I. PURPOSE

This SOP describes policies, procedures, and record keeping requirements for all documents subject to change control.

II. SCOPE

All SOP's and forms required for compliance with 21 CFR 111, the cGMP's for Dietary Supplements, including:

Subpart	Required Written Procedures
B	Fulfilling the requirements for personnel (21 CFR 111.8)
C	Cleaning the physical plant and pest control (21 CFR 111.16)
D	Fulfilling the requirements for equipment and utensils, including calibrating instruments and controls used in manufacturing or testing a component or dietary supplement; calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements (21 CFR 111.25)
F	The responsibilities of quality control personnel, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing (21 CFR 111.103)
G	Fulfilling the requirements for components, packaging, and labels and for product received for packaging or labeling as a dietary supplement (21 CFR 111.153)
J	Laboratory operations, including written procedures for the tests and examinations conducted to determine whether specifications are met (21 CFR 111.303)
K	Manufacturing operations (21 CFR 111.353)
L	Packaging and labeling operations (21 CFR 111.403)
M	Holding and distributing operations (21 CFR 111.453)
N	Fulfilling the requirements for returned dietary supplements (21 CFR 111.503)
O	Fulfilling the requirements for product complaints (21 CFR 111.553)

IV. REFERENCE

Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide: IV. Written Procedures Required by the DS CGMP Rule

21 CFR 11: Electronic Records and Electronic Signatures[1]

IV. RESPONSIBILITIES

1. The Director of Quality Assurance (or qualified designee) must:

a. Review and approve all new documents covered by the scope.

b. Review and approve all revisions and/or changes to documents covered by the scope.

2. The Department Manager (or qualified designee) must:

a. Review and approve all documents affecting areas of operation within their responsibly.

b. Ensure that all affected personnel are trained, with written records of training, whenever a document is added or revised according to this procedure.

3. The author will:

a. Prepare documents in accordance with this SOP and submit to the responsible person(s) for approval.

The author may be the original author, or the person revising the document.

V. PROCEDURE

1. Creating New Documents

a. SOP's must use the standard format template and include a standard header on each page.

b. Each SOP must have:

i. Descriptive document title (e.g. *Document Control*)

ii. Unique document number (e.g. *SOP-001*)

iii. Effective date

iv. Revision number[2]

v. Document history section, used for describing changes.

vi. Page numbers on each page (e.g. *Page 1 of 3*).

[1] Electronic documents and change control is outside the scope of this SOP.
[2] Revision numbers are usually sequential without gaps, but any valid numbering scheme may be used.

c. Forms are often associated with one (or more) SOP's. You may cross reference the form in the SOP as a separate document, or include the form in the SOP.

d. Forms must use a standard format header template, and must include:

i. A unique form number

ii. The form title

iii. The revision date.

2. Changing Documents

a. Each time a document is changed or revised, you must keep a record of the change, and the new version must be approved by all responsible persons before use.

b. Minor changes (e.g. a layout change or spelling correction) may be recorded using only the Document History section. A new SOP revision number is required, along with SOP approvals by department and quality control personnel.

c. For major changes to a procedure, form, or SOP, obtain pre-approval using the Change Control Form (for example, see Section VII. EXHIBITS). Fill out a Change Control Form to both request and document the change. A new SOP revision number is required, and the revised SOP must be approved by department and quality control personnel prior to use.

d. The Change Control Form must include:

i. The unique change control number.

ii. Date of change request.

iii. An accurate description of the change and reason for change. You should cross reference any other documents that are relevant.

iv. Identification of other documents affected by the change.

v. Appropriate approval signature(s).

e. Include the change control number in the Document History section of the revised document (see Section VI. CHANGE HISTORY, CC# column).

3. Approval and Distribution

a. The Director of Quality Assurance (or qualified designee) must review and approve all documents, SOPs, forms, and policies related to GMP compliance and included in the Scope of this document.

b. Print sufficient hard copies of the new or revised SOP for each department's binder and the SOP master file, and print the Change Control Form (if used) for circulation to approvers.

i. Circulate all the printed copies for approval signatures. All department signatures and dates must be present on these copies prior to submitting for final QA approval.

ii. Once signed and approved by QA, these copies are controlled copies.

c. When the SOP is approved, file a controlled copy in the SOP master file, and distribute working copies to the appropriate department binder(s). Working copies must also be controlled copies.[3]

d. Remove all previous controlled copies from working folders and clearly mark as "OBSOLETE" or shred.

e. Update the SOP and Form Master List to include the new document information.

f. Notify all personnel currently using the affected SOP or forms, including those personnel listed in the Responsibilities section, so that training may commence on the new procedure.

g. Keep an archive of all obsolete master version(s) of revised SOP's and forms, along with the signed and dated Change Control Form(s), if used.

Note: Obsolete versions of forms and SOP's may be required for future investigations or by regulatory inspections.

4. SOP and Form Master List

a. A list of current SOP's, forms, and their revision numbers, is kept on file and has the following information:

i. SOP or form number

ii. Document or form title

iii. Current revision number and date effective.

VI. CHANGE HISTORY

Date	By	Job Title	Rev.	CC #	Reason
4/18/2013	Marian Boardley	Author	1	N/A	Created for AHPA seminar

[3] How controlled copies are handled will depend on the size of the company, and is outside the scope of this document.

VII. EXHIBITS

Standard Operating Procedure Change Control Form	**Change Control #:**
SOP Title or Name:	**SOP #:**
Department:	**Previous Revision #:**
Requested By: **Date:**	**New Revision #:**

Purpose of Change:
Scope:
Responsibility:

Item(s) requiring change:
Other Documents Affected:
Actual changes made: By: _____ Date: _____

	Print Name	**Job Title**	**Signature**	**Date**
Approved				
Approved				

Form: CC-000 Rev: 4/18/2013 MSB