CPA members find healthy business in OTC drugs & nutraceuticals

IN THIS SECTION

- CPA News
- CPA Connection E-Newsletter
- State of the Contract Packaging Industry Report
- Contract Packaging Magazine
- Legal

CPA Connection Newsletter, June 2014
By Bob Sperber, Editor, *Contract Packaging Magazine*

CPA members find healthy business in OTC drugs & nutraceuticals

Pharmaceutical outsourcing is experiencing a 9.1% global growth rate to reach $374.8 billion by 2018, according to BCC Research in a recent report. Contract manufacturing of over-the-counter (OTC) drugs, including dietary supplements, nutraceuticals and related products, leads the sector, followed by contract manufacturing of bulk and dosage-packed drugs, contract research and finally, contract packaging.

Even without providing full, turnkey pharma-outsourcing services and dealing with the rigors of prescription drugs, co-packers are finding healthy market opportunities in the OTC world. Some of the latest evidence of this growth comes from CPA members:

FasPac, based in Dallas, specializes in form/fill/seal (f/f/s) packaging of single-serve packets, sachets and pillow packs of liquids, lotions, powders, and pills. The company now operates 14 f/f/s machines and three more are coming online by summer's end.

Atlanta-based Coregistics, which co-packs and provides supply chain services across sectors, does primary and secondary OTC pharma co-packing in multiple formats and at multiple facilities. The company recently added sachet filling as a core competency, and plans to tap more of this market's growth.

Everest Packaging is in the process of moving from its current 15,000 square-foot facility into a new 100,000 square-foot ft facility in Ontario, CA.

"The nutraceutical industry is definitely growing by leaps and bounds," says Jimmy Tsai, Everest Packaging's vice president of sales.

FasPac is dedicated to form/fill/seal and specializes in OTC pharma co-packing

Recent research findings bear-out Tsai's optimism. A 2013 report from NMI found that over five years, the use of nutritional supplements among American adults grew steadily from 62% in 2009 to 73% in 2013. A study from Freedonia found that the global nutraceutical ingredients market alone will reach almost $24 billion in 2015, while another report from Global Industry Analysts predicts that the global market for "herbal supplements and remedies" will reach US$107 billion by 2017.

How do 'healthy relationships' differ?
Compared to less complex and less regulated sectors, Dennis Wogaman, senior director, operations for Nipro Consumer Healthcare's P.J. Noyes Co., Lancaster, NH, has noticed that some common traits in the OTC business: The sales cycle is "much longer, but once the relationship is established, it's a pretty strongly bonded relationship." He adds that this is especially true because it can be costly to switch co-packers. Specifically, it can be difficult to retool operations and maintain the stability of product/package formulations, the expertise in handling details (package designs, labeling requirements); and the continuity of compliance to cGMPS as well as the standards as required by large retailers.

Regulations are also distinct for products making health claims. While prescription drugs are still more stringent, OTC products are nonetheless regulated more heavily than most other packaged goods.

In following FDA regulations, for instance, FasPac's QA/QC personnel must perform specific cleaning validations, testing record-keeping procedures for each active ingredient in a regulated product, and even a seemingly innocuous product like sunscreen can have up to six "actives," says Matt Davis, sales manager for FasPac. This can drive the validation cost up by $10,000 or more for a product run. But at the same time, "if somebody's ordering a half-million units, it's easier for our clients to absorb that cost."

And while OTC products may have special regulations, the standards and regulations aren't that different from food packaging, according to Coregistics' Kevin Hall, chief operating officer: "While the standards fall under different names, the requirements are very similar." This is especially in secondary packaging, where a well-disciplined facility that follows cGMPs "can make the transition from food to pharma without a major investment in resources or time," Hall adds. Primary packaging can be more difficult, he adds, especially if particulate control in the form of cleanroom packaging operations are required. The cost of entry in this case may be too high for some co-packers.

Assemblies Unlimited has had success with gummy bear supplements and vitamins

Added cost can be added value
Despite the added cost of compliance, "Made in the USA" is a major selling point, according to Davis, "because everyone knows the regulations are more strict in the U.S., and trusts the products." And, adds Everest's Tsai, "because the US symbolizes quality, safety and an overall track record of putting a lot of thought into the well-being of the people who use the products."

Likewise, the added cost of packaging can be a plus in the marketplace, where packaging innovation is often as important as the product itself. Everest's Tsai notes "alternate delivery methods," such as single-serve stick packs that cost more per ounce of product, but are worth more to consumers than a bulk container format. "We're selling convenience," agrees FasPac's Davis, who says this trend holds both in the U.S. and in Asian markets where space is limited—even when a carton of 14 or 15 single serve packets cost the same as a 30-day bulk supply of a particular supplement.

A co-packer good at complying with standards may have an additional competitive advantage. "If someone wants a particular SPF sunscreen lotion we have to find a co-packer that has the certifications to run it," says Randy Shaw, president of Assemblies Unlimited, Bloomingdale, IL. He notes that a co-packer recently won a sunblock contract for having not just FDA OTC compliance but additional compliance to handle insect repellant as an active ingredient.

Shaw's company acts as a project manager for brands seeking outsourcing services, and serves its brand-marketing customers by finding the right contract packaging and fulfillment partners. He explains that certifications and compliance issues are at once a barrier to entry, and a tool co-packers can acquire to attract more business.

"No two co-packers are alike," Shaw adds. Some focus on secondary packaging and displays, and some seek to do full, turnkey packaging and even more.

For more information on the FDA regulations for supplements, see the FDA's page on 21 CFR Part 111 regulations for "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements" here, as well as an FDA Guidance document on the topic here.

1833 Centre Point Circle | Suite 123 | Naperville, IL 60563 USA | Tel: 1-630-544-5053 | Fax: 1-630-544-5055 | Email: info@contractpackaging.org