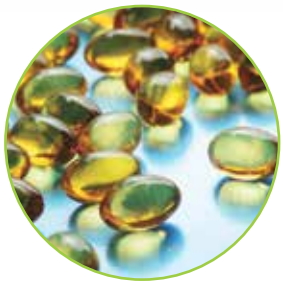

NSF DIETARY SUPPLEMENT SOP TEMPLATE BOOK

A guide to achieving and maintaining compliance to 21 CFR 111: Dietary Supplement Good Manufacturing Practices

Contents

TABLE OF CONTENTS

I. PURPOSE

This procedure contains requirements for an effective employee job-specific (SOP) training program, and Good Manufacturing Practices (GMP) training program. These programs are designed to provide employees the necessary training to perform their jobs correctly. The training programs described here will also enable employees to produce dietary supplements that are manufactured, packaged, labeled, and held under conditions that minimize the risk of adulteration, and that will ensure compliance with established specifications.

II. SCOPE

This procedure:

A. Details requirements for job descriptions

B. Details GMP training requirements for orientation training of new employees, as well as GMP refresher training for experienced employees.

C. Contains requirements for delivering job-specific (SOP) training to employees as required.

D. Applies to all regular, part-time, temporary or contract employees who are involved with any step or process associated with the production, packaging, testing, storage, or delivery of finished dietary supplement products. These requirements also apply to maintenance employees, employees responsible for sanitation activities, and employees of the Quality Unit.

E. Provides guidelines for proper documentation of training delivered.

F. Presents minimum requirements for trainers

III. RESPONSIBILITIES

Management and Quality Assurance must enforce the requirements of this procedure to ensure that job-specific and GMP training needs of employees are met on an ongoing basis.

IV. JOB DESCRIPTIONS

A. Clearly-written job descriptions must be developed for each position in the company. Duties and responsibilities must be specified, as well as the scope of the assigned responsibilities, and level of assigned authority. The basic

activities to be performed must be clearly outlined making sure to address methods, procedures, required tools, frequencies and expected outcomes.

B. Job descriptions must specify the required job knowledge or experience, as well as the minimum educational level necessary to perform the essential functions of the job.

C. Job descriptions must be maintained current at all times as controlled documents with date of issue, revision number and dated approval signatures.

V. TRAINING PLANS

A. A training plan that addresses SOP, as well as GMP orientation and refresher training needs for all employees must be developed and reviewed at least annually. Training plans may be developed by individual employee or by positions within the company.

B. Training must be delivered in the appropriate languages depending on employee needs.

C. In addition to training in the areas of company policies and procedures, safety, and job-specific topics, a comprehensive GMP training program must be developed that satisfies the requirements of the Food and Drug Administration Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements - Final Rule (21 CFR Part 111), with emphasis on employee responsibilities to protect product quality and product safety. The following topics shall be covered as they apply to individual positions:

- Personnel
- Plants and grounds
- Sanitation of buildings and facilities
- Equipment and utensils
- Production and process control systems
- Quality assurance/control
- Components, packaging and labeling
- Master manufacturing records

- Batch production records
- Laboratory operations
- Manufacturing operations
- Packaging and labeling operations
- Holding and distribution
- Returned dietary supplements
- Product complaints
- Records and record keeping

VI. GMP ORIENTATION TRAINING

A. Timely orientation of all new employees as individuals or as groups must take place to ensure that no employee is permitted to work in production, packaging, or warehouse areas prior to receiving training on GMP basic principles. Orientation training must address all elements of the "Personnel" section of the GMP Final Rule, with emphasis placed on personal hygiene, disease control, and the prevention of product contamination.

B. GMP orientation training should include a discussion of the regulations (Final Rule), and the importance of adhering to SOPs in an effort to ensure optimal quality and safety of finished dietary supplement products.

VII. GMP REFRESHER TRAINING

A. The training plan must specify a GMP training frequency for each category of employee.

B. GMP training must be delivered at minimum on an annual basis, but preferably every six months.

C. Training tools must be specified for formal GMP refresher training sessions. In addition to using updated training materials such as videos, handouts and overhead presentations, GMP refresher training should include relevant current events, or problems experienced internally or outside the company. Topics may arise from customer complaints, product recalls, regulatory audits, customer or third-party audits, internal audits, or concerns raised by site management.

VIII. GMP INFORMAL TRAINING SESSIONS

Employees must receive informal GMP training in order to address issues, concerns or problems when they occur. These sessions must be properly documented.

IX. JOB-SPECIFIC (SOP) TRAINING

A. Employees must receive training on an SOP when it is first issued, and whenever an existing SOP is revised.

B. At the time of scheduled reviews of SOPs (e.g. every two years), employees must be required to read the SOPs that are pertinent to their job, and sign a statement that they have read and understand the SOP as currently written. These signed statements must be placed in the individual employee files.

X. EVALUATION OF TRAINING EFFECTIVENESS

A. GMP training should be followed up with testing of each participant to measure the effectiveness of training and the level of comprehension that has taken place. Testing results can also serve to establish training frequencies. A minimum passing grade should be established for GMP testing. If an employee fails to receive the minimum score for any test, he or she must repeat the training and testing until an acceptable score is achieved.

B. Participant reaction to training received should be measured through use of a feedback form that can provide information on individual participant level of satisfaction with the training. The information obtained from feedback forms should be used for making changes to the content, methodology, etc. in order to improve training modules.

C. Supervisors must ensure that training and procedures are being followed by employees on the work floor. Supervisors should monitor employee performance and provide regular feedback to the employee on his or her observations.

XI. RECORD KEEPING

A. A sign-in sheet with the participant's name, signature, course name and number, date of the session, and the instructor's name and signature must be kept on file for each class held. The participant's signature attests to his or

her attending the complete session; the instructor's signature attests that the program was given and that the people listed did attend.

B. GMP training records should specify the specific topic that was the focus of the training delivered, not simply "GMPs".

C. Training delivered should be entered into training summaries maintained for each individual employee.

D. Official copies of instructional materials such as course outlines, worksheets, and instructor's notes should be retained.

XII. TRAINERS

A. GMP trainers must be qualified through successful completion of basic and advanced GMP training courses. Communication skills training such as a presentation skills workshop is recommended. For each course, any additional knowledge or skills required by the trainer must be specified. Instructor training must be documented.

B. SOP training must be delivered by supervisors or other persons with good knowledge of the SOPs, and that have also been trained as instructors.

TABLE OF CONTENTS

I. PURPOSE

To define the authorities and responsibilities of the Quality Control/Quality Assurance Department, hereafter referred to as the Quality Unit, in directing the Company towards compliance with regulatory and internal corporate requirements. This SOP also defines the Quality Unit's authorities and responsibilities in directing the Company towards meeting finished product specifications, as well as internal and customer expectations in the production of safe, quality dietary supplements.

II. SCOPE

A. The authorities and responsibilities detailed in this procedure for the Quality Unit apply to the handling of all raw materials/ingredients, in-process materials, dietary supplement products, and packaging materials.

B. These authorities and responsibilities also apply to all systems in place for controlling and assuring the safety, quality and security of dietary supplements.

C. These authorities and responsibilities apply to all satellite production and warehousing facilities.

III. RESPONSIBILITIES

A. It is the responsibility of the Quality Unit to consistently oversee manufacturing, packaging, labeling, and holding operations in the production of dietary supplements, to ensure that these functions are performed in a manner that prevents adulteration and misbranding of finished products.

B. The Quality Unit is responsible for overseeing that all dietary supplements meet specifications for identity, purity, quality, strength, and composition. The Quality Unit must also ensure that dietary supplements are manufactured, packaged, labeled, and held under conditions to prevent adulteration.

C. The Quality Unit will have overall responsibility for compliance management.

D. Management will empower the Quality Unit, under the direction of the Quality Assurance Manager to enforce the authorities and responsibilities assigned to them.

IV. AUTHORITIES AND RESPONSIBILITIES OF THE QUALITY CONTROL/ QUALITY ASSURANCE DEPARTMENT (QUALITY UNIT)

The Quality Unit shall:

A. Oversee and ensure compliance with all local, state and federal regulatory requirements.

B. Oversee and ensure compliance with all internal corporate programs and requirements designed for production of safe, quality products.

C. Ensure purity, quality, and composition of finished dietary supplement products.

D. Have the authority to approve or reject all procedures, specifications, controls, test methods, and results that impact the purity, quality, and composition of ingredients or products.

E. Review and approve all master manufacturing records, and all modifications to the master manufacturing records.

F. Review and approve all batch production-related records, including all records for packaging and labeling operations, ensuring that production records are reviewed for completion and errors.

G. Assure use of the most current revision of all documentation at all times.

H. Establish procedures for changing or revising relevant documentation.

I. Review and approve all changes to documentation such as procedures, methods, record keeping, formulas, etc.

J. Implement corrective actions when documented procedures are not followed.

K. Have the authority to approve or reject deviations committed in the manufacturing of a product.

L. Retain quality control and quality assurance records in accordance with the documented records retention procedure.

M. Conduct periodic Good Manufacturing Practices (GMP) internal audits of the entire plant, as well as satellite facilities, with documented corrective actions kept on file.

N. Oversee management of the calibration program for operational equipment, measuring and metering devices, including documentation associated with this program.

O. Oversee management of the calibration program for laboratory equipment and instruments, including documentation associated with this program.

P. Review and approve all laboratory control processes and testing results.

Q. Oversee management of all contract laboratories.

R. Review and approve the documentation setting forth the basis for qualification of any supplier.

S. Have the authority for disposition of raw materials, in-process materials, finished products or packaging materials subjected to adverse storage conditions.

T. Review all receiving records for components, packaging, and labels.

U. Ensure that packaging materials are safe for their intended purposes.

V. Determine whether all components, packaging, and labels conform to specifications.

W. Perform appropriate tests and examinations of components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications.

X. Have the authority to approve or reject raw materials, packaging materials, labeling and finished products, based upon conformance to established specifications.

Y. Review and approve the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition of the dietary supplement are met.

Z. Review and approve the documentation setting forth the basis for why the results of appropriate tests or examinations for each product specification will ensure that the finished batch of the dietary supplement meets product specifications.

AA. Review and approve the basis and the documentation for why any product specification is exempted from the verification requirements, and for why any component and in-process testing, examination, or monitoring, or other methods will ensure that such exempted product specification is met without verification through periodic testing of the finished batch.

BB. Approve or reject any treatment and in-process adjustments of components, packaging, or labels to make them suitable for use in the manufacture of a dietary supplement.

CC. Perform appropriate tests and examinations of dietary ingredient and dietary supplement batches at points, steps, or stages identified in the master manufacturing record where control is necessary to prevent adulteration.

DD. Perform appropriate tests and examinations of packaged and labeled dietary ingredients and dietary supplements to ensure that the packaging and labels specified in the master manufacturing record were used.

EE. Have final authority on distribution of the product. This shall be maintained as part of the batch record.

FF. Have the authority for control and release of withheld and retained product.

GG. Review the results of any visual examination and documentation to ensure that specifications are met for all products received for packaging and labeling as a dietary supplement (and for distribution rather than for return to the supplier).

HH. Approve and release from quarantine, all products that are received for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) before they are used for packaging or labeling.

II. Effectively manage a documented sample retention program for raw materials/ingredients, in-process materials, and finished products.

JJ. Ensure that required representative samples are collected.

KK. Ensure that required reserve samples are collected and held.

LL. Review and approve decisions for investigating product complaints, and review and approve the findings and follow-up action of any investigation performed.

MM. Conduct material reviews and make a disposition decision.

NN. Approve the reprocessing, salvage or distribution of returned dietary ingredients or dietary supplements.

OO. Approve or reject any repackaging of a packaged dietary supplement.

PP. Approve or reject any relabeling of a packaged and labeled dietary supplement.

QQ. Not approve and release for distribution:

1. Any batch of dietary supplement for which any component in the batch does not meet its identity specification.
2. Any batch of dietary supplement, including any reprocessed batch which does not meet all product specifications.
3. Any batch of dietary supplement, including any reprocessed batch which has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration.
4. Any product received from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for which sufficient assurance is not provided to adequately identify the

product and to determine that the product is consistent with the purchase order.

More information on NSF Dietary Supplements and
Health Science Division Services can be found at:

NSF International
789 N. Dixboro Road | Ann Arbor, MI 48105 USA
+1.800.NSF.MARK | +1.734.769.8010
dietarysupplements@nsf.org | www.nsf.org | www.nsfsport.com

Follow us on Twitter: @HS_NSF