Contract Manufacturer Redefined: A True Partnership

GEMINI PHARMACEUTICALS

Gemini Pharmaceuticals Shares Risks, Rewards and Requirements with its Brand Owner Allies

Contract Manufacturer Redefined: A True Partnership

Gemini Pharmaceuticals Shares Risks, Rewards and Requirements with its Brand Owner Allies | by Kate Kunkel

FDA continues to increase its enforcement of laws that require own-label supplement distributors to know the ins and outs of manufacturing processes, even if brand owners use contract manufacturers to create their products.

A certificate of analysis (CoA), a yearly one-day audit and third-party accreditations were once sufficient for brand owners to prove their GMP (good manufacturing practice) compliance with FDA regulations, but that is no longer the case. Brands cannot blame contract manufacturers for compliance missteps because FDA insists brand owners understand and track manufacturing processes.

Daniel Fabricant, ph.D., director of FDA's division of dietary supplement programs, said the agency has recently found many companies are not following even basic FDA GMP rules. At SupplySide MarketPlace in May 2013, Fabricant also said FDA's goal is to take GMP audits to the next level and dig deeper into the science behind these processes.

Bradford Williams, manager of the FDA GMP program for dietary supplements, said he expected a changing relationship between contract manufacturers and brand owners during a webinar on GMPs in January 2012.

"If you're an own-label distributor that's buying from another firm, you have to be able to reveal information to our investigators, and we expect the manufacturer to be willing to share their records, data and reports with the customer who's buying from them," he said during the webinar, which was hosted by the Council for Responsible Nutrition (CRN) and VIRGO. "If you won't do that, you are going to be unable to meet GMPs, and you're going to be caught in a catch-22 where it's impossible to legally market those products."

Williams added, "I believe firms are going to have to anticipate this when they negotiate their contracts."

Recent warning letters FDA sent to own-label distributors reflect these requirements, and the agency's emphasis on

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

- **Own label distributors**: These firms are a mixed business model.
  - They may purchase supplements outright, in bulk, packaging and labeling them under their own name and subsequently distribute them under their own name.
  - They may constitute only an office, contracting every other operation out, with the result being dietary supplements marketed under their names.
  - Since the public face of these products is the name they bear,our position has been that the own label distributor is responsible for Establishing specifications, ensuring compliance with CGMP by all engaged in producing, labeling, packing, and distributing their product, such that during an inspection, they can produce, in a relatively short time, all records to ensure that they are not causing the introduction or delivery for introduction into interstate commerce of adulterated dietary supplements.
  - An added complication is that their number/address will be the one consumers call with product complaints, and if they don't have access to the records and experts who produced the dietary supplements, the complaint management functions evaluating the process and production controls will not be able to function.
  - These need will clearly change many of the normal business relationships and attitudes, since unwillingness to share records, data and reports will probably cause responsible firms to look elsewhere for cooperative firms, as they will otherwise be unable to meet CGMP requirements for their products!

FDA's Bradford Williams explained the importance of a transparent relationship between an own-label distributor and its contract manufacturer in the webinar, "Dietary Supplement GMPs: What Can Industry Do Better?" hosted by the Council for Responsible Nutrition (CRN) and VIRGO in January 2012.

GMPs. "As an own-label dietary supplement distributor that contracts with a manufacturer to manufacture a dietary supplement that you distribute under your own label, you have an obligation to know what and how manufacturing activities are performed so that your firm can make decisions related to whether your packaged and labeled dietary supplement products conform to established specifications and whether to approve and release the products for distribution," FDA wrote in a warning letter to own-label distributor Caribe Natural LLC. FDA further noted Caribe's quality control (QC) personnel must ensure that its contract manufacturer follows procedures for the manufacturing, packaging, labeling and holding of supplements.

Another warning letter issued to Pristine Bay alerted the company that its firm has "an overarching and ultimate responsibility" to ensure all phases of the production comply with dietary supplement GMP requirements. Likewise, Entrenet Nutritionals received a similar FDA warning letter for failure to follow procedures related to product complaints, failure to keep written procedures for distributing operations and other violations.

the product is being produced so they can guarantee to their customers that they are getting a quality product."

With the increased enforcement of GMPs, FDA inspectors are better trained on what to look for during GMP audits than in years past, Finamore added. While laws used to be somewhat ambiguous and open for interpretation, he said there is no longer "a place to hide" for brand owners or contract manufacturers.

Gemini solely manufactured over-the-counter (OTC) drugs when it started in 1982, but as its team gained more experience and respect within the industry, the company also began producing nutritional supplements and vitamins about 15 years ago. When it started the vitamin and supplement side of its business, Gemini used the same basic manufacturing methods designed for drug manufacturing. Finamore explained that using singular quality systems within the company is more practical and gives Gemini a "leg up" in regard to quality practices. The company established a leadership position in following GMPs before they were mandated for supplement manufacturing.

While laws used to be somewhat ambiguous and open for interpretation, there is no longer "a place to hide" for brand owners or contract manufacturers.

FDA called out all of these companies for failure to follow GMPs, stressing the importance of fully understanding manufacturing processes and the rules that go along with them. This increased focus on FDA regulations is calling for a "true partnership" trend between manufacturers and brand owners, meaning both parties understand and cooperate to offer a profitable, sustainable business model.

Michael Finamore, director of sales and marketing for Gemini Pharmaceuticals, said by reviewing new FDA regulations, reading recent warning letters and discussing the issues with others within the industry, he has noticed FDA is becoming more stern and cracking down on own-label distributors.

"We see that FDA has increased its focus on the label owners' responsibilities," Finamore said. "[The company] needs to know what is going on with the product and how

Because the dietary supplement industry is built on customers' faith in the products they purchase, Finamore said it's up to companies to keep that faith and produce high-quality products while complying with GMPs.

"By empowering brand owners and making them responsible, it's forcing them to pay closer attention to the what and the why in the manufacturing and even the raw material sourcing processes," he said. "That allows them to market the product with greater confidence."

When Gemini enters contract manufacturing partnerships with its customers, it shares the risks, expenses and rewards. Before choosing its partners, the company considers the types of products and management styles of different brand owners, then makes sure both sides of the partnership are on the same page in regard to business practices and values.

> If a brand is truly interested in sustainability and expansion, having a contract manufacturer work as a true part of the team sets a strong foundation for future growth. <

While Gemini has always carefully chosen its contract manufacturing partners, it has started a new initiative to bring its customers deeper into its business practices. Gemini is willing to share its internal practices to customers, which could compromise competitive advantages, but Finamore said it demonstrates a true partnership between the brand owner and contract manufacturer. By knowing how Gemini operates, brand owners can better explain their confidence in Gemini's quality systems, should the agency request this information during an audit.

If both sides are aware of their responsibilities, and also understand the quality, manufacturing and supply agreements necessary to frame the relationship, the partnership has a much greater chance at success, according to Finamore. Once the agreements are in place, the companies can build personal relationships to develop a stronger foundation to support the partnership.

Another step Gemini recently started to take to develop "true partnerships" includes sharing its batch paperwork to increase customer confidence and allow for a greater understanding of manufacturing processes. While most companies are resistant to share this paperwork, Gemini believes it benefits the partnering business by demonstrating its compliance and making it a stronger company.

The paperwork Gemini shares with its clients includes information on batch and production records (BPRs), quality assurance (QA) records, adverse event reports (AERs) and ingredient supply chain information. Sharing this information allows its customers to prepare themselves for an FDA audit, but other contract manufacturers resist transparency due to fears of exposing trade secrets or potential non-conformance and non-compliance.

Gemini is willing to provide this confidential information with its clients because they are true partners in a contractual and business sense. While the information reveals confidential company processes, personnel information and trade secrets that could potentially impact Gemini's competitive advantages, the company shares it to show it values the relationships with customers.

Depending on the products and relationship, this paperwork is available in different formats to keep partners prepared for an inquiry. Many brand owners do not understand the paperwork or processes involved in their contract manufacturer's procedures. That lack of knowledge or inability to effectively answer these questions from FDA could cause irreparable harm to the brand, yet knowledge of these systems demonstrates confidence to any auditor. To ensure Gemini's customers are prepared for these inevitable questions, the company is willing to have a member of the customer's staff trained on Gemini's procedures. This way, partners are guaranteed a fair understanding of operational processes without confusion.

While Gemini is cost competitive, Finamore said its best partners are those who recognize the inherent value to a partnership that provides a competitive acquisition cost to the brand and allows both parties to grow profitably. "A true partnership allows both sides to grow," he said. "[Customers] understand there are expenses that go into this, and the appreciation of this on both sides is really what makes a partnership work." Finamore added that brand owners are beginning to recognize the cost of compliance with FDA policies is rising exponentially, and those who understand the value in a partnership extends beyond the purchase price of the item will be the ones to survive and grow in this challenging environment.

Gemini also builds strong foundations for its partnerships by explaining the technicalities of its manufacturing processes through an intensive onsite facility audit. During this tour, Gemini's customers learn the steps taken for manufacturing procedures, meet personnel that oversee production and gain insight on ways to increase QC within its own methods.

Finamore said customers often give Gemini high marks on its systems after taking a facility tour. "We believe that once people visit Gemini, meet the different people who work on our staff and see our systems work in process, they have a greater appreciation of what we offer to the marketplace," Finamore added. "They have a greater comfort in what we can deliver to their business at a competitive price."

and brand owners, businesses within the dietary supplement industry should also begin taking steps to build better partnerships as soon as possible.

Transparent partnerships will likely be an FDA requirement in the near future, and they also make an effective business strategy. Brand owners who have this kind of relationship with their contract manufacturer will maximize their profits of their brand's life cycle, and those without it will struggle to survive when FDA inspectors discover GMP violations.

Because the partners look out for each other, Finamore said this strategy works best to build a strong company and brand. If a brand is truly interested in sustainability and expansion, having a contract manufacturer work as a true part of the team sets a strong foundation for future growth. This working relationship also allows the brand to focus on product development and marketing rather than worrying about GMP responsibilities.

"Essentially, we're giving our customers the recipe to our kitchen," Finamore said. "We feel that we're a five-star restaurant, and we're showing you how to make our favorite foods. By giving someone a batch record or batch paperwork, that's really giving them the step-by-step instruction of the nuances of the products, and it details what makes a product more competitive than someone else's."

"Essentially, we're giving our customers the recipe to our kitchen. We feel that we're a five-star restaurant, and we're showing you how to make our favorite foods."

—Michael Finamore, director of sales and marketing, Gemini Pharmaceuticals

GMP audits are designed to show FDA that a supplement company's manufacturing processes work. To do this, companies should establish a procedure well before an FDA audit. This way, the agency will see the process is designed for best practices, not just as a response to a problem.

With the growing trend toward greater responsibility and deeper understanding between contract manufacturers

Gemini Pharmaceuticals has taken the lead on building partnerships between contract manufacturers and its brand owner clients, fostering the kind of relationship where manufacturing practices can be shared with confidence. This forward-looking concept of a solid partnership bodes well for the brands who work with Gemini as well as for the stability and future growth of the entire dietary supplement industry.