


Eurofins GMP for Dietary Supplements 21 CFR Part 111




In the United States, the Food and Drug Administration (FDA) regulates the manufacturing, packaging, holding and labeling of Dietary Supplements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Definition of Dietary Supplements:

The FDA defines Dietary Supplements as products taken by mouth that contain a “dietary ingredient” in forms such as tablets, capsules, powders, energy bars, and liquids. “Dietary ingredients” include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet.

 In addition to being used to add nutrients to your diet, Dietary Supplements are used for sexual enhancements, weight management, bodybuilding, and sports nutrition.

 Dietary Supplements may not contain articles that are approved as new drugs, other undeclared drug ingredients, or make disease claims.

The US FDA requires persons who manufacture, package, label, or hold a Dietary Supplement to establish and follow current Good Manufacturing Practices to ensure the safety and quality of the Dietary Supplement and to ensure that the Dietary Supplement is packaged and labeled correctly.

Eurofins Food Assurance offers the following services:

Auditing

- Eurofins GMP for Dietary Supplements Audit – Based on 21 CFR Part 111
 - A 1.5 day audit conducted onsite with a professional auditor with industry experience
 - A successful audit results in a certificate illustrating compliance to 21 CFR Part 111
 - Accepted by Amazon as part of their Amazon Seller Dietary Supplement Requirements
- SQF Food Safety Code for Dietary Supplements Certification – (GFSI) FSC 31: Dietary Supplements
 - A 2 day GFSI benchmarked accredited audit conducted onsite with a professional auditor with industry experience
 - A successful audit results in SQF Certification as well as a listing in the SQF Certified Site Directory

- Supplement Safety & Compliance Initiative (SSCI) Audit – Based on 21 CFR Part 111
 - A 3 day audit conducted onsite with a professional auditor with industry experience
 - A successful audit results in a certificate illustrating compliance to 21 CFR Part 111
 - SSCI is led by retailers who are concerned about customer safety (e.g. Walmart, Nature’s Way, GNC, NOW Foods, Nature’s Bounty)
 - Accepted by Amazon as part of their Amazon Seller Dietary Supplement Requirements



Contact us at the link below for more information and a Proposal for Certification: auditing@cpt.eurofinsUS.com

The Amazon Seller Requirements for Dietary Supplements accept Eurofins GMP for Dietary Supplements and SSCI audits, both of which Eurofins Food Assurance can perform.

Training

- Dietary Supplements 21 CFR Part 111 Training – Understand the history of regulations, registration requirements, 21 CFR subparts
 - 2 Day Course
 - LIVE Virtual or Onsite
 - Public or Private
 - Global Virtual Course Capabilities
- Foreign Supplier Verification Program – Provides knowledge to implement the requirements of FSVP for importers, into the United States, of Dietary Supplements per FDA regulations
 - 2 Day Course
 - LIVE Virtual or Onsite
 - Public or Private
 - Global Virtual Course Capabilities

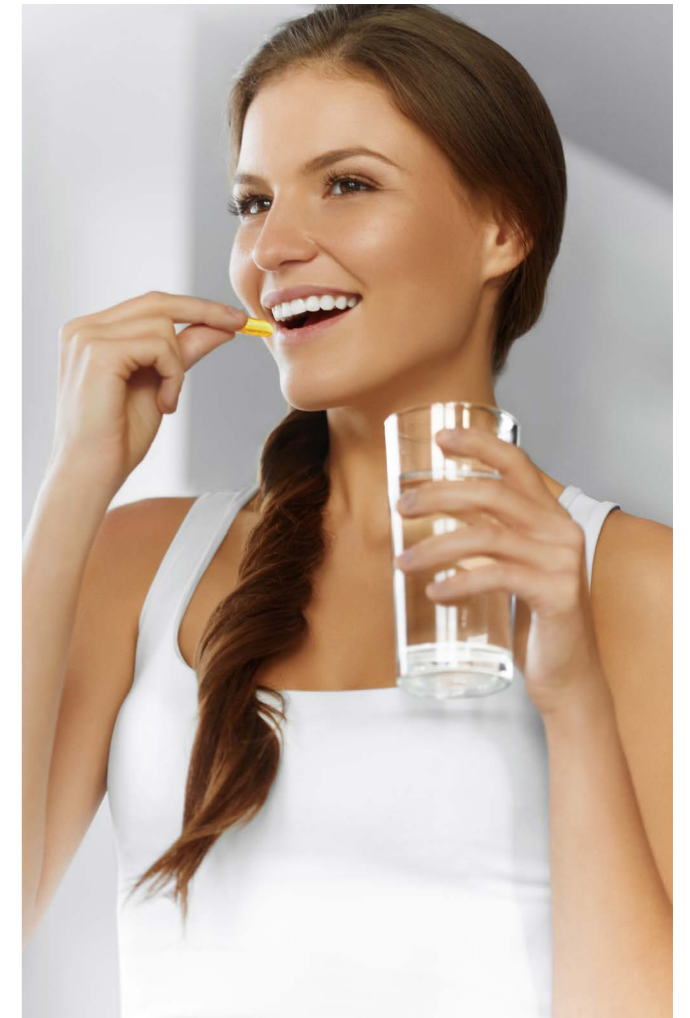
A full list of training courses can be found at: www.eurofinsus.com/foodassurance-meetus

Consulting

- Dietary Supplements Consulting
 - GMP for Dietary Supplements Gap Analysis
 - SQF Dietary Supplements Certification Gap Analysis
 - Support for program creations
 - Supply Chain
 - Adulteration and Fraud
 - Foreign Supplier Verification Program (FSVP)

Label Review

- Dietary Supplements Label Reviews – Including
 - Statement of Identity
 - Net Content Statement
 - Nutrition Facts Panel
 - Ingredient/Allergen Statements
 - Address Line, Ad Copy, and Claims
 - Nutrient content, health, and other regulated label statements, such as: Organic, Natural, Non-GMO, etc.



If you manufacture, distribute, package, hold, or label Dietary Supplements, Eurofins Food Assurance can help.




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 Eurofins Food Assurance

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