and in a timely manner.					X	X	X	X	X	
7.1.8	Surfaces are corrosion-proof and easy to clean.					X	X	X	X	X	
7.1.9	Walls, ceilings and floors are neat and clean.					X	X	X	X	X	
7.1.10	Ceilings and light fixtures are easy to clean and free of foreign matter (dust, condensed water)					X	X	X	X	X	
7.1.11	Adequate floor drainage exists (to guard against floods, back-ups, etc). For food and dietary supplements, drains have removable grates installed.					X	X	X	X	X	
7.1.12	Drain lines are easy to clean and drain, and are installed to prevent cross contamination.					X	X	X	X	X	
7.1.13	Waste water does not to flow back or pile up in deposits.					X	X	X	X	X	
7.1.14	Warehouse area is clean and orderly.					X	X	X	X	X	
	COMMENTS:										
7.2	**Pest Control Program**										
7.2.1	The facility has an active and documented Pest Control Program, which identifies the individual responsible, site plan with trap/bait locations, inspection schedules, and pest targets. Bait, if used, is located outside the facility, whereas capture systems may be used both within and outside the facility.					X	X	X	X	X	X

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

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7.2.2	Written procedures are utilized for the application of pesticides. All devices/chemicals used in pest control are proven to be appropriate to the application. MSDS's are present for any pesticides used.					X	X	X	X	X	X
7.2.3	Pesticides, insecticides, fungicides and rodenticides are properly labeled and stored in a locked secure area (away from primary products and/or materials)					X	X	X	X	X	X
7.2.4	Windows are intact. If open, windows are fitted with screens. Doors have strip curtains.					X	X	X	X	X	X
7.2.5	Floors, walls, ceilings, doors and window frames are completely sealed to prevent entry of pests.					X	X	X	X	X	X
7.2.6	Building exterior is protected from rodent and pest entry.					X	X	X	X	X	X
7.2.7	Goods and equipment are stored away from walls (18 inches)					X	X	X	X	X	X
7.2.8	Ultraviolet insectocutors are in use.					X	X	X	X	X	X
7.2.9	Routine documented inspections of the facility are conducted to ensure that pest control programs are effective (auditor shall note frequency).					X	X	X	X	X	X
7.2.10	Facility documents and charts all observed pest (and pest action) activity including findings/observations, trap and corrective actions.					X	X	X	X	X	X
7.2.11	If a 3rd party manages the Pest Control Program, the auditor shall record the contractor name, details of services, and visit history.					X	X	X	X	X	X
	COMMENTS:										
7.3	**Sanitization**										
7.3.1	Documented and validated procedures exist for the housekeeping, cleaning, sanitizing, and preservation of Manufacturing lines and equipment (and include designated responsibilities).						X	X	X	X	X
7.3.2	There is a program in place which addresses tools/parts reconciliation, cleaning and/or sanitizing verification, and the use of appropriate lubricants (i.e., food grade).						X	X	X	X	X
7.3.3	There written & comprehensive lab cleaning & sterilization program (incl. environmental monitoring)						X	X	X	X	X
7.3.4	Where CIP is used (Cleaning in Place), validated procedures direct the activity.						X	X	X	X	X
7.3.5	Cleaning schedules and usage logs exist for major equipment to include: dates, products, lot #(s), person who used/cleaned, etc.					X	X	X	X	X	X
7.3.6	Critical points of the cleaning process are monitored and recorded including time, temperature, chemical concentration, flow rate, pH, etc.						X	X	X	X	X

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7.3.7	The cleaning and storage of brushes and other utensils used for cleaning is controlled and are clearly identified.						X	X	X	X	X
7.3.8	After cleaning, equipment is stored properly.					X	X	X	X	X	X
7.3.9	Storage areas and/or facilities are included within the Master Cleaning/Sanitation Schedule.					X	X	X	X	X	X
7.3.10	The cleanliness and/or sterility of water sources are maintained through active treatment, sampling, and monitoring. Records exist that these activities take place (including both process contact & utility water).						X	X	X	X	X
7.3.11	If the facility utilizes a 3rd party/contract cleaning company, the auditor shall record details.					X	X	X	X	X	X
	COMMENTS:										
7.4	**Hygienic Practices**										
7.4.1	A personal hygiene program is in place to provide training, control and supervision of hygienic practices (including employee appearance and contamination sources)						X	X	X	X	X
7.4.2	Employees wear clean clothing suitable for manufacturing activities. Additional protective apparel and or coverings are provided, and worn when required.					X	X	X	X	X	X
7.4.3	Designated areas (outside of manufacturing areas) have been provided for storage of clothing and/or personal belongings.					X	X	X	X	X	X
7.4.4	Employee personal hygiene expectations (i.e., proper hand sanitization) are prominently displayed within the facility (including restrooms and manufacturing areas).						X	X	X	X	X
	COMMENTS:										
8	**Material Control**	**Nap**									
8.1	**Incoming Material Receipt**										
8.1.1	Written procedures describe the receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of all materials and chemicals used within the facility. All incoming chemicals must be logged, stored and controlled according to written procedures to ensure correct use. MSDS must be available for all chemicals.					X	X	X	X	X	X
8.1.2	Procedures are in place to quarantine and document any material found to have foreign body contamination.					X	X	X	X	X	X
8.1.3	Incoming materials meet packing, shipping, and labeling requirements. Discrepancies are recorded and reported (i.e., over, short or damaged). Approval status for all inventory is evident.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

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8.1.4	All stock received (including date of receipt, lot number(s), quantity of receipt, etc) can be traced within an information system (i.e., ERP or MRP).					X	X	X	X	X	
	COMMENTS:										
8.2	**Incoming Material Inspection/Testing**										
8.2.1	Adequate resources (qualified people, testing equipment, etc) are available to perform this function.					X	X	X	X	X	
8.2.2	Incoming materials/components are inspected using a defined sampling plan (including sample size, frequency & required tests). Inspection results are recorded. CofA's or CofC's are required.					X	X	X	X	X	
8.2.3	Inspection results are approved by authorized persons before being placed into storage or manufacturing.					X	X	X	X	X	
8.2.4	All incoming materials are inspected to current written specifications and/or approved standards.					X	X	X	X	X	X
8.2.5	Incoming inspection test methods are documented and referenced on material specifications.					X	X	X	X	X	
8.2.6	Incoming inspection measurement and test equipment are calibrated and current.					X	X	X	X	X	
8.2.7	Test data is recorded according to applicable procedures or regulations.					X	X	X	X	X	
	COMMENTS:										
8.3	**Traceability**										
8.3.1	A Traceability system exists, which identifies finished products back to raw materials, and packaging & raw materials forward to finished products.					X	X	X	X	X	X
8.3.2	The traceability control system is controlled manually or electronically with information easily obtained. System allows for review and traceability of material during all phases of processing, including traceability of material to manufacturer. All lot information is defined and recorded.					X	X	X	X	X	X
8.3.3	Inspection samples are properly identified for traceability through the inspection process.					X	X	X	X	X	
8.3.4	An Emergency Release process (for material prior to verification) is defined, documented, and followed. QA must approve any material released under deviation and/or prior to verification.					X	X	X	X	X	
8.3.5	Records of test reports, certifications, statistical data, etc., are on file and traceable to specific lots.					X	X	X	X	X	X
	COMMENTS:										

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8.4	**Rejected Material**										
8.4.1	Written procedures exist for the prompt retrieval and containment of nonconforming material found during incoming inspection, manufacturing and/or during customer complaint processes.					X	X	X	X	X	
8.4.2	Authorized company representatives routinely review the status of non-conforming material to arrive at timely dispositions. Disposition decisions are effectively and promptly communicated.					X	X	X	X	X	
8.4.3	All rejection reasons are recorded.					X	X	X	X	X	
8.4.4	Rejections are investigated until root cause is determined. Actions taken are per supplier's CAPA program (KE 18.3).					X	X	X	X	X	
	COMMENTS:										
8.5	**Retain Samples**										
8.5.1	A material retain program is defined and utilized. Retains are stored in an appropriate manner and environment, protecting the integrity of each sample, per the appropriate retention period.					X	X	X	X	X	
	COMMENTS:										
8.6	**Product Recalls**										
8.6.1	Documented procedures exist for tracking raw materials and recalling finished products. In the case of foods and dietary supplements, this procedure must outline plant recall team members, their alternatives, and a 24/7 emergency contact list.					X	X	X	X	X	X
8.6.2	Mock recalls are conducted on products/materials per specified frequency (minimum requirement of once per year).						X	X	X	X	X
8.6.3	There is a process to notify customers when non-conforming products have been shipped.					X	X	X	X	X	
8.6.4	Records of inadvertent shipments of non-conforming product are maintained in a database.					X	X	X	X	X	
	COMMENTS:										
9	**Manufacturing Operations**		**Nap**								
9.1	**General**										
9.1.1	There is a Process Flow Chart for each major manufacturing process.					X	X	X	X	X	X
9.1.2	Written procedures for start-ups and 1st piece approvals are available.					X	X	X	X	X	
9.1.3	Filling, assembling, packing, and other operations are performed in such a way that products are not adulterated and/or contaminated.					X	X	X	X	X	

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9.1.4	Effective measures shall be taken to protect against metal and foreign materials.					X	X	X	X	X	X
9.1.5	High risk Manufacturing areas are properly maintained and controlled (i.e., positive air pressure, water, temperature, air filtration, incoming and out going materials).					X	X	X	X	X	
9.1.6	Manufacturing facility is managed according to the current ISO 22716 Cosmetic GMP standard.							X			
	COMMENTS:										
9.2	**Manufacturing Equipment**										
9.2.1	Standard operating procedures are written (and trained to) for each major piece of equipment used in manufacturing.					X	X	X	X	X	
9.2.2	Written and/or electronic records are kept for major equipment (documenting usage history of each piece, in support of maintenance programs listed in 3.7).					X	X	X	X	X	
	COMMENTS:										
9.3	**Manufacturing / Batch Records**										
9.3.1	The Manufacturing or Batch Record is checked at each level of the process, and approved by QA.						X	X	X	X	
9.3.2	Manufacturing or Batch Records contain information such as material names, lot codes and input quantities.					X	X	X	X	X	
9.3.3	A printed label (representative of those used) is included in the Manufacturing or Batch Record.						X	X	X	X	
9.3.4	All containers, processing lines and major equipment used during Manufacturing are identified and recorded in Batch Records as appropriate.						X	X	X	X	
	COMMENTS:										
9.4	**Manufacturing Standards and Reaction Plans**										
9.4.1	Manufacturing floor inspection standards are itemized, controlled, outline key criteria, and are referenced within a Master List.					X	X	X	X	X	
9.4.2	Physical test equipment, standards, and boundary samples are located as close to the point of manufacture as practicable.					X	X	X	X	X	
9.4.3	Reaction plans have been developed for situations when processes or operating parameters are out of control or trending out of control. Any actions taken on the process are recorded.					X	X	X	X	X	
	COMMENTS:										
9.5	**Selection and Calibration of Inspection, Measurement and Test Equipment**										

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9.5.1	Testing and Measurement equipment are accurate to one decimal place beyond any and all specifications tested against.					X	X	X	X	X	X
9.5.2	A calibration program is utilized for the identification, traceability and control of all inspection, measurement, and test equipment.					X	X	X	X	X	X
9.5.3	Calibration records are maintained indicating that inspection, measurement, and test equipment are recertified at regular intervals, and include those records traceable to national standards.					X	X	X	X	X	X
9.5.4	Equipment calibration procedures describe the removal of and/or major repair process for equipment that cannot be properly calibrated.					X	X	X	X	X	X
9.5.5	Gauge control and calibration stickers are attached to inspection, measurement, and test equipment and reflect current calibration status.					X	X	X	X	X	X
	COMMENTS:										
9.6	**Special Processing Restrictions (GMO, Irradiation, Botanical Solvents)**										
9.6.1	Products are manufactured in such a way as to prevent contamination from GMO substances.									X	
9.6.2	Irradiation and/or chemical fumigation techniques are not used on any products.								X	X	
9.6.3	Any solvents used (in botanical processing) are USP-approved.									X	
	COMMENTS:										
10	**Packaging Operations**		**Nap**								
10.1	**General**										
10.1.1	Procedures are established and followed for the receipt, inspection, storage, handling, & reconciliation of packaging materials.					X	X	X	X	X	
10.1.2	Packaging procedures are readily available to employees at appropriate packaging work areas.					X	X	X	X	X	
10.1.3	Where different packaging and labeling operations are being carried out simultaneously, adequate separation is provided.					X	X	X	X	X	
10.1.4	All finished goods packaging containers (including trucks) are confirmed to be clean, dry and pest free before sealing and shipping.						X	X	X	X	
	COMMENTS:										
10.2	**Labels and Artworks**										

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10.2.1	A procedure exists for the approval of labels and artworks.					X	X	X	X	X	X
10.2.2	Supplier-developed labels contain all pertinent information to meet contractual and legal obligations (e.g., MOA number, product name, ingredient statement, handling statement, & Net Contents statement).					X	X	X	X	X	
10.2.3	Supplier-developed finished good labels are legible and are capable of meeting Amway labeling requirements for manufacturing date, expiration date, and lot/batch number.					X	X	X	X	X	
10.2.4	Access to the label storage areas is limited to authorized personnel.					X	X	X	X	X	
10.2.5	A procedure for the destruction of obsolete and out-date labels exists.					X	X	X	X	X	
10.2.6	Artwork numbers are verified with the specification before printing.					X	X	X	X	X	
	COMMENTS:										
11	**Storage & Finished Product Handling**		**Nap**								
11.1	**Storage**										
11.1.1	Incoming materials, packaging components and finished products are stored per specifications, and in a manner which prevents damage, contamination, cross-contamination, loss or degradation.					X	X	X	X	X	X
11.1.2	Storage facilities have procedures to ensure that Incoming Materials, Work-In-Progress & Finished Goods are properly segregated and visually identified as to Test Status (approved, rejected/quarantined, awaiting inspection, etc.). Documented procedures are available in areas which define stock status.					X	X	X	X	X	X
11.1.3	In accordance with Amway requirements regarding "tamper-evident" packaging, incoming materials, packaging components and finished products are stored in containers designed to protect against adulteration. Hazardous materials are segregated.					X	X	X	X	X	
11.1.4	Storage facilities have proper storage of product off floors (and away from walls at least 18").						X	X	X	X	
11.1.5	Outside/contract storage facilities are shown to meet or exceed Amway standards and applicable regulatory GMP requirements.					X	X	X	X	X	
11.1.6	Storage facilities have procedures and records for the inspection of inbound and outbound trucks (i.e., damage, security seals, adulteration, etc).					X	X	X	X	X	X

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11.1.7	Storage facilities have temperature and humidity controls (where required by specifications and/or product critical characteristics). Controls are monitored/recorded using calibrated devices. Materials are re-evaluated, as appropriate, to determine their suitability for use after prolonged storage or exposure to heat or humidity.					X	X	X	X	X	X
11.1.8	Storage records identify finished/packaged goods by name, code, lot, quantity & storage location.					X	X	X	X	X	X
11.1.9	Transportation providers meet required GMP standards for product storage and transportation.						X	X	X	X	X
11.1.10	Transportation systems are validated and monitored to ensure product remains in acceptable storage conditions during handling (where required by specifications and/or product critical characteristics).					X	X	X	X	X	
	COMMENTS:										
11.2	**Finished Product Handling**										
11.2.3	The Inventory System is audited per defined procedures (i.e., cycle count frequency & accuracy).					X	X	X	X	X	
11.2.4	Stock is rotated on a FIFO (first-in, first-out) basis unless otherwise defined. Obsolete/expired inventory is disposed in a timely manner.					X	X	X	X	X	
11.2.5	Where scrapping is directed by Amway for Amway's products, photos and Certificates of Disposal are maintained. Amway is informed of any disposal actions taken on its projects.					X	X	X	X	X	
	COMMENTS:										
12	**Laboratory Control**	**Nap**									
12.1	**General**										
12.1.1	Lab resources are sufficient for the success of the function (qualified people, testing equipment, etc).					X	X	X	X	X	
12.1.2	GLP (good laboratory practice) gowning and PPE (personal protective equipment) practices are followed.					X	X	X	X	X	
12.1.3	Documented procedures exist for the management, storage and disposal of hazardous and biohazardous substances & wastes inside the lab.					X	X	X	X	X	
	COMMENTS:										
12.2	**Test Equipment & Media**										
12.2.1	All inspection, measurement and test instruments are well maintained, calibrated, clean and with orderly placement.					X	X	X	X	X	

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12.2.2	A process exists for the control, storage, maintenance & documentation of lab/chemical standards and reagents. Reagents are labeled with the expiration date. Toxic reagents are double locked, controlled by authorized staff, and registered as required by government regulations.						X	X	X	X	
	COMMENTS:										
12.3	**Test Planning**										
12.3.1	Updated product specifications are readily available (and used) within the Lab.					X	X	X	X	X	
12.3.2	Test Plans are developed, indicating laboratory inspection frequency, # of samples & required tests.					X	X	X	X	X	
12.3.3	Test results are recorded and saved in accordance with documented procedures. A certificate is provided for all batches/lots, where required.					X	X	X	X	X	
12.3.4	Where reduced testing is used, a sound and reasonable statistical basis must be demonstrated.					X	X	X	X	X	
	COMMENTS:										
12.4	**Reaction Planning**										
12.4.1	There is a procedure for handling out of specification (OOS) test results, including formal investigation and appropriate follow-up by QA personnel.					X	X	X	X	X	
	COMMENTS:										
12.5	**Micro Lab Operations**										
12.5.1	A documented program exists for effective lab cleaning, sanitization, and environmental monitoring.						X	X	X	X	
12.5.2	A microbiology culture media QC program is established and utilized to ensure proper handling/storage.						X	X	X	X	
12.5.3	The micro lab is properly segregated (preparation room, incubation room, and counting room).						X	X	X	X	
12.5.4	Microbiologically sensitive ingredients are monitored, tested and documented against specified limits.						X	X	X	X	
12.5.5	Authorized and qualified persons are appointed to control pathogen strains.						X	X	X	X	
	COMMENTS:										
13	**Process Control**	**Nap**									
13.1	**Process Control Documentation**										

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13.1.1	Process Flow Diagrams and/or Manufacturing Instructions are available at operating workstations, and show necessary quality checkpoints, including frequency and control limits. Records are in place to prove implementation. Visual observations of operator practices evidence their use.					X	X	X	X	X	
13.1.2	Methods utilized for establishing & monitoring critical process control points are documented.					X	X	X	X	X	
13.1.3	Process data is utilized for Statistical Process Control (SPC) as an important tool for maintaining control of manufacturing operations and reducing process variation. Continuous reduction in process variation is actively pursued based on data analyses.					X	X	X	X	X	
13.1.4	Manufacturing is set up to meet Customer Specifications and Requirements. Systems are in place to ensure that the most current customer specifications are in use.					X	X	X	X	X	
	COMMENTS:										
13.2	**Manufacturing Process Change Control**										
13.2.1	There are procedures for controlling manufacturing process changes.					X	X	X	X	X	
13.2.2	All process changes are documented, reviewed, and approved by appropriate personnel before change is made. Employees are properly trained on manufacturing process changes.					X	X	X	X	X	
13.2.3	Risk-based tools and/or activities (such as controlled trials and Process Failure Mode & Effects Analyses) are utilized prior to making changes in key operations.					X	X	X	X	X	
13.2.4	All manufacturing process changes are promptly communicated to customers. New processes are not implemented without customer knowledge and approval.					X	X	X	X	X	
13.2.5	Proper line clearance procedures are in place, utilized, verified, and recorded for each line change (i.e., changes to and clearance of products, molds, ancillary equipment, screens, materials etc).					X	X	X	X	X	
	COMMENTS:										
13.3	**Process Capability**										
13.3.1	Processes operate to a target versus a maximum or minimum value.					X	X	X	X	X	
13.3.2	Statistical Process Control (SPC) or other effective tools are used to control and improve manufacturing processes. Process Capability Indices (such as CpK) are reviewed.					X	X	X	X	X	
13.3.3	Process capability (to customer requirements) is verified after equipment installation, maintenance work, manufacturing start-up, and process changes.					X	X	X	X	X	
	COMMENTS:										

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13.4	**Manufacturing Process Controls**										
13.4.1	Documented procedures are in place for product contamination prevention (i.e., examination of screens, filters, magnets, Manufacturing equipment, and inspection of overheads, light shields, and adjacent surfaces).						X	X	X	X	
13.4.2	The facility has electronic sorting equipment, metal detectors, etc. and associated written procedures for the calibration, maintenance and operational practice for the removal of foreign materials. Verification testing is conducted and documented to ensure detection devices are effectively rejecting defective products/materials.							X	X	X	X
	COMMENTS:										
13.5	**Preventive Maintenance**										
13.5.1	A preventive maintenance program has been documented and implemented.					X	X	X	X	X	
13.5.2	Complete preventive maintenance records are readily available for all process equipment.					X	X	X	X	X	
13.5.3	Records indicate that high wear parts, for critical processes, are kept in stock.					X	X	X	X	X	
13.5.4	Preventive maintenance program is reviewed on a routine basis for effectiveness, and ensures that equipment does not become a source of contamination.					X	X	X	X	X	
	COMMENTS:										
13. 6	**HACCP (Hazard Analysis & Critical Control Points) and Related Prerequisite Programs**										
13.6.1	The following Prerequisite Programs (PRP) are present and functioning adequately to support HACCP compliance (Sanitation (KE #7) GMPs (throughout sQAC Standard) Environmental Monitoring Program (KE #11) Integrated Pest Management (KE #7) Supplier Qualification (KE #19) Specs for Raw Materials, Finished Good, Packaging Components (see KE # 4) Preventive Maintenance (KE #3) Recall/ Traceability (KE #8)										X
13.6.2	HACCP Team idenitifed with job titles. All Team members are current employees and represent a cross functional team										X
13.6.3	Product adequately described to include: product description, packaging, shelflife, intended end user, storage/ distribution conditions and special considerations.										X
13.6.4	A detailed process flow diagram is present (indicating CCPs) and is verified annually										X

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13.6.5	Written Hazard Analysis (HA) has been conducted for raw materials and for each step of the process to assess for significant food safety hazards (biological, chemical, physical)										X
13.6.6	CCPs are established as a result of the HA, based upon sound scientific/ historical rationale for hazards that are "reasonably likely" to occur (no evidence of a significant hazard without an associated CCP.										X
13.6.7	Each CCP has been verified to control, eliminate or significantly reduce the associated food safety risk to an acceptable level.										X
13.6.8	HACCP responsibilities (for monitoring each CCP) are clearly assigned and documented together with actions to be taken should deviations occur.										X
13.6.9	Established CCPs are properly monitored, documented and reviewed prior to each product release.										X
13.6.10	Critical Limits (CLs) have been established for each CCP. They are clearly defined and can be adequately measured										X
13.6.11	Monitoring procedures are clearly stated, easy to follow and specify a clear corrective action that will control the food safety risk before it goes out-of-control (adequate frequency, forms completed w/ name/ initials, dated & reviewed)										X
13.6.12	HACCP documentation is readily available. The HACCP Plan is verified annually or as changes occur. Responsible parties are clearly identified for validation/ verification activities.										X
	COMMENTS:										
14	**In-Process and Finished Product Release & Control**	**Nap**									
14.1	**General**										
14.1.1	Non-conforming material is quarantined while awaiting disposition.					X	X	X	X	X	
14.1.2	A Process Control Plan exists for each product produced. (including key product and process characteristics, target values, tolerances, sampling plan, test methods, inspection frequency, etc.)					X	X	X	X	X	
14.1.3	Defined in-process and finished product inspections and tests are conducted to ensure conformance to customer specifications and applicable regulations.					X	X	X	X	X	
14.1.4	Quality inspection sampling plans utilize acceptance criteria appropriate to the AQL (Acceptable Quality Level) selected (e.g. Critical 0.65, Major 1.0, and Minor 4.0)					X	X	X	X	X	
14.1.5	Process Control Plans, inspections/test plans, etc. periodically reviewed for effectiveness.					X	X	X	X	X	
	COMMENTS:										
14.2	**In Process Product Release & Control**										
14.2.1	In-process quality control tests are performed at regular time intervals and/or appropriate points throughout manufacturing operations, including all shifts of operation.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
14.2.2	Dimensional analyses are documented on components per specified frequency (i.e., after tool changeover, unexpected repairs, shift changes, at line start up).					X		X			
	COMMENTS:										
14.3	**Finished Product Release & Control**										
14.3.1	QA is responsible for finished product approval and release (electronically, in writing, or by other approved formats). A system is in place to ensure that only approved products are shipped. The Finished Product Release process is periodically reviewed for effectiveness.					X	X	X	X	X	
14.3.2	Where "Ship On Test" practices are utilized, adequate controls are in place to prevent release without completed test results.					X	X	X	X	X	
14.3.3	Supplier specifications are in alignment with applicable Amway Specifications.					X	X	X	X	X	
14.3.4	QA assures the safety, stability, & durability of products, and is able to provide a CoA that meets all defined customer requirements.					X	X	X	X	X	
	COMMENTS:										
14.4	**Control of Non-Conforming Material**										
14.4.1	A Material Review Board routinely meets to review non-conforming material dispositions.					X	X	X	X	X	
14.4.2	QA determines the disposition of rejected material and has final approval of any material release.					X	X	X	X	X	
14.4.3	Inspection of reworked/reprocessed finished product is required and documented. Reworked/reprocessed lots are appropriately identified and traceable.					X	X	X	X	X	
14.4.4	Recycled input materials (such as re-grind) are properly identified, to control their re-introduction.					X		X			
	COMMENTS:										
15	**Records**	**Nap**									
15.1	Records (i.e., batch records, inspection records, shipping and receiving records, training records, internal audit records, corrective action records, preventive maintenance records, storage records) are complete, maintained in a secure area, and readily available for inspection.					X	X	X	X	X	
15.2	Inspection and Manufacturing/process/batch/lot records are reviewed per a defined schedule and retained according to an SOP.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
15.3	Batch Records: a) contain a list of raw materials, names, characteristics, identification, lot #(s), weights. b) include total and theoretical weights/measures, c) include min/max percentage (values outside acceptable ranges require investigation). d) include detailed manufacturing instructions & process control set points to ensure purity, quality & consistent composition. e) include documentation of each significant step in the manufacturing process. f) contain special notes of investigation/deviation from the prescribed process. g) are reviewed and approved by Quality Assurance (QA) for each individual batch run. h) are retained for at least 1 year after the expiry date of the batch.						X	X	X	X	
15.4	Retrievability of records is tested and documented through mock recall exercises.						X	X	X	X	
15.5	Inspection & Manufacturing records are maintained in accordance with governmental regulations.					X	X	X	X	X	
15.6	**Canadian market specific directive**: Supplier must be willing to provide regulatory information (such as stability data, validation data or any other Health Canada required document) to Amway Canada upon request.							X	X	X	
	COMMENTS:										
16	**Internal Audits**			**Nap**							
16.1	The internal audit program not only evaluates conformance to established policies, programs, procedures and work instructions, but also quality system effectiveness.					X	X	X	X	X	X
16.2	Internal audit reports are written in a standardized format and are distributed to the appropriate functional areas.					X	X	X	X	X	
16.3	Internal audit corrective/preventive actions are established, approved, implemented & measured (per the supplier's CAPA program, KE 18.3).					X	X	X	X	X	X
16.4	Internal audits (and Management Review of audit results) are scheduled and conducted on the basis of status and importance of activity.					X	X	X	X	X	X
16.5	All findings from 3rd Party Audits have been reviewed by Management and have been closed.					X	X	X	X	X	
	COMMENTS:										
17	**Customer Learning & Response**			**Nap**							
17.1	**General**										
17.1.1	Quality issues are communicated through the supplier's designated Quality Assurance contact.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
17.1.2	Supplier contacts are routinely updated and provided to customers, across all functional lines (Purchasing, Quality Assurance, R&D, Technical/Regulatory, and Supply Chain Planning).					X	X	X	X	X	
17.1.3	There is a system to notify customers of delayed delivery dates.					X	X	X	X	X	
17.1.4	Any corrective or preventive actions (arising from Amway-related audit findings, complaints, or returns) have been closed (per supplier's CAPA program, KE 18.3).					X	X	X	X	X	
	COMMENTS:										
17.2	**Product complaints**										
17.2.1	An established customer complaint investigation and response program exists. Complaints are documented, reviewed, addressed, investigated, and maintained in a corrective and preventive action database, and communicated to all related departments. Food Safety complaints should be investigated and evaluated by the HACCP team.					X	X	X	X	X	X
17.2.2	The response time for customer complaint acknowledgement, investigation, corrective/preventive action resolution and customer notification is tracked and managed.					X	X	X	X	X	
17.2.3	Verification of customer satisfaction is recorded after appropriate actions have been implemented.					X	X	X	X	X	
17.2.4	Supplier regularly performs complaint data analysis, and utilizes this information to reduce the likelihood of future customer complaints.					X	X	X	X	X	
17.2.5	Returned product from customer is analyzed, leading to appropriate corrective & preventive actions (per supplier's CAPA program, KE 18.3).					X	X	X	X	X	
	COMMENTS:										
18	**Quality Metrics Tracking & Improvement**	**Nap**									
18.1	**Quality Metric Tracking**										
18.1.1	Key internal supplier metrics, such as lead time, total cost of quality and cycle time, are measured and tracked. Quality costs are routinely reviewed for continuous improvement and quality planning opportunities.					X	X	X	X	X	
18.1.2	Key performance indicators (KPIs) are tracked (conformance to specifications, customer and consumer complaints, process capabilities on key process control points, etc.)					X	X	X	X	X	
18.1.3	Quality trends of incoming materials/components and finished goods are periodically analyzed using appropriate statistical tools to determine process capability levels.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
	COMMENTS:										
18.2	**Quality Metric Improvement**										
18.2.1	Quality System continuous improvement Action Plans are based on statistical analyses and address monitoring and improvement of Quality Key Performance Indicators.					X	X	X	X	X	
18.2.2	Supplier maintains a measurement system in to show the effectiveness of continuous improvement activities.					X	X	X	X	X	
	COMMENTS:										
18.3	**Corrective and Preventive Actions (CAPA)**										
18.3.1	The company maintains a root cause corrective & preventive action system that provides for prompt identification and correction of conditions adverse to quality.					X	X	X	X	X	
18.3.2	Written Corrective and Preventive Action procedures include, at minimum, the following: a) Containment actions a) Analyzing data to determine root cause of non-conformance b) Analyzing quality system weaknesses to determine the root cause of the escape point(s) d) Corrective and Preventive Actions (CAPA's) e) Verification of CAPA effectiveness f) Communication of closure to customers					X	X	X	X	X	
	COMMENTS:										
19	**Accountability for Suppliers**	**Nap**									
19.1	**General**										
19.1.1	The facility has documented and established cGMPs, relative to their industry, which extend to temporary employees, visitors, contractors and supplier representatives.					X	X	X	X	X	
19.1.2	Sub-supplier quality levels are routinely measured, and include performance targets and/or goals. Where improvement is necessary, improvement plans are developed with sub-suppliers.					X	X	X	X	X	
19.1.3	Sub-suppliers deemed 'critical' to on-going operations, are subject to a well-defined & effective Supplier Management Program, and use documented prevention techniques (capability studies, SPC, etc.)					X	X	X	X	X	
19.1.4	Sub-supplier visits and/or reviews are made to evaluate performance and promote quality improvement.					X	X	X	X	X	
19.1.5	Policies regarding sub-supplier change control are followed.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
	COMMENTS:										
19.2	**Approved Sub-Supplier Lists**										
19.2.1	An approved sub-supplier list exists for each class of material or product purchased.					X	X	X	X	X	
19.2.2	A review system is in place to ensure that only approved sub-suppliers are used.					X	X	X	X	X	
	COMMENTS:										
19.3	**Sub-Supplier Qualification**										
19.3.1	A process exists to qualify and approve new sub-suppliers and materials (prior to first order).					X	X	X	X	X	
19.3.2	The sub-supplier qualification process provides assurance that chosen suppliers will meet physical, chemical, visual, functional, dimensional and industry/regulatory requirements.					X	X	X	X	X	
19.3.3	Quality history, delivery, price and service considered when making sourcing decisions.					X	X	X	X	X	
	COMMENTS:										
19.4	**Verification of Purchased Products and Materials**										
19.4.1	Appropriate statistical verifications have taken place for those items received on Certificates of Analysis or Certificates of Conformance.					X	X	X	X	X	
19.4.2	Written procedures detail sub-supplier notifications & corrective/preventive actions for rejected material.					X	X	X	X	X	
19.4.3	Items listed on sub-supplier specifications are tested by the sub-supplier, or by an authorized and accredited outside laboratory.					X	X	X	X	X	
19.4.4	Supplier utilizes validated test methods which can be made available to Amway so that a statistical correlation can be established between the Amway and supplier test method results.					X	X	X	X	X	
	COMMENTS:										
20	**Safety & Security**		**Nap**								
20.1	**Workplace Environment and Employee Safety**										
20.1.1	The working environment is observed as being safe.					X	X	X	X	X	
20.1.2	The work place is arranged in consideration of safety, including sufficient space to perform operations.					X	X	X	X	X	
20.1.3	Safety devices are in place and operational (machine guards, lockout devices, etc). Where required by regulation, Safety Checks are performed before machine operation.					X	X	X	X	X	

AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)

KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Question Supports these Business Lines: Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
20.1.4	Employees are issued (and use) proper PPE (safety glasses, cut-free gloves, etc)					X	X	X	X	X	
20.1.5	First Aid Facilities and/or First Aid kits are available to all employees.					X	X	X	X	X	X
20.1.6	Facility is equipped with adequate and operational fire hydrants, fire extinguishers and fire alarms.					X	X	X	X	X	
	COMMENTS:										
20.2	**Safety Program**										
20.2.1	Safety procedures are fully developed.					X	X	X	X	X	
20.2.2	There is an Employee Accident Report log book on site.					X	X	X	X	X	
20.2.3	Employee Accident reports (to government agencies) are all acceptable (issues resolved).					X	X	X	X	X	
20.2.4	Contingency plans for catastrophic events (fire, tornado, flood, etc.) have been established in the interest of risk management and business continuity.					X	X	X	X	X	
	COMMENTS:										
20.3	**Infectious or Communicable Diseases or Wounds**										
20.3.1	Any person, by medical examination or supervisory observation, that is shown to have, or appears to have, an illness, or open lesions, by which there is reasonable possibility of food, food-contact surfaces, or food-packaging materials being contaminated, shall be excluded from any operations until condition is corrected. Personnel shall be instructed to report such conditions to supervisors.					X			X	X	X
20.3.2	Blue metal-detectable plasters (i.e., wound coverings, band aids) are issued to employees.								X	X	
	COMMENTS:										
20.4	**Hazardous Material Control**										
20.4.1	A Hazardous Material Control Program manages the use, storage, labeling, and handling of hazardous substances within the manufacturing facility (including pesticides).					X	X	X	X	X	
20.4.2	Flammable materials are stored in XP (explosion-proof) rooms.					X	X	X	X	X	
	COMMENTS:										
20.5	**Facility and Data Security**										
20.5.1	Periodic facility assessments are conducted and documented to determine potential gaps in security, and assess the effectiveness of controls.					X	X	X	X	X	

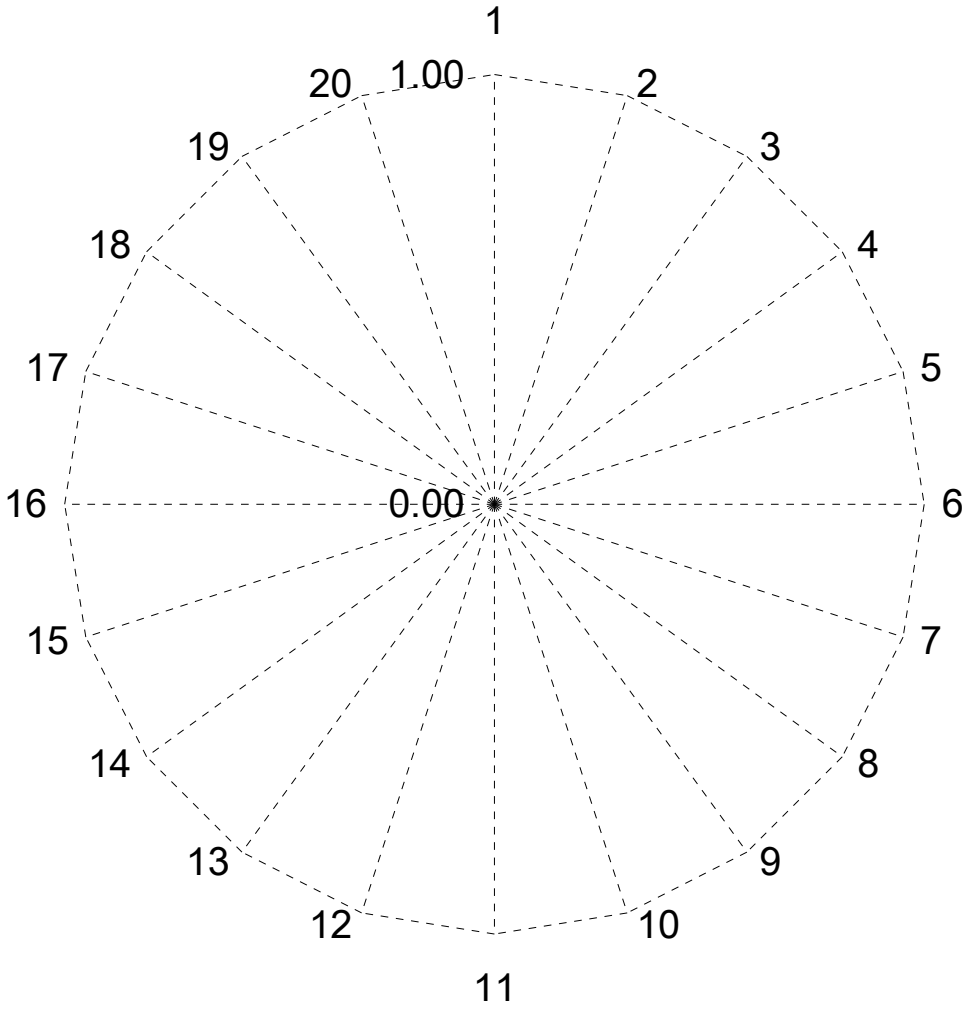
AMWAY Supplier Quality Assurance Capability (sQAC) Audit Checklist (Non-Drug)													
						Question Supports these Business Lines							
KEY ELEMENT # SUB-SECTION SCORES	QUALITY SYSTEM ELEMENT / QUESTION	Acceptable	Not Acceptable	Not Applicable	Not Reviewed	Packaging/Components	Chemical	Beauty	Food & Food Packaging	Dietary Supplement	HACCP
20.5.2	Access by employees, visitors, truck drivers, delivery personal and contractors (through doors into the facility) is controlled by security badge access (or other means).					X	X	X	X	X	
20.5.3	Plant surveillance cameras and /or alarms are in use.					X	X	X	X	X	
20.5.4	There are security fences, doors and/or gates around the perimeter of the facility.					X	X	X	X	X	
20.5.5	Outbound trailers are sealed (NOTE: Amway verifies seal numbers against Bills of Lading for received packaging products/materials).						X	X	X	X	
20.5.6	Separate outside storage containers are locked.					X	X	X	X	X	
20.5.7	Exit doors are clearly marked and locked from the inside.					X	X	X	X	X	
20.5.8	Computer controls (i.e., passwords, back-up) are used for critical systems to ensure security and accountability. Key documents and systems are backed up at a frequency appropriate to their criticality.					X	X	X	X	X	
	COMMENTS:												

ACTIVE

Amway sQAC Audit Checklist (Scoring Summary)

(Non-Drug)

	Key Element	Score	Weight %	Points
1	LEADERSHIP	Nap	5	NAp
2	TRAINING	Nap	4	NAp
3	BUILDINGS FACILITIES, EQUIPMENT DESIGN, INSTALLATION & MAINTENANCE	Nap	10	NAp
4	TECHNICAL STANDARDS	Nap	5	NAp
5	WRITTEN PROCEDURES	Nap	4	NAp
6	VALIDATION / VERIFICATION	Nap	3	NAp
7	HOUSEKEEPING, PEST CONTROL, SANITIZATION & HYGIENE	Nap	10	NAp
8	MATERIAL CONTROL	Nap	7	NAp
9	MANUFACTURING OPERATIONS	Nap	8	NAp
10	PACKAGING OPERATIONS	Nap	4	NAp
11	STORAGE & FINISHED PRODUCT HANDLING	Nap	4	NAp
12	LABORATORY CONTROL	Nap	5	NAp
13	PROCESS CONTROL	Nap	5	NAp
14	IN-PROCESS & FINISHED PRODUCT RELEASE & CONTROL	Nap	5	NAp
15	RECORDS	Nap	3	NAp
16	INTERNAL AUDITS	Nap	3	NAp
17	CUSTOMER LEARNING & RESPONSE	Nap	3	NAp
18	QUALITY METRIC TRACKING & IMPROVEMENT	Nap	3	NAp
19	ACCOUNTABILITY FOR SUPPLIERS	Nap	4	NAp
20	SAFETY & SECURITY	Nap	5	NAp
	Totals	**NAp**	**100**	**0.0%**



ACTIVE

Amway sQAC Audit Checklist (Auditor Comments Summary)

(Non-Drug)

1	**Leadership**
2	**Training**
3	**Building Facilities & Equipment Design, Installation and Maintenance**
4	**Technical Standards**
5	**Written Procedures**
6	**Validation/Verification**
7	**Housekeeping, Pest Control, Sanitization & Hygiene**
8	**Material Control**
9	**Manufacturing Operations**
10	**Packaging Operations**
11	**Storage & Finished Product Handling**
12	**Laboratory Control**
13	**Process Control**
14	**In-Process and Finished Product Release & Control**
15	**Records**
16	**Internal Audits**
17	**Customer Learning & Response**
18	**Quality Metrics Tracking & Improvement**
19	**Accountability for Suppliers**

ACTIVE

Amway sQAC Audit Checklist (Scoring Explanation)

(Non-Drug)

Rating Scale:	Score:	
Excellent	90 to 100	**NOTE:** **Scores may be given in quarter point (0.25) increments**
Good	75 to 89.9	
Satisfactory	60 to 74.9	
Conditional	50 to 59.9	
Unsatisfactory	Less than 50	

Explanation of Amway Audit Rating Values

Points	Description	Full Explanation
NAp	Not Applicable or Not Audited	The procedure or process is not relevant to the supplier's commodity and/or the facility audited.
0	System **Non-Existent**	The procedure and process is not included in the supplier's Quality System, but was expected to be.
1	System **Deficient**	The procedure or process is included in the Quality System but planning and execution both require substantial improvement. The system is documented but not followed.
2	System **Improvement Needed**	The Quality System is in place but it is not properly documented or executed. There is a high probability that the Quality System will not produce consistent results. Improvements to the process or documentation are required.
3	System **Acceptable**	The procedure or process is included in the supplier's Quality System. Planning and execution meet Amway requirements. There is a high probability that the supplier's Quality System will produce consistent results.
4	System **Outstanding**	The procedure or process reflects industry best practice and is ingrained into the culture of the facility. Planning and execution are thorough and exceed Amway requirements. It is certain that the Quality System will produce exemplary results.