



Training for a Culture of Quality

By Dr. Cheryl A. Luther, General Manager, Dietary Supplements and Sports Nutrition, NSF International

The dietary supplement industry faces increasing scrutiny from regulatory agencies and the media. The U.S. Food and Drug Administration (FDA) has seized products and shut down several manufacturers for violations of 21 CFR 111 Good Manufacturing Practices (GMPs), federal courts are handing down hefty fines and contempt sentences, and the recent New York Attorney General actions against several herbal supplements made major headlines.

Ironically, negative attention on a few bad players also provides two major opportunities for reputable companies: a reminder to ensure their quality systems are in compliance and the ability to differentiate themselves in the marketplace. Adhering to current GMPs is critical for producing safe, high quality supplements and for making sure any media attention is positive. But keeping up to date with GMPs can be difficult – the 21 CFR 111 regulation is reviewed annually, the FDA often issues new guidance documents, and your company may experience changes to your manufacturing process by changing locations, adding equipment or making new supplement forms. In addition, the regulation can be difficult for companies to interpret in practical, real-world terms.

NSF International has conducted hundreds of GMP audits for clients committed to quality and yet found some serious oversights in quality management systems. For example:

- > A worker putting ungloved hands in the dough of a ready-to-eat dietary supplement bar and then pushing the dough down into an extruder hopper
- > Pets and other animals in or near the warehouse, including four horses in a lean-to with a door to the manufacturing floor and a dog that accompanied the auditor throughout the visit
- > Live plants in the warehouse

These examples highlight the importance of integrating a culture of quality into every step of the production process and making sure it is embraced by every employee in your organization – from production line workers to senior executives. Whether your company has integrated quality management into every aspect of its operations or you're the lone champion of quality in your organization, there has never been a better time to make your case for a corporate investment in quality.

FINANCE DIRECTOR: What happens if we train these people and they leave?

CEO: What happens if we don't and they stay?

While it's difficult to calculate the precise return on investment of quality, it's hard to argue against the value of quality training for dietary supplement industry professionals. In fact, 21 CFR 111 requires dietary supplement personnel to have GMP training on a regular basis. And training costs are certainly lower than the cost of high-profile consent decrees, warning letters, 483s, FDA fines, legal battles and product recalls, not to mention the damage to brand perception or damage to your contract manufacturing reputation.

Fortunately, resources are available to help dietary supplement manufacturers develop comprehensive quality management systems as well as technically competent leaders that will help ensure consumer safety and avoid significant legal and financial exposure.

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Training is the First Step

NSF International offers training courses throughout the year in locations that are convenient for dietary supplement industry professionals. Courses are offered at major industry trade shows and in dietary supplement industry hotspots. Core classes cover every aspect of GMP compliance including a full overview of 21 CFR 111, how to prepare for an FDA inspection and botanical testing for Identification.

21 CFR 111 Dietary Supplement GMP Overview

As a part of maintaining compliance to 21 CFR 111, dietary supplements personnel must have qualified GMP training on a regular basis. The regulation requires each company – whether selling within the U.S., or importing to or exporting from the U.S. – to have at least one qualified person to offer GMP training and industrial guidance to teach other employees how to implement and be complaint within the law.

The NSF “train the trainer” course details what it is required to meet the identity, strength, composition and purity requirements established in 21 CFR 111, and how the regulations vary based on product type (vitamin, herbal mix, probiotic, etc.). The course outlines what quality, manufacturing, holding and purchasing departments are required to do. Ninety percent of the law applies to manufacturing, but quality serves as the final authority prior to release to consumers and buyers must be aware of regulations in purchasing ingredients. In addition, break-out sessions provide information specific to virtual companies and warehouses, who need to be able to demonstrate they are 21 CFR 111 compliant and follow a lawful supplier approval process, as well as have systems for addressing complaints, returns and recalls.

The course also covers the latest annual rule updates, guidances and trending of causes for FDA warning letters.

FDA Inspection Readiness

The FDA is actively inspecting companies involved in the manufacturing, packaging, labeling, holding and distributing of dietary supplements, and more than half of these inspections result in a warning letter.

NSF Dietary Supplement

789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA
Tel: +1 (734) 827 6856 | dietarysupplements@nsf.org | www.nsf.org

Companies are inspected for four main reasons:

- > They had to issue a recall
- > Their competitors or customers have complained about their product to the FDA
- > They make or use a raw material that is under scrutiny by the FDA
- > Luck of the draw

Ensuring the most positive outcome for a GMP inspection requires careful planning and preparation well before audit occurs, successful management of many issues during the inspection itself and thorough follow-up after the inspection.

The more you know what to expect, and the better you can demonstrate knowledge of your operations, the smoother the visit will be for both parties. The NSF course provides the tools necessary to successfully manage an inspection, including a process for your company to develop so everyone knows their role during an inspection.

Botanical Testing: Identity, Identity, Identity

The key to botanical testing of dietary supplements is identity, identity, identity. Companies must be able to accurately identify all botanical materials used as a raw material or in the finished product.

Current GMP regulations require genetic/laboratory testing of botanicals, not chain of custody documentation or even organoleptic/sensory testing. This process is fairly straightforward for single ingredients like ginger root, but becomes more complex for herbal blends, botanical derivatives and excipients, whose core components are more difficult to identify.

The NSF course provides hands-on experience using test equipment. Knowing what's involved in testing is vital for quality and lab staff, and even purchasing – when outsourcing raw materials and testing services, they will know what instrumentation should be used and what the terminology means.

For more about the NSF Dietary Supplements Training Program and a calendar of upcoming training, please visit www.nsf.org or e-mail dietarysupplements@nsf.org.