Why Third-Party GMP Certification Should Not Be Optional for Dietary Supplement Firms

By Scott Ravech

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Quality took on a whole new meaning for me when I joined Deerland Enzymes as CEO in 2008. During my first tour of our manufacturing facility, I noticed that one of the enzyme products we produced was in fact the exact product that a naturopath had suggested for one of my sons. This personalized and drove home to me the seriousness of the responsibility that we as industry members have to ensure that the products we manufacture are absolutely safe for consumption.

Current good manufacturing practices (GMPs), which require that companies have proper controls for the manufacturing, packaging, labeling, and storing of dietary supplements, are a key facet of product safety. FDA first introduced GMP regulations for dietary supplements (21 CFR Part 111) in 2007, with the intent of industry-wide compliance by 2010. By now, all companies should be GMP compliant.

The industry itself—as well as consumers—pushed for greater safety regulations following concerns about substandard dietary supplement manufacturing practices and labeling. Unfortunately, those concerns continue to have merit. In 2013, FDA reported that as many as 70% of the GMP inspections it performed on dietary supplement manufacturing facilities identified GMP noncompliances. Independent testing by such groups as Consumer Reports and ConsumerLab.com continues to find incorrect or misbranded supplement labels in the market and, in some cases, supplements that contain unacceptable levels of contaminants.

As manufacturers, we need to take supplement safety seriously. It is our responsibility to provide, above all else, safe dietary supplements that consumers can take without fear of harm. There is also a great need to provide our regulatory authorities (FDA) with more resources, greater funding, and expanded authority, enabling them to take fast action against companies unwilling to comply with the requirements of the GMP regulations.

The Value of Certification

While the law dictates that dietary supplement companies must meet their GMP obligations, it does not require that a manufacturer be certified as GMP compliant. I strongly believe, however, that third-party certification is an important step beyond self-monitoring.

Certification validates that products manufactured match the identity, composition, potency, and purity declared on the product label. It also ensures that the processes, procedures, and documentation required for GMP compliance are in place and effective. Certification not only supports a company's credibility in the marketplace; it also promotes the credibility of the supplement industry as a whole.

Investing in a third-party certification audit to confirm compliance with all of FDA's regulations has one important additional benefit: it provides an objective, fresh set of eyes on the facility and its safety parameters. Even a company with excellent quality systems in place can gain wisdom from the additional perspective an auditor can provide.

The third-party audit not only serves to validate GMP compliance but also provides guidance for continuous process and documentation improvement. I compare this approach with that of a professional athlete, committed to improving his or her personal performance. A coach can help athletes hone their skills, even if an athlete is the best at what he or she does. Even the best baseball players have a hitting or a pitching coach. The best golfers have swing coaches. A third-party auditor is a company's "coach" for continuously improving its processes.

All players in the dietary supplement supply chain, from product developers to retailers, should insist on compliance with the GMP law. Third-party certification signifies that compliance. Businesses that sell supplements directly to consumers want the assurance that the companies supplying those products are complying with the highest standards available. Certification sends a strong message that the investment and commitment have been made to assure safety and regulatory compliance.

A third-party auditor may inspect a company's facility multiple times a year to ensure regulatory compliance as well as product and ingredient safety. Through this process, a company can learn about the things it is doing well and the things upon which it can improve. The rigor and scrutiny that come with this oversight help keep a company sharp. It ensures companies stay up to date on the regulations and keeps the industry mindful of how best to maintain the high degree of quality of the products being purchased and consumed. Also, as customers make more frequent trips to inspect their manufacturers' facilities, companies will find themselves much better prepared for these routine visits as a result of third-party audits.

Through audits, I have learned that the bar for quality and safety is constantly moving higher. Although the law hasn't changed, its interpretation by regulators and the public certainly can, and does. Having a third party examine a firm's practices helps the company stay up to date on the latest applications of the law and drives a company in a constant push towards continuous improvement. The result is that we know that the products we produce meet or exceed the stringent standards for safety and compliance.

I certainly recognize that many companies are in fact GMP compliant without having to be certified, and I applaud them for that. But, in my opinion, a qualified outside auditor provides additional regulatory safeguards to protect a company and its customers from the threat of negative FDA exposure.

Obtaining GMP certification through a third party isn't required by law, and dietary supplement manufacturers that choose self-monitored compliance over third-party certification may still be doing everything right. But, third-party certification is an excellent investment for dietary supplement companies that want to ensure compliance and continue to improve the quality of their products and the regulatory DNA of their companies.

Scott Ravech was named CEO of Deerland Enzymes (Kennesaw, GA) in 2008. He currently serves as co-chair of the dietary supplement committee of the Enzyme Technical Association (ETA) and is a voting member of the Council for Responsible Nutrition (CRN; Washington, DC).