



NNFA GMP Certification Program Overview

Program Objectives:

The NNFA GMP Certification Program is designed to verify compliance of member suppliers of dietary supplements with a standardized set of good manufacturing practices (GMPs) developed by NNFA. This program is based upon third party inspections of member suppliers and comprehensive audits of their GMP programs in the areas of Personnel, Plant and Grounds, Sanitation, Equipment, Quality Operations, Production and Process Controls, and Warehouse, Distribution, and Post-Distribution Practices. This program ensures that all elements of the manufacturing process are reviewed to provide reasonable assurance that processes are sufficiently controlled so that products meet their purported quality.

Member suppliers that meet minimum NNFA GMPs standards and have received an “A” compliance rating after an NNFA GMP audit will be entitled to apply for certification and use of the NNFA GMP certification mark. NNFA certification and display of the GMP certification mark demonstrate to retailers, consumers and the public-at-large that products have been manufactured using good manufacturing practices and bring a means of self-assessment to the dietary supplement industry.

Organization:

NNFA:

The NNFA, the largest dietary supplement trade association in the United States, has developed GMP standards based upon dialogs with member suppliers, other trade associations, and the FDA. The NNFA GMPs are a living document and will be updated periodically based upon feedback from consultants, member companies, best quality practices and the FDA. NNFA will facilitate certification of member suppliers by providing education and training upon request.

GMP Advisory Committee:

The GMP Advisory Committee, under the direct supervision of NNFA, is comprised of three experts selected for their expertise and training in GMPs. Whenever possible, the Committee members will have a diverse background, including food, dietary supplements, pharmaceuticals, and botanicals, representing the needs of the membership.

The functions of the Advisory Committee include:

- Periodic review of the NNFA GMPs
- Review and revision of suggested programs, procedures and records, necessary to meet GMPs
- Review and revision of the Audit Checklist and Performance Rating System
- Selection of auditing companies and assessment of their performance
- Resolution of any disagreements between auditors and member suppliers

Third Party Auditors:

Several agencies are selected to conduct audits of supplier members utilizing the NNFA GMPs and associated performance standards.

Auditing companies are selected by the Advisory Committee, based upon geographical location, resources, and prior experience conducting audits and inspections of food or dietary supplement manufacturers.

Auditing companies must be independent, with no known or potential conflict of interest, for each company for which they are contracted to complete an audit review. Auditors have agreed and been trained to conduct GMP audits only according to the audit checklist and performance rating system developed by NNFA.

Arrangements for initial audit, resolution of any findings, and any follow-up audits, are to be made jointly by the auditing company and the member supplier, but must follow the protocol developed by the NNFA.

Auditing companies are limited to the determination of compliance of a member supplier to NNFA GMPs, and any decision with regard to certification is at the sole discretion of NNFA. It is a conflict of interest for an auditing company to currently consult with any member supplier for which it conducts an audit; or to have consulted with that member supplier for a three year period prior to the audit.

Auditing companies shall provide NNFA with copies of all audit and corrective action reports. They must also agree to the accompaniment of members of the NNFA GMP Advisory Committee on a specified number of audits each year so that the NNFA may assess the quality of audits and the need for revision of the audit checklist and/or performance rating system.

On-Site Audits:

The purpose of the audit is to verify compliance of a member supplier's GMPs with the requirements of the NNFA GMPs. It also provides for an exchange of information between the company and the auditor that will identify areas for improvement required to meet minimum NNFA GMP standards.

The member supplier must allow access to all facilities, which are involved with the manufacture, packaging, testing, and/or distribution of dietary supplements. The member supplier must also have a qualified representative available to answer the auditor's questions.

Audits will be conducted by experienced auditors that have been trained in the NNFA GMPs and performance rating system, and have the required education, experience and training to conduct on-site audits. Typical education and experience of auditors is:

- A four year college degree in biology, chemistry, or food science
- Expertise in food or pharmaceutical GMPs
- Experience in the manufacturing processes for foods or dietary supplements
- Successful completion of training in the NNFA GMPs

Auditors are responsible for all phases of the audits, including completion of the audit checklist, the audit report, follow-up on corrective actions, and any secondary audits.

A fee will be charged for the audit according to fee schedules submitted by the auditing companies. There will be additional charges to cover the auditor's travel and lodging expenses; these expenses are to be determined by the company and auditing company in advance of the audit.

Communication will occur directly between the auditing company and the member supplier during all aspects of the auditing process following guidelines developed by NNFA. Any disputes that cannot be resolved within these guidelines shall be referred to the GMP Advisory Committee for resolution.

Performance Rating System:

The levels of compliance are as follows:

- A. A member supplier has excellent compliance with NNFA GMPs, with few deficiencies noted
- B. A member supplier has good compliance with NNFA GMPs, but several significant deficiencies were noted
- C. A member supplier has fair or poor compliance with NNFA GMPs, many deficiencies noted; a re-audit of the facility required

The compliance ratings determine need for corrective actions and follow-up inspections.

Member suppliers earning an "A" rating may immediately apply to NNFA for certification and the right to use the NNFA GMP certification mark. Member suppliers earning a "B" rating may apply to NNFA for certification and use of the certification mark once there is written verification that the outstanding deficiencies have been corrected. Member suppliers earning a "C" rating may apply to the NNFA for certification and use of the certification mark after successful completion of a second audit and once there is written verification that outstanding deficiencies have been corrected.

Appeal Procedure:

A member supplier has the ability to appeal an assigned compliance rating. The appeal must be in writing and must address each of the deficiencies and the reasons for the appeal. The written appeal must be submitted directly to the GMP Advisory Committee c/o NNFA along with the required appeal fees.

The GMP Advisory Committee will review the appeal within 30 working days and attempt to resolve the issue through discussion with the member supplier and auditing company. If this is not possible, a site visitation will be arranged.

The Advisory Committee's review of any appeal is contingent upon prior payment of a fee to offset the expenses associated with appeal process.

Certification Procedure:

Once a member company has documented compliance with NNFA GMPs, they may apply to NNFA for certification and the right to use the GMP certification mark. The application will be reviewed together with the audit and corrective action reports. Upon successful completion of certification, the official NNFA GMP certification mark may be used on the member supplier's labels, marketing and advertisements. Certification will be valid for a period of no more than three years from the date of the award.

Note: To obtain certification, a member company must be audited under the NNFA audit process described above. Compliance with other programs (e.g., ISO) will not be accepted as a substitute for the NNFA audit process.

Fees:

The certification program is self-funded through the assessment of fees for services rendered. Fees will be of three types:

- a. Registration fees: \$250.00 (includes program manual and referral to approved auditors).
- b. Certification and use of certification mark fees: \$1000.00, initial certification; \$250.00, annual maintenance. (*Member suppliers will be assessed a fee to offset the cost of certification, including review of the application, the issuance of the certification and mark, and maintenance of the database*)
- c. Appeal fee: \$500.00, with possibility of additional charges to cover any additional time or expenses incurred to resolve dispute.