NATURAL PRODUCTS INSIDER

Quality, Supply Agreements—Why Should Brands Care About These?

by Michael Finamore

A brand owner/own label distributor's mission is to market and sell products. Part of that equation is to buy the highest quality dietary supplements at a competitive price from the contract manufacturing organization (CMO). Historically, the brand owner/own label distributor sends a formula to a CMO, gets a quotation, issues a purchase order, receives the finished product with a certificate of analysis (CoA), and then is free to sell the product. A formula, a quote, a purchase order and a CoA—what other paperwork is needed? Why clutter up a straight-forward process with other documents and paperwork that are not mandated by FDA?

Prior to the implementation of cGMPs (current good manufacturing practices) for dietary supplements, this was the accepted procedure. Product sales and marketing was the responsibility of the brand owner/own label distributor, and making the product was the responsibility of the CMO—case closed. However, times have changed, and this is no longer the situation. The brand owner/own label distributor can no longer abdicate the responsibility for the quality of their products to the CMO.

While 21 CFR Part 111 has codified many new and existing practices for the dietary supplement industry, technically there is no requirement for either a quality agreement or a supply agreement between the brand owner/own label distributor and their chosen CMO. So why is the industry abuzz with everyone talking about these detailed documents?

The first step is to understand the unique character of each document, and then recognize how they together form a dynamic foundation for all aspects of a business relationship. The quality agreement is a comprehensive written agreement (usually augmented with a checklist) that defines and establishes the quality and cGMP obligations of each party involved in the contract manufacturing of dietary supplements. In general, the quality agreement should clarify which responsibilities are assigned to each party per the applicable requirements under 21 CFR Part 111 and per other current industry standards. It will serve as the basis for dispute resolution, audits and accessibility to product information.

For other aspects of the business relationship, a supply agreement is the preferred document. In this case, items such as general business terms and conditions, confidentiality, pricing or cost issues, delivery terms, or limits on liability or liquidated damages are addressed. The supply agreement helps the supply chain and upper management of both companies in working together, as it removes ambiguity on a whole assortment of issues that might arise over time. For instance, if things don't go as planned with a certain project or order, the supply agreement will hopefully provide a means or a framework for handling that issue. The partnership can continue working well because the next steps are clearly defined and agreed to in advance by both parties. If constructed properly, it can avoid any conflict between terms and conditions of purchase and sale, and alleviate the stress of how to handle an unplanned conflict.

While quality agreements are not required, FDA has offered a guidance document for creating a quality agreement on its website. A careful reading of warning letters published by FDA shows that quality agreements are becoming a foundational requirement across the industry. While this example is aimed at the pharmaceutical industry, this excerpt from an FDA warning letter issued in 2011 stated "… specifically, your firm has not established a quality agreement with the contract manufacturer … the responsibilities between XXX company and the contractor have not been clearly defined. Additionally, a similar observation was made regarding your failure to establish a quality agreement with your contract manufacturer of the drug, …" Again, while not yet required for the natural product industry, historically, FDA produces these documents as an official "look inside" the thinking of the agency. Prudent dietary supplement businesses should work to design programs in light of these suggestions—because the key letter in cGMP is the "c" for "current" thinking.

While there are a variety of templates available on the web that may be used as the basis of a quality agreement, FDA's guidance document will help with the fine-tuning of the chosen document and can help clear up ambiguity among related regulatory positions.

While not yet specifically required by FDA, it's apparent that current industry practices have an expectation of both a quality agreement and a supply agreement to be present in a manufacturing relationship. This forward-looking practice simply puts in writing the expectations the parties may already have, and also more clearly defines responsibilities, which currently may be misplaced or misunderstood. To both an auditor and FDA, the presence of these documents demonstrates proactive thinking and conscious efforts by a company to address responsibilities rather than simply ignoring them, thus giving the FDA that "feel-good" impression critical for a successful audit. Although industry has thrived without these documents for years, it is clear that for future growth and sustainability, quality and supply agreements will be necessary documents for successful business relationships. ■

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