Contract Packaging

What's going on at the packaging line?

By **Gil Y. Roth**
CONTRACT PHARMA

IT WOULD BE A DISASTROUSLY bad pun to write, "Contract packaging is growing at a blistering pace," but the sentiment holds true. Contract Packaging Organizations (CPOs) seem to be growing at a rapid pace, with some companies posting 20% annual gains in this $1 billion+ industry.

Outsourcing has grown in this field for a number of reasons. Rafi Maslaton, a partner at Tefen Ltd., cites several: "Contract packaging allows for advanced, flexible scheduling for sponsors, where they don't have to bear the high cost of overhead for a facility, as well as the capital expense of building out a facility. Also, the high quality of packagers is important. With so many consent decrees and failed FDA inspections around, Big Pharma companies are happy to outsource to a provider they know will provide quality."

Joe Urban, Pharm.D., senior director at ProClinical Pharmaceutical Services, contended that contract packaging is on the rise for the same reasons pharmaceutical outsourcing in general has increased. "The industry overall is focusing on its core competencies; they simply can't do it all for every single project. The prospects for CPOs look good for the next five to 10 years."

According to some industry figures, this has led sponsors to develop a strategic outsourcing vision, rather than a case-by-case, tactical one. "There's no doubt that the major pharma companies are adopting a strategic plan for outsourcing," said Renard Jackson, executive vice president for contract services at Cardinal Packaging Services. "That said, there's still overcapacity in some areas."

Among the CPOs that we interviewed for this article, most felt that another wave of mergers, even ones as sizeable as the Pfizer/Pharmacia deal, will ultimately benefit the contract packaging industry. Lorann Morse, BlisTech's director of global technical sales, commented, "On the clinical packaging side of the business, we've found that mega-merger downsizing tends to be internal. That is, the new companies are finding it tough to justify carrying overhead internally, so it makes more sense for them to outsource. When I used to work at a sponsor-side company, we evaluated this a lot."

"With any major acquisition, there's going to be a rationalization of existing facilities," said Mr. Jackson. "There's a measure of uncertainty when this happens: will the new firm avoid strategic outsourcing in favor of a tactical approach? We think that's not likely to happen."

Mr. Maslaton sees a more complicated picture for the future health of the CPO industry, but remains optimistic. "Look at the Pfizer/Pharmacia deal," he said. "Now there's plenty of internal packaging capacity available, especially if the merged company spins off some overlapping products. So this might negatively affect contract packaging.

"However, there are also plenty of generics hitting the market," he noted. "Look at the generic version of Prozac over at Barr Labs. They set a speed record for changeover from brand

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to generic, which meant they needed to package even more of the product than they anticipated. I think the number of today's blockbusters converting to generic status will help fuel the increase in contract packaging."

One company that sees a growth opportunity in contract packaging is DPT, which recently acquired a packaging facility in Lakewood, NJ from West Pharmaceutical Services. The facility has allowed DPT to expand into solid dosage packaging, including thermoform and cold form blister packaging. Paul Johnson, senior vice president and general manager at DPT, explained the company's approach: "We have a five-year strategic plan at the company, which we revise every two years. During the last revision, we foresaw that we needed more packaging capacity. We knew it wasn't a matter of 'if,' but 'when.' And, since it's very expensive to build a site from the ground up, we chose to make this acquisition."

The site fulfilled several of DPT's needs, said Mr. Johnson. "We wanted a northeast U.S. location [DPT is based in San Antonio, TX], additional capacity, and an expansion of offerings that would still fall within our core competencies."

The addition of the facility to DPT's offerings has enabled the company to expand its packaging offerings to include solid, semisolid and liquid dosage forms. Mr. Johnson said the company, for the time being, is done with strategic expansions like the Lakewood acquisition. "For now, we're engaged in tactically expanding," he remarked. "In particular, we need to identify and clear up any bottlenecks in the supply chain."

Expanding Bottlenecks

Bottlenecks and reduced efficiencies can be a drag on CPOs and sponsors alike. Mr. Maslaton's consulting group spends a good deal of time trying to identify and correct such things. "Let's say you purchase a new packaging line that can run 250 bottles per minute," Mr. Maslaton conjectured. "When you qualify the line, you find that you can only run 150 BPM. But you just spent $1 million on the equipment. In fact, it might run at only 100 BPM, due to inefficiencies. Why do we lose all that?"

A lack of Key Performance Indicators (KPI) can account for it, according to Mr. Maslaton. "Packaging lines suffer because of poor execution, poor configurations and poor planning/scheduling. None of these are measured properly. So let's qualify all possible improvements and find all specific actions. By instituting real KPI, packagers can achieve overall equipment effectiveness," he warned.

Photo courtesy of DPT

Adding Value

If BPM was the sole measure of a contract packager, the business would devolve into a commodity, with low cost trumping other considerations. However, the intensive regulatory backdrop in the pharma industry means that CPOs must offer more than just fast packaging lines. The FDA has raised the bar on both CPOs and sponsors, with cGMP requirements enforced by more frequent site inspections. "We're definitely headed to a zero-defect environment," said Shawn Reilley, Anderson Packaging's vice president of sales and marketing.

"Contract packaging would be a commodity only if everyone had the same equipment, the same capacity and the same personnel," said DPT's Mr. Johnson. "The best CPOs offer a point of differentiation and specialty services. Sure, CPOs are involved in the later stages of the drug development process. The work isn't as R&D intensive, and they have much shorter lead times than other parts of the process." But that doesn't reduce CPOs to providers of a commodity, he assured. "Packaging assignments aren't just given to the lowest bidder. For some sponsors, cost may start out as the top driver, but the first time a product misses shipment, service becomes their #1 priority in a CPO."

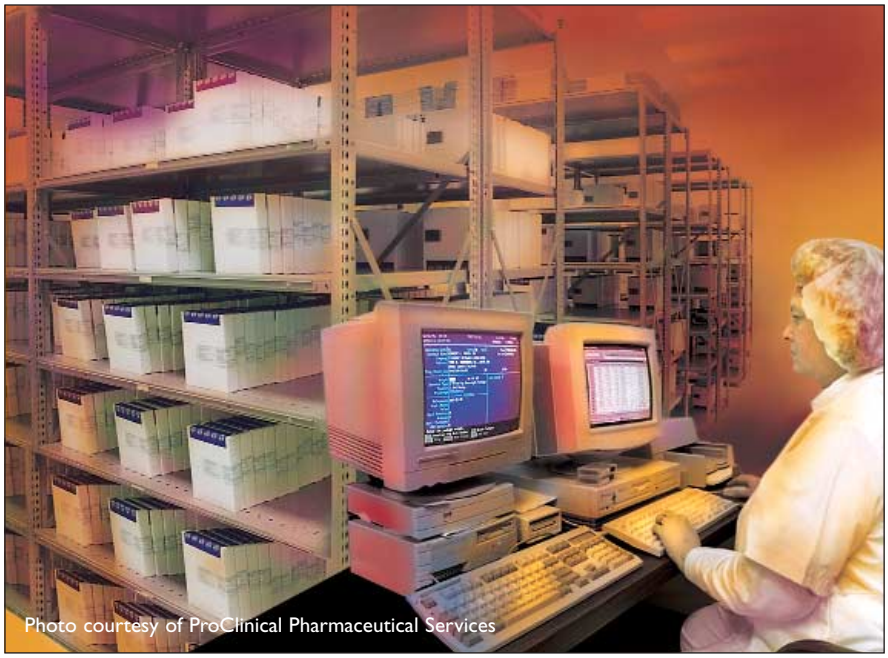

Photo courtesy of ProClinical Pharmaceutical Services

Mr. Johnson contended that DPT's well established early-phase capabilities, coupled with its skills in tech transfer and validation, can keep sponsors with them for more than a single stage of development and commercialization. Sponsors may come for analytical development and scale up, and stay for the commercial packaging. In addition, he said, companies that only know DPT through its new packaging facility, have inquired about bringing earlier-phase work to the company's main location.

Similarly, Cardinal Heath, with its Cardinal Packaging Services division, can offer a fully integrated, global system for packaging and other services. "Sponsors stay with us through multiple stages of development, into clinical packaging and beyond," said Mr. Jackson.

Despite the advances in the offerings and reputations of CPOs, some contend that it still receives short shrift. "Contract packaging is perceived as a nonscientific discipline," said one industry source. "Some firms have deprioritized packaging and, in some places, the expertise to do it right is lacking. It can be tough to find educated, intelligent, flexible and efficient project managers because, if they're very good at their job, they tend to move up to bigger roles in the industry."

In fact, for DPT, the expertise of the personnel was part of the reason for its acquisition of the West facility in Lakewood. "We picked up a skilled management team when we bought the site," said Phil Brancazio, DPT's vice president of operations. "Not having to train a new staff enabled us to 'hit the ground running' with the new facility."

The personnel at other CPOs may also be aided by a new wave of Big Pharma mergers. With the consolidation of internal efforts in newly merged companies, layoffs are bound to occur. This means that qualified, trained packaging staff may be looking for work, and can find it at a CPO.

New Regulations

Industry experts contend that the contract packaging industry is growing faster than the overall pharmaceutical industry at this point, and upcoming regulatory pressures may cause ever faster growth. Last December, the FDA announced a proposal to reduce medication errors in hospitals by mandating bar codes on all drugs and biologics. At present, manufacturers ship drugs to hospitals in bulk, where they are repackaged in the pharmacy and then sometimes packaged again for in-patient dispensing.

At a recent public meeting to discuss bar code labeling, FDA Deputy Commissioner Lester M. Crawford, Jr., D.V.M., Ph.D., pointed out that as many as 100,000 patients die in the U.S. each year because of preventable medical errors in hospitals, at a healthcare cost of (according to some studies) $177 billion annually. Dr. Crawford added, "The healthcare industry has projected that the use of bar coding across the medical supply chain could result in substantial annual savings."

Bar coding each unit dose in an acute care setting would mean that each unit dose must be blister packed, and such a large market would be a boon to the contract packaging industry. No wonder companies like DPT, Anderson Packaging, and Cardinal Packaging Services have enhanced their blister capacity in recent years.

In fact, Anderson recently acquired several new thermoforming lines to increase its blister packaging capacity by 25%, to more than one billion units per year. Mr. Reilley, commenting on

the increase, remarked, "We realize that a primary mission of a contract packager to our strategic customers is to provide excess capacity for product launches and peak periods. So it's important to note that 70% of this new incremental capacity has been purchased with no identified programs, providing flexibility for us and our customers."

Mr. Reilley also pointed out that the new bar coding regulations are about more than creating a bigger market for blister packaging. "Bar coding unit doses is absolutely the *right* thing to do," he said. "There's no denying that medical errors cost thousands of lives and billions of dollars each year."

However, pharma companies are worried about the increase in price, as well as the difficulty of putting enough information on the necessarily small bar codes. Presently, they are consulting with the FDA to help set the standards for bar coding, and are blanching at the possibility of having to provide a bar code that includes the National Drug Code (NDC), lot number and expiration date of each unit dose. If the bar coding is done according to Code 128 Subset C standards, which were proposed by PhRMA back in 1990, industry experts predict that blister packages will have to increase in size to fit all this information, which will raise material costs, as well as lower packaging capacity by as much as 60%. A number of other bar code standards are under consideration, as are the rather crowded labeling requirements for hospital unit-dose packaging.

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"Blister packaging is definitely a major industry trend," said Cardinal's Mr. Jackson. "We've set up the largest blister organization in the world to accommodate that. Much of the existing pharma company packaging capacity is geared toward bottling, so we're in a good position to handle this change."

Other Rules

New federal regulations may also be a boon to ProClinical. In May 2002, the Consumer Product Safety Commission (CPSC) mandated child-resistant (CR)/senior-friendly packaging for clinical trial materials. The company's patented 'Pick and Peel' blistercard system can satisfy those requirements, according to Dr. Urban.

ProClinical recently signed an agreement with Graphic Packaging Corp. (GPC) that will bring its child-resistant (CR)/senior-friendly blister packaging to commercial pharmaceutical products. "We feel blistercards, which have traditionally been used in all phases of clinical trials, have a tremendous opportunity in the commercial marketplace. With a blistercard, each dose is protected, product stability can be enhanced, and tamper-evidence is clear," said Dr. Urban.

Similarly, BlisTech has also created competitive advantages out of changing regulations. Last year, the company opened a new storage and distribution facility in Dartford, Kent, UK, near London. The site serves as BlisTech's main breakout point for the transportation of clinical supplies throughout the world. In addition, the Dartford site also hosts Qualified Person (QP) to help sponsors comply with EU regulations for material distribution. "The presence of a QP lets us help assist sponsors in the clinical process in the EU," said Ms. Morse.

The past year or two has taught us that the pharma industry has moved into a new world. The contract packaging industry seems uniquely prepared to handle the regulatory changes, the rise in clinical trials, and the pending boom in generics. ■