NATURAL PRODUCTS INSIDER

High Quality, Low Price

The brand owner manufacturing dilemma

by Michael Finamore

All brand owners are now aware of FDA's aggressive enforcement of cGMP (current good manufacturing practice) regulations concerning their business practices, which have added financial and legal challenges beyond anyone's anticipation. Additionally, these same brand owners are also recognizing they need to expect more from their contract manufacturer, which is also adjusting to these changing conditions.

This comes with a cost that is far beyond the historical manufacturing costs and expenses for the natural products industry, and is forcing own label distributors to re-evaluate their relationships with their contract manufacturers.

Every brand owner rightfully wants to claim "the highest quality supplement." In many cases before cGMP regulations, the diligence into the how, why and where of the manufacturing of a product by the own label distributor ended after the product formulation was set, and the liability and responsibility was passed entirely to the contract manufacturer. With cGMP regulations, an entire system needs to be in place to demonstrate full control and confidence in the product—starting with ingredient sourcing from reputable suppliers, manufacturing products in compliance with cGMPs, testing ingredients and finished products, and transparent quality systems. All of these steps have incremental costs that are not readily apparent, and each additional layer contributes to the overall cost of the product.

Many brand owners want to use branded ingredients. These are ingredients that a supplier has identified as unique, and through studies or research can claim a distinct benefit related to their product. As can be expected, most branded ingredients usually come with a premium price. The contract manufacturer has little leverage to help the own label distributor keep costs down when branded ingredients are specified. This shouldn't discourage the use of a branded ingredient, as many offer great value. Just keep in mind that it will impact the cost of the product, and balancing the perceived quality and science of the branded ingredient against the benefits of a generic ingredient are a challenge the brand owners must discuss with their manufacturing partners.

Manufacturing a supplement to 21 CFR Part 111 standards is a requirement per U.S. law. The cGMPs have resulting additional costs that most contract manufacturers didn't worry about 10 years ago. However, over the last two years, it has become clear that contract manufacturers that cut corners or don't fully comply with all aspects of the regulations are putting not only their business at risk, but the own label distributor's operation as well.

It is clear that brand owners must do their due diligence regarding any contract manufacturer they use or may be considering. This includes an extensive audit of the contract manufacturer by either a member of the brand owner's staff or a consultant hired for this task to ensure cGMP compliance throughout the supply chain. Additionally, own label distributors now have the charges associated with the contract manufacturer qualification process, which have direct and continuing out-of-pocket costs.

In most cases, the brand owners' formulas will directly impact testing costs. Every ingredient specified on the label has to be tested at least once, and maybe twice, before it can be used in a product, which may cost thousands of dollars before the contract manufacturer can even begin the project.

Additionally, there is some confusion with finished product testing, where some contract manufacturers are doing limited testing and believing they are compliant. The contract manufacturer audit must ascertain the scientific reasons developed to allow for reduced or limited testing. In addition, the testing plan should address all of the ingredients on the label, not just the largest volumes or easiest to test. The more testing that needs to be done and the greater depths the audit team must investigate, the greater the cost.

Quality systems are at the heart of producing a high-quality product, but this also comes with a cost both for the contract manufacturer and the brand owner. For instance, the brand owner is now specifically obligated to review and understand all of the quality documentation, e.g., batch records and certificates of analysis (CoAs), provided by the transparent contract manufacturer with each lot of finished product. These expenses and risks can be minimized by working with a transparent contract manufacturer that provides value in the relationship. Brand owners that are not willing to incur these costs will not be given a second chance by FDA under the current regulations.

The contract manufacturer or brand owner that tries to cut corners to save a few pennies will likely end up with a product that is not to the level of quality they expect. Partnering with an audited, transparent contract manufacturer providing a high-quality product at a fair price now is the own label distributor's best bet to avoid the cost of recalls, FDA warning letters and cease-and-desist orders. ■

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