Packaging Equipment & Trends

Serialization and robotics integration gains momentum

Kristin Brooks
Contract Pharma

PACKAGING PHARMA AND biopharma products has become an increasingly complex business as the products themselves and the requirements surrounding them change and evolve. Depending on the product, the variety of equipment capabilities needed can be wide-ranging. Innovative packaging designs and new materials, serialization requirements, sensitive products, large- and small-scale projects, are impacting equipment designs and the packaging process. Incorporating views from both packaging equipment suppliers and contract packagers, trends in the space are dominated by increased automation, serialization needs, and the flexibility to accommodate the nuances today's pharma/biopharma products present.

We spoke with several industry experts in the packaging arena to discuss advances in equipment technology and capabilities, as well as packaging trends, serialization efforts, new materials and overcoming obstacles in the packaging process. "The requirements for packaging equipment are as varied as the products it processes, said Dr. Johannes Rauschnabel, chief pharma expert at Bosch Packaging Technology. "Manufacturers of generics, and also contract manufacturers, require very robust and flexible machinery with high outputs, while complex medicines for targeted treatment demand for flexible platforms and smaller batch sizes."

Photo courtesy of Optima

Capabilities & Trends

The latest packaging equipment increasingly incorporates robotics, an area that according to equipment manufacturers, is gaining momentum in the industry. Additionally, more equipment is likely to be equipped with advanced programs to enable communication with other equipment on the packaging line. According to Kim Norris, sales project coordinator at ESS Technologies, Inc., "We are seeing more and more requests to integrate robotics into packaging lines with or without track & trace capabilities. Robots can automate machine-loading processes, allowing the machine infeed to meet the production capabilities of the packaging machine. We have seen a marked increase in requests to integrate our robotic packaging systems' track & trace/serialization applications. ESS has developed a number of track & trace case packers that integrate OEM track & trace modules with ESS case packers to follow each product from collation to case packing to palletizing."

Fabio Trippodo, president of MG America, added, "The integration of robotics is changing the industry, allowing flexibilities, as well as feeding and connecting speeds that were not previously possible."

From a contract packaging perspective, the last five years has seen a sharp uptick in expanding equipment capabilities. Al DeMarco, operations manager at Reed-Lane, said, "During this timeframe at Reed-Lane, we increased capacity with integrated blister/cartoning threefold; increased integrated solid-dose bottle/cartoning nearly fourfold; expanded wallet and face seal carding lines by 50%; added a high-speed labeling line for ampoules and tubular vials; and modernized and consolidated pouching capabilities with a high-speed, large footprint, servo-driven pouching line for tablets and liquid-gels. We also added bright stock labelers and secondary cartoners to accommodate the tight timeframes involved in new product launches."

Additionally, thin film pouching, micro-tablet dosing into the desired

packaging format, such as pouches, bottles, and blisters, are among the latest equipment capabilities, as noted by Bob Macadangdang, client development and relationship manager at Sharp Packaging Solutions. He added that the company is looking to expand thin film pouching, and serialization/track & trace services.

So, what are the most popular types of equipment right now to accommodate these needs? According to Ms. Norris of ESS, monoblock filler/capper systems, automated case packers, and robotic pallet cells for packaging applications, are most sought after. The company has also seen an increase in robotic systems for material handling and assembly applications.

Also, with the high influx of injectable products on the market, packagers have had to keep pace with equipment capabilities, and the demanding challenges they present, such as temperature requirements. "While we've continued to invest to keep up with continued demand in blisters and bottles, the need for expanded capacity for parenterals and injectable products continues to grow," said Justin Schroeder, executive director of marketing, business development and design at Packaging Coordinators, Inc. (PCI). "We support the evolving market for alternative delivery forms such as transdermals, injectables such as vials and syringes, as well as devices and infusion delivery forms. We've expanded both our packaging capabilities in this area, as well as the infrastructure to support the needs of these products, including a substantial expansion of Cold Chain storage at 2-8°C. The logistical requirements for these high value Cold Chain products can sometimes be just as complicated as the packaging process itself."

In addition to serialization demands, cost can also play in role in evolving packaging trends. Rich Wrocklage, director of Packaging Development & Engineering at Reed-Lane, noted, "There are increasing trends towards packages that present the end user with a lower price point, such as larger count bottles for OTC products. In addition to perusing additional opportunities in bottle filling, blister packing, card sealing and pouching, Reed-Lane is moving into serialized packaging and compliance packaging for Rx products."

As a testament to equipment manufacturers keeping pace with the latest trends, Eric Allen, vice president of sales and marketing at Aphena Pharma Solutions, noted, "We are seeing more innovative package designs that are driving machine manufacturers to meet these sometimes challenging packaging design requirements."

Packaging & Serialization

Serialization is the foremost area contract packagers are looking to expand capabilities, not surprising with the passage of the Drug Quality and Security Act (DQSA) on November 27, 2013. The DQSA establishes requirements to facilitate the track-

ing of prescription drug products through the pharmaceutical supply chain, the criteria of which will be implemented through a timeline beginning January 2015 and running through 2026.

"The implementation of track & trace serialization technologies is becoming more prominent," said Ms. Norris of ESS. "As the federal government moves closer to mandating track & trace, ESS is seeing a noticeable increase in packaging machinery that integrates with OEM track & trace modules, and we expect this trend to continue as portions of the law come into effect over the course of the next decade."

Serialization and anti-counterfeiting technology are important aspects of packaging equipment, which must comply with various regulations. Dr. Rauschnabel told us, "Different serialization guidelines and legislations, such as the FDA's DQSA or the European Union's Falsified Medicines Directive 2011/62/EU, require the implementation of coded packages with numerical identifiers for nearly all prescription drugs. This calls for a modular machinery concept that is compatible with existing line concepts and equipped with the matching software, such as the CPS (Carton Printing & Verifying System) from Bosch Packaging Technology. The modular and scalable concept allows for the development of a complete system including a central control unit based on functional features such as checkweigher, labeler and tamper-evident module."

DQSA impacts both equipment manufactures and packagers. The companies we spoke with provided their thoughts on DQSA and how it will impact technology, packaging products, and services. Matthias Poslovski, technical sales director at OPTIMA pharma GmbH, contended, "This is a very important aspect and the impact on our products and services are extensive in that, 100% IPC, camera prior to filling, stopper height control via camera, crimp quality control via camera, print of single vials, print with track & trace, particle monitoring, are now all relevant features for cGMP equipment."

The ESS Technologies CEL 5 and CEL 5-E Robotic Case Erector / Loader System integrates with OEM track & trace modules and serialization equipment.

Mr. Schroeder noted, "Serialization within the industry has a significant bearing on the packaging process. We are undertaking a substantial investment in expanding our serialization capability across all delivery forms in meeting market demands in 2014. We're working closely with clients and suppliers, as well as industry groups like GS1, in meeting the evolving domestic and international regulations. It's a major undertaking that's happening across our U.S. and EU based sites to support the 100+ countries we package products for."

Complying with this regulation will result in additional cost to the consumer, according to Greg Lane, vice president of Quality and Regulatory Affairs, Aphena Pharma Solutions. He remarked, "Brand drugs may be able to absorb the additional costs better than generics, but counterfeit drugs in the supply chain is definitely a growing problem. Something needed to be done and this is one solution. "With the rollout of DQSA and other regulations, companies are likely to invest in upgrading and expanding existing serialization capabilities to satisfy requirements and meet client needs.

Packaging Process Needs

Companies can have numerous needs and face various challenges in the packaging process, and be they technical or a result of dealing with temperamental products, new packaging features, or serialization requirements, companies look to address their needs through the latest packaging equipment solutions and services. The most commonly sought characteristics, according to several contract packagers, are ease of changeover, tool-less changeovers, and minimized product-specific tooling costs, flexibility of multiple package configurations, and a wide range of size

capabilities, as well as operator safety and parts and services as they relate to overall equipment effectiveness (OEE).

The equipment manufactures we spoke with stressed several areas of significant importance in the development of equipment as well as focus areas for clients. "Due to the rising amount of highly potent substances in pharmaceutical products, the focus of recently developed packaging equipment is on process, operator, and product safety. Pharmaceuticals, biopharmaceuticals, vaccines and antivirals must be manufactured and packaged with the utmost caution and attention-to-detail," said Bosch's Dr. Rauschnabel. "The market requires engineering expertise to design equipment that can handle, package and protect such substances."

Mr. Allen of Aphena commented, "Issues that arise are usually ones that were not considered or evaluated. To avoid these from coming up in a packaging environment, it's key to establish a cross-functional team during the early stages of a project, which involves equipment selection and development of the user specification."

Ms. Norris of ESS added, "Local parts and service from the manufacturer are a concern. Adequate training of operators and maintenance personal on an ongoing basis is essential to ensure that all personnel on all shifts are properly trained to operate and maintain the systems for maximum OEE." She also noted that a small footprint and quick, tool-less changeover are advantages that affect efficiency and OEE.

Based on the experiences of the contract packers we spoke with, some concerns that arise in the packaging process include, "out of specification raw materials and drug products and, for biotech products, tracking time of refrigeration (TOR) and excursion times create a challenge," as noted by Mr. Macadangdang of Sharp.

Mr. DeMarco of Reed-Lane added, "Some of the challenges we are facing include new developments in child-resistant package opening features and increased use of green and recycled materials."

Mark Schissler, manager of Technical Services at Reed-Lane, noted, "Increasing the performance in one section of a fully integrated packaging line can stress the upstream and downstream areas, requiring additional development or equipment upgrades to realize the full benefits of the initial upgrade."

"E-pedigree track & trace requirements have a profound impact on the packaging process," noted Vladimir Spehar, director of strategic business development at Jones Contract Packaging Services. "It has been talked about for several years but it's still relatively new in our business, so we will be partnering with a service provider that has an established history in serialization and database management."

With these complex packaging requirements and challenges that exist in

Bosch's CPS 1900 with Labeler is able to print and verify up to 350 cartons per minute and has an integrated labeler.

the packaging process, where can we expect to see improvements in future equipment? According to Mr. Poslovski of Optima, "In the future, we expect to see more robotic technology as the requirements become more individualized. For example robotic systems are used to process specific syringe systems or as a transport system in a tight space."

Ms. Norris of ESS, added, "ESS has incorporated PackML programming into our packaging equipment to allow the machinery to communicate more efficiently with other equipment in the packaging line. We see this trend continuing industry-wide. We also expect to see robotic automation gain more popularity in packaging and manufacturing. Robots are becoming much more cost-effective, user-friendly, and dexterous, making them a viable solution to manual for even hard automation packaging and manufacturing processes."

Additionally, we can expect integrated packaging centers. According to Ralf Klotz, regional sales manager of Uhlmann Packaging Systems, "Functionalities from what was once multiple machines will be combined on single platforms. For example, solid dose bottle filling with desiccant, cottoner, and capper in one machine such as our IBC series for bottling. This allows more capabilities in a significantly reduced footprint. Our BEC series for blistering combines primary and secondary packaging for the highest efficiencies."

While integration, automation, and the incorporation of robotics are increasingly employed, Chris Siegele, serialization specialist for Omega Design Corp. pointed out, "As more processes become automated, some manual operations are not being lost. Instead, operators are working along an 'electronic path' determined by the specific parameters of semi-automated systems."

Packaging Material Trends

Product packaging is seeing a surge of new materials aimed at patient adherence/compliance, child safety, convenience packaging, as well as green materials, all of which affect equipment solutions and production lines. As these trends expand in the industry, equipment manufacturers and packagers must make adjustments to accommodate them.

"Consumer compliance has become an important factor in the development of pharmaceutical packaging design," said Mr. Spehar of Jones Packaging. "If the packaging is easy to manage, patients are more likely to take their medications properly, so we design packaging that encourages higher levels of compliance. Another important trend influencing packaging is end-user convenience. More consumers are turning to smaller products that can be easily stored in travel bags, purses or even gym bags. In response to this growing demand, Jones has invested in a fully automated solid dose plastic vial filling line. Also, our specialized equipment is able to meet the increased demand for unit dose sachets, which are very convenient for consumers on the go."

Mr. Allen of Aphena noted, "We are seeing more products that require higher barrier films. Film manufacturers are developing multi-layer thermoform barrier materials as an alternative to using cold form materials for products requiring higher barrier materials."

While innovative packaging materials are accommodating requirements for issues such as child safety, environmental concerns, and moisture resistance, they can be difficult to work with. Kim Norris, ESS Technologies said, "The increasing demand for lightweight materials offers challenges that affect form-fill-seal and blister equipment, as well as the cartoning and case packing equipment downstream. The accuracy of packaging equipment and the soft handling of robotic technology can enhance performance when using lighter weight materials."

New materials and products are introduced to the market every year, and, like in any other industry, have pros and cons. According to Mr. Wrocklage of Reed Lane, "Running green materials and materials with higher moisture barriers, for example, can require revisions to existing systems, while hydroscopic products can require special desiccants that absorb moisture at a lower rate and packaging environments that can hold maximum and minimum RH conditions."

Mr. Schroeder of PCI added, "With the requirements of these new molecules and their sensitivities to moisture and oxygen, the materials suppliers are continually pushing the envelope in creating higher barrier materials. These include higher barrier films or even desiccated films, bottles, or closures. There is a learning curve with these materials and fortunately as a contract packager we are often on the leading edge in trialing and commercializing these structures."

Packagers as well as equipment providers must keep abreast of these latest materials and address the challenges they present. Mr. Klotz of Uhlmann Packaging Systems noted, "Materials with greener footprints are increasing in popularity. Custom solutions for kits, titration packs, and advances in materials will continue to push equipment suppliers to find creative and cost effective solutions."

The flexibility required to continually serve the pharma/biopharma industry's packaging needs are profound. Just as these needs are constantly changing, industry trends are revealing innovative equipment and packaging process solutions to address extremely complex requirements. •

KRISTIN BROOKS has been the associate editor of *Contract Pharma* since 2004. She can be reached at kbrooks@rodmanmedia.com