

# Breaking Design Barriers

*Custom automation supports industry innovation and the need to be more productive.*

by David Visczek  
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**C**ustom packaging solutions are an outgrowth of two trends: the development of newer drugs and delivery systems requiring new packaging, and the interest in new technologies for improving line productivity. Machines might be custom designed and built, or lines might require custom configuration, integrating machines from different vendors or automating processes for which there is no "standard" equipment.

### CUSTOM CONSULTATION

The pharmaceutical market "is an emerging one for custom services. Typically, drug companies perform process development in a lab, and then replicate it in the manufacturing environment. They tend to rely on commercially available pieces of technology," says Ron Juras, executive vice president, ATS Automation Tooling Systems Inc. (Cambridge, ON, Canada).

Custom solutions come into play when products have unique or complicated handling needs, says Juras. In addition, they can satisfy demands for improved throughput, cost reduction, and quality improvement. "There is substantial value in designing and modifying machines," Juras says. To support turnkey solution services, ATS has launched the ATS Compliant Solutions engineering consultant service. The "front-end" service meets the unique set of challenges that drug

companies face in productivity and regulatory standard compliance, the company said.

ATS often performs proof-of-principle (POP) projects that demonstrate that improved high-risk processes can be accomplished. Customers facing difficult automation challenges may ask for POPs, or ATS will decide to conduct a POP on a portion of an automation task to reduce risk, says James Rorko, sales manager.

In developing its Lyoscan high-performance vision inspection system launched this year, ATS first provided a POP prototype. For inspecting lyophilized biologics and vials, the Lyoscan employs up to 25 digital cameras, and the ATS Smart Vision system for high-speed single pass-through inspection.

"Lyophilized product is by its nature very inconsistent in appearance from one vial to the next without having any effect on the quality of the product. One of the challenges for an automatic vision system for lyophilized products is being able to discern normal inconsistencies on the surface of the lyo cake from abnormal ones and to reduce the false-reject rate," says Rorko.

ATS created a model of each vision system "to prove that the cameras could capture the image at the specified speed and that the software could then process the images quickly and accurately," he says.

Lyoscan's inspection and quality control performance is achieved

through specialized optics and tooling and optimized vision inspection tools using ATS Smart Vision. Because proper lighting is key for capturing usable images, ATS developed "an unconventional lighting scheme using ATS experience in machine vision and software tools that we have developed over the past 20 years," says Rorko.

Micron PharmaWorks (Odessa, FL) specializes in building and rebuilding pharmaceutical blister machinery equipment, as well as integrating lines. "Many OEMs are in business to sell standard machines. They don't have time to do custom work. Custom machines are one-of-a-kind, often built for a company that is looking to get an edge in the market or to solve a particular problem that is unique to their process," says Ron Brower, vice president, sales and service.

The company is often called on for custom transfer system projects for linking dissimilar machines. In helping one customer convert its existing thermoformer to increase blister output, Micron PharmaWorks designed and implemented a selective blister transfer that picked and transferred good blisters, while reconciling faulted blisters.

Anderson Packaging replaced manual cartoning of pouches with a Micron PharmaWorks semiautomated pouch system. It takes pouches from two machines and merges, collates, counts, and stacks them for manual packing, says Brower.

Blister quality was Barr Labs' concern when it sought to implement an

additional step in blister card inspection to ensure 100% fill accuracy. Micron PharmaWorks developed a vision inspection system for checking cards after they have been punched and have left the thermoformer as a final step before cartoning. The system has since been adopted by other manufacturers, Brosser says.

In standard machine vision inspection for form-fill-seal (FFS) applications, defects are detected before filling, perforation, and punching; finished blisters with missing broken, or incorrectly colored product are automatically rejected.

"On older machines, there is always a chance that a faulty blister could accidentally get transferred as a good blister. They wanted one more layer of safety before cards were cartoned, even to the point of handling the product one more time," says Brosser.

The company built an inspection station that sits between the cartoner and a thermoformer capable of scanning up to 275 blisters per minute. A conveyor moves product through a chassis housing color cameras for top and bottom inspection. A redundant magazine supports blisters reinsertion by hand when there is product overflow from the thermoformer, orienting and pacing blisters for camera inspection. Reject and reject verification occurs without stopping the machine.

In another case, when Micron PharmaWorks was approached to produce a machine that could scan bulk products for defects and remove faulted products, the system used several concepts derived from similar projects. "This is usually the case in custom applications. An OEM will apply knowledge learned from other projects to create a unique system," Brosser says.

While speed is paramount for many lines, many customers are increasingly looking for flexibility in custom-designed equipment.

"People are less certain about their markets. Now that seven have come

AT&T employed special optics and lighting in the Lysocan vision inspection system for lyophilized biologics and vials.

down in price, they are saying, 'I don't need to go that fast, but I need to be able to change at a moment's notice.'" says Tim Baxter, vice president, sales and marketing, RD Systems, (South Beloit, IL).

"Often, companies with unique requirements come to us as a last resort. Medical device companies in many cases need help getting control of the product after manufacturing and before packaging. We don't want to make a machine that already exists as a standard, so we take on a lot of risk. It is hard to have a catalog, because the machines we make are never the same," Baxter says.

#### PRIVATE SOLUTIONS

RD Systems developed a system for making and filling a uniquely configured intravenous solution bag. The bag is composed of a trilaminar clear material and a coated foil. "This was a very complex bag to make, containing three separate compartments and three valve ports, joining these two dissimilar materials was a challenge, and the end result is still proprietary. The entire bag-making process is automated, with the exception of loading of raw materials where required," says Baxter.

The company built a machine for automated assembly of defibrillator pads. It can be set to support up to 50 different pad configurations. The system includes a bank of three Avery thermal printers for on-demand printing of graphics and labeling on the pads at the start of the production process. Printing on demand allows for the customer to stock two thicknesses of blank foam and carry 90% less stock than would be required with preprinted material.

"The printers are unique as they print on a foam substrate that is 2-



3 mil thick. There were only two printers that could handle the thickness, and only one of them offered ribbon savings capabilities. The thermal printers employ a heavily waxed-based resin in the ribbon that fills the foam crevices, making for a pristine graphic," says Baxter.

How are the pads packaged? "There is no packaging machine that exists that can pack these pads automatically. This product is not what you would call manufacturer-friendly. Everything about it is sticky. The biggest problem is the large size of the finished pads that makes mechanical handling difficult. An automated solution would need to get hold of the product while it is under complete control," he says.

More companies are turning to integrators for single source work. Custom innovation is often required in off-the-shelf equipment integration, says Stewart Harvey, vice president, general manager, IMA News Packaging Systems, (Leominster, MA).

"Companies in many cases are reducing their engineering staffs. They may do one or two new or reconfigured lines a year. The expertise at the vendor level tends to be a little higher. We develop dozens of custom-configured lines a year for individual customers," says Harvey.

"Ninety-five percent of what we see in tablet counting and packaging is standard equipment," Harvey says. The need for custom work arises when companies want new packaging styles

## Custom Automation

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or when companies are automating manual processes or adding functions, such as vision technology. In addition, designs for new or reconfigured lines vary because of different requirements in room size, machine spacing, type of product, speed, secondary packaging, and coding.

It is very difficult to offer a canned package. You are building a custom package line, composed, in many cases, of standard products, but configured in different ways. If it is



For Anderson Packaging, Micron Pharma-Works built a pouch system that merges, collates, counts, and stacks pouches before manual packing.

successful, it generally becomes a standard product quite quickly," Harvey says.

Harvey cites the example of a recent project pairing a counting machine with a bagging machine. "They were both standard technologies, but the handshakes between the two, as well as the mechanical and electrical interfaces, were all custom." Custom solutions, in fact, often become standard solutions. Fargo Automation (Fargo, ND) developed a robotic pick-off solution with a reach-in device for a customer with

Multivar FPS clip-chain machines. It has since adopted the patented device for use with many applications utilizing this clip-chain-style machine, says Walter Stewart, sales manager.

The servo-driven reach-in device uses suction to capture packages before they are cut, "grabbing the web as the machine starts to index, mimicking the speed of the thermoformer. We then have control of every package. Once they are cut loose from the web, we then go into a much higher rate of speed, where we may flip them over, nest them, and carton or case pack them," says Stewart.

Kable Automation (Summit, NJ, and Caravaggio, Italy) provides custom packaging machinery for assembling products including inhalers, syringes, needles, tubing sets, and IV

catheters. Often its custom designs become "standard" solutions that Kahle builds in quantity, says Julie Logotheis, president Kahle USA.

Innovative medical devices and drug-delivery systems always require custom machinery, she says. "Pharmaceutical companies are adopting more-complicated equipment for packaging their drugs. Packaging has progressed from sealed ampules to vials to pre-filled syringes to prefilled syringes with safety devices. New inhaler and injector pen delivery systems require custom handling and assembly solutions, where the drug needs to be married to the device as part of the manufacturing process. The more complex the delivery system, the more proprietary will be the technology on the manufacturer's floor," Logotheis says.

When a manufacturer is developing a proprietary solution, Kahle often is involved with the company during the product design phase. Companies make sample components to support machine design and construction. "We will help evaluate the design and provide input to facilitate automated assembly. In some cases, our input on machinery's handling and feeding capabilities can drastically change the design," she says.

After the design is set, equipment building and assembly begin. Product is fabricated by a molder. In some cases, Kahle employs standard machinery, custom configured to specific needs. For example, custom solutions are often required for syringe assembly to support new syringe styles. The machines will be configurations of

Kahle's high-speed, continuous-motion syringe-assembly machine, or its safety-syringe assembly machine. Kahle then often integrates production floor equipment.

Kahle provides machine validation services for documenting the functional and design requirements specifications and the factory acceptance test, installation qualification, and operational qualification protocols, all outlined in Title 21 CFR Part 820. "Validation is an edge we bring to the project. Validation begins from the moment the device is under design. Machines and software are designed according to the specifications of the product contract, and challenged step-by-step, with reference to the expected result," Logotheis says. ■