

Contract Packaging

Contract Packaging for the Healthcare Market:

Big Challenges, Big Rewards

Companies that perform contract packaging for the pharmaceutical and medical device industries make up a relatively small, highly skilled group. Members of this somewhat exclusive club shoulder unique regulatory burdens, intense scrutiny, and high capital costs, but the rewards—often paid out in long-term client loyalty—can be great.

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The current hot topics of conversation among contract packagers of drugs and devices include consolidation, serialization, high quality demands, and a more-fragmented pharmaceutical market. Industry is not shying away from these issues, however, and appears to be openly discussing them and acting accordingly.

CONSOLIDATION

Joe Luke, vice president of sales and marketing at New Jersey-based contract packaging company Reed-Lane and a Healthcare Compliance Packaging Council board member, says he has seen quite a bit of consolidation in contract packaging recently and some companies exiting the business altogether. So too has Justin Schroeder, executive director of marketing, business development & design, Packaging Coordinators Inc. (PCI) of Rockford, IL.

“Some significant players” in contract packaging “have either gone out of business or taken a different direction” in recent years, Schroeder



Contract packager Reed-Lane works with a range of packaging formats.

says. (PCI itself is the combination of the commercial packaging services of Catalent, acquired in May 2012 by Frazier Healthcare, and AndersonBrecon, subsequently acquired by Frazier from AmerisourceBergen in May 2013.)

Schroeder points to the capital intensity of healthcare packaging as a cause of consolidation. “Year over year we are spending tens of millions of dollars in capital to acquire new equipment, to have best-in-class facilities, and to build the IT infrastructure

it takes to support this business,” he says. “It’s very capital intense. Not everybody has the wherewithal to be able to do that.”

One counterpoint to this consolidation trend, it’s worth noting, is the “channel partnering” described by Kay Halbrook, market development manager for Wisconsin-based Outlook Group Corp., a contract packager with some healthcare-product clients.

Halbrook explains the cooperation among her company and other contract packagers, wherein Outlook



Packaging Coordinators Inc. has a dedicated staff to support pharmaceutical serialization initiatives.

Group might manage one part of the process for an end brand owner and look to one of its peers to manage another. “You find a partner who doesn’t do what you do, and you don’t do what they do, and you work together and share customers.” Thus, she says, a loose, cooperative network of contractors is formed.

SERIALIZATION

Perhaps one of the leading trends in pharmaceutical packaging in particular is the push toward serialization, wherein each and every package produced contains a unique identifier so that it is possible to see where the product traveled through the supply chain, how it arrived at the pharmacy, and whether it is legitimate or counterfeit. Serialization is supported by the Drug Quality and Security Act, which was signed into law by President Obama in November 2013.

The pharmaceutical industry is at “the edge of implementation” of serialization, says Schroeder.

PCI’s Schroeder describes the pharmaceutical industry as being at “the edge of implementation” of serialization. Many pharmaceutical clients that Schroeder’s company serves, he says, “are pushing aggressively forward with their serialization plans, so that’s had us investing in serialization infrastructure to be able to support that.”

PCI has a dedicated staff just for the serialization initiative alone, and Schroeder describes the investment required to bring serialization to commercialization as “multi-million dollar, as you’d expect.”



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John Mazelin, executive director of the Contract Packaging Association and vice president, business development for the B4B Alliance, names serialization as a major concern right now as well, and he adds that confusion over satisfactory compliance criteria for serialization remains, which, until FDA provides further guidance and information, challenges pharmaceutical firms and contract packagers alike.

GREAT (QUALITY) EXPECTATIONS

Contract packagers serving medical device and pharmaceutical clients point to an increased focus on quality as another trend within industry. The Contract Packaging Association's Mazelin points to a growing "culture of zero defects" and a strong desire for quality improvement.

"FDA sets that expectation for the product," Mazelin explains, "then the [pharmaceutical and medical device] companies adopt that expectation because FDA is promulgating it, and those companies, in turn, push their suppliers for zero defects, which is a good target."

Eileen Williams, business development manager at compounding, filling, and packaging company Unicep (headquartered in Idaho), agrees with Mazelin that a strong focus on quality is a trend for contract packagers today. She says she has found that Unicep's commitment to a strong quality system is highly valued by its clients. That system includes an FDA-registered facility, ISO certification, cGMP training for all employees, and a willingness to be audited by clients.

"Maintaining our quality systems to the highest level, remaining ahead of the curve, and continuing to evolve," Williams says, are crucial. "And we work very hard never to be caught unprepared when it comes to regulatory changes."

That increased regulatory scrutiny is cited over and over again by

contract packagers in the healthcare space, including Outlook Group's Halbrook. She mentions how the level of documentation contractors are expected to perform has increased "dramatically" as the ability to "electronically document every turn and twist of a project" has increased.

Companies must have a "tight system" in place to do it, Halbrook says, "and there has to be some pretty strict rigor out on the manufacturing

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floor and the automation to keep that going. There's an extensive system that must be put in place," Halbrook adds, "so the barrier to entry around that is pretty high."

A benefit of that high barrier, however, is that once a contract packager overcomes it, trust is established between the contractor and its client, which tends to result in long-term loyalty.

FRAGMENTED PHARMA

PCI's Schroeder explains how the so-called patent cliff, reached when a drug "goes off patent" and its generic forms enter the market, has "changed the face of" pharmaceutical packaging.

"It has created a much more fragmented stable of products that we support," Schroeder says, and has led to some decline in the stability of the branded market.

"But," he adds, "that creates new opportunities for packagers with the generic products as well."

Schroeder also points to the chal-

lenge pharmaceutical companies currently face to simply get products through their pipelines, and the relatively small number of drug candidates in general.

"We see fewer and fewer blockbuster drugs" being brought to market, Schroeder observes. "We see a lot more niche indications and orphan drugs, which can result in shorter runs and more expensive products. That can be a much more expensive drug that we're packaging," he says. "We have to accommodate that with equipment that can better handle shorter runs and quicker changeovers and less costly investment for tooling. We also need systems in place that respect the value of the products and keep scrap to an absolute minimum."

NO PAIN, NO GAIN

Consolidating (or, in some cases, cooperatively teaming up with competitors), figuring out and implementing serialization, striving for even higher quality, and navigating the fragmented pharmaceutical market are top concerns for contract packagers of healthcare products—but there are others as well.

Pricing pressure "has always been a factor," Reed-Lane's Luke says, "but more so over the past few years."

Luke also lists "plant rationalization," in which a customer asks for quotes "to assess whether they should outsource or keep work in house," and "an uptick in the number of virtual companies" as trends he's noted.

Contract packagers are also venturing into the relatively new market of nutraceuticals in increasing numbers, Mazelin points out, as well as into the fast-growing biotechnology market, Schroeder adds.

Each of these endeavors confers some risk and, in many cases, hefty investment for contract packagers; however, those who stay the course are likely to reap benefits. ■