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I. SSCI Overview

Overview: SSCI™ stands for the Supplement Safety & Compliance Initiative and is a global dietary supplement safety and compliance benchmark created to recognize supplement safety, authenticity, and compliance standards around the world for equivalency.

SSCI™ is a retailer driven, non-profit initiative providing guidance and leadership regarding the controls necessary to assure the authenticity, safety and cGMP compliance of dietary supplements throughout the supply chain. SSCI creates a dietary supplement safety system through collaboration between numerous leading industry experts from retail, manufacturing, certifying bodies, quality control, ingredient processing areas and more. SSCI is also designed to harmonize global standards for dietary supplements throughout the entire supply chain.

Among the many standards present in food manufacturing today, third party certification schemes are increasingly becoming more prevalent and widely accepted. These schemes help meet the demands of a globalized market for improving food safety across the food supply chain. However, certification schemes for dietary supplements are not uniform, leading to inconsistency of audits in the marketplace. SSCI was created to meet the demands of a globalized market for improving dietary supplement safety across the supply chain. Implementation of SSCI benchmarking can enable manufacturers to:

- Establish conformity to supplement safety and quality management standards
- Drive continuous improvements, increase operational efficiency/productivity
- Protect their brand
- Gain acceptance and recognition of their products, processes, and services around the world
II. PERSONNEL

Overview: Adequate facilities, well designed equipment, and written procedures are essential elements of cGMPs and are critical to manufacturing high quality dietary supplements, but all these things can be derailed by the lack of good hygienic practices. The certification body must be able to evaluate and to determine there is demonstrated evidence that good hygiene practices are consistently followed. This must be part of the onboarding process for new hires and refresher training for veteran employees. Written job descriptions shall exist for all employees involved in the manufacturing, packaging, testing or holding of dietary supplements.

A. Sources of Microbial Contamination

Overview: Written procedures must be in place to exclude from operations any person who might be a source of microbial contamination due to a health condition, including their exclusion from areas where exposure to components, in-process material, finished dietary supplements or product contact surfaces could result in microbial contamination. The auditor must therefore be knowledgeable about how the manufacturer performs such procedures, including:

1. Excluding from working in any operation that may result in contamination by any person who, by medical examination, the person's knowledge, or supervisory observation, is shown to have or even appears to have an illness, infection, open lesion or any other abnormal conditions that could result in microbial contamination of components, dietary supplements or product contact surfaces until the health condition no longer exists.

2. Instructing employees to notify their supervisors if they have a health condition as described in A(1) above.
B. **Hygienic Personnel Practices**

Overview: Working in operations during which contamination of components, dietary supplements or product contact surfaces could occur, requires hygienic practices to protect against such contamination. The certification body must review the written procedures for personnel responsibilities and Personnel Protective Equipment (PPE) including records showing such hygienic practices including:

1. Wearing outer garments of proper construction (*e.g.*, without buttons or material that could be lost) in a manner that protects against the contamination of components, dietary supplements, or any contact surface.

2. Maintaining adequate personal cleanliness.

3. Washing hands thoroughly (and sanitizing, if necessary, to protect against contamination with microorganisms) in an adequate hand-washing facility with dispensed soap, hot water and disposable towels or hand drying units both before starting work and at any time when the hands may have become soiled or contaminated. Handwashing facilities must be adequate in number and convenient to entry points/workstations to facilitate compliance.

4. Removing all unsecured jewelry, body piercings (*nose studs, etc.*), fake eyelashes, fake fingernails and any other objects that might fall into components, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods in which components or dietary supplements are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition.
effectively protects against contamination of components, dietary supplements, or contact surfaces.

5. Maintaining gloves used in handling components or dietary supplements in an intact, clean, and sanitary condition. The gloves must be of an impermeable material and must not become the source of contamination themselves.

6. Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints. PPE described must be mandatory in an open product area and made available to employees.

7. Not storing clothing or other personal belongings, including but not limited to cell phone, keys, headphones, outdoor clothing, etc., in areas where components, dietary supplements, or any contact surfaces are exposed.

8. Not eating food, chewing gum, drinking beverages, or using tobacco or vaping products in areas where components, dietary supplements, or any contact surfaces are exposed.

9. Taking any other precautions necessary to protect against the contamination of components, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

C. Personnel Qualifications and Training

Overview: The manufacturer shall provide training for all individuals who are permitted into production areas or testing facilities, including technical, maintenance, sanitation and office personnel. This training shall include basic training in the theory and practice of cGMP as well as training specific to the duties assigned to them, where applicable. Visitors or untrained personnel
shall not be taken into production and testing facilities unless they receive basic instruction in advance and are closely supervised. The certification body must be able to review records that demonstrate these qualifications and training, including checking that:

1. All employees, including quality personnel and supervisors, who are engaged in manufacturing, packaging, labeling, or holding, or in performing any quality operations must be qualified by education, training, or experience. This shall be demonstrated through written job descriptions, resumes, documentation of general cGMP training as well as on the job training on the specific procedures/processes associated with the job.

2. Personnel responsible for quality operations must be clearly identified. Each person who is identified to perform quality operations must be qualified to do so through a combination of education training and experience. This shall be demonstrated as described above.

3. Records are required sufficient to show (1) through (2) along with written procedures for fulfilling the requirements (1) through (2) documentation of training, including the date of the training, the type of training, the person(s) trained, and the name of qualified trainer.

III. FACILITIES, EQUIPMENT, AND UTENSILS

Overview: The facilities and equipment shall be designed, constructed, and maintained to facilitate the processes contemplated in the specification. The design shall minimize the risk of potential errors and avoid the potential for any possible contamination or cross contamination, including filtration air handling, and environmental monitoring, with other products manufactured in the same facility. Through proper location, design, construction and adaptation, a facility can
avoid cross-contamination, build-up of dust or dirt on equipment, and minimize outside contamination (e.g., insect/rodent) which would adversely affect the quality of finished dietary supplement products. The layout and equipment must be amenable to thorough cleaning, sanitation, maintenance, and repair. Written instructions for cleaning the facilities, equipment and utensils, cleaning logs and verification process (not necessarily by management) must be established, followed and verified. A manufacturer must demonstrate how each of the elements enumerated below is covered during the course of a facility audit inspection/assessment. An auditee must be able to locate documents that evidence all these requirements. The grounds of the physical plant shall be maintained in a condition that protects against the contamination of components, dietary supplements, or product contact surfaces.

A. Facilities

The certification body must be able to locate and verify records demonstrating all of the following:

1. Grounds
   a. Removing litter and waste and keeping vegetation in the immediate vicinity of the facility well maintained so that it does not attract pests, minimize pest harborage conditions, or provide a place for breeding of pests. Unused equipment shall be placed away from the building to prevent pest harborage.
   b. Maintaining cleanliness in roads, yards, and parking lots so they do not constitute a source of contamination in areas.
   c. Adequately clean and maintain draining areas that may contribute to the contamination of components, dietary supplements, production/packaging equipment or product contact surfaces.
d. Documented process for waste management including storage, waste treatment and disposal so that they do not constitute a source of contamination in areas where components, dietary supplements and contact surfaces are exposed.

e. If the facility grounds are bordered by grounds not under the manufacturer's control, and if those other grounds are not maintained in the manner described in this section, the manager must exercise care in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination.

f. The physical plant must be maintained in a clean and good sanitary condition.

g. There must be a documented facility maintenance program sufficient to prevent components, dietary supplements or contact surfaces from contamination or cross contamination.

h. Properly storing equipment and utensils,

i. Floors, walls, and ceilings must be capable of being adequately cleaned and kept clean and in good repair.

j. Fixtures, ducts, and pipes do not drip or show signs of leakage (ceiling stains) and condensation, or condensate which could contaminate components, dietary supplements, or contact surfaces.

k. Adequate ventilation or environmental control equipment such as airflow systems, including filters, fans, and other air-blowing equipment, that minimize odors and vapors in areas where they could contaminate
components, dietary supplements, or contact surfaces (e.g., maintain positive room pressure in critical areas).

l. Fans and blowers must be located and operated in a manner to minimize the potential for microorganisms and particulate matter to contaminate components, dietary supplements or contact surfaces. Cleaning and maintenance (of fans and blowers) to prevent possible contamination from dirt, where located in the production or packaging areas.

m. When necessary, equipment that controls temperature and humidity, must be in place, calibrated and maintained.

n. Aisles or working spaces between equipment and walls that are adequately unobstructed and shall have adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary supplements or contact surfaces with clothing or personal contact.

o. Interior surfaces (walls, floors, ceilings) are smooth, free from cracks and open joints, do not shed particulate matter, and permit easy and effective cleaning and sanitizing.

p. Weighing of starting materials are carried out in a separate weighing room designed for such purpose unless technological solutions such as advanced gravity systems permitting weight detection in-line are in use.

q. Testing laboratories for the quality unit are not immediately adjacent to production areas, especially for control of biologicals and have:
i. Separate rooms as needed to protect sensitive instruments from vibrations, airflow, humidity, electrical interference.

ii. Adequate and suitable storage space for samples, reagents and records.

iii. Adequate warehouse space to avoid mix-ups and cross contamination.

iv. Separate HVAC control from the production area to avoid cross contamination.

r. Lighting: Production areas are well lit, particularly where visual on-line controls are carried out, components or dietary supplements are examined, measured, processed, or held and all areas where contact surfaces are to be cleaned. Piping, light fittings, ventilation points and similar areas are designed to avoid recesses that are difficult to clean shall be made accessible. Ceiling lights shall have sleeves or covering to protect the products from splinters or foreign contamination in case of breakage.

s. Rest rooms shall be clean, well maintained with washing area and not open directly to the production and product handling/storage areas.

t. Maintenance shops fully separate from the areas of production and within adequate distance from production to ensure no contamination or interference. Any tools or parts stored in production areas shall be maintained clean in rooms, lockers, or organized on clearly labeled storage locations (e.g., SS type shadow board) designated for their storage. Tool status identified as “clean or dirty.”

u. Storage and holding areas:
i. Are of sufficient capacity to allow for orderly storage of various categories of materials and products including raw materials; packaging materials; intermediate, bulk and finished products; quarantined ingredients and dietary supplement products.

ii. Are maintained clean and dry with acceptable temperature, humidity limits, which are checked and monitored, where applicable.

iii. Receiving and dispatch bays adequately protect materials and products from weather conditions.

iv. Receiving areas have been designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.

v. Quarantine areas are separate from other storage areas, clearly marked, and access restricted to authorized personnel.

vi. A separate sampling area for raw materials shall be provided, and if sampling is performed in the storage area, it shall be conducted so as to prevent contamination and cross-contamination. Sampled containers shall clearly be identified with “qc sampled” type labels.

vii. Rejected, recalled or returned materials/dietary supplement products are segregated and clearly marked as such from other storage.

viii. Highly reactive materials are stored in safe and secure areas.

v. Areas for changing clothes are sufficiently close to the area of production to avoid contamination and appropriate in size for the number of users. Foot traffic control: captive shoe program, shoe covers, foot bath, aseptic mats, etc.
B. Design and Construction Requirements for the Physical Plant

Overview: Proper design of a buildings or facilities used for or in connection with receiving, manufacturing, packaging, testing, labeling, or holding a dietary supplement, *i.e.*, the physical plant, can alleviate many concerns regarding contamination and quality unit. The auditor must be sure that the facility and equipment are laid out in such a way as to allow production to take place in areas that are preferably connected in a logical order corresponding to the sequence of the operations or to the requisite cleanliness levels. Workspace design shall provide proper flow of equipment and products so as to minimize mix-up of raw materials between different dietary supplement products or components, cross-contamination between separate operations, and deviations in manufacturing and control steps. Accordingly, the auditor must be able to confirm that the physical plant is:

1. Suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitization.

2. Designed with adequate space for the orderly placement of equipment and holding of materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mix-ups of any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement, *e.g.*, components, and dietary supplements during manufacturing, packaging, labeling, or holding.

3. Permits the use of proper precautions to reduce the potential for mix-ups or contamination of components, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. The physical plant must have and use separate or defined areas of adequate size or other control
systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mix-ups of components and dietary supplements during the following operations:

a. Receiving, identifying, holding, and withholding from use, components, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, labeling, or holding of dietary supplements.

b. Components, dietary supplements, packaging, and labels awaiting material review or waiting disposition decision must be quarantined until approved by the Quality unit before use.

c. Separating the manufacturing, packaging, labeling, and holding of different product types e.g. separation of operations involving dietary supplements and other foods, cosmetics, and pharmaceutical products.

d. Performing laboratory analyses and holding laboratory supplies and samples.

e. Cleaning and sanitizing contact surfaces.

f. Packaging and label operations.

g. Holding components or dietary supplements.

4. Facility equipment is designed and constructed in a manner that prevents contamination of components, dietary supplements, or contact surfaces. The auditor must be able to confirm that the design and construction includes:

a. Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair.
b. Fixtures, ducts, and pipes that do not contaminate components, dietary supplements, or any product contact surfaces. Examples of product contact surfaces include containers, utensils, tables, contact surfaces of equipment, and packaging.

c. When fans and other air-blowing equipment are used, such fans and equipment must be located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary supplements, or product contact surfaces.

d. Equipment is sufficient to control temperature and humidity, when such equipment is necessary to ensure the quality of the dietary supplement.

e. Aisles or working spaces between equipment and walls are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary supplements, or contact surfaces with clothing or personal contact.

5. Adequate light is provided in:

a. All areas where components or dietary supplements are examined, processed, or held.

b. All areas where contact surfaces are cleaned.

c. Hand-washing areas, dressing and locker rooms, and bathrooms.

d. Production areas with food-safe light bulbs, fixtures, skylights, or other glass or glass-like materials (shielded or shatter-proof) when the light bulbs, fixtures, skylights or other glass or glass-like materials (shielded or shatter-proof) are suspended over exposed components or dietary supplements in
any step of preparation, unless the physical plant is otherwise constructed
in a manner that will protect against contamination of components or dietary
supplements in case of breakage of glass or glass-like materials. Generally,
glass shall be avoided when possible.

6. Providing effective protection against contamination of components and dietary
supplements in bulk fermentation vessels, if applicable, for example:
   a. Use of protective coverings.
   b. Placement in areas to eliminate harborages for pests over and around the
   positive pressure on vessels.
   c. Placement in areas that facilitate regular checking for pests, pest infestation,
   filth or any other extraneous materials.
   d. Use of skimming equipment.

7. Using adequate screening or other protection against pests (i.e. self-closing
mechanisms on personnel doors, air-curtains, etc.), where necessary.

8. Guidelines for use of cleaning compounds, sanitizing agents, pesticides, and other
toxic materials.
   a. Using or holding of toxic materials in a physical plant in which components,
dietary supplements, or contact surfaces are manufactured or exposed is
precluded unless those materials are necessary:
   i. To maintain clean and sanitary conditions.
   ii. For use in laboratory testing procedures.
   iii. For maintaining or operating the physical plant or equipment.
   iv. For use in the plant's operations.
b. If the use of toxic materials is unavoidable, they must be stored in a lock and key environment and access shall be limited to authorized personnel only. Identifying all cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials in a manner that protects against contamination of components, dietary supplements, or contact surfaces.

9. Pest control.

a. Not permitting animals or pests in any area of the physical plant. Guard or guide dog(s) are not allowed in high risk cGMP zones where contact could result in contamination of components, dietary supplements, or contact surfaces.

b. Using effective measures to exclude pests from the physical plant such as physical barriers to prevent animals or pests in any area of the physical plant and to protect against contamination of components, dietary supplements, and contact surfaces on the premises by pests. Adequate measures to exclude pests from the physical plant include insect monitors and elimination systems, electrical discharge insect control systems, or equivalent.

c. Verifying that insecticides, fumigants, fungicides, or rodenticides were not used or stored on premises unless documented precautions were taken to protect against the contamination of components, dietary supplements, or contact surfaces by these agents. Pesticide application shall be carried by a qualified Pest Control Operator (PCO).
10. The auditor must ascertain that the water supply is adequate by locating evidence that:

a. Water is readily available at suitable temperature and pressure for all uses where water does not become a component of the dietary supplement.

b. When water is a component of the dietary supplement, (e.g., when the water is an actual component,) when water contacts components, dietary supplements, or any contact surface, that the water is in compliance with all Federal, State, and local requirements and does not contaminate the dietary supplement. Written records sufficient to show compliance with this subsection are required. Backflow in place and checked according to local ordinances.

c. Proper steps are taken to ensure microbial limits are not exceeded or unacceptable levels of lead from deteriorating pipes for municipal water supplies.

d. Proper steps are taken to ensure appropriate water treatment procedures, including filtration, and chlorination so that it does not contaminate the finished dietary supplement product if well water is used. If well water is used, then it must comply with EPA or equivalent requirements for potable water.

e. Distilled, deionized and other water pipes are sanitized according to written procedures that detail the action limits for microbiological contamination and the measures to be taken if testing shows elevated levels.
11. Plumbing. The auditor must locate evidence that the physical plant plumbing is of an adequate size and design, adequately installed, and maintained to:

a. Carry sufficient amounts of water to all required locations throughout the physical plant.

b. Properly convey sewage and liquid disposable waste from the physical plant.

c. Avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition.

d. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

e. Exposed pipes shall be labeled with the direction of liquid flow and not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities. Fixed pipework is clearly labeled to indicate contents and direction of flow. Potable and non-potable waterlines to be identified.

f. Drains should be adequately designed to minimize the potential for cross-contamination and to ensure adequate flow during peak demand. If open channels are used, they should be adequately designed to facilitate quick draining to ensure that no puddling occurs. Floor cleaning, sanitation, and micro activity as part of the environmental program must be documented.
12. Sewage disposal. Sewage must be disposed into an adequate sewage system or through other adequate means.

13. Bathrooms. Employees must be provided with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not be a potential source of contamination to components, dietary supplements, or contact surfaces. Bathrooms must have adequate supplies like hot water, hand towels or air dryer, toilet paper, hand washing detergent and sanitizers.

14. Hand-washing facilities. Hand-washing facilities must be provided that are designed and located to employees to ensure that an employees' hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

15. Handling trash adequately. Trash must be conveyed, stored, and disposed of to:
   a. Minimize the development of odors.
   b. Minimize the potential for the trash to attract, harbor, or become a breeding place for pests or become a pest harborage area.
   c. Protect against contamination of components, dietary supplements, any contact surface, water supplies, and grounds surrounding the physical plant.
   d. Control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.

16. Appointing one or more employees to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.
C. Equipment and Utensils

Utensils/equipment must be of appropriate design, construction and workmanship for intended use and to be adequately cleaned and properly maintained. If possible, Equipment and Utensils shall be of dedicated use to avoid cross contamination. The auditor must verify that:

1. Manufacturing and Process equipment is designed, located and maintained to satisfy its intended purpose and includes equipment to hold or convey, or measure, to carry out processes in closed pipes and vessels, and for use in automated, mechanical or electronic systems.

2. Repair and maintenance do not present any hazard to the quality of the product and is not be a source of contamination.

3. Equipment/utensils prevent lubricants, fuel, coolants, metal/glass fragments, filth, extraneous material, contaminated water or any other contaminants from adulterating components, or finished dietary supplement products.
   a. Metal detection equipment usage, where applicable, as part of the packaging process where there is a risk of metal contamination.

4. Compressed air to clean any contact surface is treated in a way such that it does not cause cross-contamination or contaminate contact surfaces with filth. Filtered at the point of use at a minimum. Verification of the air quality shall be noted including microbial if it is product or packaging material content.

5. Equipment is installed/maintained to facilitate cleaning, corrosion-resistant, made of nontoxic materials, smoothly bonded/maintained to minimize accumulation of dirt, filth, organic material, particles from components that could cross-contaminate other components, dietary supplement products or contact surfaces.
6. Logbooks or other documentation are available for major or critical equipment recording, equipment calibrations, maintenance, cleaning or repair operations, including the dates and identity of personnel carrying out the operations.

7. The parts of any equipment or utensils that contact the product or intermediate are not reactive or absorptive to such an extent that it will adversely affect the quality of the final product.

8. Freezers/refrigerators and cold storage area are be fitted with thermometer or temperature recording device and have an automated device for regulating temperature or automated alarm system to indicate temperature changes. The monitoring devices need to be calibrated and possibly mapped if they are used for stability studies.

9. Scales and measuring equipment are of an appropriate range and precision for use in the manufacturing process. Daily verification of the scales must be recorded including the calibrated standards used and the person performing the job is to be trained.

10. Instruments used to measure, weight (including load cells on large tanks), regulate, or record temperatures, hydrogen-ion concentration (pH), water activity, etc. are maintained, adequate in number and precise/accurate for their purpose. Such instruments shall be calibrated before first use, and at frequency recommended by the manufacturer of the instrument or in-house procedure, to ensure the accuracy and precision of the instrument.
11. Bulk vessels are equipped with protective coverings and located in areas where they can be checked regularly for pests, pest infestation, filth or any other extraneous materials.

12. Defective equipment shall be removed from production and quality unit areas and clearly labeled as defective. If equipment cannot be removed, it must be labeled as “Out of Service”.

IV. DOCUMENTATION AND RECORDS

Overview: Current Good Manufacturing Practices require a facility to establish and follow clearly articulated written procedures that can be audited by a certification body. The meaning of a “Good Practices” program is that if something is not written down, it is assumed that the act did NOT happen. Adequate documentation constitutes a critical component of quality assurance. Seamless communication through well-written instructions, records, and documentation prevents errors from undocumented communication and allows for trace back analysis in the batch history in the event of a serious adverse event related to consumption of the finished dietary supplement product.

Written procedures and documented batch records must be available for inspection and review at all times. Clearly written documentation allows traceability of batch history for potential recall and adverse event investigation. Any departure from the written materials must be noted in writing as well as any possible changes in the starting materials, intermediate products or final product. Appropriately approved and dated specifications for raw materials, finished products and packaging materials, pre-blends, in-process, and products shipped in bulk. Records must be retained for at least one year past the shelf life date—if shelf life dating is used—or two years beyond the distribution of the last batch of dietary supplements associated with those records.
Documentation of standard operating procedures as well as equipment maintenance and cleaning must also be available.

A. Specifications

Overview: Requirement details for acceptable conformity and the basis for quality evaluation. Appropriately authorized and dated specifications for raw materials, finished products and packaging materials, blended raw ingredients, and products shipped in bulk must be in place and kept as original records, as true copies (such as photocopies, microfilm or other accurate reproductions of the original records), or as electronic records with retained metadata.

The auditor shall be assured a specification is established in the following situations:

1. Component - For each component used in the manufacture of a dietary supplement, a component specification is established for the following:
   a. Identity
   b. Purity, strength and composition of the dietary ingredient.
   c. Limits on any types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement.

2. For any intermediate production, in-process control limits shall be available to the auditor for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the finished dietary supplements and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement and shall include:
a. Adequate documentation of the basis for why meeting the in-process control limits, in combination with meeting component specifications, helps ensure that the specifications are met for the identity, purity, strength, and composition of the finished dietary supplements and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement.

b. The auditor must be able to determine that this documentation was reviewed and accepted by quality unit personnel.

3. Labels and other packaging materials- Specifications for finished dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications). The auditor must be able to determine that the packaging component that may come into contact with dietary supplements is food grade, safe and suitable for its intended use.

4. Bulk or finished goods - For each dietary supplement manufactured, a product specification for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement must be established.

5. Bulk products received from a third-party supplier for packaging or labeling as a dietary supplement, must be adequately identified and meet the specifications and the requirements of the purchase order.
Specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure the specified packaging was used and correctly applied are required.

The auditor shall verify that specifications for raw materials, bulk products, and packaging materials include:

a. The name, references to any compendial guidance documents, and a copy of printed packaging artwork.

b. Directions for sampling and testing or reference to procedures.

c. Qualitative and/or quantitative requirements with acceptance limits/criteria as applicable.

d. Storage conditions and precautions including environmental controls to assure raw materials and products are maintained in a suitable environment to ensure quality.

e. Maximum period of storage before re-examination required.

Specification sheet AT A MINIMUM shall include the test to be performed, specification range for acceptance (qualitative and/or quantitative requirements), the method performed, and reference if applicable.

a. The finished product specification shall have the following information:

i. Name of the product.

ii. Description of the form and package details.

iii. Directions for sampling and testing or a reference to procedures.

iv. Qualitative and/or quantitative requirements, with the acceptance limits/criteria as applicable.
v. Storage conditions and any special handling precautions.

vi. Shelf-life stability.

9. Testing Documentation

There shall be written procedures for testing materials and products at different stages, describing the methods employed, and the equipment used as well as documentation that the laboratory methodology that was established was actually met.

a. Analytical methods shall be scientifically valid and suitable for their intended use. Results must be recorded and verified compared to reference standards and/or calibrated measurements where applicable.

b. The auditee must demonstrate that the specifications contain the following tests, as applicable to the dosage form, the following parameters:

i. Appearance.

ii. Thickness.

iii. Hardness.

iv. Average tablet/capsule weight (if appropriate).

v. Weight uniformity (if appropriate).

vi. Friability (if appropriate).

vii. Analytical analysis and description.

viii. Possible contaminants (based upon methods of manufacture and formation of side products).

ix. Microbiological (Total Plate Count, Yeast and Mold, and typical objectionable organisms if appropriate).

x. Heavy Metal Contaminants.
xi. Where pesticides are used in the vicinity of the manufacture and storage of the composition.

1. Appropriate pesticide testing plans must be developed based on a risk assessment of the supply chain to identify pesticides used in the production of botanical materials as appropriate.

c. For botanicals and multiple ingredients, specification shall include use of appropriate analytical method, e.g. NIR, TLC, HPTLC with comparison of reference standard and acceptance criteria.

d. The testing shall include manual documentation of the following, and electronic data systems may be used but shall include the same information including review and approvals by a second person:

i. Name of the material, intermediate, or product and dosage form.

ii. Batch number.

iii. Reference to the relevant specification and testing procedure.

iv. Test results, including any calculations or observations and reference to any certificates of analysis.

v. Dates of testing.

vi. Signature or initials of person performing the testing.

vii. Signature or initials of individuals who verified the testing and any needed calculations.

viii. Dated signature of individual responsible for release.

ix. Indication of either release, rejection, or some other status determination.

e. Laboratory Reagents
i. Any laboratory reagents shall be prepared in accordance with written procedures.

ii. Laboratory reagents and controls intended for prolonged use must be marked with preparation date, storage conditions, and expiration date as well as the signature or initials of the preparer.

iii. The date of receipt of any substance used for testing operations such as the reference standards or reagents shall be indicated on the container along with any required storage conditions.

B. Stability

a. If expiration dating is used, stability studies shall be done to provide justification for dating.

b. Such stability testing shall be performed on the final product as well as any stored intermediates or bulk products and materials.

c. If a product is reformulated, a reassessment is required to determine if additional stability testing is needed.

C. Master Manufacturing Records

Overview: Master Manufacturing Records shall exist for EACH product AND batch size to be manufactured. To ensure uniformity from batch to batch, the audit must demonstrate master manufacturing records are prepared, dated, and signed by one person and independently checked, dated, and signed by a person in the quality unit. Each Master Manufacturing Record shall include:

a. The name of the product being manufactured.

b. A description of the delivery form, the product and batch size.

c. A complete listing (e.g. formula page) of raw materials and intermediates designated by common or usual names (or synonyms, when appropriate), substances that disappear during processing.
d. An accurate statement of the quantity/weight or ratio of each raw material to be used, including the unit of measure for each batch size where the quantity is fixed.

e. Where the quantity is not fixed, the calculation for each batch size or rate of production shall be included and qualified.

f. Statement of any intentional overage amount of a dietary ingredient.

g. Statement of theoretical yield of a manufactured Dietary Supplement expected at each point, step, or stage of the manufacturing process where control is needed to ensure Dietary Supplement quality.

h. The expected yield for finished Dietary Supplement, including maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision made.

i. Description of packaging and representative label or master artwork.

j. The production location and major production equipment to be used

k. Detailed production instruction, including the:

   i. Detailed stepwise, sequences to be followed (e.g., checks on materials, pretreatments, sequence for adding materials, mixing times, temperatures).

   ii. Ranges of process parameters to be used.

   iii. Sampling instructions and in-process controls with their acceptance criteria/limits, where appropriate.
iv. All points where testing must be performed, the type of tests that must be performed, and criteria for permitted values of the test results.

v. Any requirements for bulk storage of the products including the container, labeling and special storage conditions.

vi. Time limits for completion of individual processing steps and/or the total process, where appropriate.

vii. Expected yield ranges at appropriate phases of processing or time.

viii. Frequency for expected equipment and line cleaning unless covered in the master cleaning schedule.

D. Batch Production Records

Overview: Records for each batch are necessary to permit any investigations that might be useful in the future to determining any possible variation that is observed. Dietary Supplement Manufacturers must prepare a batch production record every time a batch of a dietary supplement is manufactured. The batch size(s) must be qualified. The batch production record must accurately follow the appropriate master manufacturing record, perform each step in the production of the batch and clearly reference any departure from the master manufacturing record. The audit of batch production records must indicate:

1. The batch, lot, or control number of the finished dietary supplement that has been assigned according to the regulatory requirements for filling, assembling, packaging, and labeling:

2. The identity of equipment and processing lines used in producing the batch.
3. The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained.

4. The unique identifier that is assigned to each component (or, when applicable, to a product that is received from a supplier for packaging or labeling as a dietary supplement), packaging, and label used.

5. The identity and weight or measure of each component used.

6. A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing.

7. The actual results obtained during any monitoring operation.

8. The results of any testing or examination performed during the batch production, or a cross-reference to such results.

9. Documentation that the finished dietary supplement meets specifications established in accordance with 111.70(e) and (g).

10. Documentation, created at the time of performance, of the manufacture of the batch, including:

   a. The date on which each step of the master manufacturing record was performed.

   b. The initials and dates of the persons performing each step (unless automated verification/system is in place), including:

      i. The initials and dates of the person responsible for weighing or measuring each component used in the batch.
ii. The initials and dates of the person responsible for verifying the weight or measure of each component used in the batch.

iii. The initials and dates of the person responsible for adding the component to the batch.

iv. The initials and dates of the person responsible for verifying the addition of components to the batch.

11. Documentation—created at the time of performance—of packaging and labeling operations, including:

   a. The unique identifier that is assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels.

   b. Description of packaging and representative label or master artwork. The results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to the physical location of such results.

12. Documentation at the time of performance for quality unit personnel:

   a. Reviewed the batch production record, including:

      i. Review of any required monitoring operation.

      ii. Review of the results of any tests and examinations, including tests and examinations conducted on components, in-process materials, finished batches of dietary supplements, and packaged and labeled dietary supplements.
b. Approved or rejected or any reprocessing or repackaging; with the date, signature of the quality unit personnel, and the reason for the decision.

c. Approved and released, or rejected, the batch for distribution, including any reprocessed batch.

d. Approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement.

13. Documentation at the time of performance of any required material review and disposition decision.


15. Documentation of any material review, disposition decision and follow-up including:

   a. Identification of the specific deviation or unanticipated occurrence.

   b. Description of investigation into the cause of deviation from specification or unanticipated occurrence.

   c. Evaluation of whether deviation or occurrence resulted or could lead to failure to ensure quality of the Dietary Supplement or failure to package and label the Dietary Supplement as specified in the master manufacturing record (MMR).

   d. Identification of the action(s) taken to correct/prevent a recurrence.

   e. Explanation of what was done with the component, finished supplement, packaging or label.
Scientifically valid reason for reprocessing the finished product that is rejected or any treatment or in-process adjustment of a component that was rejected.

Signature of individual(s) designated to perform quality unit operations, who conducted material review and made disposition decision and of each qualified individual who provided information relevant to that material review and disposition decision.

E. Packaging Instruction Records

Overview: Manufacturers of Dietary Supplements are required to take the necessary actions to determine whether packaging for dietary supplements meets specifications so that the condition of the packaging ensures the quality of the dietary supplement. This requires the auditor to determine how the manufacturer controls the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies. While label reconciliation is not required for cut or rolled labels, this is only possible for an audit if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations. The audit must demonstrate that prior to packaging and labeling, the manufacturer examines packaging and labels for each batch of dietary supplement to assure the packaging and labels conform to the master manufacturing record. Most importantly, the auditor must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution, including any holding operations and distribution. The audit of filling, assembling, packaging, labeling, and related operations.

1. The dietary supplement manufacturer must fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the dietary
supplement and that the dietary supplement is packaged and labeled as specified in
the master manufacturing record. The audit shall consider documentation of the
following:

a. Cleaning and sanitizing all filling and packaging equipment, utensils, and
dietary supplement packaging, as appropriate.

b. Protecting manufactured dietary supplements from contamination,
particularly airborne contamination.

c. Using sanitary handling procedures.

d. Establishing physical or spatial separation of packaging and label
operations from operations on other components and dietary supplements
to prevent mix-ups.

e. Identifying, by any effective means, filled dietary supplement containers
that are set aside and held in unlabeled condition for future label operations,
to prevent mix-ups.

f. Assigning a batch, lot, or control number to:

i. Each lot of packaged and labeled dietary supplement from a finished
batch of dietary supplement.

ii. Each lot of dietary supplement, from a finished batch of dietary
supplement, that is distributed to another person for packaging or
labeling.

g. Examining a representative sample of each batch of the packaged and
labeled dietary supplement to determine whether the dietary supplement
meets the specification.
h. Suitably disposing of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

2. The audit of packaging instructions is required for each product and for each pack size and type shall include:

a. A description of the packaging operation and equipment to be used.

b. All instructions for sampling and in process controls and permitted deviations.

c. Any special precautions required, including review of the production line clearance prior to beginning packaging.

d. Product name, strength and dosage form.

e. Package size in terms of expected serving size, unit count, weight, or volume in the final container.

f. Complete list of the packaging materials required for a standard batch size, including quantities, sizes and types with the code reference number relating to the specifications of each packaging material.

g. A representative packaging label or specimen indicating where the batch number is positioned as well as the shelf life of the manufactured product.

F. **Production and Process Controls**

Overview: All Current Good Manufacturing Practices require productions operations to follow clearly defined procedures. The dietary supplement cGMPs requires quality unit personnel to ensure that manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the
master manufacturing record (ref: 21 CFR 111.105). Accordingly, a certification body’s standard must demonstrate how each of the elements enumerated below is addressed during the course of a facility audit inspection/assessment. Certification bodies must investigate/inspect a manufacturer for the following requirements:

1. Requirements for Components, Packaging, and Labels and for product received for packaging, repackaging or labeling as a dietary supplement using designated quality unit personnel to:
   a. Approve or reject all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a dietary supplement product.
   b. Review and approval of documentation setting forth the basis for qualification of any supplier.

2. Process must exist for verifying supplier’s invoices, letter of guarantee, certification, or related documentation for each shipment of components.

3. Holding of components in quarantine by Quality Unit Personnel:
   a. Until representative samples are collected.
   b. Until Quality Unit personnel review and approve the results of any tests or examinations conducted on the representative samples.
   c. Until Quality Unit personnel review, approve and release the components for use in the manufacture of a dietary supplement.
4. Assignment of a unique identifier for components for each unique lot to trace the lot to the supplier as well as the date received, name of component, status of components (quarantined, approved, or rejected), and to the dietary supplement manufactured and distributed.

5. Documentation of the disposition of each unique lot received utilizing the unique identifier.

6. Certificates of analysis:
   a. Auditor must check for description of the test or examination method(s) used.
   b. Auditor must look for limits of the test or examinations.
   c. Auditor must look at actual results of the tests or examinations.

7. Special requirements for animal-derived components: may be subject to other federal regulations (e.g., 21 CFR 189.5 (cattle) and 21 CFR 123 (fish and fishery products)).

8. The certification body must document how the firm holds components under conditions to protect against contamination and deterioration and avoid mix-ups.

   a. Quality Unit Personnel need to hold components in quarantine:
      i. Until representative samples are collected, and a visual identification has been conducted on the immediate containers and closures.
      ii. Until Quality Unit personnel review and approve the results of any tests or examinations conducted on the packaging and labels.
iii. Until Quality Unit personnel review, approve and release the packaging and labels for use in the manufacture of a dietary supplement.

b. Ensure that all representative samples are collected.

c. Ensure that all reserve samples are collected and held.

d. Determine whether all specifications are met.

G. Quality Unit Operations

1. The certification program’s standard shall direct the auditor to audit the following with quality unit personnel:

a. Specifications.

b. Sampling Procedures.

c. Testing methods/procedures (compendial and non-compendial methods):

   i. Organoleptic methods used for botanicals.

d. Analytical worksheets and laboratory data notebooks.

e. Testing reports including both in-house and qualified 3rd party laboratories along with 3rd party certificates including both chemical and analytical qualifications for such laboratories and follow-up of 3rd party testing practices.

f. Data from environmental monitoring including warehouse mapping of verification of storage conditions if required to maintain quality of components and/or finished dietary supplement.

g. Procedures for and records of instrument calibration and log records of equipment maintenance.
2. The certification program’s standard shall address investigation by the auditor over proper retention of batch records and review those records.

3. The certification program shall instruct the auditor review analytical test results, yields, environmental controls, etc.

4. Sampling of Raw Materials and Reference Samples.
   a. The certification program standard shall investigate sampling performed within approved written procedures that describe the following:
      i. The method of sampling.
      ii. The equipment used.
      iii. Amount of sample taken.
      iv. Type, size and condition of the container sampled.
      v. Lot identity of containers sample.
      vi. Storage conditions at time of sampling.
      vii. Instructions for cleaning and storage of sampling equipment.

5. The certification program standard shall direct the auditor to investigate reference samples taken for each batch of finished product as well as for raw materials and the storage location for reference samples.

6. The certification program standard shall direct the auditor to investigate analytical methods, reference citations to methods, validation records and the results recorded in laboratory notebooks or forms along with calculations.

7. Tests performed shall include the following information:
   a. Name and form of the raw material or finished product.
   b. Batch number and supplier of the raw material.
c. Citation reference to the specifications and testing procedures.

8. Signature of persons performing the laboratory testing operations and initials of someone verifying the tests and calculations.

9. Clear signature on decision from Quality Unit to either release or reject the raw material or finished product and date.

10. The certification program’s standard shall address laboratory reagents, glassware and solution, reference standards and culture media.

11. The certification program’s standard shall address written procedures for laboratory operations and in-process controls.

12. The auditor’s investigation of laboratory reagents shall include the date of preparation and the signature of the technician preparing them, expiration dates on labels, and proper storage conditions.

13. Receipt dates of any substance used for laboratory operations including reagents, reference standards, voucher specimens for botanicals, etc. shall also be present.

14. The certification program’s standard shall direct the auditor to evaluate analytical methods performed to test each product.

15. The certification program’s standard shall direct the auditor to evaluate the system for retaining reserve samples of all batches and that there is sufficient quantity of each retained reserve sample.

16. Considerations for Live Microbial Ingredients and Microbial Contamination (See Appendix I)

17. Other Aspects of Quality to be Investigated in the Audit:
a. The certification program’s standard shall direct the auditor to inquire about management’s role in communicating quality responsibilities, meeting quality requirements and informing the organization about performance against established quality objectives as part of a greater overall quality communication program.

b. The certification program’s standard shall direct the auditor to inquire and verify the bio-terrorism registration status as per the Bio Terrorism Act of 2002.

c. The certification program’s standard shall direct the auditor to investigate whether the audited firm contains a Supplier Quality Performance Program or equivalent with an FSVP component to enable manufacturers to mitigate regulatory risks and drive continuous process improvement.

d. The certification program shall direct the auditor to determine whether management contains a procedure to escalate significant quality events to management personnel to ensure appropriate oversight, corrective action (including recall) is performed in a timely manner based on standard quality risk management principles.

e. The certification program shall direct the auditor to inquire about any written allergen control plans or equivalent at the facility to minimize the potential for cross-contact.

f. The certification program’s standard shall direct the auditor to investigate whether packagers of iron-containing dietary supplements are issuing a
general conformity certificate under Consumer Product Safety Commission (CPSC) regulations, where applicable.

g. The certification program's standard shall direct the auditor to cover evaluation of a FSMA Food Defense Plan for mitigation strategies to protect against intentional adulteration.

18. Inspection and auditing of Quality Assurance Agreements:

a. The certification program’s standard shall direct the auditor to ask for quality assurance agreements in place with major customers, 3rd party testing laboratories and 3rd party contract manufacturers.

b. The certification program’s standard shall direct the auditor to verify written contracts covering the manufacture and/or analysis arranged under contract.

c. The certification program’s standard shall direct the auditor to determine cGMP responsibilities of the own-label distributor or brand from the contract manufacturer through quality assurance agreements, (i.e., does the own label distributor order out of a catalog or do they impart control and direction over specifications by telling the contract manufacturer what dietary and other ingredients shall be contained in the product and at what serving level?).

H. Handling of Recalls and Product Complaints

Overview: Complaints and Recalls can and will occur, so a well-documented process must be in place to avoid confusion and increase safety. A person shall be designated as the responsible official for handling product complaints and deciding the measures to be taken. In the US, FDA describes such a “responsible person” as one who “may receive a report of a serious adverse event
with such dietary supplement.” All complaints, serious (those resulting in hospitalizations or
death) or otherwise, including communications of defective products, must be reviewed in
accordance with written standard operating procedures. It is critical for the auditor conducting an
audit to review the product complaints file and how the manufacturer/own label distributor handled
them and what the follow-up procedure is for recalls of known or suspected defective products,
the auditor’s standard program shall be able to investigate when the recalls were initiated as well
as how recalls were conducted, even for reviews conducted by quality unit that did not result in a
recall.

1. Handling of Complaints
   a. Auditors must identify the responsible official at the firm regarding product
      complaints. Certification bodies must investigate/inspect a firm for the
      following requirements for a product complaint:
         i. Complaints shall be recorded with original complaint, follow up
            intake interviews, and further details from subsequent follow up.
         ii. The certification program owner must contain, as part of a separate
             program or as part of the certification program, procedures and
             instructions for the auditor whereby the head of Quality Unit, the
             Responsible Person for product complaints and adverse events, and
             any medical personnel at the company are interviewed.
         iii. The head of Quality Unit, the Responsible Person, and any medical
             personnel involved in in-house determinations as to adverse event
             severity shall be interviewed by the auditor regarding recalls,
             product complaints, and assessment of adverse events.
iv. Auditors shall check as to whether other batches were checked for defects in addition to the reported defect.

v. The auditor must review written documentation of all of the decisions and measures taken as a result of any product complaint and was the batch number recorded including whether the batch records related to the product complaint was reviewed by the auditor to determine if there was proper oversight by the head of Quality Unit and the Responsible Person.

vi. The certification program owner shall verify that each product complaint template includes the following:

1. Name/address of complainant.

2. Name and phone number or email address of the person submitting the complaint.

3. Chief complaint made and associated batch numbers.

4. Responsible official for investigation of the complaint.

5. Label of the product if applicable.

6. Date of received complaint.

7. Action taken (dates/identity of intake interviews, follow up, and subsequent actions).

8. Response directed to the original complaint.

9. Final closure of the complaint

vii. Complaint records shall be retained in accordance with federal statues or foreign government laws in terms of length.
viii. The auditor must investigate whether retained complaint records uncover trends or that Quality Unit performed a trend analysis on records.

ix. The certification program shall review how product complaints were triaged.

x. The certification program shall assess whether competent authorities were notified of a serious or life-threatening adverse event.

2. Handling of Recalls
   a. The speed and efficiency of a recall can go a long way to minimize the adverse effects of the recall and assure the consumer of safety:
      i. Written procedures describing actions to be taken, including a clear flow chart of when a recall must be conducted.
      ii. The certification program shall identify the responsible individuals for recalls and serious adverse event reporting to investigate how follow up was performed as directed in the standard operating procedures.
      iii. The auditor must review the manufacturer's written procedures and note if they have been regularly checked and updated for performing a recall operation.
      iv. The auditor shall evaluate the capability of a firm to perform a recall quickly.
v. If a recall is open or a new recall occurred since the last audit, the auditor shall review and document the time between notification or discovery of the defect and reporting to competent authorities.

vi. Using an active recall or mock recall, the auditor shall determine if the distribution records were available to the recall coordinator at the manufacturer, along with information on wholesalers and directly supplied customers was sufficiently complete to initiate the recall.

vii. The certification program shall assess whether there are adequate procedures designating an area for recalled products that is secure, separate from other products, and adequate.

viii. The auditor shall review the records on the progress during the recall process and any final reports issued, including reconciliation between delivered and recovered quantities of any defective products.

ix. The recall procedure reviewed in the certification program shall evaluate who was designated in evaluating the information, how the recall was initiated, who shall have information about the recall and how the recalled material shall be treated.

x. The auditor must review provisions and records for a mock recall.

I. Handling of Returned, Rejected, and Reprocessed/Reworked/Recovered Materials

Overview: Finished products may be returned to a manufacturer for a variety of reasons, including observable defects, slow retail sales, overstocks, wrong quantity ordered, etc. Similarly,
raw materials and intermediates may be reworked for recovery into new batches of products. Many firms have a Return Goods Policy and provide a form to be filled out by a customer, which shall accompany any product being returned. The forms include the customer’s name, address, product identification, date of the return, quantity returned, and reason for the return. It is critical that returned dietary supplements remain under the supervision and control of Quality Unit so that they may conduct a material review and proceed with a disposition decision to either accept as-is, rework the product, or destroy it. Whether it is accepted as-is, designated for rework or destroyed depends on whether the Quality Unit determines the product still meets product specifications.

Returned Materials

1. The certification program shall direct the auditor to ensure returned products are quarantined.

2. The certification program shall direct the auditor to investigate the appropriate dispositions on returned products.

3. The certification program shall specifically direct the auditor to evaluate returned materials for each of the following:
   a. Name/address of the consignee.
   b. Name and label of the product.
   c. Batch number and quantity returned.
   d. Reason for return.
   e. Use or disposal of the returned product.

Rejected Materials

4. The certification program shall investigate whether rejected materials and products are clearly marked, separated/quarantined and stored in restricted access areas.
5. The certification program shall direct the auditor to confirm that materials designated for rejection were actually quarantined and destroyed.

Reprocessed/Reworked/Recovered Materials

6. The certification program shall direct the auditor to evaluate flow charts (if applicable) to determine how decisions are made to recover materials and ensure the quality of the final product was not affected.

7. The certification program shall specifically direct the auditor to evaluate records of any reprocessing activities performed.

8. The auditor shall investigate additional testing performed of any finished product manufactured from reprocessed inputs or into which a recovered product was incorporated.

9. The certification program shall evaluate whether the additional testing was sufficient to ensure quality of the final product met the appropriate specification.

10. The certification program shall direct the auditor to evaluate the outcome of a material review and disposition decision by Quality Unit personnel to salvage a returned dietary supplement for redistribution.

V. AUDITS

Overview: While a dietary supplement manufacturer can follow the procedures set forth in this guidance document and self-assess compliance, certification by an unbiased third party provides a number of benefits to a supplement manufacturer. In this manner conformance by the manufacturer is assessed by an independent audit company in accordance with a standard protocol. Certification is then reviewed on an objective scale based on the number and severity of the nonconforming acts according to the guidance document. Previous audits do not suffice to show
satisfaction of the standard's requirements; thus, a new review of the facility and grounds is
necessary even if the auditor has found them satisfactory in the previous audit. During the
Certification Audit visit, the requirements set forth by the government can be reviewed with the
manufacturer and any necessary corrective action can be identified at the end of the visit, the
manufacturer's facility can be given a numerical score that objectively indicates the number and
severity of nonconformance, and awarded a Certification if sufficient criteria are met. The auditor
and certification body must have written requirements for the minimum yearly training for each of
the individuals employed to assist in an audit. The documentation of this training is of paramount
importance in keeping the auditors knowledgeable about the current requirements of the FDA and
any other concerns of regulatory bodies that would impact the dietary supplement quality and
safety.

A. Demonstration of Required Elements

Overview: A certification body’s standard must demonstrate how each of the
documentation elements enumerated previously in this guidance document in addition to
recording and documenting the company’s response during a facility audit
inspection/assessment.

B. The Audit Must Find the Necessary Evidence that Controls are in place and
Processes are Performed Adequately and Supervised by Competent Individuals.

1. All handling of raw materials, other components, and dietary supplements, such as
receipt and quarantine, sampling, testing, release, storage, labeling, dispensing,
processing, packaging, and distribution shall be performed in accordance with
written procedures/instructions and documented.
2. Incoming raw materials shall be checked to ensure the consignment corresponds to the purchase order. Containers shall be appropriately labeled, free of damage and cleaned as necessary.

3. Procedures for documenting, recording and reporting damaged containers shall be in place.

4. Incoming raw materials, components and finished dietary supplements shall be physically or administratively quarantined immediately after receipt or processing, until they have been released for use or released by the quality unit for distribution.

5. Intermediate and bulk products purchased as such shall be handled in the same manner as raw materials upon receipt.

6. Preventive maintenance or checks on equipment and utensils, especially unique types of equipment and utensils, shall be conducted regularly including review of such items as mixing bowls, etc. for evidence of pitting or potential metal shavings.

7. Storage of all materials and products under appropriate conditions established by the manufacturer and permitting batch segregation and stock rotation.

8. Checks on yield and reconciliation of quantities – performed to ensure no discrepancies outside acceptable limits.

9. Operations of different products should not be carried out simultaneously or consecutively in the same room unless there are written procedures and controls in place to prevent cross contamination or mix-ups.

10. Products and materials shall be kept from microbial and other contamination at each stage of processing.

11. Prevention plans/precautions to prevent generation and dissemination of dust.
12. All materials, bulk containers, equipment and rooms shall be labeled at all times to indicate product or material being processed, its strength, and batch number, and stage of production.

13. Labels assigned to containers, equipment or premises/rooms shall be clear, unambiguous. Labels shall indicate quarantine, accepted, rejected, clean, etc.

14. Deviations from instructions or procedures shall be avoided as far as possible, but any deviations shall be approved in writing by the quality unit.

C. **The Audit Shall Cover Review of Processes and Controls to Protect Products from Potential Cross Contamination.**

1. Cross-contamination of components, dietary supplements or product contact surfaces must be avoided. Cross-contamination can result from a number of sources such as the uncontrolled release or transfer of other raw materials, dust, gases, vapors, sprays, organisms, etc. from raw materials, products in process, equipment or personnel.

2. Cross-contamination shall be avoided by technical and organizational measures, including but not limited to:

   a. Proper segregation during storing/warehousing. Raw materials shall be stored separately from each other providing enough space to prevent cross contamination. There must be an allergen storage control where allergens are present in the facility.

   b. Segregation of areas for production and cleaning in between runs.

   c. Technical barriers include airlocks, airflow/handling and air extraction.

   d. Investigation by the audit of any risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air.
Cleaning/decontamination procedures and effectiveness:

i. The auditor must check to see whether the cleaning/decontamination procedures are adequate and effective based on review of environmental data.

f. Use of closed systems during all production when possible.

g. Donning protective clothing inside all production areas, especially when special risk of cross-contamination when possible.

h. Testing for residues and use of cleaning status labels on cleaned equipment.

i. The review of Standard Operating Procedures on prevention of cross-contamination by the auditor shall be an element of the certification program.

D. The Audit Shall Cover the Review of the Raw Material Qualification, Receipt, Labeling, Inspection/Testing and Release before it is used in the Manufacturing Process

1. Raw materials shall be purchased from approved suppliers as outlined in the companies approved supplier program and maintained in the approved supplier listing.

2. Containers shall be checked for integrity of package and seal.

3. Raw materials shall be labeled with the following:

   a. Name of the premix ingredient or raw material dietary ingredient.

   b. Manufacturer's/supplier's lot number, batch number, and/or internally generated lot number assigned upon receipt.

   c. Status of the material must be conspicuous (i.e., expiration date or re-test date, quarantine, on test, released, rejected) if manually controlled. If
electronically controlled, appropriate elements of the system must be validated against 21CFR Part 11.

4. The auditor shall evaluate the Standard Operating Procedure utilized for the verification of the identity of the contents of a representative sample for each lot of material received and used in the production process.

5. The auditor shall review the raw material disposition by the quality unit.

6. Prior to rejecting a raw material, the quality unit with other functional departments may appropriately assess the usage of the material under a planned deviation, unless it is a dietary ingredient that has failed identity testing after a thorough out of specification investigation.

7. Rejected raw materials and products shall be clearly, and appropriately marked and stored separately in restricted access areas.

8. Rejected raw materials shall be quarantined until it can be returned to the supplier or destroyed.

E. Packaging Materials and Packaging Operations

1. Packaging materials (labeling, cartons, inserts) are to be stored in a secure location with limited access by authorized employees.

2. Each delivery or batch of printed or primary packaging material shall be given a unique lot or identification number.

3. During the facility tour and/or documentation review the auditor will perform spot verification of expiration dating of raw materials and packaging materials. During the review of disposal records the process of destruction will be verified with the review of the destruction form for selected items.
4. The auditor must assess the potential for cross-contamination, mix-ups or unplanned substitutions in packaging.

5. Name/batch number of the product being handled shall be displayed at each packaging station or line.

6. The products and packaging materials to be used shall be checked on delivery to the packaging department for quantity, identity and conformity with the Packaging Instructions.

7. The auditor shall assess the handling and controls in place of packaging components to prevent the potential for cross contamination.

8. Samples removed from the packaging line shall not be returned unless inspected, investigated and approved by authorized personnel.

9. Unused batch-coded packaging materials shall be destroyed, and the activity recorded.

10. Filling, sealing, and labeling shall be completed in a single process. If required and labeling cannot be completed at the time of filling the (brite stock) product is to have at a minimum the lot number applied to avoid mix-up and/or mislabeling.

F. Finished Product Disposition and The Control of Rejected, Reworked and Returned Product

1. After release, finished products can be stored as usable stock under conditions established by the manufacturer per a Standard Operating Procedure.

2. Reworking of rejected products shall take place only if final product quality is unaffected and if specifications are met:

   a. Only acceptable if performed in accordance of such Standard Operating Procedures previously put in place by the manufacturer.
b. Any such reprocessing activities shall be detailed in records.

3. Quality will review and approve all rework or reconditioning procedures which may include verification testing.

4. Returned products shall be evaluated by the Quality unit and can be reconditioned if there is confirmation that their quality is still satisfactory, otherwise it must be destroyed. Quality unit must assess the nature of the ingredients, special storage conditions, product history and stability, and remaining shelf life or time elapsed since released into commerce:

a. Any quality issue that will impact product integrity, efficacy and safety will make it unsuitable for re-work or re-issue.

G. Training, Competency, and Calibration of Auditors for the Certification of cGMP Facilities

Overview: Organizations often underinvest in the competence of their auditors. This weakens the overall effectiveness of the program and leads to a wide disparity in auditor performance. Auditors may become complacent in their auditing process that they may ignore to use the validated and approved SSCI auditor checklist, which serve the purpose of ensuring that any auditor assigned to a facility will uncover the same issues of non-compliance, resulting in similar scores. Programs are only good as their weakest auditors, so auditor’s calibration is critical and a must. Auditors who do not receive annual training may check boxes and meet the absolute minimum if they do not understand the fundamental principles behind each question asked from a validated auditor tool. A competent audit staff enhances confidence in system performance. Training reinforces knowledge gained during audits and enhances employee acceptance of the certification program’s standard. Competent auditors shall exhibit professional behavior during
the performance of audit activities including being diplomatic, ethical, open-minded, observant, perceptive, versatile, decisive, and self-reliant.

1. Auditor Training
   a. The certification program’s standard shall require at least 40 hours of annual cGMP part 111 training for its auditors (contractors and employees). The training shall also include revised or new FDA guidance documents, skills training, FSMA, 21 CFR part 117 and other related training based on emerging regulatory and industry issues.
   b. The certification program shall annually submit records demonstrating how it tracks and provides the minimum of 40 hours of annual cGMP part 111 or related training as outlined above to the SSCI benchmarking committee:
      i. This training is considered on an individual basis; accordingly, while the average training for the certification body may satisfy the requirements above, each auditor must also independently satisfy the requirements.

2. Auditor Competency/Calibration
   a. The certification program’s standard shall contain an auditor competency/calibration program.
   b. The auditor competency program shall include requirements for the qualification of an auditor that includes professional training, years of experience working in the industry or a combination thereof.
   c. The auditor competency program shall track competency areas including an annual assessment of professional knowledge on part 111 and the cGMP
final rule preamble, 21 CFR Part 117, FSMA, assessment of examination and analysis skills, decision making and/or problem solving skills, communication of findings to quality managers at a facility, and corrective actions for auditors based upon poor performance.

d. The certification program's standard shall contain an auditor calibration program in the event of a grievance is filed against a specific auditor.

e. The auditor calibration program shall track performance and compare findings/scores between different auditors in any given facility as well as by the same auditor in the facility and utilize these findings for improvement.

f. The certification program shall establish auditor evaluation criteria (qualitative and quantitative):

i. Qualitative assessment includes personal behaviors, demonstration of knowledge and skills.

ii. Quantitative assessment includes determination of number of years of work experience, education, number of audits, documented evidence on hours of training received by each auditor.

g. The certification program shall establish methods to evaluate/assess auditor competency and learning:

i. Review of records – education, training, employment, credentials, audit experience (foods vs. dietary supplements vs drug/OTC facility experience).
ii. Feedback: the certification program shall implement surveys, questionnaires, complaints from audited companies, performance evaluations, and peer review and provide information to the auditor on how the performance of the auditor was perceived.

iii. Interviews: the certification program shall conduct personal interviews to evaluate personal behavior and communication skills to verify information and knowledge assessment and ability to acquire additional knowledge through training.

iv. Observations: the certification program shall observe behaviors and skills through role playing in dynamic didactic training exercises designed to simulate real audits, monitor audits through on-the-job training, mock audits, and evaluate new auditors through an apprentice program.

v. Testing: the certification program shall provide oral and written examinations to evaluate personal behaviors, knowledge, skills, and application of knowledge.

vi. Post-audit review: the certification program shall direct management to review audit reports and conduct interviews with the audit management and provide feedback to auditors designed to identify strengths and weaknesses assessed during auditor performance.

3. Auditor Tool

Overview: The SSCI benchmarking committee requires the use of the SSCI auditing tool to complete audits because it has been validated through pilot audit exercises. If the certification
program owner refuses to use the SSCI auditing tool, they may use their own in-house auditing
tool once it has been verified for equivalency by the SSCI Benchmarking Committee. The
certification program’s standard shall direct the auditor to complete all portions of the auditor tool.
The certification program’s standard shall contain an auditor tool, covering all required quality
management systems and additional areas required by FSMA or outlined in FDA guidance
documents and/or key areas to assure product quality to help the auditor and track the audit in
evaluating a company for compliance to U.S. federal or state regulations:

a. The auditing tool shall cover the following areas:

   i. Quality Management System.
   ii. Production and Process Controls.
   iii. Facilities and Equipment.
   iv. Laboratory Controls.
   v. Materials Management.
   vi. Packaging and Labeling.
   vii. Cleaning and Sanitation Controls.
   viii. Environmental Monitoring Programs.
   ix. Prerequisite Programs and Preventive Controls as applicable.