

The Importance of Quality Control Agreements in the Dietary Supplement Industry

by Abhishek Gurnani

Dietary supplement distributors regularly contract out all or most of their product manufacturing operations. In many instances, distributors do not even physically touch the product before it is sent to the consumer. Often such relationships are memorialized via simple purchase orders or standard supply agreements with minimal boilerplate clauses on quality control (QC) responsibilities and GMP (good manufacturing practice) obligations. In some instances, dietary supplement distributors have not established procedures simply because they believe the contract manufacturer is responsible for compliance with GMPs. In other instances, a lack of communication between the distributor and contract manufacturer results in QC lapses.

A lack of adherence to dietary supplement GMPs may cause the dietary supplement products to be adulterated within the meaning of Section 402(g)(1) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed or held under conditions that do not meet the GMP requirements for dietary supplements. With an increase in enforcement of dietary supplement GMPs, it is crucial to fully define QC responsibilities between the parties. Development of a separate quality agreement that outlines and assigns GMP responsibilities to the relevant party will not only ensure compliance with dietary supplement GMP regulations, but it will also help a distributor ensure the product placed into commerce is not adulterated.

Regulatory Background

In its final rule concerning GMPs for dietary supplements released on June 25, 2007, FDA made it clear that dietary supplement distributors are subject to GMPs despite having contracted out all or some of their manufacturing activities:

“In cases where a distributor contracts with a manufacturer to manufacture a dietary supplement that **the distributor then distributes under its own label, the distributor has an obligation to know what and how manufacturing activities are performed** so that the distributor can make decisions related to whether the packaged and labeled product conforms to its established specifications and whether to approve and release the product for distribution.”¹ [emphasis added]

Also, in a number of recent warning letters, FDA has further voiced its opinion on GMP responsibilities between distributors and contract manufacturers:

- “As an own-label distributor that contracts with other manufacturers to manufacture dietary supplements that your firm releases for distribution under your firm’s name, FDA considers you to be a manufacturer of such dietary supplements. **You have ultimate responsibility for the dietary supplements that you introduce or deliver for introduction into interstate commerce.**”² [Emphasis added]
- Your firm introduces or delivers, or causes the introduction or delivery, of dietary supplement products into interstate commerce in their final form for distribution to consumers.

As such, your firm has an overarching and ultimate responsibility to ensure that all phases of the production of that product are in compliance with dietary supplement cGMP requirements.³ [Emphasis added]

It is clear the ultimate responsibility of ensuring a quality product is released into the market rests with the label owner, even in instances where third parties are involved in product development. However, what is often unclear is how a label owner might go about defining and establishing QC obligations for manufacturing partners to follow.

Quality Agreements

FDA defines quality agreements as a “comprehensive written agreement that defines and establishes the responsibilities of Quality Units of each of the parties involved in the contract manufacturing...”⁴ The quality agreement should clarify which GMP activities are to be carried out by each party per the applicable regulations under title 21 of the code of federal regulations.

In May 2013, FDA issued a draft guidance on quality agreements pertaining to the contract manufacturing of drugs.⁵ This guidance document provides valuable insight into FDA’s position on QC responsibilities between multiple parties, and it stresses the importance of assigning responsibilities between the label owner and contracted facilities. Although the guidance is for drugs, the supplement industry can benefit from a review of this guidance and extrapolate certain practices to their own businesses.

Tips for a 'Quality' Quality Agreement

While there are no specific requirements for quality agreements with respect to dietary supplements, the following tips can help ensure compliance with dietary supplement GMP regulations when using contracted facilities:

- Quality agreements should be separate, or at least severable, from other commercial contracts such as supply agreements, custom manufacturing agreements, etc.;
- Drafting and reviewing quality agreement language should include not only legal counsel, but also qualified personnel from quality assurance (QA) and QC departments;
- Quality agreements should clearly document responsibilities for each of the required GMP activities. An easy method is to use matrices or charts to identify which party is responsible for a given GMP requirement (e.g., responsibility for facility and equipment maintenance at contract facility, responsibility for documenting steps in the manufacturing process, responsibility for test method validation in a scenario where a contract laboratory is performing

product testing, responsibility for setting raw material specifications, etc.);

- Quality agreements should include procedures for documentation and notification of any changes. This includes changes to raw material suppliers, manufacturing processes, testing procedures or any other element that could affect the quality of the product manufactured by the contracted facility;
- Quality agreements should provide audit authority to the label owner and identify procedures for obtaining GMP-related documentation from the contracted facility as well as contact information of key personnel involved in fulfilling the QC obligations established under the agreement; and
- Quality agreements should clearly identify the purpose, scope and terms of the agreement as well as procedures for dispute resolution.

Quality agreements are not expressly required under FDA dietary supplement regulations, nor does the presence of a quality agreement absolve the parties from GMP obligations. A quality agreement is merely another valuable tool which allows for the streamlining of QC processes, and also provides

additional assurance of quality and safety of the dietary supplement product entering the stream of commerce. While distributors may be able to contract out every single manufacturing function, they are still ultimately responsible for ensuring that an unadulterated product meets the marketplace. A well-drafted, comprehensive quality agreement can help distributors and contract manufacturers meet their GMP obligations and also withstand an increased wave of not only GMP-related enforcement by FDA, but also litigation between parties. ■



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For a list of references, email INSIDERreferences@vpico.com.