Learn how to

GROW YOUR BUSINESS WITH CONFIDENCE *and* MINIMIZE YOUR RISK

TABLE of CONTENTS

Expert Insight

TOP 10 ISSUES YOU ARE MOST LIKELY TO BE CITED FOR **DURING THE NEXT GMP AUDIT**

It's the question many managers ask themselves as they prepare for their upcoming audit. NSF International conducts hundreds of GMP audits at dietary supplement manufacturing facilities annually.

HERE'S WHAT OUR HIGHLY TRAINED, GLOBAL NETWORK OF AUDITORS FOUND IN 2016…

1. Ensuring that the batch production record follows the master manufacturing record and that each step is performed appropriately.
2. Establishing procedures to prevent pests and animals from entering the facility (installation of screens and barriers, rodent traps, insect traps, lights, etc.)
3. Properly using equipment and utensils to protect components and dietary supplements from contamination from any source.
4. Establishing appropriate roles and responsibilities for quality control personnel.
5. Ensuring walls, floors and ceilings are adequately cleaned and kept in good repair.
6. Maintaining, cleaning and sanitizing all equipment, instruments, utensils and contact surfaces.
7. Taking necessary precautions to prevent contamination, such as microbial, filth, chemical and foreign material contamination, throughout the manufacturing process.
8. Establishing adequate precautions against contamination by microorganisms, chemicals, filth or other extraneous materials.
9. Establishing supplier qualification procedures, including initial qualification, periodic examination (re-qualification) and disqualification.
10. Establishing procedures and programs for maintenance of equipment.

NSF supports the dietary supplement industry worldwide by providing high-quality training on a variety of topics including developing a compliant product label. Our comprehensive training approach goes far beyond just content delivery. Our instructors' extensive industry expertise provides tangible, real-world case studies of workplace situations and one-on-one interaction.

Visit **our training page** to learn more about the courses we offer year-round.

Are you ready?

TAKE YOUR **GMPs** to the **NEXT LEVEL**

Is your GMP facility compliant with FDA regulations? Good Manufacturing Practices (GMPs) are guidelines that provide a system of processes, procedures and documentation to assure a product has the identity, strength, composition, quality and purity that appear on its label.

THE ADVANTAGES OF THIRD-PARTY GMP FACILITY REGISTRATION

- Provides peace of mind toward meeting FDA regulations
- Prepares you for potential FDA inspections
- Builds trust among your customers that your facility runs a safe and quality operation
- Ensures qualification of your suppliers

HOW NSF STANDS ABOVE THE REST

- Provides access to a global network of auditors and public health professionals
- Program developed to meet federal expectations of the FDA's 21 CFR Part 111 regulation compliance for dietary supplement cGMPs
- Implements two comprehensive audits each year to ensure continued compliance
- Grants access to an innovative online system for resolving any non-conformances found within a facility during an audit
- Helps promote your GMP registration to the industry

Our highly trained global network of auditors and technical staff is committed to helping your facility reach its GMP ambitions.

For more information on NSF GMP Registration email us at **dietarysupplements@nsf.org**

Expert Insight

THE TOP 4 THINGS TO LOOK FOR IN A **DIETARY SUPPLEMENTS TESTING LABORATORY**

Are you using the best lab to test your dietary supplements?

Testing incoming ingredients and products is required by the FDA, but not all companies have the capabilities to conduct this testing in-house. *If you decide to outsource your testing, take the necessary steps to ensure you are working with a qualified laboratory.*

HERE ARE THE TOP 4 THINGS TO LOOK FOR:

1 The lab can test complex matrices.

Experience with dietary supplements is key. These are complex products, so the analytical test methods used for food may not be valid for supplements. The best way to verify that a lab has the capabilities to test your matrix is to qualify it. Do not hesitate to ask questions—you are their potential client!

2 The lab can detect contaminants at trace levels.

Contaminant testing at trace levels requires a different set of tools than when testing for identity, purity and potency. Make sure the lab is capable of evaluating your products for potential contamination from pesticides, aflatoxins, heavy metals, known adulterants and industrial contaminants at the trace levels required to meet regulatory requirements.

3 The lab has proper equipment and an expert staff.

Verify the lab's resources, either through an in-person visit or a trusted referral. Ensure the laboratory has experienced lab personnel and the proper instrumentation to perform the testing required. Confirm it is following internationally recognized quality systems and has a degreed staff that is highly trained to ensure that valid test results are consistently produced. Inquire about the type of instruments the lab uses to perform the testing you require.

4 The lab is accredited to conduct dietary supplement testing.

Many labs, such as NSF International, maintain accreditation to ISO/IEC 17025, an international quality standard applicable to analytical laboratories and laboratory methods. As the accreditation scope varies from lab to lab, check that the scope of the accreditation covers the supplement testing methods you need. This accreditation speaks to the quality of the lab because it verifies that the lab follows internationally accepted laboratory and quality control procedures.

For more information about dietary supplement testing, **visit us on the web.**

Expert Insight

HAZARDS OF PRODUCT LABEL DEVELOPMENT – TOP 5 LABEL CLAIM ISSUES TO AVOID

The FDA's label inspections have been increasingly stringent, as evidenced by warning letters citing seemingly minor violations that are often easily overlooked.

BELOW ARE THE FIVE MOST COMMON MISTAKES IN LABEL COMPLIANCE THAT NSF INTERNATIONAL EXPERTS COMMONLY SEE IN DIETARY SUPPLEMENT LABEL REVIEWS.

1. **Label claim made for the source of the dietary ingredient rather than the dietary ingredient.** For example, a claim made for calcium stating the total weight of calcium carbonate and not the calcium only.

2. **Free amino acids being added to the total claim for protein.** The label claim for protein should not include free amino acids.

3. **A botanical ingredient listed by a name other than the standard common name or genus/species.** Use the names standardized in *Herbs of Commerce*.

4. **The part of the plant not being listed for botanicals.** The plant part must be listed for all botanical ingredients. Use the standard common name followed by the statement of the part of the plant (e.g. root, leaves) from which the dietary ingredient is derived.

5. **Dietary supplements being used as meal replacements.** If a product is a meal replacement, it must use a Nutrition Facts panel and not be called a dietary supplement. According to the FDA, dietary supplements must be labeled as such and must not be represented for use as a conventional food or as the sole item of a meal or the diet. They must also have a Supplement Facts panel.

NSF supports the dietary supplement industry worldwide by providing high-quality training on a variety of topics including developing a compliant product label. Our comprehensive training approach goes far beyond just content delivery. Our instructors' extensive industry expertise provides tangible, real-world case studies of workplace situations and one-on-one interaction.

Visit **our training page** to learn more about the courses we offer year-round.

Are you prepared?

FULFILL *your* FDA ANNUAL TRAINING

2018 NSF Dietary Supplements Training

GMP OVERVIEW TRAINING

January 30-31	Tampa, FL
February 6-7	Dallas/Fort Worth, TX
March 7-11	Anaheim, CA EXPO WEST
April 10-11	Secaucus, NJ SUPPLYSIDE EAST
May 15-16	Des Plaines, IL
June 26-27	Seattle, WA
July 25-26	Ann Arbor, MI
August 21-22	Salt Lake City, UT
October 16-17	Toronto, CA
November 6-7	Carlsbad, CA
December 4-5	Miami, FL

LABEL CLAIM AND PROMOTION TRAINING

July 28	Ann Arbor, MI

For more information on our Training Programs visit **our training page**.

VENDOR QUALIFICATION AND AUDITING TRAINING

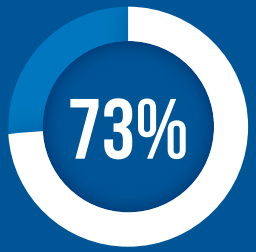
February 1-2	Tampa, FL
March 7-11	Anaheim, CA EXPO WEST
February 8	Dallas/Fort Worth, TX
April 10-11	Secaucus, NJ SUPPLYSIDE EAST
May 17	Des Plaines, IL
June 28	Seattle, WA
July 27-27	Ann Arbor, MI
August 23	Salt Lake City, UT
December 6	Miami, FL

FSMA TRAINING

February 7, 14, 21	Webinar 3 DAYS/3 WEEKS
March 7-11	Anaheim, CA EXPO WEST
April 10-11	Secaucus, NJ SUPPLYSIDE EAST
May 18	Chicago, IL
November 8	Carlsbad, CA

Did you know?

Consumers see value in certifications, and would **buy more** and **pay more for** products that show a certification.



Would **PREFER A CERTIFIED PRODUCT** over one that is not

Are willing to **PAY MORE** for a product that is INDEPENDENTLY TESTED AND CERTIFIED

Data gathered in an independent study conducted on behalf of NSF International.

DIFFERENTIATE YOUR BRAND *at the* SHELF

NSF
Contents Tested & Certified

More than ever, consumers are seeking to live cleaner but are unsure of what "clean" actually means, especially when it comes to choosing dietary supplements.

The NSF Contents Tested & Certified mark on package can help simplify their decision at the shelf and improve your competitive edge in the market. The mark means the product has been tested to be sure the ingredients listed on the package are actually in the product, which provides assurance of your supplements' quality, potency and safety.

NSF International is the leading accredited third-party certifier of dietary supplements, functional foods and dietary supplement raw ingredients (ANSI-Accredited Product Certification Body - Accreditation #0216).

For more information visit us at **www.nsf.org** or via email at **dietarysupplements@nsf.org**

Did you know?

NSF **SETS THE BAR** in **SPORTS NUTRITION**

Today, athletes are more educated about nutritional products and demand reputable, third-party tested products they can trust. NSF Certified for Sport® helps athletes, coaches and trainers make more informed decisions when choosing sports supplements. The program is recognized by the NFL, NFL Players Association, MLB, MLB Players Association, PGA, LPGA and Canadian Centre for Ethics in Sports.

Our scientists screen sports supplements for more than 270 banned or prohibited substances. Certification also means that supplement manufacturers and their suppliers have met our stringent independent certification process.

WHAT PEOPLE ARE SAYING

For over a decade, Major League Baseball and the Major League Baseball Players Association have jointly recognized and relied on the NSF Certified for Sport® program as a means to provide our players with certified safer options for dietary supplements.

Major League Baseball and the Major League Baseball Players Association

We hear every day from players and clubs alike that they were just waiting for the Garden of Life® SPORT line—NSF Certified for Sport® Certification finally opened the door. With every product in our Garden of Life® SPORT line being NSF Certified for Sport®, and holding all of the other third party certifications that Garden of Life consumers have come to expect – especially USDA Organic, Non-GMO Project Verified and NSF Certified Gluten-Free – the sport world has really embraced what we are calling, 'The Cleanest Performance Line Ever.'

Garden of Life®

Expert Insight

TOP 3 NEW DIETARY INGREDIENT NOTIFICATION **PITFALLS**

Are you ready to submit a new NDIN?

HERE ARE THE MOST COMMON PITFALLS COMPANIES FACE, AND HOW YOU CAN AVOID THEM.

1 **Approximately 25% of NDINs submitted to FDA were deemed incomplete due to:**

- Missing history of use section and no other evidence of safety provided
- Missing conditions of use, including serving size, duration of use, target population, etc.
- Incomplete identity information
- No description of final dietary supplement, including use level of the NDI

2 **Approximately 15% of NDINs submitted were for ingredients that are not dietary ingredients:**

- Avoid making drug claims (e.g. treats or prevents a disease or adverse condition)
- Avoid referencing studies on therapeutic properties of your NDI
- Make sure your NDI fits one of the six defined ingredient categories
- Make sure your NDI is not already present in the food supply and therefore exempt from notification

3 **Other common NDIN safety pitfalls include:**

- No documentation that compares the NDI to historically consumed material, including consumption levels
- Proposed serving level/duration/frequency that is not relevant to those described in the history of use
- Inadequate animal and/or clinical study
- Key safety parameters not assessed

Want to take the guesswork out of submissions? NSF International's Applied Research Center (ARC) offers services that include:

- Ingredient notifications
- Preparation and submission
- Product use and safety review
- Chemistry and toxicology

For more information, contact **arc@nsf.org**

TAKE THE GUESSWORK OUT of NDI & GRAS

HOW CAN NSF HELP INCREASE YOUR SPEED TO MARKET?

NSF International's Applied Research Center (ARC) provides analytical methods development, quality, safety and efficacy testing and research, chemical risk assessments. NSF International's Applied Research Center (ARC) also offer consultation in chemistry, microbiology, and toxicology to help position your product for marketplace success.

Drawing on more than 70 years of public health expertise, NSF's global network of quality and scientific professionals will help your company meet domestic and international requirements, providing you with guidance to increase your speed to market.

The NSF International's Applied Research Center (ARC) services to the dietary supplement and food industries include:

> New Dietary Ingredient (NDI) Notifications

> GRAS (Generally Recognized as Safe) Dossiers

> Risk Assessments

For more information, contact **arc@nsf.org**

GLOBAL TESTING EXPERTISE

NSF has testing facilities for dietary supplements and ingredients in the U.S., Germany and China. NSF's global headquarters in Ann Arbor, Michigan, USA has state-of-the art laboratories run by our professional team of chemists, microbiologists and toxicologists.

NSF's extensive array of instrumentation and technologies offers a solution to complex problem solving, and the laboratories are designed to solve even the most complex supplement testing issues.

Aside from method development, NSF offers mainstream testing services such as contaminant testing, athletic banned substance testing and ingredient identity testing at our U.S. laboratory. NSF's global testing complements NSF's existing testing services with particular expertise in raw materials and ingredients.

NSF's testing labs offer comprehensive microbiological, molecular-biological and chemical analytics for nutritional supplements (including athletic banned substance testing) including:

- Qualitative or quantitative tests of functional components
- Heavy metals
- Pesticide residues
- Solvent residues
- Plant extract identification
- Nutrition labeling
- Method development
- Microbial contaminants

For more information about dietary supplement testing, **visit us on the web**.