SCOPE

1. The authorities and responsibilities detailed in this procedure for the Quality Unit extend to all raw materials/ingredients, in-process materials, dietary supplement products, and packaging materials handled.
2. These authorities and responsibilities also apply to all systems developed for controlling and assuring the safety, quality and security of dietary supplements.
3. These authorities and responsibilities apply to all satellite production and warehousing facilities.

This SOP is required reading for employees of the Quality Unit and for Production Management

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.

RESPONSIBILITY: The Department Manager is responsible for ensuring this procedure is communicated and adhered to by all staff.

1. It is the responsibility of the Quality Department 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.
2. The Quality Department is responsible for overseeing that all dietary supplements meet specifications for identity, purity, quality, strength, and composition. The Quality Department must also ensure that dietary supplements are manufactured, packaged, labeled, and held under conditions to prevent adulteration.
3. The Quality Department will have overall responsibility for compliance management.
4. Management will empower the Quality Department, under the direction of the Quality Assurance Manager to enforce the authorities and responsibilities assigned to them.

INSTRUCTIONS:

AUTHORITIES AND RESPONSIBILITIES OF THE QUALITY CONTROL/ QUALITY ASSURANCE DEPARTMENT
The Quality Department shall:

1. Oversee and ensure compliance with all local, state and federal regulatory requirements.
2. Oversee and ensure compliance with all internal corporate programs and requirements designed for production of safe, quality products.
3. Ensure purity, quality, and composition of finished dietary supplement products.
4. 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.
5. Review and approve all master manufacturing records, and all modifications to the master manufacturing records.
6. 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.
7. Assure use of the most current revision of all documentation at all times.
8. Establish procedures for changing or revising relevant documentation.
9. Review and approve all changes to documentation such as procedures, methods, record keeping, formulas, etc.
10. Implement corrective actions when documented procedures are not followed.
11. Have the authority to approve or reject deviations committed in the manufacturing of a product.
12. Retain quality control and quality assurance records in accordance with the documented records retention procedure.
13. Conduct periodic Good Manufacturing Practices (GMP) internal audits of the entire plant, as well as satellite facilities, with documented corrective actions kept on file.
14. Oversee management of the calibration program for operational equipment, measuring and metering devices, including documentation associated with this program.
15. Oversee management of the calibration program for laboratory equipment and instruments, including documentation associated with this program.

16. Review and approve all laboratory control processes and testing results.
17. Oversee management of all contract laboratories.
18. Review and approve the documentation setting forth the basis for qualification of any supplier.
19. Have the authority for disposition of raw materials, in-process materials, finished products or packaging materials subjected to adverse storage conditions.
20. Review all receiving records for components, packaging, and labels.
21. Ensure that packaging materials are safe for their intended purposes.
22. Determine whether all components, packaging, and labels conform to specifications.
23. Perform appropriate tests and examinations of components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications.
24. Have the authority to approve or reject raw materials, packaging materials, labeling and finished products, based upon conformance to established specifications.
25. 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.
26. 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.
27. 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.
28. 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.
29. 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.

30. 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.
31. Have final authority on distribution of the product. This shall be maintained as part of the batch record.
32. Have the authority for control and release of withheld and retained product.
33. 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).
34. 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.
35. Effectively manage a documented sample retention program for raw materials/ingredients, in-process materials, and finished products.
36. Ensure that required representative samples are collected.
37. Ensure that required reserve samples are collected and held.
38. Review and approve decisions for investigating product complaints, and review and approve the findings and follow-up action of any investigation performed.
39. Conduct material reviews and make a disposition decision.
40. Approve the reprocessing, salvage or distribution of returned dietary ingredients or dietary supplements.
41. Approve or reject any repackaging of a packaged dietary supplement.
42. Approve or reject any relabeling of a packaged and labeled dietary supplement.
43. Not approve and release for distribution:
    a) Any batch of dietary supplement for which any component in the batch does not meet its identity specification.
    b) Any batch of dietary supplement, including any reprocessed batch which does not meet all product specifications.
    c) Any batch of dietary supplement, including any reprocessed batch which has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration.
    d) 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.

MONITORING:
Regular audits / inspections of manufacturing areas and controls must be in place to ensure that procedures are effective and working.

VERIFICATION AND RECORD KEEPING:
Regular audits / inspections of manufacturing areas and controls must be in place to ensure that procedures are effective and working.
Internal audits records must be completed, which will include:

- non-conformances
- corrective action
- responsibility
- date of completion

RECORDS APPLIED TO THIS PROCEDURE:

- Internal Audit records
- Hygiene and Housekeeping records

DOCUMENTATION RETENTION:
The records applied to this procedure are to be kept on file for a minimum of 3 years.