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↑ pp.20

METERED DOSE INHALER LINE: CENTRALIZED CONTROL FROM CANISTERS TO PALLETS

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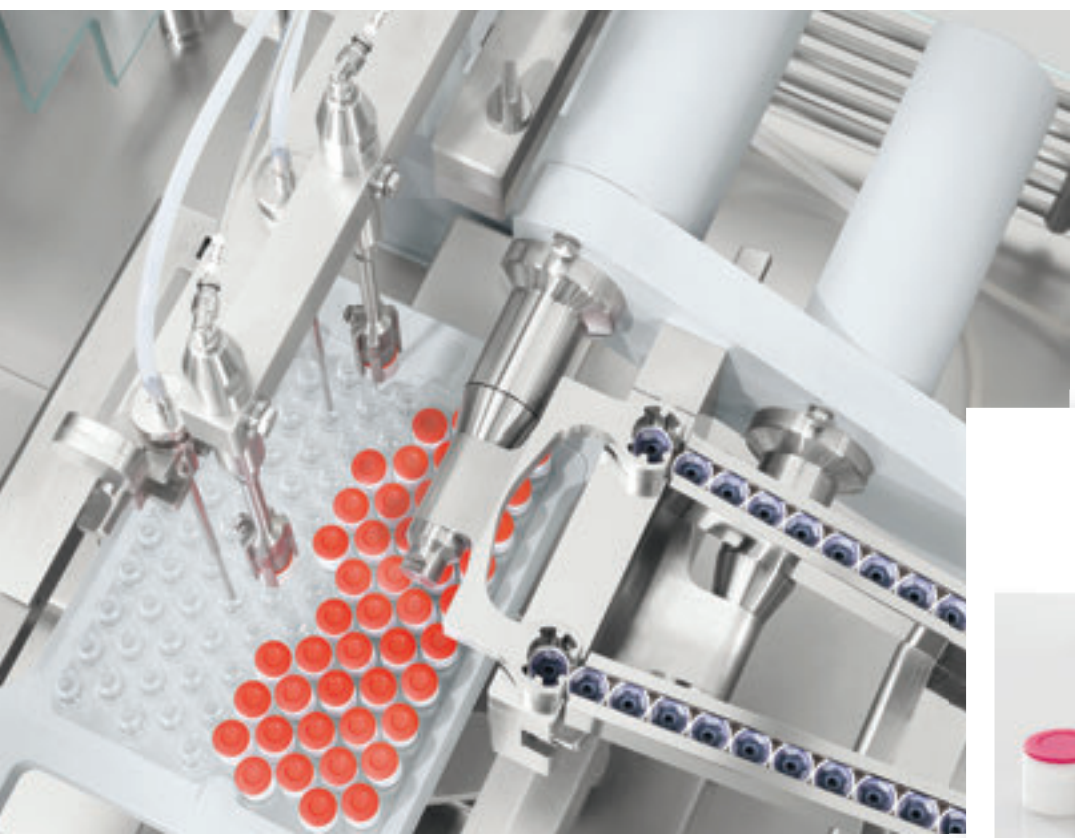

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Embracing Automation in the Life Sciences

Manufacturers make efficiency gains with centralized control, data analytics, and more. Plus, check out new technology at Healthcare Packaging EXPO.

"It shouldn't be too surprising that the pharmaceutical industries are looking to optimize production with AI, considering that single batch values for some drugs can exceed $3 million," says *Automation World*'s Dave Greenfield. But the industry lags behind others in using analytics to improve production.

We hear these sentiments time and again—life science manufacturing is slow to adopt new technologies, with good reason. Patient safety and regulatory compliance are key. But more and more, companies are seeing that technology advancements can go hand-in-hand with safety and quality.

Our cover story highlights Kindeva's new metered dose inhaler line (pp. 20), with 18 components integrated to place a full packaging line under one central control system. This was quite the undertaking, with machines from various suppliers all working together to give operators a "one machine," consistent feel.

On pp. 33, Melissa Griffen offers a detailed overview of digital transformation activities happening in the pharma space. This includes the transition away from paper (yes, still), new inspection technologies, and even the mining of 483s and warning letters to better prepare for regulatory inspections.

This September, we're back at in-person events, as Healthcare Packaging EXPO and PACK EXPO return to Las Vegas (Sept. 27 to 29) with **PMMI**'s PACK Ready safety protocols in place. Check out new machines and technologies, ideas for reusable packaging, networking events, and plenty more. See you there!

KEREN SOOKNE is the Director of Editorial Content of *Healthcare Packaging*. She may be reached at ksookne@pmmimediagroup or at linkedin.com/in/kerensookne

TIM HAYES,
CONTRIBUTING EDITOR

1 New Smart Fabrics Monitor Your Health

A recent *Medgadget* article discussed new smart textiles designed to help monitor the wearer's health. There is already a range of wearables available that monitor health, but they typically need to be battery-powered. These textiles, however, harvest energy from nearby Wi-Fi and radio networks. The fabrics can be used to produce smart garments that are ideal for everyday use since they're water repellent, breathable, and machine washable. Imagine a shirt that is designed to make your life easier by monitoring your health and protecting you from accidents as it wirelessly transmits information to your mobile device. Sounds like the future, right?

2 Moderna's mRNA Flu Vaccine Enters Trials

Moderna was a major player in the race to develop a vaccine for COVID-19. Now, according to a recent *Engadget* article, the company is using the same mRNA-based technology to combat the seasonal flu. The company announced that it has begun human trials as part of a Phase 1/2 clinical study. The vaccine goes by the name mRNA-1010, and it's designed to fight the four most common strains of the virus. These include A H1N1, H3N2, influenza B Yamagata, and influenza B Victoria.

3 Ransomware Attack Targeted Ireland's Health System

An *AP News* article discussed a "serious" ransomware attack targeted at Ireland's health system in May. The country's health service shut down its IT systems and canceled appointments and elective procedures after learning of the attempted attack. It was later determined that hackers (who appear to operate out of Russia) used Conti ransomware. According to officials, none of the coronavirus vaccinations were affected, but they anticipated major problems for radiology services, elective surgeries, diagnostics, and obstetrics and gynecology appointments. Recovery may take months, and according to *Digital Journal*, some extracted data has already surfaced on the dark web.

4 Student Develops Device for Stab Wounds

A recent *India Times* article discussed a new device developed by a university student that aims to improve the way stab wounds are treated. The device is called REACT, and it consists of a silicon balloon sleeve and a handheld actuator. The balloon component, called a tamponade, is inserted into the wound, and then the actuator inflates to create the right amount of pressure to stop a hemorrhage in under a minute. It was developed to treat deep wounds in the abdomen, but the concept can likely be applied to wounds in other parts of the body.

5 California to Provide Digital Vaccine Records

If you've been vaccinated for COVID-19, you received a card containing the dates of your shots and the brand of the vaccine. According to a recent *Los Angeles Times* article, the state of California has launched a digital vaccine verification program that aims to replace the cards. The digital replicas offer an easier alternative to the paper cards that are easily lost. The electronic version will contain all the same information as the physical cards as well as a QR code that can be scanned to confirm authenticity.

6 Major Medical Centers Are Nixing Aduhelm

Last month, we discussed Aduhelm, Biogen's recently-approved Alzheimer's drug that received pushback from medical professionals who believe the FDA put the cart ahead of the horse.

Now, according to a *New York Times* article, two major medical centers, Cleveland Clinic and Mount Sinai, have decided not to administer the drug to patients. Cleveland Clinic released a statement saying that a panel of its experts reviewed scientific evidence on the drug's safety and efficacy and decided not to carry it at this time. However, a spokesperson for the clinic noted that individual physicians can prescribe Aduhelm, but patients would have to receive the monthly intravenous infusion elsewhere. Providence has also declined to administer the drug. It is the first Alzheimer's drug approved in 20 years.

To keep up with the latest news bits from around the world visit healthcarepackaging.com to subscribe and get **Quick Hits** sent right to your inbox.

OPTING TO MANUFACTURE IN THE U.S.

"You are further removed from it overseas. With complicated devices like SAM [Sustained Acoustic Medicine, a wearable ultrasound device] with so many different working parts and polymers that connect, it is really difficult to play detective for complications that happen overseas versus finding solutions here."

-DR. GEORGE LEWIS, FOUNDER AND CEO OF ZETROZ SYSTEMS

"The IHMA is calling for supply chains and authorities to review their anti-counterfeiting plans before the situation exacerbates further in the scramble to secure vaccines. The news comes as research indicates that some fraudulent vaccines have been sold for upwards of $1,000 per dose."

-DR. PAUL DUNN, CHAIR OF THE INTERNATIONAL HOLOGRAM MANUFACTURERS ASSOCIATION (IHMA)

"A simulated infected meeting participant who was exhaling aerosols was placed in a room with two simulated uninfected participants and a simulated uninfected speaker. Using two HEPA air cleaners close to the aerosol source reduced the aerosol exposure of the uninfected participants and speaker by up to 65%. A combination of HEPA air cleaners and universal masking reduced exposure by up to 90%."

-WILLIAM G. LINDSLEY, CDC, ON INDOOR COVID-19 EXPOSURE

BY THE NUMBERS

$72 BILLION

THE COST of drug diversion per year according to the Justice Department's National Drug Intelligence Center, as reported by *Invistics*.

62%

THE PERCENTAGE of the plastic healthcare packaging market represented by prefilled inhalers, syringes, and cartridges in 2021. The market will reach $37.2b this year.

Source: Future Market Insights

46

THE NUMBER of Innovation Stage sessions at PACK EXPO Las Vegas at the three stages in Central Hall.

$6 BILLION

THE ESTIMATED VALUE that the global biomedical textiles market will reach by 2031, with 40% of demand stimulated by non-implantable applications.

Source: Fact.MR

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Cybersecurity 101: The Difference Between IT and OT Attacks

According to *2021 Cybersecurity: Assess Your Risk,* a report from **PMMI** Business Intelligence, Information Technology (IT) attacks "specifically target the enterprise IT systems at a manufacturer, seeking to gain entry through vectors such as email, a CRM system, or an ERP program, which can span across an operation."

Operational Technology (OT) attacks exploit systems on the plant floor through vectors such as individual sensors on the production line, SCADA/HMI panels, or even unsecured PLCs. Motion and vision systems have been targeted by malware attacks, so it's key that manufacturers know their updates come from trusted suppliers. IT and OT networks can be connected to some extent, causing vulnerabilities to both ends of the operation. An example would be having access to an ERP system directly on the plant floor.

—Kim Overstreet

COVID-19 and Drug Diversion: Incidents Left Undiscovered

Healthcare compliance analytics firm **Protenus** announced new research that details the effects of clinical drug diversion on healthcare organizations, providers, and patients. The research, published in the *2021 Drug Diversion Digest*, reports COVID-19 operations may have hindered close monitoring for suspicious activity. "When comparing 2020 data to that of 2019, the number of publicly reported incidents decreased by almost 61%," says the company. "This is a stark underrepresentation of what is actually occurring across the healthcare industry, as COVID-19 created tremendously stressful working conditions for healthcare professionals, which has been known to exacerbate known drivers of drug diversion and misuse." *—Keren Sookne*

Colorado Passes a Bill to Restrict the Marijuana Industry

The state passed House Bill 1317 that rolls back the customer purchase limit for high-potency concentrates to 8 grams per day, roughly a fifth of the previous limit. Per *MJBizDaily*, it requires warnings on packages for concentrates as well as guidance on serving sizes, and authorizes a new real-time tracking system to monitor the concentrate purchase limits. It also mandates new public health research and adds rules to ensure patients 18 to 20 years old have a "substantial" relationship with their physician. A young man with severe epilepsy has already filed a lawsuit, arguing that the laws will jeopardize his access to needed medication. *—Tim Hayes*

Suppliers in the News

- **Kao Collins** launched "InkAnswers," a digital search tool that matches inkjet inks with packaging materials used in the pharma and nutraceutical industries.
- Pelican BioThermal has rebranded to **Peli BioThermal.**
- AIM revised its Standard 7351731, offering guidance for evaluating the immunity of medical devices from exposure to RFID.
- Nutraceutical packaging equipment company, **Nutra-Pack Systems**, has launched, offering an array of new machinery.
- **Westfall Technik** opened its 40,000 sq ft medical molding plant/clean room in Chicago.
- Coldplasmatech GmbH's PlasmaPatch for chronic wounds, developed by **Schreiner ProTech**, won the FINAT Innovation Award.

—HCP Editors

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BioBased Shippers Cut Petroleum Sourcing By 100%

From fossil carbon to harvested carbon: a new alternative to EPS is poised to transport goods including healthcare, food, and protective packaging while cutting water and greenhouse gas use in manufacturing.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

For decades, EPS (expanded polystyrene, frequently misidentified as "styrofoam") has been the gold standard material for passive temperature-controlled shipping because of its price, performance, and its light weight compared to other materials. For these very reasons, it has been difficult to replace—it's been a proven solution for the life science industry, which is hesitant to change what is safe and validated. But new sustainable offerings are emerging for passive shippers.

First, it's important to acknowledge there are a number of different ways to measure "sustainable" in packaging and operations. As Josh Russo, Director of New Product Development at **LifeMade**, noted at ISTA's TempPack, disposal doesn't tell the whole story. Companies develop different KPIs to determine what makes for an improvement, looking at the entire lifecycle of their product or materials. Amazon and Hello Fresh both count carbon reduction among their initiatives, while Pfizer includes goals around decreasing greenhouse gas (GHG) emissions as well as waste disposed of and water withdrawal.

Scott Dyvig, Director of New Business Development at LifeMade, explained the company's "good, better, best" motto for incremental improvement in sustainable offerings. Last year, the company debuted its EnviroCooler EVG™, an EPS cooler infused with a bio-based additive, designed to allow it to break down in a bioreactive landfill in four years. Russo noted that this is not an oxo-biodegradable material—it will not leave behind microplastics which are a serious issue in natural ecosystems.

From 'popcorn' to Bioffex

Cut to 2021: LifeMade has launched its Bioffex™ technology, which has been in development since approximately 2012. The target is to replace packaging that uses EPS, including applications in healthcare, food, and more.

The initiative began within the Lifoam business unit as "Project Popcorn" to use PLA—polylactic acid, made from the sugars in corn starch—to replace EPS. "The goal was to have a bio-based material that performed similarly to EPS but has a compostable end-of-life story. It took PhDs working continuously on the project and a couple patents and trade secrets to get the formulation finalized," said Dyvig.

Bioffex products are sourced entirely from renewable materials, sugar beets and corn, and despite the name, "polylactic acid" is not an acid but a polyester. Zero petroleum is used in the material. "They take starch—corn or sugar beets—and brew lactic acid. Then they condense and polymerize it," said Russo. "We're buying pelletized PLA from a major raw material manufacturer, and what's special is the patented process developed by LifeMade that creates an expanded bead foam. This is enabling us to come to market with products that you've already seen—very similar in form factor."

LifeMade has secured a USDA BioPreferred certificate at a 100% level for its Bioffex products, which falls under purchasing criteria for many government organizations and may one day be a part of industry KPIs for sustainability initiatives.

Reduction in natural resources

Beyond the 100% reduction in petroleum from the raw materials compared to EPS, there are additional advantages in manufacturing Bioffex products.

Water usage: The technology requires 81% less water to manufacture compared to EPS. Dyvig said that it doesn't require as much steam to produce, and those savings can be included in sustainability metrics. "So if a company ships a hundred thousand EPS containers, we can say you're going to save X thousands, or X hundred thousand gallons of water because the production of the technology uses less

Beyond the 100% reduction in petroleum from the raw materials compared to EPS, there are additional advantages in manufacturing Bioffex products in water and energy usage. ↘

steam and uses more precise application of steam than the equivalent in EPS. You can quantify the amount of water reduced and freshwater reduction, a KPI that people look at in their choice of packaging," he noted.

Greenhouse gasses: Eliminating the hydrocarbon gas needed to expand the material reduces GHG potential by 83% over EPS in the foaming and molding of the products themselves.

Energy usage: Bioffex production uses less energy than EPS production—potentially up to 50% less. Savings depend on the size and dimensions of the container, but in addition to the water savings from using less steam, there is subsequently less heat energy required to create steam.

LifeMade's vertical integration (making rather than buying) means they're creating beads 100 feet from molding operations, which cuts down on transportation emissions.

Like many sustainable offerings, utilizing Bioffex technology currently comes at a cost. The material is more expensive than EPS, but Dyvig said, "The cost per pound doesn't necessarily tell the whole story."

Performance

Results from chamber tests show that thermal performance is comparable to EPS, and the company is prepared to test against any standard profile. Bioffex products may also have additional advantages in transit aside from thermal performance, and the development team continues to study how those qualities can be applied to transit scenarios. In either case, the material behaves similarly to EPS in terms of reliability and repeatability, which is a key factor for quality departments feeling comfortable with repeatable, consistent protection.

Looking ahead, LifeMade is partnering with PLA suppliers to look at other sources and materials with sustainable "beginning of life" stories, including other polymers.

End of life

While the beginning-of-life story of Bioffex products is important, it is disposal that puts it in a unique category. LifeMade is collect-

ing data in industrial composting and landfill environments and is in the process of becoming home compostable-certified.

The company wants the customer to have multiple paths of disposal. Dyvig said, "There are opportunities for reuse, but there will always be a need for single-use shipping solutions due to the convenience and repeatable performance. When you look at single-use sustainable options, there's an emphasis on end of life. What access do consumers have at their house once the patient has received their medication? That's an evolving target—they may have access to curbside or composting... but that does not mean they'll use it.

"One of the areas that we feel is important for Bioffex is a lot of the sustainability is already 'banked.' The savings in petroleum, water, energy, and greenhouse gases are in the books by the time the end user does or does not do what they're supposed to."

For cases where industrial composting is not selected or unavailable, Russo said, "We're testing both Envirocooler EVG and Bioffex products in the anaerobic landfill environment per ASTM D5511, and they're showing very promising results. Degradation for EVG will be measured in years, not measured in decades or centuries as traditional EPS is measured. Meanwhile, even though Bioffex technology is optimized for aerobic composting, in biologically active landfill conditions it's still biodegrading faster than EVG by a big margin."

Bioffex products are ideally disposed of via industrial composting facilities, which an audience member pointed out are not everywhere yet. Websites like FindaComposter.com and communication with end users on proper composting and disposal are key. Most importantly, once a Bioffex container enters the industrial composting stream it will degrade swiftly, reducing to safe and usable compost in well under one month.

While industrial composting sites are not yet available in every location, the ability to compost Bioffex products and use that compost in agriculture tells a circular story, beginning and ending in the earth.

For new transport packaging developments, visit PACK EXPO and Healthcare Packaging EXPO.

3 Fast Facts: Cohesive Peel Technology

How might a cohesive peel system help with variability in seal strength?

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

While many in the medical device packaging industry are familiar with adhesive peels, cohesive peel technology can offer advantages in reducing the variability in seal strength, reducing fiber tear, and offering a consistent peel for the end user. **DuPont** and **PAXXUS** representatives held a webinar to discuss the technology.

Adhesive vs. cohesive

Adhesive peel: As the film is peeling, it typically leaves both surfaces in the same state that they were in before they were sealed, explained Doug Dodrill, Chief Technology Officer at PAXXUS. As is shown by the light green section of sealant (*next page, top image*), it's strictly separating without transfer of molecules between the surfaces.

Cohesive peel: When the surface peels away from the Tyvek®, the sealant splits in the middle of the layer (see the light green section—*next page, bottom image*). "Basically, it's sacrificing the 'skin layer' and transferring the skin over to the Tyvek surface, rather than peeling cleanly," said Dodrill.

1. How is a cohesive sealant created?

The main principle: start with one polymer and add an additional incompatible polymer (or two) to disrupt the polymer matrix. "That weakening of the polymer matrix is actually what creates the cohesive peel. Polybutene is a common one but there are many other combinations of incompatible polymers that will create the same effect," said Dodrill.

Jose Arevalo, Global Business Development Manager at DuPont, added, "The additive you put in creates a weak point in that film structure, so when you go to open it, it will break along that weak point that you've designed into the film layer." The sealant is designed so that when the bonds within the sealant layer itself are weaker than the adhesive seal bonds, it will split and leave the polymer behind, rather than separating completely from the Tyvek (or other material).

There are various ways to tailor cohesive film behavior to an application. Adding a colorant to the seal offers the ability to see the transfer occurring against the white Tyvek background. A key

element of the new EU MDR is the ability to prove the integrity of the package at the time of use. The colorful cohesive peel technology that transfers to the Tyvek is an example of a visual indicator that allows a nurse to know the package was sealed properly. Pre-opening, a nurse can also inspect the tinted seal for channels or non-uniformities.

2. How is seal strength altered?

Factors that alter the seal strength include (but are not limited to) what chemicals are mixed and the percentages of secondary polymer added to the matrix.

"You also have to look at the viscosities of each of the polymers that you're blending together. You're controlling how the islands of the secondary polymer are fitting into the matrix in the primary polymer. If the viscosity or the melt index of the resins is very similar, then they tend to create a very easy and uniform dispersion, which may or may not be a desirable depending on what type of seal strength you're trying to create," said Dodrill. "If there's a big disparity between the viscosities of the two, then you tend to end up with larger islands of the secondary polymer which would increase the seal strength in that situation."

He likened it to ingredients we're all familiar with: if you mix toothpaste and honey together, they mix fairly easily, whereas toothpaste and tar are going to be an entirely different mixture.

3. How might this reduce variability?

With adhesive peel technology, as seal temperatures and/or dwell time increase, seal strengths tend to increase.

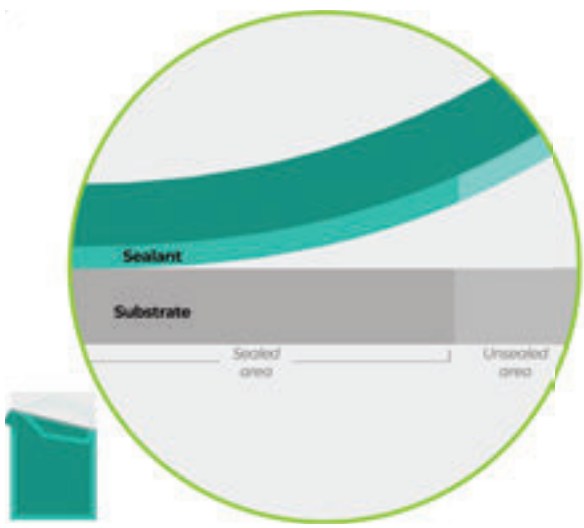
In the case of cohesive peel technology, PAXXUS has found that above approximately 265°F, once the seal is activated, seal strength remains consistent up to the limits of the Tyvek at about 300°F. This represents an approximate 35-degree operating window.

Dodrill reported that seal strengths are typically on the order of 1.5 pounds/inch, which can be adjusted up or down. Mark Sundt, Technical Service Consultant at DuPont, confirmed this estimate in trials with the technology. He added, "Quantitatively, it was nice to see that once you got to a certain threshold point, you saw the seal strength somewhat level off and stay consistent over several degrees."

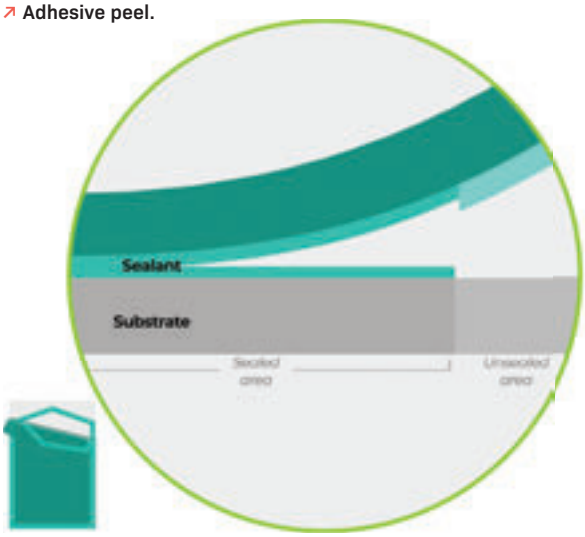
After evaluation, Sundt noted that beyond the quantitative results for seal strength remaining consistent over a wide range of temperatures, there were also subjective features to factor in.

"What was also nice—as you went from lower temperature to a higher sealing temperature—how it felt when you opened the package didn't change. That would obviously make sense as the measured seal strength remained consistent. The opening felt very uniform, so it was a very familiar feel," he said.

Sundt pointed out that due to the mechanism of the cohesive failure happening within a layer of the film—leaving part of it on the other web surface (Tyvek)—the propensity for fiber tear to occur is likely lessened. The stress of the peel is essentially moved away from the Tyvek surface, allowing for a smooth peel and less variation.



↗ Adhesive peel.



↗ Cohesive peel.

PACK EXPO Las Vegas and Healthcare Packaging EXPO (Sept. 27-29, Las Vegas Convention Center) will reunite the packaging and processing community. With more than 1400 exhibitors, no other event in 2021 will bring together a more comprehensive gathering of suppliers offering new products, technologies, and solutions. Attendee registration is open at **packexpolasvegas.com.**

It's Time to Step-Up Machine Safety

Life science manufacturers and OEMs understand the need to comply with machine safety standards, but new requirements may necessitate bringing in a third party to help mitigate risk.

STEPHANIE NEIL, EDITOR-IN-CHIEF, *OEM MAGAZINE*

Polytron is a systems integrator (SI) specializing in automation and controls, industrial networks, simulation, smart manufacturing, and cybersecurity. But another area of expertise the company offers as a service that is very valuable, and sometimes overlooked, is machine safety assessments and verification/validations.

Polytron's Safety Practice helps companies to protect packaging and processing equipment, and, of course, people. The safety team hold certifications in global safety competency, with Functional Safety Engineer (FSE) certified by TÜV Rheinland and Certified Machine Safety Experts – CMSE – TÜV NORD. These certifications held by the Polytron team validate that a manufacturer's safety projects will be delivered with proven competency and expertise in best-in-class machine safety practices and thorough understanding of safety standards.

"In the safety business, we have a safety lifecycle from risk assessment, safety definitions, designing, implementation, validation, and help with overall standards—either compliance or helping to write standards for the end users," says Sean Daswani, Project Manager and Safety Business Leader at Polytron. "We have done and are currently working with a life science area manufacturer and are in the process of guiding them through retrofits of existing equipment, but also using these standards to create detailed specifications for the OEMs to follow while designing/building new equipment. Having a consistent safety program that is based on standards is beneficial for everyone."

In their work guiding machine builders, Polytron encounters a few different issues. "One is, the OEMs in the U.S. that are trying to sell machines over in Europe have an issue with certain requirements of the machinery directive that has to be met to get machines to the EU," Daswani says. Here in the U.S., the standards are not as strict,

but there are still standard enforcements, like the new ANSI B11.0 (2020), which outlines the responsibilities of the machine builder. "We've helped manufacturers with standards, but they require risk assessments at the OEM facility to identify hazards and they want to know what [the OEM] has done to mitigate those."

Part of that mitigation may include that the manufacturer brings Polytron in during the factory acceptance test (FAT) to offer an equipment assessment as a third party. There is value-add for the OEM as well. "Once we do the safety risk assessment, identify hazards and safeguards, and get everything to acceptable levels, we hand over that documentation with all of the standards that meet the specifications," Daswani says, noting that this helps bridge the disconnect that often occurs between the end user and the machine builder when it comes to conforming to equipment standards.

The documentation, comprised of the industry standards for risk assessment, can be used later during validation to ensure all scenarios—from devices to wiring—have passed and the equipment is safe for operators.

New safety concerns

Since the pandemic, there's another reason to conduct a safety analysis, and that has to do with workforce safety programs put into place and manufacturers having to decide what level of risk to take in the production environment. With minimum operators on the plant floor due to social distancing guidelines, or the need to shift operators around, it could mean putting someone in charge of a machine that they are not familiar with, which could lead to unexpected downtime.

"We see manufacturers moving toward standardized machine safety programs across the organization for greater plant floor efficiency in maintenance, workforce training, and documentation for equipment safety standards. This approach allows the manufacturer to maintain insurance standardization and stockholder confidence in a safe work environment," Daswani says.

These industry drivers are requiring changes related to a comprehensive safety design on new and existing equipment, including detailed documentation to meet ISO and ANSI standards following the lifecycle of the equipment, equipment risk assessments for hazard standardization, an analysis of the performance level achieved by each safety function using an industry-accepted tool such as the Safety Integrity Software Tool for the Evaluation of Machine Applications (SISTEMA), as well as the need for third party verification and validation.

"In the U.S., the owner of the equipment, typically our customer [the manufacturer], is responsible for the safe functioning of their equipment and is legally liable for ensuring that," Daswani says.

A Significant Safety Standard

Manufacturers should be aware of their machine supplier's responsibilities, in addition to their own. The new ANSI B11.0 (2020) is broader than the previous version and provides clarity on the responsibilities assigned to the machine supplier (OEM). Here's a snapshot:

The **component supplier**, **machine supplier**, and the **machine user** shall be responsible for achieving acceptable risk within the scope of their work activity.

The **machine supplier** shall determine what risk reduction measures, if any, are required to achieve acceptable risk with any components it integrates into the machine.

The **machine supplier** shall obtain documentation from the component supplier as required for the component(s), including installation requirements, operating instructions, and maintenance requirements.

When engineering controls (guards, control functions, or devices,) are provided, the **component user/machine supplier** shall be responsible for ensuring that it is integrated and installed in accordance with the requirements of this standard.

The **supplier** shall use the risk assessment process in designing and constructing the machine and for developing the information for operation and maintenance of the machinery, considering the lifecycle of the machine.

The **supplier** shall provide risk reduction measure(s) as determined in the supplier risk assessment and the appropriate machine-specific "base" (type-C) safety standard.

... **machinery suppliers** shall use a risk assessment process such as the one described in clause 6 in the design, construction, reconstruction, and modification of machinery to meet the applicable requirements of clause 7 and any applicable machine-specific "base" (type-C) safety standard.

Suppliers and **users** are required to perform a risk assessment (see clause 5) to reduce risk to an acceptable level.

The **supplier** shall provide information for operation and maintenance of machinery that consists of documents, signs, signals, symbols, and/or diagrams used to convey information to the user.

The **machinery supplier** shall inform the user(s) of any machine-specific PPE requirements.

The **supplier** shall provide materials or information in the manual for the user to incorporate into its training program(s) (see clause 8).

Source: ANSI B11.0 (2020)

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↙ An MGS Stealth CT Cartoning module loads pouches and literature into a carton that is then weighed and serialized.

Metered Dose Inhaler Line: Centralized Control from Canisters to Pallets

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Take a dive into a "one machine" concept for a metered dose inhaler line.
2. System integration was key for 18 modules with a central control system.
3. Company stands to save millions with its TV/monitor information display system.

"Digital disruption has reached the healthcare sector, and with it comes an imperative for life-science companies to retool core technology to remain competitive," says McKinsey and Company about the changes underway in healthcare automation.

One manufacturer taking this to heart is **Kindeva Drug Delivery** ("Kindeva"), with its recent endeavor to implement 18 machines and components into a "one machine concept" for their new metered dose inhaler (MDI) line developed by **MGS Machine**.

The project began in November 2018, and Kindeva was established as a standalone company in 2020. After establishment, Kindeva's business model persists as a contract development and manufacturing organization (CDMO) that develops and manufactures complex drug and combination products for pharmaceutical and biotechnology companies.

Kindeva wanted the one machine concept, taking bulk inhaler canisters all the way through multiple layers of packaging, case packing, and palletizing. With so much to focus on bringing a new inhaler to market, they wanted to collaborate with a company that could deliver the entire packaging line as one.

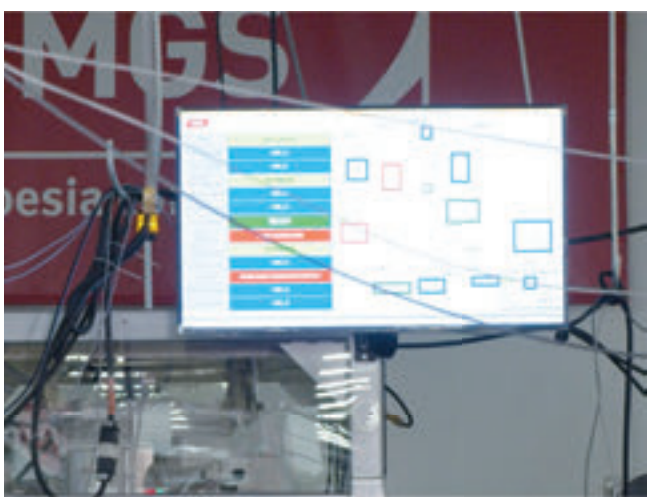
Their vision was that any operator that walked up to the line would have one common interface, with a cohesive look between each piece of the system including the same buttons, stack lights, programming, messaging, and startup/shutdown procedures. From an operator standpoint, they wanted all 18 machines to "feel" the same.

Selecting a partner

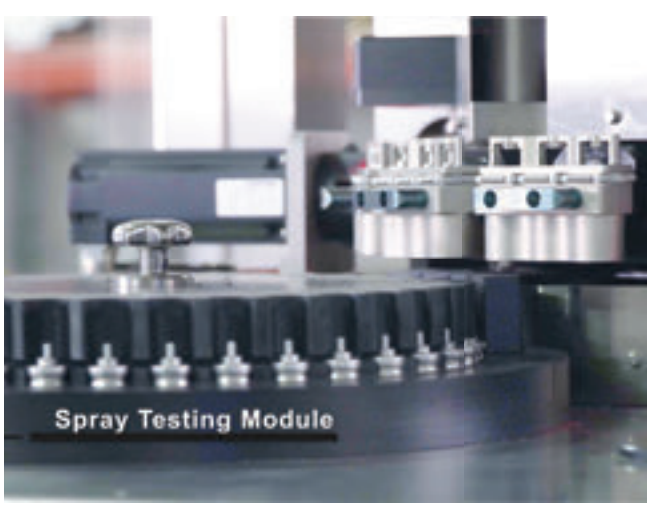
Heading the project was Jeff Annesley, U.S. Engineering Manager at Kindeva, who previously worked at 3M for 15 years as a project engineer for multiple divisions. Annesley says, "This is a very large line that's very complex. We sent a relatively high-level RFI with product characteristics and process requirements, casting a pretty wide net." Not only did they need to ensure that the vendor they chose was capable of building this system, but they wanted a level of interest and enthusiasm which helped to narrow it down.

Jeff was introduced to MGS Machine by a colleague who was

↑ Depalletized canisters are oriented for automated processing.



↑ Marquee Display Monitors allow operators to see real-time data for the entire system.



↑ The Brooks Machine & Design Spray Testing Module primes and tests each individual canister for proper discharge.

working on a project with the OEM that was roughly the same size and order of magnitude as the MDI line. "Within a week, I was up there with my manager and that was the first time I met Russell [Kostreba, of MGS]. He had built the machine and asked if we wanted to see it run. He ran the whole line himself by touching one button," says Annesley. "At that point, I looked over at my manager and said, 'I think we may have found the vendor.' Of course, there was a lot of due diligence that we went through to get to securing the deal with MGS."

Having a technical expert at the outset who understood the details of such a complex line (and that it could be done) helped solidify the decision. Annesley notes, "One thing that really puts MGS in a unique position is that in addition to a salesperson, they also have an application engineer to interact with during the RFP."

After they were awarded the contract, the magnitude of the project led MGS to create a role for a project technical lead, which Russell Kostreba ended up filling.

Once selected, MGS provided a shop tour to walk through some of the ways that they could integrate smaller projects. "There was a variety of projects out on the shop floor to show different types of capabilities and we introduced people on our team to help Kindeva understand how we would shepherd a project like this. There's an entire team of people that it takes to make something like this happen, so during that visit, we tried to expose the team from Kindeva to who those people would be, what those technologies might be, and our capabilities," says Josh Pangier, Director of Project Management at MGS.

OEM sourcing and purchasing

With 18 machines to consider, sourcing was a critical part of the journey. MGS took responsibility for most OEM sourcing, purchasing, installation, and controls. "There were some OEMs that we specified—in particular **Brooks Machine & Design** for the tray unloading station," explains Annesley. "Coming off of the fill line we have a canister that gets placed into trays, so a strategic decision was made early on to have the same vendor provide the design of the tray loading station on the end of the fill line and the unloading station at the beginning of the packaging line because the common piece there is the trays storing the canisters. We wanted to make sure that there was clear communication and machine design compatibility between the end of the fill line and the beginning of the packaging line."

Pangier says, "In any type of automation process, no matter where it is on a packaging line, it's not just about building the machine but about how it interfaces with the commodity and the end users' processes. We learned all kinds of details between Kindeva, MGS, and Brooks and it took collaboration amongst all the parties to make that part really successful."

Ultimately, the line combines 18 machines and components from over 10 suppliers into that one machine concept, starting with bulk canisters and ending with aggregation of cases to pallets. See it in action at hcpgo.to/MDI.

1. Depalletizing & Tray Unloading Module

Purpose: The Depalletizing & Tray Unloading System from Brooks Machine & Design automatically takes bulk canisters stored in trays on pallets and singulates them onto a conveyor.

Details: A vision guided **Fanuc** robot with MGS programming locates the tray, picks it up, places it onto a conveyor, and inspects to ensure all canisters are present. Once the inspection is valid, the tray enters an inverter where it is rotated 180 degrees to orient the canisters for automated processing. Empty trays are returned to a pallet utilizing the same vision guided robot.

2. Spray Testing Module

Purpose: The Brooks Machine & Design Spray Testing Module automatically tests each individual canister for proper discharge.

Details: Individual canisters are passed through priming stations and are then tested to ensure proper discharge. Canisters that do not fire (no fire) or continuously discharge (continuous fire) are rejected. Valid canisters are sent downstream.

3. Canister Checkweigher

Purpose: The **Mettler Toledo** Canister Checkweigher weighs canisters to ensure that there is an appropriate amount of product to provide patients with a full quantity of doses.

Details: Canisters are passed over a precision weigh cell—underweight and overweight canisters are rejected. Valid canisters are sent downstream.

4. Canister Labeling Module

Purpose: The **Accraply** Canister Labeling Module applies labels with product information onto each canister.

Details: Each label is printed with a lot code and expiration date. Proper printing is verified using an integrated **Optel** vision inspection system. Labels with an invalid lot or date are rejected while valid canisters are sent downstream. Labels are wrapped around the canister and a vision system inspects each canister to ensure the label is present and properly applied. Canisters that do not have a properly applied label are rejected. Valid canisters are sent downstream.

5. Inhaler Assembly Module

Purpose: The MGS Inhaler Assembly module assembles individual components into the final inhaler and verifies proper assembly.

Details: Bulk Actuators are dumped into a hopper; a centrifugal bowl is utilized to singulate and orient them. Labels are dispensed and applied to each actuator and placed into a starwheel. A vision system is used to verify label placement and actuator cap presence. Actuators without a cap or proper label do not receive a canister. Canisters from the Mettler Toledo Canister Checkweigher are

↑ The Canister Labeling Module from Accraply applies labels with product information onto each canister.

↑ Prior to the MGS assembly module, bulk actuators are dumped into a hopper; a centrifugal bowl is utilized to singulate and orient them.

↑ Linear servos insert the canisters into the actuators when the components are properly aligned in the starwheels.

singulated and placed into a starwheel. A linear servo inserts the canisters into the actuators when the components are properly aligned in the starwheels. The fully assembled inhaler is inspected by a vision system to ensure the dose counter on the actuator has the correct number of doses displayed. Fully assembled inhalers that have passed all inspections are picked up by a robot and placed into the Flow Wrapping Module.

6. Flow Wrapping Module

Purpose: This **Campbell Wrapper** Flow Wrapping module wraps the assembled inhaler in a sealed foil package that also contains a desiccant pack.

Details: A desiccant feeder dispenses a desiccant pouch and combines it with a fully assembled inhaler. The foil for the pouch is printed with a lot and date code that is inspected by an integrated Optel Vision system. The desiccant and fully assembled inhaler are wrapped and heat sealed into a pouch.

7. Leak Detection Module

Purpose: The **Bonfiglioli** Leak Detection Module verifies the integrity of the pouch.

Details: Pouches are loaded into a vacuum chamber where a vacuum leak down test is performed. Any pouches that fail the leak down test are rejected, while good pouches are sent downstream.

8. Pouch Checkweigher

Purpose: The Mettler Toledo Pouch Checkweigher weighs pouches to ensure all components are present inside the pouch.

Details: Pouches are passed over a precision weigh cell—underweight and overweight pouches are rejected. Valid pouches are sent downstream.

9. Pouch Accumulation Module

Purpose: The **Ambaflex** Pouch Accumulation Module provides a buffer of material to absorb the imbalance in product flow that would otherwise impact overall production.

Details: A vertical spiral conveyor is used to provide approximately four minutes of product accumulation.

10. Stealth CT Cartoning Module

Purpose: The MGS Stealth CT Cartoning module automatically loads the finished pouches and two pieces of literature into a carton that is then weighed and serialized.

Details: Two pieces of literature are picked, inspected, and then placed into a conveyor. Finished pouches enter a vision guided Fanuc robotic infeed where they are picked and placed onto the previously placed literature. Cartons are automatically fed, opened, loaded with pouches and literature, glued, and closed. Cartons are then weighed via a Mettler Toledo system to ensure all components are present. Overweight and underweight cartons are rejected. Valid cartons are printed and inspected by a printer and camera controlled by an integrated Optel Serialization system. Cartons that fail the vision inspection are rejected and valid cartons are sent downstream.

11. Stretch Banding Module

Purpose: The **Omega** Stretch Banding Module combines serialized cartons into one stretch wrapped bundle.

Details: Product enters the module where they are upstacked into a product matrix. The product matrix is discharged through a stretch wrap film and the film is heat sealed to create a completed bundle.

12. MatriX Case Packing and Palletizing Module

Purpose: The MGS Stealth MatriX Case Packing and Palletizing module combines stretch wrapped bundles into groups and loads them into a case. Cases are closed, labeled, serialized, and automatically placed onto a pallet.

Details: Stretch wrapped bundles are inspected by an integrated Optel camera that aggregates cartons into bundles. Stretch wrapped bundles are upstacked and organized into a specific matrix. Cases are automatically opened and fed to a load station where the specified matrix is inspected by an Optel camera that aggregates the bundles into a case. The fully loaded case is closed and discharged to a labeling station. The integrated **Label-aire** labeler dispenses and applies a serialized case label that is subsequently inspected by another integrated Optel Camera. An MGS palletizer robot picks up the case and positions it in front of another Optel Camera for final aggregation of the case to the pallet.

13. Central Control System with Marquee Monitoring

Purpose: True to its name, the MGS Central Control System provides a central control and monitoring station for the entire line as well as final integration of the Optel Serialization System.

Details: The MGS Central Control System allows a single person to control the entire system if local module control is not desired. Functionality includes the ability to start/stop, monitoring production and maintenance data, set and change recipes, initiate product integrity challenges, and perform final pallet labeling and aggregation. The Central Control System also controls the **Marquee** Display Monitors that allow operators to see real time data for the entire system.

System integration

The original plan was to design and build the MGS portion of the line "in parallel with sourcing a number of components from OEMs and then integrating them all together at one time. That looked good on paper—and then reality hits and you end up working through issues," Pangier says.

Some product and process development went on concurrently according to Annesley, with MGS playing a key role in some instances. For example, the original pouch didn't fit into its carton so they couldn't get started on system design until that was sorted. "We may not be experts at trying to fit products in cartons, but MGS is and that's a key strength," he notes.

"Meanwhile, we're off sourcing other parts of the project that were solid. I think we did nine or 10 revisions of the schedule over that two-year period," says Pangier. "It's all about hitting the end user's market window—if they're not successful, we're not successful. We spent a lot of time collaborating on schedule adjustments or pivots. Throw in the global pandemic and it was even more challenging. The leak tester and the front-end Brooks components ended up being the last pieces in that were most affected by the pandemic."

MGS helped OEMs integrate requirements into their machines so the operators would have the aforementioned similar feel to each component. In cases where MGS saw that an OEM wasn't solving an issue, they took on the challenge internally. Some pieces of equipment were thought to be turnkey, but as the team found gaps, MGS made their own alterations to ensure a better result.

Part of the success came from personnel at Kindeva. Kostreba says, "Jeff is excellent at project management, and management of people and meetings. Everything's informative and the people he

Fast Facts: Remote Services and FAT

1. Much of the project took place in person—75% of the line was at MGS prior to the pandemic. The remaining 25% was installed and started up at MGS without full supplier support.
2. The team employed Kindeva's **Microsoft** Holo Lens, while MGS invested in laptops, webcams, and gimbals. They met with Kindeva remotely via Microsoft Teams.
3. MGS had protocols in place to get a small number of visitors on site–this was scaled down from the norm.
4. Visitors were onsite for key milestones:

+ For the As-Built Review, all but two components were at MGS. Kindeva could see components hooked up, but not necessarily running yet. At this point, Kindeva sent in the lift for film rolls to test and use in-line as part of the FAT. They also sent all reject bins, elevated platforms, etc. so MGS was working with real production items for testing.
+ At the Optel integration point, product was moving through the line so Optel's vision systems could be tested.

selected were great at their jobs. So from our standpoint, I felt like we had an army of Kindeva experts to keep us on our toes because they would help to find gaps and then we would fill the gaps with our own little army of experts. Probably the best part of the project is the number of experts doing their job well, working like we were one team instead of two companies."

Central control

The central control system (CCS) operates, as the name implies, as a master control system while every machine operates in the background as its own machine. The programming for the modules remains in the modules themselves.

The CCS monitors what each machine is doing and communicates back and forth. Kostreba explains, "Machines upstream and downstream communicate with each other individually for stop or wait commands, and the central control system can also start and stop machines, go to dispatch configuration, half speed, full speed, etc. Then it reports all of that information for everybody in the room to know what's going on."

Annesley says, "A requirement from the beginning was that these equipment modules all have to operate as a single unit. In order to do that, you have to have an orchestrator so there can be that level of coordination between each module. That was something that I would say uniquely positioned MGS because they understood that from the very beginning. This wasn't necessarily the case with all vendors—there are different ways you can approach this. MGS also had very capable technical employees, their control staff had a great understanding of the standards that needed to be put into place and communicated to each one of these OEMs so that they can speak the same language and be coordinated by a single central control station."

Operators can start and stop the system from the CCS or locally at the machine. MGS had to develop programming to ensure that this is done safely. Local maintenance can be done on one module without stopping the entire system.

As was mentioned above, a key goal of the project was to have each OEMs' technology shine in its particular role, while still ensuring that an operator at Kindeva could walk up to a machine and see the basic control was the same as for other machines. Each machine has its own HMI. MGS did not ask OEMs to change their HMIs—their core standards are the foundation of their equipment—but messaging and content look the same to make the operator experience as easy as possible.

"We were adamant that it had to have a certain kind of button

layout, and very standardized controls when it came to basic start and stop functions. Then laid over the top of that was the central control system, which gives visibility to the whole line," Pangier explains.

OEMs have different ways of interfacing with the CCS. "From a technical standpoint, we had to translate that. We designed an interface box and sent it to the OEMs and said, 'Put this box in and interface in this way and give us this information and we'll handle the rest.' Everything uses Ethernet for communication. We had to lay out that expectation, otherwise I think that each of the OEMs would have provided what they provide through their own lens," says Pangier.

Not every OEM was as understanding, so in some cases, MGS stepped in and fixed a system's programming themselves instead of debating about scope. With such a large system and a set deadline, the project team would hold status meetings with OEMs. If an issue was difficult to resolve, MGS would say, "Let's work on it for this long and if we can't break through, here's the stop point" in which the MGS controls department would take over to remain on schedule, according to Pangier.

Case in point: Nearing the deadline, there was an error in handling emergency stops with bad product in process. The source of the issue was a conveyor running through the checkweigher, which came from an outside supplier. "We found an error in that it could let bad product downstream. This required pulling in that supplier's engineering team in Europe to get them to understand what we wanted, but their solution was that we needed to expand everything by about four feet. Of course, there wasn't room to expand that much with walls on both sides," says Kostreba. "It was already built on our shop floor when this was happening. So our controls people used the CCS to monitor the safety network. We installed mechanisms to make sure that bad product never made it through. So we

↑ The Ambaflex Pouch Accumulation Module provides a buffer of material to absorb the imbalance in product flow.

↑ The Omega Stretch Banding Module combines serialized cartons into one stretch wrapped bundle.

↑ The MGS Central Control System offers central control and monitoring for the entire line as well as final integration of the Optel Serialization System.

solved the problem because their solution was going to take months and our solution took days."

Ultimately, MGS absorbed all the delays and challenges and delivered the machine a week early, during COVID-19.

Monitors save millions

Adding strategically placed monitors on the line may sound like a small add-on. But Kostreba estimates that the TV/monitor information display system they installed for another customer saves $26 to $52 million per year, based on the product running and time saved.

In a larger system, operators are working in various locations and don't necessarily have visibility into other areas. There can be considerable downtime caused by an operator who's stopped and assumes they're waiting on someone else when the issue is actually at their part of the system. Diagnosing takes time, too, in realizing there's a problem, and walking back and forth between HMIs and machines. Says Kostreba, "If you go in real operator speeds trying to figure out what's going on—not being an expert—it can take a minute and a half. We timed this just watching operators at a different facility. Every problem is different, of course. But when you take that one minute or a minute and a half saved on one stop, all you have to do is save five minutes an hour to get those millions saved on that specific customer's process. Five minutes per hour saved is pretty realistic. When you start having big machines, long distances to walk, and complicated mechanisms where you forget what's going on, or people stand and stare at something thinking it's not their problem, five minutes an hour is really easy to save."

The monitors give a line-level view of everything that's happening—machine data, errors—so operators can just look up. They are located in such a way that from almost anywhere in the room, they can see a monitor and know what's happening in other parts of the line. Saving even seconds on each error means big savings annually.

"So they naturally, by looking at the monitors, can kind of check each other. Every customer has a goal that they're trying to produce a certain amount of product and

our information display system helps them without having to walk around to know where they need to go in the system," says Pangier. After a while, when the machine stops, everybody looks up and immediately knows what to do.

Many people may not understand the value of such monitors right away. "I knew that it was something that would be of benefit, but I didn't realize how useful it would be and how the operators would respond to it," says Annesley. "Once the operators saw that it would allow them to understand about the other areas of the line, it just became the line that everybody wants to work on because they're informed, and the machine functions in a way that they can understand. That makes everybody's job that much more enjoyable because they're not confused and frustrated when they're working on a machine. That was when it clicked for me, even though this was a scope change and added cost, I realized this is really going to help these operators."

If people feel like they're productive and able to address issues—rather than being confused and frustrated—the end result is going to be higher productivity, which is the ultimate goal. (On a project for another customer, MGS had installed the carefully placed monitors on a second line. Operators clamored to work on that line, so much so that the customer retrofitted monitors on their first line as well.)

Collaboration for problem solving in real-time

Kindeva benefitted from MGS' collaborative approach to projects where engineering, sales, and machine builders all work hand-in-hand. Less emphasis was placed on titles—it was more about everyone at both companies working together to get the project done.

"When we had a couple of commodity problems such as getting materials into the facility, I dealt with a lot of people I wouldn't expect to in the procurement process. I texted somebody that worked at the factory to get a measurement for me—that was three minutes instead of three weeks of emails," Kostreba notes. "I met with one of Jeff's employees and the manufacturer of the labels about the adhesive. I was directly in contact with their vendor to handle label issues."

From an operator to a packaging engineer to someone responsible for the adhesive on the MDI labels, everyone had a seat at the table rather than having to have everything flow through Annesley, Kostreba, and Pangier to get distributed. Says Pangier, "Things get lost that way, so it would have taken much longer under a different format especially with a project of this magnitude. A lot of it hinges on how teams are structured and whether you've got that level of collaboration. It's not just about the equipment—it's the equipment, the process, and the people—and then putting that all together."

PACK EXPO Las Vegas Is Back

After more than a year of virtual events, the largest in-person and most comprehensive packaging and processing event in North America, PACK EXPO Las Vegas, will take place in September, co-located with Healthcare Packaging EXPO.

MELISSA GRIFFEN, CONTRIBUTING EDITOR

As the COVID-19 pandemic's grip loosens on society, in-person events are coming back, including PACK EXPO Las Vegas and the co-located Healthcare Packaging EXPO, which will take place Sept. 27-29 at the Las Vegas Convention Center. To keep all attendees and exhibitors safe, efforts are being put in place, with updated health and safety protocols that meet current government regulations and industry standards. PACK Ready—**PMMI**'s commitment to safety—provides a detailed list of protocols implemented by the Las Vegas Convention Center and show management.

With more than 1,500 exhibiting companies, the show produced by PMMI, The Association for Packaging and Processing Technologies, will welcome tens of thousands of people.

Through in-booth demonstrations and free education on the show floor, attendees will not only see technology in action and have the opportunity to talk with suppliers, they will also learn about best practices and industry breakthroughs.

Can't-miss seminars

Returning on all three days of the show are free, educational, 30-min **Innovation Stage** seminars, showcasing breakthrough technologies, best practices, and case studies, presented by industry experts. Topics will include processing; connecting your supply chain network to build resilience; sustainability in healthcare packaging; continuous improvement success (based on stories from 700 consumer packaged goods and food/beverage manufacturers); and Industry 4.0 and digital transformation best practices.

The interactive **Forum** will also be returning with 45-min sessions, which begin with short presentations on the latest industry trends delivered by topic experts and OpX Leadership Network members, followed by small group discussions with peers. Keep an eye out for the sessions listings online.

Bringing the healthcare industry together

A can't-miss is the Healthcare Packaging EXPO located in the Lower South Hall, offering the widest range of equipment and technology solutions for life sciences, serving as the only event with packaging and processing suppliers showcasing targeted solutions for pharmaceutical, medical device, nutraceuticals, and biologics alongside crossover solutions from related industries, such as food and beverage. Full-scale machinery will be on display with demonstrations throughout the hall along with the latest advances in packaging and processing within the pharma industry. Exhibitors will offer a range of solutions for the life sciences, including sustainable upgrades, anti-counterfeiting, cleaning and sterilization, temperature-controlled logistics, serialization/track and trace, and tamper-evidence.

Also at the show

The **PACK to the Future** interactive exhibit debuts this year, showcasing the industry's past, present, and future. It will display curated items and machinery from some of the world's largest CPGs and packaging companies. Industry experts, futurists, and business and financial leaders will speak daily on where the industry has been, where it is now, and what the future holds for packaging and processing. Sessions will be broken into 30-min increments on advancements such as artificial intelligence, sustainability, and more.

The **Reusable Packaging Learning Center**, hosted by the **Reus-**

For those who are unable to attend in person, PMMI now offers virtual aspects of the live event via **PACK EXPO Xpress**, where you can search for products and innovations in digital showrooms and connect with solution suppliers during the event no matter where you are. Visit hcpgo.to/xpress.

able Packaging Association, will show how implementing reusable packaging systems can improve material handling performance, reduce operating costs, create new economic values, and lower environmental impacts in the supply chain. The information will be conveyed in company presentations, product demos, case study findings, and industry panels.

The **Future Innovators Robotics Showcase,** sponsored by **Rockwell Automation**, will feature student teams from Las Vegas-area high schools demonstrating creations they designed and built, reflecting how the next-generation workforce is driving innovation. Come watch these fun demonstrations and feel free to ask questions.

Attendees are invited to download the free **PACK EXPO Las Vegas app** to organize their schedules, so they can participate to the fullest. It includes all the features of the My Show Planner on the PACK EXPO Las Vegas website at www.packexpolasvegas.com. The app allows users to create a personal itinerary for navigating the show by simply clicking on an exhibitor or session and adding it to their schedules, along with their personal appointments. Attendees can use the app to search for exhibitors by name, keyword, vertical market, or category, as well as search for educational sessions by venue or topic. The app includes interactive floor plans, exhibitor messages, event reminders, shuttle bus schedules, frequently asked questions, news, and notifications.

The registration fee, which includes access to both PACK EXPO Las Vegas and Healthcare Packaging EXPO, is $30 until Sept. 3, after which it increases to $130. For more information and to register online, visit packexpolasvegas.com.

Connect with Women in Packaging and Processing

The Packaging & Processing Women's Leadership Network (PPWLN) breakfast takes place Tuesday, Sept. 28 from 7:30am to 9:00am. Everyone has had to work differently over the past year due to the pandemic, but COVID-19 was a tipping point for some other transformations occurring behind the scenes. Specifically, a transition to digitalization and more automation on the plant floor, the push for workforce diversity and gender parity, as well as a new generation (Gen Z) who are starting their careers as digital natives and care passionately about the earth and equality. Hear from a panel on this "new world of work." PPWLN is sponsored by **Emerson**, **ID Technology**, **Morrison Container Handling Solutions**, **Plexpack**, **Septimatech**, and **SMC**.

Booth Listings

Healthcare Packaging EXPO exhibitor listings as of August 6, 2021. For all PACK EXPO exhibitor listings, visit www.packexpolasvegas.com

Company Name	Booth
Actionpaq Corporation	SL-6266
Adhesive Products Inc.	SL-6208
Alconox Inc.	SL-6523
All Packaging Machinery Corp.	C-3609
Amcor Healthcare Packaging	SL-6631
American Carton Company	SL-6709
AmeriPak	SL-6632
AmeriVacS	SL-5810
AMETEK MOCON	SL-6465
AMRI	SL-6745
AZCO Corporation	C-2528
Antares Vision	C-3938,SL-6502
APPS Inc.	SL-6801
ARCO	SL-6533
Arvato Systems NA	SL-6711
ATC By Pfeiffer Vacuum	SL-6920
AWS Bio-Pharma Technologies, LLC	SL-6805
Axicon	SL-6919
Aylward Enterprises, LLC	SL-6704
AZCO Corporation	C-2528
Backer Marathon, Inc.	SL-6476
Badger Plug Company	SL-5846
Banner Engineering Corp.	SL-6008
BAUSCH Advanced Technology Group	SL-6639
Bedford Industries, Inc.	SL-6332
Belden	SL-6520
Bell-Mark Sales Company	C-2109
Bergami USA	SL-6727B
BEUMER Group	SL-5817
Bihl+Wiedemann, Inc.	SL-6160
Bimba Manufacturing Company	SL-6153
Bosch Rexroth Corporation	C-5214
Bottling-Experts (BEXP)	SL-6715
Brenton	C-3225
Brooks	SL-6565
BUNTING	SL-5917
CAM Packaging Systems	SL-6107
Carlo Gavazzi Inc.	SL-6438
CAVU Group	SL-6728
CDA USA Inc.	SL-6521
Chase-Logeman Corporation	C-4636
Chroma Color Corporation	SL-6263
Clearwater Paper	SL-6558
Cognex Corporation	SL-6156
Colamark USA	SL-6622
Colbert Packaging Corporation	SL-6629
Columbia Machine, Inc.	C-2838
Columbia/Okura	C-2838
Com-Pac International, Inc.	SL-6621
CompanyBox	SL-6751
Controls Engineering	SL-6714
Countec Co., Ltd.	SL-6529
Coval Vacuum Technology, Inc.	SL-5838
CURTI USA CORPORATION	SL-6740
DA Technology INC	SL-6922
Delta Modtech	C-1617
Desiccare, Inc.	SL-6458
Do-It Corporation	SL-6468
Domino Amjet, Inc.	C-3825
Doran Scales, Inc.	SL-5842
Dorner	C-1455
DPSS Lasers Inc.	SL-6517
Dude Solutions	SL-6654
DVP Pumps, Inc.	SL-5870
Dycem Corp	SL-6910
Eagle Flexible Packaging	SL-5805
EFP LLC	SL-6903
Emerson	SL-6307
Encoder Products Company	SL-6440
Esco Technologies	SL-6640
ESS Technologies, Inc.	SL-6633
Extrutech Plastics, Inc.	SL-6914
Fette Compacting America, Inc.	SL-6610
FILAMATIC	C-2216
Formost Fuji Corporation	C-4000
FOX IV Technologies, Inc.	SL-6301
FP Developments, Inc.	SL-6901
Franz Ziel USA Inc.	SL-6731
Fromm Packaging Systems	SL-6620
GBA Builders	SL-6646
GEA	SL-6314
Good Natured Products Inc.	SL-6727A
GrandBell Co.,Ltd	SL-6481
Greener Corporation	SL-5834
groninger	SL-6507
Hapco Inc.	SL-6708
Harpak-ULMA Packaging, LLC	SL-6101
Harro Hofliger, Inc.	SL-6701
HDG Verpackungsmaschinen GmbH	SL-6368
Heat and Control, Inc.	C-1623
Heinlein Plastik-Technik Gmbh	SL-6720
HERMA US, Inc.	SL-6608
Herrmann Ultrasonics, Inc.	SL-6056
Hishi Plastics U.S.A., Inc.	SL-6057
Hoosier Feeder Company	SL-6403
Illig Maschinenbau Gmbh & Co. KG	SL-5963
Imperial Printing & Paper Box Manufacturing Co.	SL-6812
INOVINOX USA, LLC	SL-6504
Integrated Packaging Systems	SL-6556
Isolation Systems, Inc.	SL-6912
ITHPP	SL-6645
J.W. Winco, Inc.	SU-7458
Kaneka Biopolymers	SL-6923
Key International, Inc.	SL-6525
Keystone Package Testing	SL-5857
Klockner Pentaplast, Health & Protection and Durables	SL-6734
KOCH Packaging Systems, Inc.	SL-6364,SL-6601
KOMP-ACT SA	SL-6756
Körber	SL-6549
Lenox Laser	SL-6817
Lifoam	SL-6753
Liveo Research Inc.	SL-6554
LLumin, Inc.	SL-6011
Longford International Ltd.	C-4444
Luciano Packaging Technologies, Inc.	SL-6722
M.O. Industries, Inc.	SL-6717
M&O Perry Industries	SL-6907
MACTEC Packaging Technologies LLC	SL-6732
Marchesini Group USA Inc.	SL-6535
Mariani S.r.L.	SL-6636
Medical Packaging Inc., LLC	SL-6739
Meech International	SL-6470
METTLER TOLEDO	C-1814
MG America, Inc.	SL-6614
MGS Machine Corp.	C-4400
MHI - Maruho Hatsujyo Innovations	SL-6738
Middleby Processing & Packaging	SL-6002
Mitsubishi Electric Automation, Inc.	SL-6661
Morrison Container Handling Solutions	C-1851
MULTIPOND America Inc.	SL-5969
Multivac, Inc.	SL-6349
National Gear Repair	SL-6905
New England Machinery, Inc.	SL-6514
Nielson Scientific LLC	SL-5844
NJM Packaging C-3514,	SL-6501
Nulogy	SL-6916
Nutec Systems Inc.	SL-5925
Nutra-Pack Systems	SL-6536
OFF. MECC. BOLONDI IVANO	SL-6510
Omron	SU-7537
Optel Group	SL-6606
OPTIMA Pharma	SL-6748
Ossid	C-3014
Oxford Lasers Inc.	SL-6921
Pack3000	SL-6537
Packaging Digest	SL-6904
Packworld USA, Ltd.	SL-6410
Pacmac Solution Pvt Ltd	SL-6915
PallayPack Inc	SL-6719
Paper Machinery Corporation	SL-5914
Paxiom Group Inc.	C-1823
Paxxus	SL-6256

BOOTH LISTINGS

Company Name	Booth
Performance Feeders, Inc.	SL-6437
Perlen Packaging AG, Perlen	SL-6516
Pharmapack North America	SL-6802
Pharmaworks LLC	C-3414,SL-6501
Phoenix Engineering	SL-5800
PKB	SL-6531
Planar Motor Inc.	SL-6564
PMMI	Central Lobby
Preco, Inc.	SL-6909,SU-7241
Premier Plastics, Inc.	SL-6532
ProAmpac	SL-6135
Prodieco & Natoli Engineering	SL-6619
Prosys Innovative Packaging Equipment Co.	C-3844
QT9 Software	SL-6712
QuickPouch	SL-6755
Rasco Industries, Inc.	SL-6540
Rollstock Inc.	SL-5823,SL-5825
Romaco Group	SL-6702
Sarg S.r.L.	SL-6750
SATO America	N-11007
SEA Vision USA	SL-6534
Secomea Inc.	SL-6026
SensoScientific, Inc.	SL-6723
Serpa Packaging Solutions	C-3418,SL-6501
Sesotec Inc.	SL-6331
Shawpak	SL-6563
Shibuya Hoppmann	SL-6233
Shred-Tech	SL-6526
SMAC-MCA	C-1962
SOLOMON Technology Corporation	SL-6257
Somic America, Inc.	SL-6460
Sonoco TEQ, LLC	SL-6506
Span Tech, LLC	SL-6125
Spartech	SL-6913
Spectrum Solutions	SL-6725
Spee-Dee Packaging Machinery	C-2607
Starview Packaging Machinery Inc.	C-3436
Steriline S.r.l	SL-6746
Steven Label & Robinson Printing	SL-6726
Syntegon Packaging Technology, LLC	C-2800
Tapeswitch Corporation	SL-6729
Technoflex	SL-6924
Tedelta North America LLC	SL-6560
Teufelberger Ges.m.b.H.	SL-6807
ThermoPod, LLC	SL-6811
Thomas Packaging LLC	SL-6611
Tolomatic, Inc.	SL-5836
TOPS® Software Corporation	SL-5814
Toss Machine Components, Inc	SL-6410
Totani America, Inc.	SL-6509
Uhlmann Packaging Systems L.P.	SL-6601
Ultrasource LLC	SL-6337
Unitech Srl	SL-6029
Universal Machine and Engineering Corporation	SL-6512
Universal Pack, S.R.L.	SL-6736
Valley Grinding & Mfg. / Mario Cotta America	SL-6721
VC999 Packaging Systems Inc.	SL-5935
Vecna Robotics	SL-5866
Viscotec	SL-6511
VISIOTT TRACEABILITY SOLUTIONS	SL-6710
Vorne Industries	SL-5903
Weber Packaging Solutions, Inc.	C-2430
Weiler Labeling Systems	C-3518,SL-6501
WIPOTEC-OCS, Inc.	SL-6106
Witko Inc.	SL-5850
Wittenstein	C-4606
Wrapade Packaging Systems, LLC	SL-6615

↙ Adoption of AI in validation and other processes, including data collection and management, can result in valuable predictive qualities within a manufacturing facility.

Data and AI Accelerate Digital Transformation in Pharma

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Manufacturers must focus on replacing paper with data through digital transformation.
2. Starting small is the way to approach digital transformation, keeping the end state in mind.
3. Artificial Intelligence will allow for robust real-time processes and predictive qualities.

As the name implies, "Pharma 4.0" is Industry 4.0 applied to pharmaceutical manufacturing, which is the addition of cyber-physical systems to computerize manufacturing while focusing on the human element. The concept has been gaining traction in recent years and was a common theme in the 2021 Parenteral Drug Administration (PDA) Annual Meeting.

The four pillars of Pharma 4.0, as explained by Gilad Langer, Industry Practice Lead at **Tulip Interfaces,** a digital technology provider, are:

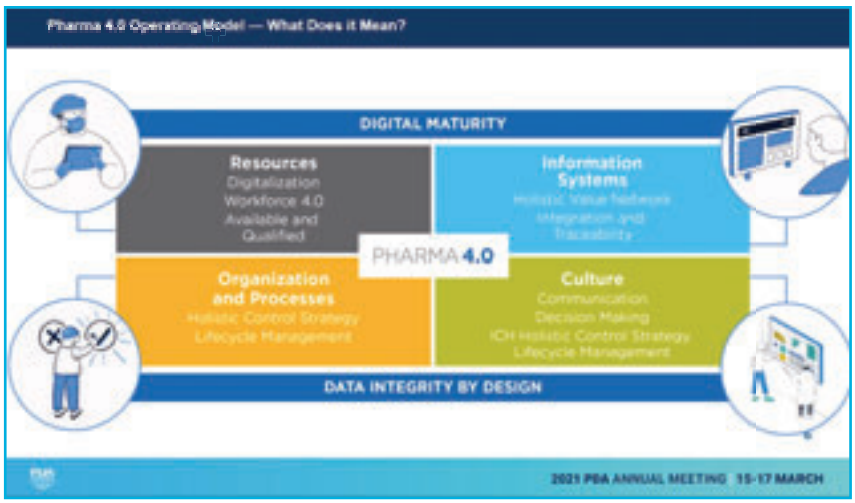
- Resources
- Information Systems
- Organization and Processes
- Culture

These pillars focus on digitization, digitalization, and the human element. Further, Pharma 4.0 allows for the democratization of technology. In other words, what once was available only to experts is now available to the general workforce. The shift to this democratization can be eased through the new generations entering the field, who are all but raised on technology, making them what Langer called "digitally native." Yet, the pharmaceutical industry is not taking full advantage of these advancements.

One of the main facets of the Resources pillar is digital transformation which centers on real-time data and information to increase productivity, enable machine operators to do their jobs more efficiently, and further allow the use of predictive technologies, augmented reality (AR) and virtual reality (VR), Big Data, artificial intelligence (AI), and machine learning (ML). It allows for connectivity through integrated systems, equipment, people, and other software systems; real-time visibility into operations; transparency for quicker reaction time; and, at its highest levels, predictability and self-optimization in that the system can predict the outcome of a batch or machine's performance and self-correct. In this kind of environment, apps, smart sensors, or the Industrial Internet of Things (IIoT) are used as a means of first capturing the data from the floor, which is then transferred to the cloud, available for use. (For more on predictive maintenance, see pp. 41.)

Replacing documents with data

Thus, a focus of digital transformation is replacing the use of paper as a means of data collection. Paper is cumbersome and



↑ These pillars focus on digitization, digitalization, and the human element.

↑ Organization and Processes need to become digitally native, and continuous improvement is at the core of this transformation.

time-consuming, placing additional unneeded demands on the workforce, yet factories–and especially those in pharma–still rely heavily on its use.

Referencing the Pharma 4.0 pillars, Langer pointed out that digitally native workers come into the workplace only to be brought into a Culture which teaches them to use Organization and Processes that are centered on paper. This is a waste of ability to help transition into the digital era and serves only to create a workforce gap.

At the same time, digital transformation is not one large operational problem to be tackled at once, but rather is made up of a multitude of small changes facilities can make which don't take as large of an investment to fix, according to Langer. The Organization and Processes need to become digitally native, and continuous improvement is at the core of this transformation.

Langer envisions this process taking a number of years to fully accomplish, with one foot on each side of "the digital divide." This paradigm shift to digital data will happen gradually, requiring the industry to switch from its current document mindset, and it is

Artificial Intelligence Implemented in Regulatory

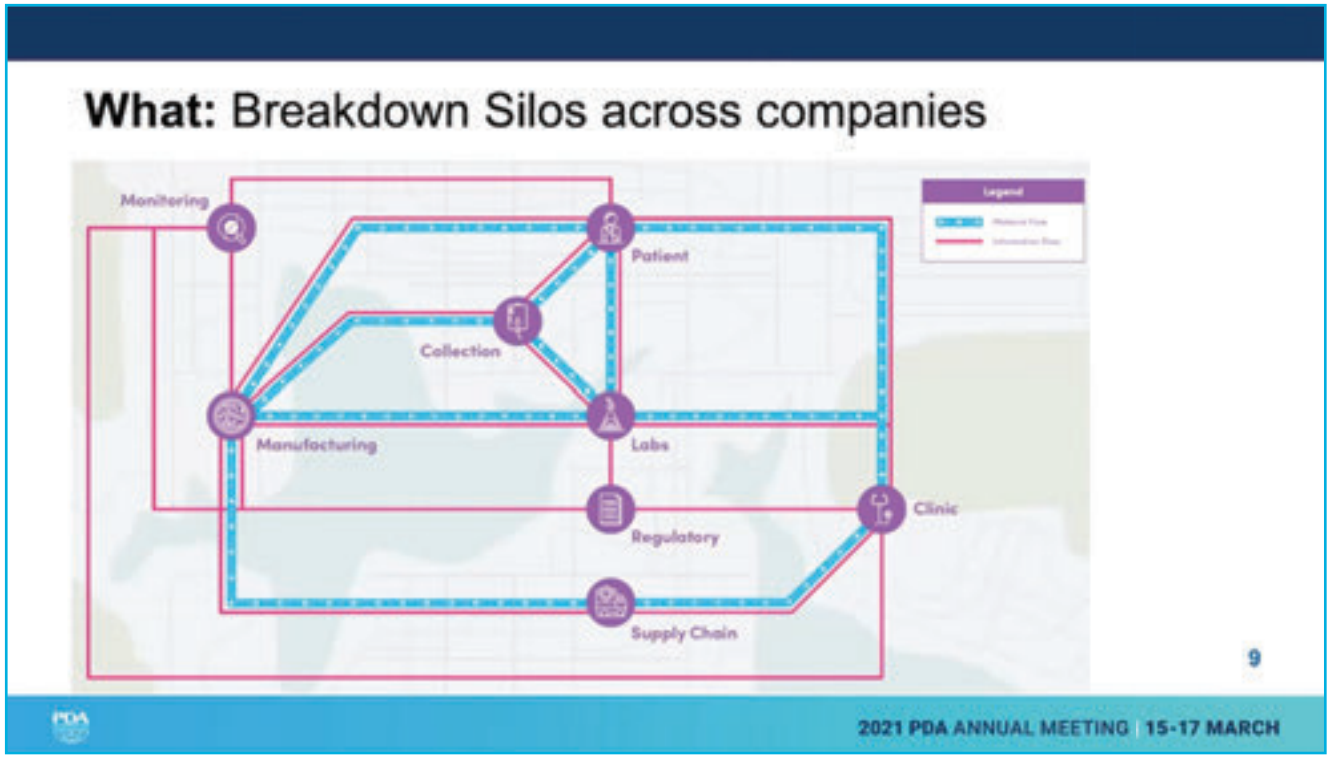
Jerry Chapman, Senior GMP Quality Expert at **Redica Systems** (Redica), explained that meeting regulatory requirements and business demands is often hindered by the complexity of facilities, supply chains, products, and especially evolving regulations. Redica provides an integrated set of data inspection enforcement documents that includes all FDA inspected and registered sites since 2000.

By mining enforcement data, such as in 483 observations and FDA warning letter citations, companies can better understand and meet the changing expectation of regulatory agencies. Redica uses proprietary AI expert models, built using machine learning and honed by industry experts, to do the heavy lifting for companies, saving them time and helping them better meet their facilities' needs.

The AI expert models are created to facilitate analyses which can then be used for (1) inspection preparation, (2) tracking and trending inspection observations, and (3) finding observations and citations "hiding in plain sight" within the deficiency descriptions of warning letters.

An expert model cleans up documents, putting them through optimal character recognition and proofing them to give a company a proper data set. The documents go through processes that break sentences down into n-grams–or the continuous sequence of words–better allowing the AI to understand the content.

The n-grams are then organized based on the FDA's six GMP classification categories along with data integrity, which is becoming increasingly important. Running the expert model allows companies to figure out what is non-conforming in the facilities and why. Redica has expert models for medical devices, clinical trials, APIs, human cell and tissue/GTP, and more. Some of these models are still being tested.



↑ **Unified platforms would simplify the collecting and sharing of data between departments and companies and eliminate complex, redundant systems.**

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Data and Risk Management in the Drug Supply Chain

Problems occurring in the supply chain affect the rest of the chain downstream and can result in drug shortages. The disruptions caused by the pandemic only widened the supply chain's gaping holes. Digital transformation, as aforementioned, makes data readily available, which allows for risk management, and must be supported by integrating emerging technologies and related implementation approaches to drive rapid transformation and equip teams for ongoing innovation.

never too late to start.

"What we want to do is create digital content that is human-centric for one small problem at a time," said Langer. He went on to explain a few examples applied with a set of technologies called no-code apps or digital content. "Basically, all of your engineers, all those who are within the operational domain of your manufacturing plant, can use something that feels like and looks like a PowerPoint to create these digital sets." They do this by logging events, creating data sets that can then be stored in the cloud in a way that will allow advanced algorithms like AI and ML to use the data.

More sophisticated ways to capture data—such as work order terminals that interact with an ERP to get input on work orders on the floor, and batch processing and recording, capturing batch record data—can be used, though simple checklists on mobile devices, simple deviation/exception recording on a laptop or tablet, and especially digital logbook solutions are also effective.

Digital logbooks run operators through simple screens on interactive apps with built-in quality checks and built review-by-exception. Langer suggested incorporating digital logbooks as a simple way to introduce digital transformation to the floor along with batch records. Data entered in is displayed in tables, graphs, charts, and other familiar formats, which are easily consumed by advanced algorithms. This data is simple and transparent and does not require

sophisticated databases.

AI, Blockchain, and robotics are the most transformative technologies that promise to change the way businesses and industries operate, particularly in management of supply chain. These technologies help support adaptation to demand and performance fluctuation which can happen overnight and easily get out of control.

CGI, an IT and business consulting service firm, offers a unified platform powered by a concept called Connected Quality, intended to offer greater visibility with a real time wholistic view of the entire supply chain. This would allow a company to bring its supply chain management together and support predictive decision-making and advanced mitigation of issues.

Connected Quality is the concept of having unified, harmonized global systems and processes. It's ensuring the right data is collected. An RPA platform is limited to having proper data sets that have been mastered and are consistent as RPA bots work off of repetitive data or administrative tests. Large, high quality data sets are required to apply ML or AI to the layer of your systems, so that the bot can learn properly and give best results.

Managing your data

Vasu Rangadass, CEO of software solution provider **L7 Informatics** (L7), Inc, agreed with Langer, that starting small is the way to approach digital transformation though the end state needs to be kept in mind. Otherwise, as Rangadass put it at the PDA event, the process will be like putting together a puzzle without knowing what it should look like in the end, which only wastes time and resources.

Rangadass went on to explain that digital transformation requires a clean set of data. The traditional way of collecting data is to gather it from all sources and put it into one single database as a system of reference. But this creates "digital silos," which then require validation and as companies merge, are acquired, and receive new products, this leads to complications with outdated data. This results in high IT expenses as IT maintains various complex, redundant systems. Unified platforms would simplify the collecting and sharing of data between departments and companies and eliminate those complex, aforementioned redundant systems.

Unified platforms have common data models, codes, tooling, architecture, and a common business process that spans capabilities across departments and companies in order to provide greater process intelligence all from one system that offers the applications needed.

L7's ESP software solution has taken on concepts from Robotic Process Automation (RPA) composable unified platforms with an FDA regulatory compliant framework, which is applicable to the manufacturing scene. Applying such a digital solution can take anywhere from three to nine months, said Rangadass, depending on the complexity of the process, the quality control (QC) process, and the manufacturing process. When a system has become digitized, the application speed increases. L7 customers tend to start the digitalization process with QC and batch records.

"We want to remove barriers to connectivity. We have connectors to 150 different wire process equipment, environmental monitoring systems, software systems, etc. These connectors play an important part, and we package them as part of the platform to reduce any kind of impedance for customers," said Randagass. "While connectors are very easy and cheap to build, not having them in one place is a challenge, so we package all the connectors so customers can easily deploy the platform and that gives them contextualized data whether it's environmental or from the wire process equipment."

Validation and the regulatory aspect

L7's efforts towards regulatory compliance with ESP span to its creation as a Good Manufacturing Practice (GMP)-compliant platform, which can be up to 80% validated, meaning that customers need only drop in their processing and validate the last 20%.

Langer further pointed out that if companies choose a vendor in the GMP space, their platforms will come pre-validated, and from there they could build on the platform with no-code apps. Validation for no-code is also different from software validation in that it must be validated based on intended use, as in the end:

- The apps are instruments in processes for capturing data.
- That data will prove the results, which further proves the companies are in control of the data and that they are complying.

Toni Manzano, CSO and Co-Founder of **Aizon**, an AI platform provider, added to this by explaining that the way to validate software with cloud web browsers has completely changed as technology has continued to evolve and we cannot make the assumptions once made about classical software.

"The FDA is even moving from classical computer system validation to computer system assessment where documentation is not the base of the pyramid. Risk assessment is now the base of the pyramid so you can see that everything is changing but you can assess the risk and act accordingly," said Manzano. He explained that principle component analysis (PCA) can be used as a classic algorithm to find relationships between variables within data, but AI must come into the picture in order to make robust real-time processes to keep product manufacturing under statistical control. This involves critical factors that affect processes and which further rely on feedback from the floor, supplying data to run the AI and determine that it is working properly.

"Technology has come a long way in the last several years and will dramatically reduce the cost of information technology to use new platforms," said Rangadass. "Digital transformation is necessary to reduce costs and increase the speed of drugs to market."

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GSK's Head of Sustainability on Advil Bottles' 20% Plastic Reduction

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. The new material will reduce the amount of plastic in the environment by nearly 500,000 pounds annually.
1. The technology was seven years in the making, and is being evaluated for use in other applications.
3. GSK is also ramping up installation of on-site solar energy generation where conditions allow, including Nairobi and Brazil.

It's no secret that consumers are demanding environmentally friendly products and packaging, and this includes over-the-counter (OTC) medications. In April, GSK Consumer Healthcare announced its commitment to reducing the plastic in over 80 million Advil bottles by 20% (annual volume), which the company reports will result in a reduction of nearly 500,000 pounds of plastic in the environment annually.

The updated bottles have already begun hitting retail shelves in the U.S. The Advil portfolio will have transitioned by 2022 online and on retail shelves nationwide, with the exception of Advil "easy open" bottles. "The first focus has been to do this in the U.S. because that's where we have our biggest Advil business and where we can create the biggest impact in terms of saving plastic," says Sarah McDonald, Vice President of Sustainability at GSK Consumer Healthcare. "So that's been the first focus, and then we'll move onwards from there to other geographies."

Healthcare Packaging spoke with McDonald (virtually) to discuss the project, goals, and more.

Resin technology

GSK says the initiative is a first-of-its-kind sustainable plastic technology for OTC medicines. This new barrier resin technology reduces the amount of resin required to mold and craft the high-density polyethylene (HDPE) bottles, while maintaining the same barrier protection properties. HDPE is recyclable in the #2 stream in the U.S.

This is accomplished via a nucleating agent added into the resin itself—GSK worked with **Dow** and **Milliken** on the materials side and **Alltrista Plastics** on the component manufacturing side. "We have a bi-modal HDPE resin and by adding this agent, it allows us to reduce the quantity of plastic that we use to make the bottles while maintaining the same protective barrier qualities," explains McDonald. "This means we don't need a discreet barrier layer so it does not impact recyclability."

This material change allows for a 20% reduction in material usage for HDPE bottles while maintaining all critical performance characteristics of the bottle. Alltrista molds bottles via compression blow forming (CBF)—GSK did not have to purchase new machinery. (CBF continuously extrudes plastic, cuts it into "clumps", and transfers the clumps into compression cavities where they are pressed into preforms and stretch-blown into finished bottles.)

"The success of our reduction is a combination of materials and more accurate molding using CBF, which allows for even distribution of the remaining resin," explains Edward Candelaria, Technical Lead for the project and Director of Packaging Technology CH Americas at GSK. Unrelated to the resin change and CBF, GSK also implemented an 11% reduction in the weight of the caps (the process and materials remained the same).

McDonald says, "It required considerable testing to reach confidence that we were hitting the reduction we wanted and also the level of protection we needed. It also needed a lot of testing to make sure we were confident in passing regulatory requirements. It was about seven years of work behind the scenes together with our partners on the materials side and on the manufacturing molding side."

"We're really pleased to get this on the market and proud of the work from our partners as well. We couldn't have achieved this without our partners, Dow, Milliken, and Alltrista. It was a team effort, and we're very excited to see this coming through onto shelf because consumers more and

↖ **A material change allows for a 20% reduction in material usage for HDPE Advil bottles while maintaining all critical performance characteristics of the bottle.**

more want products that use less plastic—they're very conscious of their footprint and want plastics that are recyclable. There's lots more to come, but we're excited that it's coming through onto the shelf now in the U.S. in Advil's biggest market," she notes.

Speaking of consumers, communicating sustainability improvements is key. "Initially because it's going to take some time for the change to flow through onto shelf, communication that's happening now and around Earth Day is digital," she says. "So there is banner advertising on our partner retailers' sites and communication on advil.com. Then as more of the reduced-plastic bottles flow through onto shelves we will then communicate in-store to highlight the change. Obviously we want to do that when there's a critical mass of the updated bottles on shelf in-store."

Other future goals

The new sustainability goal set by Advil is part of GSK's broader ambition to reduce its plastic footprint by 8,000 tonnes annually and for 100% of packaging to be recyclable or reusable where quality and safety permit.

The plastic and packaging focus is informed by requirements set by the Ellen Macarthur Foundation—GSK joined the Ellen MacArthur Network in 2020. "With the new technology available to us, we saw this as an opportunity to invest in the future of our brands and sustainability goals. Advil's switch to the new 20% less plastic bottles uses a first-of-its-kind sustainable plastic technology for over-the-counter (OTC) medicines and kicks off a series of plastic reduction initiatives across the product portfolio at GSK," says McDonald.

In addition to the 8,000 tonne reduction, they're currently looking at how they can use this resin technology in other places. "A lot of development has gone into it and it's a really great technology given the three-way benefits: less plastic, same barrier properties, and no impact to recyclability," she says. "So we're looking at where we can use this in other places, as well as pursuing other ways of reducing or taking out plastic."

Another focus for GSK is in boosting renewable energy usage, including on-site electric-

ity generation where conditions allow. In 2020, GSK announced new environmental sustainability goals in both climate and nature, "aiming to have a net zero impact on climate and a net positive impact on nature by 2030," per the company.

"By 2030 we aim to use 100% renewable electricity in our manufacturing sites, and there's a whole program happening in our supply chain towards that goal," says McDonald. "In some sites, there is investment happening in renewable power generation directly on-site with installations of solar panels. But obviously that depends on the conditions on the site, whether there's space and whether there is sufficient sunshine to make the installation viable." A few developments of such sites include:

- GSK's Cape Town on-site solar electricity generation went live in Feb. 2020.
- The company's Nairobi on-site solar is scheduled to go live in May 2021.
- A site in Brazil is planned to go live in 2021.

The company has a rolling program where they are investing in on-site capacity. Concurrently, there is work happening with purchase agreements to source renewable electricity where on-site generation isn't possible.

As the Nov. 2020 announcement highlighted, GSK is making the connection between protecting and restoring the planet's health, in order to protect and improve people's health. McDonald concluded, "As a world leader in consumer healthcare, we at GSK are proud to transition Advil to a more environmentally friendly packaging, further supporting GSK's commitment to sustainability."

Seeking sustainable packaging? PACK EXPO Las Vegas and Healthcare Packaging EXPO (Sept. 27-29, Las Vegas Convention Center) will reunite the packaging and processing community. Attendee registration is now open. Visit: packexpolasvegas.com.

Sustainable Derivatives

Additionally, as part of their 2025 sustainability commitment, GSK also joined the Action for Sustainable Derivatives (ASD), which aims to increase the transparency and traceability of palm oil derivatives' supply chains. While the company is not a big consumer of palm oil compared to other CPG players, they've collaborated with ASD to introduce the Sustainable Palm Index (SPI), an evaluation scorecard for suppliers of palm oil and palm kernel oil derivatives, intended to support procurement decisions.

Predictive Maintenance Pain Points in Packaging Machinery

KIM OVERSTREET, SENIOR CONTENT STRATEGIST, ALIGNMENT, PMMI MEDIA GROUP

TOP THREE TAKEAWAYS

1. Predictive maintenance can help avoid unplanned downtime.
2. Some packaging machines are more "downtime-prone" than others.
3. Washdown areas represent an additional challenge.

Predictive maintenance is the ability to monitor a machine, or machine component, and avoid unplanned downtime by foreseeing machine failure and allowing the opportunity to take preventative action. The possibility of machine failure shutting down a production line ranks high on most manufacturing managers' list of worries, and report research showed that manufacturing managers at CPG companies consider their packaging machines to be more prone to downtime than the other types of machines they use.

According to **PMMI**'s *Packaging and Predictive Maintenance*, most of the predictive maintenance solutions currently on the market are designed to monitor critical assets such as AC induction motors, pumps, and gearboxes; and they tend to be based on vibration sensor solutions.

You May Be Interested: OpX Asset Reliability Roadmap

Optimizing your company's current investment in existing production equipment is a widely shared goal among those in the manufacturing space.

PMMI's OpX Leadership Network recently commissioned an Asset Reliability Solutions Group to undertake a work product on asset reliability in order to get brand owners and OEMs on the same page regarding definitions, key performance indicators (KPIs), calculations, and leadership guidance when developing an asset reliability initiative.

For this free download, visit: hcpgo.to/asset.

The critical functions of packaging machinery, however, tend to be under servo control, even though many machines do employ standard AC motors. Servo technology does not lend itself to vibration monitoring, so OEMs are currently using thermal imaging to gather necessary data on servo systems. It is expected that in the future, predictive maintenance opportunities will be built directly into the servo drive, allowing for standard predictive maintenance solutions to be applied.

Some types of packaging machinery are more prone to downtime than others, and CPGs reported interesting results with regard to which are most likely to break down. In the "extremely likely" category, form, fill & seal machines were reported in the lead—with 14.3% of manufacturing managers at CPG companies rating them as extremely likely to suffer downtime. Next reported in the "extremely likely" to fail category are labeling, decorating, and coding machines—which were placed in this category by 13.3% of respondents.

Interestingly though, when the three categories of "likely to fail" (extremely, moderately, and slightly) are aggregated, labeling, decorating, and coding machines come out in the lead as the least reliable type of machine; while form, fill & seal (f/f/s) machines only make it into third place.

There were seven causes reported by respondents as the most common cause of packaging machine downtime. Within these seven leading types of downtime, three rated higher: general wear and tear (26.3%), operator error (21.1%), and product changeover (22.1%). Of these three, the only one that clearly could not be addressed by predictive maintenance is operator error.

Machines that are used to package multiple types of items and require a changeover of parts when switching between products were also mentioned as a problem area for respondents, and according to the report, "there is a clear and definite need for OEMs to work with predictive maintenance specialists to design bespoke predictive maintenance solutions that can monitor the product changeover process."

One other specific area with a need for predictive maintenance solutions is in washdown areas. Predictive maintenance features based on vibration sensing can become dislodged by high pressure water washdown processes, and companies who want to implement predictive maintenance in washdown areas need to ensure that they find a predictive maintenance partner who understands their specific needs.

Download PMMI Business Intelligence's *Packaging and Predictive Maintenance* report by visiting: hcpgo.to/predictive.

↑ The types of packaging machinery most likely to fail, as reported by CPGs.

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Salary Confidence Cautiously Returns

MATT REYNOLDS, EDITOR, *PACKAGING WORLD* WITH KEREN SOOKNE, DIR. EDITORIAL CONTENT

Are we there yet? Is it safe to say we're emerging from the uncertainty of a pandemic into the (forgive the now-cliché) new normal? Are we recalibrating to adjust to what global consumer trends monitor Mintel calls the "next normal?" If the results of the annual Institute of Packaging Professionals (IoPP) Salary Survey are any evidence, the answer seems to be "almost." Uncertainty is diminishing, and confidence is returning. We're on the downslope, but we fully aren't there yet.

Getting down to brass tacks, overall reported salaries rebounded slightly in this year's reporting, up 5.7% after a dip last year. But only a little more than a third of this year's 828 respondents also took the survey last year, with another quarter who may or may not have (they don't recall). The remainder absolutely didn't take it last year.

Since people are mostly different, the reported salary number is less of an indicator of what's happening than the reported change in salary. We're looking for change velocities more than dollar figures. And according to this year's crop of respondents, fewer people this year reported having received a traditional salary increase last year (63% in 2020 compared to 73% in 2019). Not surprisingly in a pandemic year, pharmaceutical respondents edged out others with 74% receiving increases.

Expectations for future traditional salary increases are flat from last year (71% expected to earn more in the coming year in both last year's and this year's results). But the number of people worried about making less in the coming year dropped from 8% in last year to 5% this year, a hint of relief of anxiety. (However, 19% of nutraceutical respondents reported fears.) It feels like we're on the cusp of returning to normalcy.

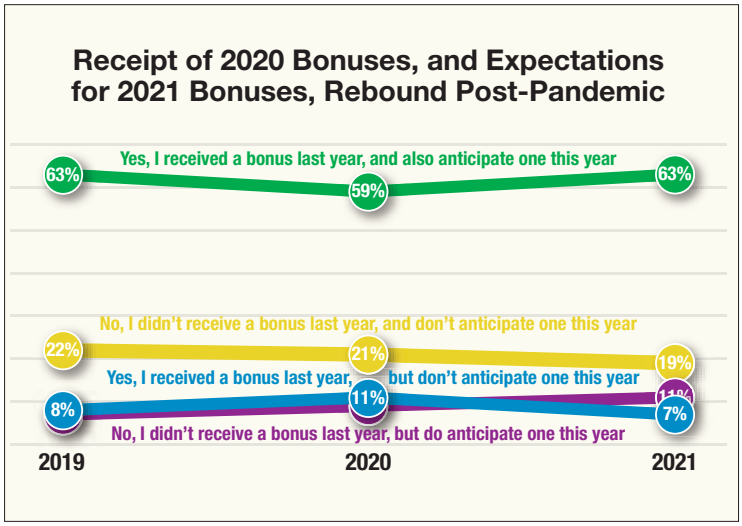
Another hint of this is in bonuses. Last year, when responding at the outset of the pandemic, respondents were more worried about not receiving bonuses in 2020. But it looks like some of those worries were unfounded, with more people actually having received bonuses in 2020 than had expected to. Across all industries, 63% of respondents said they received a bonus in 2020 and expect to receive one this year. Among the 147 pharma, medical, and nutraceutical respondents, that number was over 71%. And more people this year expect to receive bonuses than did last year, another hint of greater

What Keeps You Up At Night?

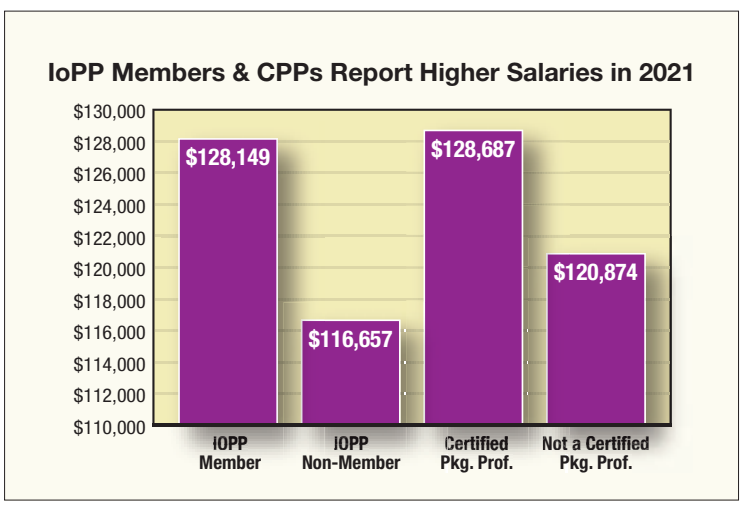
Survey participants were asked to comment on the one thing that kept them up at night regarding job security. 605 of the 828 total respondents weighed in, and this is what they had to say…

2021 Category	Percentage	Count
Nothing	15%	92
Stability (company)	14%	85
Job loss	12%	74
COVID	8%	48
Stability (industry)	7%	44
Economy	7%	40
Personal Performance	6%	37
Regulations/Policy	6%	35
Undefined	5%	28
Personal Compensation	4%	24
Ageism & continued relevance	4%	24
Staffing/Staff shortage	3%	21
Health/Mental health	2%	11
Opportunities for growth	2%	11
Uncertainty	1%	8
Automation	1%	8
Competition	1%	6
Management	1%	5
Job satisfaction	1%	3
Sustainability	0%	2
Total	100%	605

Source: Institute of Packaging Professionals 2021 Salary Survey



Fears of Missing Bonus Unfounded. Last year's results revealed a 4-percentage point reduction (from 63% in 2019 to 59% in 2020) in the number of people who both received a bonus last year (2019) and expected one this year (2020). Now, in 2021, it appears that number has rebounded back to 63%, indicating that while traditional salary increases were stagnant, fears about not getting a bonus were unfounded. This is further supported by the 4-percentage point reduction (from 11% in 2020 to 7% in 2021) in people who got a bonus last year (2020), but don't anticipate one this year (2021). Perhaps this hints at some companies being sure to keep single-year bonuses in the compensation structure in 2020, while not committing as readily to more permanent traditional salary increases.



IoPP, CPP Bump. Once again, IoPP members reported higher salaries than non-members, and Certified Packaging Professionals (CPPs) earned higher salaries than their non-certified colleagues.

Remember, the average respondent regardless of IoPP affiliation earned 5.77% more than they did the previous year. That's why it's noteworthy that IoPP members earned 7.7% more than the previous year, beating the overall average, while IoPP non-members only earned 4.0% more than last year, trailing the overall average.

confidence. Notably, a common tactic for businesses in uncertain times is to maintain compensatory continuity in the form of single-year bonuses instead of more permanent, lasting salary increases.

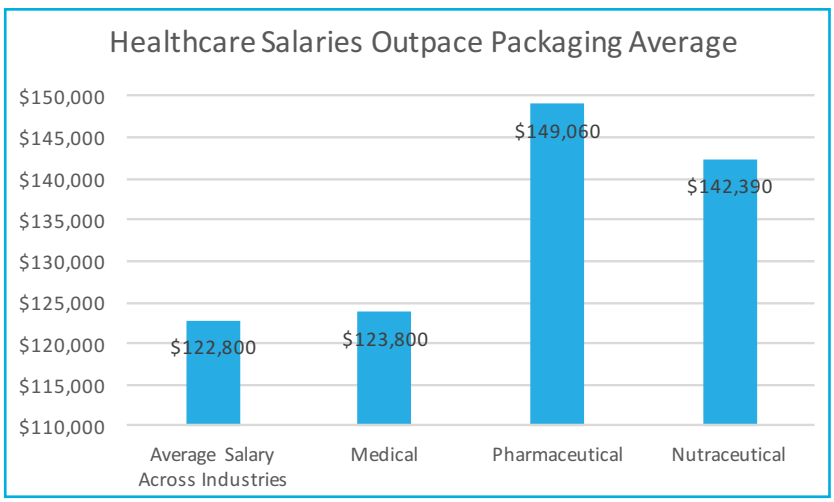
Respondents fared awfully well in terms of pandemic employment, with only 1% overall reporting unemployment compared to the 8% (at the time of writing, even higher when responses were collected) national average. Pharmaceutical and medical respondents reported 0% and 2% unemployment respectively, though nutraceutical respondents reported 9%. That stands to reason, packaging was proven an essential job function during the last 16 months, and lots of brands fared extremely well, struggling only to keep up with demand.

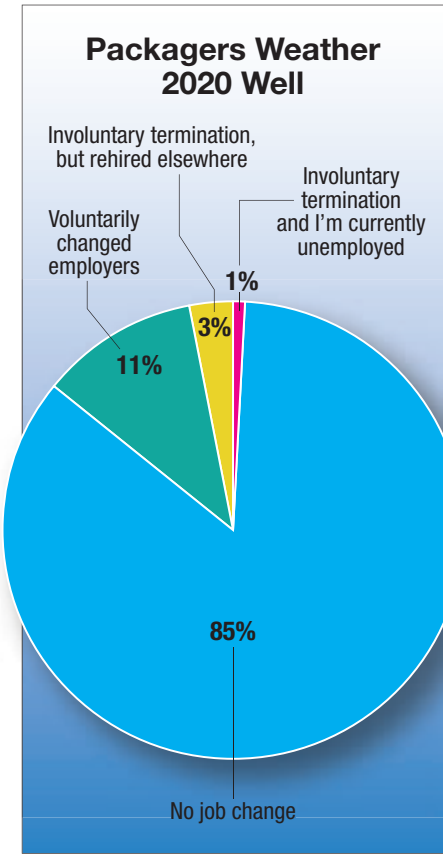
But respondents are still battle-worn from the last 16 months. One indicator that we're not fully back to normal is that people are exhibiting quite limited job-seeking behavior. People are still in "hunker down and hold on to what 'ya got'" mode, and loyalty is high to companies who kept respondents employed in uncertain times. Job security is as high as we've seen it in this survey, and people are sticking around and avoiding the risk of seeking new digs. Of the 147 respondents in health-related fields, 54% reported feeling very secure in their job, compared to 49% feeling very secure overall.

One noteworthy finding was a fairly clear striation between generations, age groups, and experience levels. Younger and less experienced folks exhibited the most confidence in their future, and the most upward mobility (as stands to reason when early in careers). There's a magical "five years of experience" marker that seems to be a jumping off point for the greatest salary increases (percentage wise). With a tight and tightening job market, people are making more at lower age, education, and experience levels, though an undergraduate degree offers greater momentum. Obviously, the

highest age, education, and experience levels command the highest salaries. But even so, upward mobility is diminished at that plateau, and there's less confidence in continued earning momentum. Notably, we saw the words "age, ageism," and "continued relevance" frequently listed, unprompted, as threats to job security in the verbatim section, something we haven't noticed previously. All in all, it feels like the post-pandemic thaw is on. The usual indicators of uncertainty that peaked last year are waning, and confidence in a more lucrative tomorrow (more by way of bonus than of traditional salary increase) is improving.

Check out the link for more survey insights on bonuses, salary predictors, survey methodology, and more: hcpgo.to/Salary2021.





In a tumultuous year, survey respondents fared quite well, with only 1% reporting unemployment, and an impressive 85% reporting no change at all. At the time of this writing, the national unemployment rate is at 8% (was higher when responses were collected), for comparison's sake. Respondents reported slightly more movement in life sciences, voluntarily leaving for new jobs—Medical (14%), Pharma (19%) and Nutraceutical (18%)—understandable in a pandemic year. In uncertain times, people tend to hunker down and stay put. Meanwhile, the packaging industry—including most of the job functions encompassed within it—was deemed quite essential by employers during the pandemic. Retention efforts by brands were rewarded by workforce loyalty.

Compensation Bounces Back After Two-Year Lull

Percent Earning	2021	2020	2019	2018
Less than $50,000 (calculated)	4%	5%	3%	3%
$50,000 - $59,999	5%	5%	5%	5%
$60,000 - $69,999	7%	7%	8%	8%
$70,000 - $79,999	9%	11%	8%	9%
$80,000 - $89,999	8%	10%	10%	8%
$90,000 - $99,999	10%	11%	9%	8%
$100,000 - $124,999	20%	19%	22%	23%
$125,000 - $149,999	14%	12%	13%	13%
$150,000 - $174,999	10%	9%	8%	8%
$175,000 - $199,999	5%	5%	4%	5%
$200,000 or more (calculated)	9%	7%	8%	10%
Avg. (x $1,000)	$122.00	$115.78	$120.72	$121.71
Base	828	996	1004	923

Source: Institute of Packaging Professionals 2021 Salary Survey

Blow-Fill-Seal Expands in Aseptic Filling, Vaccines

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Recent developments in technology have bolstered the use of BFS in aseptic processing in the life sciences.
2. There has been an uptick in vaccine filling via BFS—also large-scale integration of a syringe needle with a BFS container.
3. Vaccines (typically heat-sensitive) bring temperature challenges, but they can be overcome with careful BFS design.

While not a new concept, blow-fill-seal (BFS) technology isn't as prevalent in pharmaceutical aseptic filling operations compared to traditional filling. But in recent years, BFS technology has started to gain more traction in vaccine production, temperature-controlled product filling, and pre-filled syringe manufacturing said Leonard Pauzer, Director, Process Technology at **IPS-Integrated Project Services** at the 2021 PDA Annual Meeting held virtually.

With BFS, the reduction in container weight is beneficial from a logistical standpoint, while a reduction in contamination and particulates—filling and closure happen at once—is a value-add for quality. Additionally, a manufacturer can change container shapes (with the cost and several weeks to change a mold) without purchasing a new machine, which offers new delivery options for patients.

While BFS technology provides unique solutions to pharmaceutical manufacturers, it also brings new facility, quality, and process changes. Recent advancements include the following:

1. **Pre-fabricated PODs:** "We've seen an increase in the past two years of blow-fill-seal being used," Pauzer noted. "Companies have been looking at and installing BFS into a POD, allowing for rapid deployment and ease of installation."
2. **Temperature control:** This adds a new facet to BFS capacity.
3. **Vaccines:** Not only has there been an uptick in vaccine filling via BFS, but Pauzer has also seen "integration of a syringe needle with a BFS container, which in the past has not been done on a large scale."

For those not familiar with the technology, here's a brief overview for rotary BFS filling. If you're already familiar, jump ahead to **BFS vs. traditional filling**.

- The liquid product moves through the machine's piping.
- Simultaneously, LDPE pellets are melted and extruded into a continuous ribbon of parison (melted resin).
- Product and parison are fed into the fill machine. Sterile air is applied to the center to expand the parison so that the new container can enter the mold and form properly.
- Simultaneously containers are formed, filled, and sealed.

As Pauzer explained, "an aseptic BFS machine can utilize technology referred to as 'rotary filling' with a closed parison. Forming, filling, and sealing of containers occurs within a continuous ribbon of parison flowing around the needles." The outside environment will not affect the product as long as the parison is running.

BFS vs. traditional filling

In the closed parison process, BFS machines do not have a traditional air shower like in isolators or RABS, and the filling needles are completely enclosed within the parison so it is not possible to perform continuous viable and non-viable particle monitoring throughout the filling of a batch because you would have to penetrate the parison.

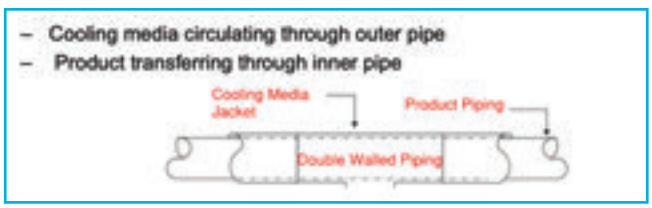
"I reference PDA *Technical Report 77* because most of us who are used to an isolator or RABS know that you'll do continuous monitoring for viable and non-viable, and you can also do surface plating either at the end or beginning of the process," he said. The BFS situation is so different that this is not possible—this is a challenge to some quality groups and also changes how brands think about environmental monitoring for aseptic filling.

While both filling techniques can run at speeds of approximately 300 to 400 containers/min, there are some parameter differences to note. With BFS, the container is plastic instead of glass, and the relatively tiny critical zone is installed within the machine. "The critical zone or environment for a BFS machine is approximately 36 square inches of space that includes the needles. All this monitoring is outside the parison. Compare that to a medium-sized isolator or RABS which has approximately 2,304 square inches of Grade A environment. Where our needles are located in BFS is not considered grade A," he said.

Controlling temperature

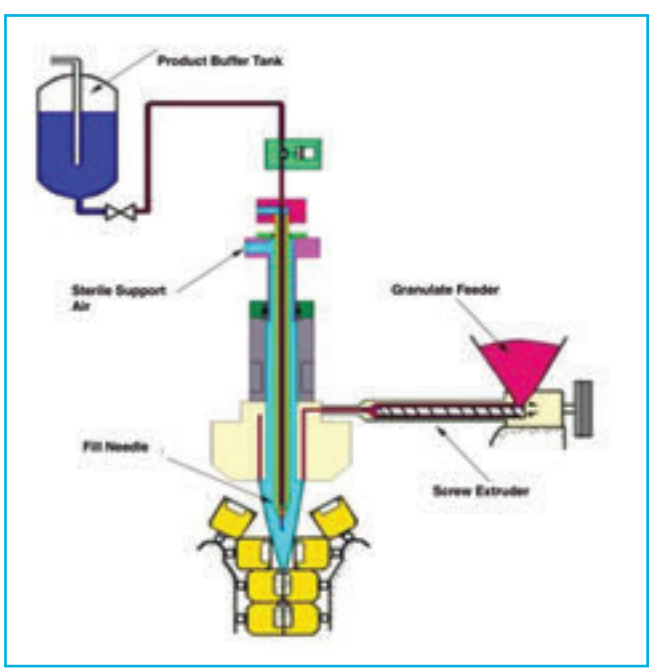
Vaccines bring temperature challenges, but they can be overcome with careful BFS design. Most vaccines are heat sensitive, and can be out of refrigeration anywhere from 10 hours up to 30 or 70 hours—depending on the product—with a typical target tempera-

↑ The critical zone for a BFS machine is approximately 36 square inches of space, small compared to a medium-sized isolator or RABS which has approximately 2,304 square inches of Grade A environment. (Images this page credit: IPS.)



↑ Double walled piping for temperature control.

↑ The height of one BFS system required IPS to use a double stacked POD, referred to as a 'high hat' configuration.



↑ While product runs through the system, resin pellets are melted and extruded into a continuous ribbon of parison. (Credit: Rommelag.)

ture of 2 to 8°C.

Pauzer said BFS technology has advanced to the point where you can refrigerate or control throughout the product filling. "At the point of dosing, you're merging with a warm parison. The molds are cooled, but you do have to take that into account when you design your facility. Today, you can bring the product right to the point of dosing at a specific temperature."

Most vaccines require a range of 2 to 8°C, but this may depend on the product and viscosity. He said most companies try to target 4°C because it allows for variation while staying in the 2 to 8°C window.

One design he highlighted includes a double-walled piping system with cooling media circulating through it, which is a fairly new development. Cooling media will depend on the site and country as the U.S. and Europe, for example, differ on which type of glycol is accepted. He offered the following temperature control considerations:

- Maintain the product temperature in the buffer tank. This improves dosing accuracy.
- Consider a dedicated chilling system. Any reduction in temperature variation reduces risk.

"Many companies have a house glycol unit but there's quite a bit of variation in that. What we've learned is if you dedicate a very detailed, designed unit for your blow-fill-seal, it gives you the best results," Pauzer said. He described a tiered cooling concept with multiple temperature control units, each with a consecutively tighter range to increase control as they stepped down. Three units were individual circuits on the BFS machine, one covering the product tank, one for product piping, and another for the molds.

Determine how you will evacuate the glycol out of the piping when you need to clean-in-place (CIP) and steam-in-place (SIP).

Consider where safety relief devices within the cooling will be placed. "This is very small tubing... and now you have a jacket on top of it or another pipe around it. We have to get safety devices in because we are now running steam through the inner pipe, radiant energy goes out to the glycol, and it expands the glycol. We're dealing with a process that was not previously done, so this was a 'first of its kind' for us working with a vendor to create this," he said.

Pauzer explained they ran into some challenges with piping radiuses, ultimately opting for a complex fabrication process: "Our risk assessment looked at what would happen to the product if it sat for a minute, two minutes, and then what happens to product temperature on continuous flow."

In the example he highlighted, valves were not cooled while the tank and long runs of the piping were. They insulated the loop as much as possible, which helped in maintaining temperature.

Other challenges when making the switch

Automated inspection brings considerations, particularly because

BFS containers are opaque (See sidebar, next page). "We have industry standards for glass vials and syringes. Even plastic vials are used in automated inspection machines. Inspection standards and criteria will be compared to vials and syringes for comparable products. It's a different way of thinking," Pauzer said.

The container has the benefit of being flexible, but if it is secondary packaged at a different location, then a tray and rigid container are needed for shipment.

Companies must establish a viral boundary. "Closed parison gives you your first level of containment for viral boundary. Now this can be discussed with the quality group, but many companies believe that it is your first level," he explained. "Then you think about aligning the technology with existing technology—some companies will introduce this technology into a facility that already has a traditional vial and syringe filling line. And you're going to have contrasts on how the viral boundary is managed. For BSL-1 products, this is not too challenging, but as you increase in your biosafety levels you have to take this into account and understand how you're going to manage it." Finally, most vaccines require a chemical or heat inactivation step. Both are possible because a BFS machine has an integrated CIP and SIP system within it. Pauzer noted, "Some products need a specific chemical. So rather than a cleaning step, you need a true inactivation step before opening the machine up and before going to drain with your product."

Designing for a POD

A POD is a prefabricated clean room which can be transported to a facility, using a truck, plane, or ship. The room is completely built in a factory, with wall panels, doors, and even some equipment and furniture, then loaded and shipped. One critical factor not to be overlooked is the sheer weight of a BFS system. The base or foundation has to be strong to support it. "When you combine all the equipment within a POD, it's 31,000 pounds—the filler itself is 28,000 pounds. We're talking about a unit that's nominally 14 feet high, 10 feet wide, and 20 feet long," he said. "The challenge also is that

is just your filling machine. You have to include in any air handling, ductwork, lighting, and structure above it."

The height of the BFS system for the highlighted project required IPS to use a double stacked POD, referred to as a "high hat" configuration to accommodate the two levels. (They only extended the second level where the BFS was.) The location of the BFS machine within the POD needed to be strategically chosen because it had to be moved into place.

Adding a needle

Dealing with COVID-19, the industry as a whole has been figuring out on the fly how to get mass vaccine doses out to the public. "For years, the industry has been moving away from multi-dose containers. Vaccines used to be distributed 10 doses per vial and the doctor's office would draw out of one container. There has been a push to go to single-dose prefilled syringes—it reduces the doctor making that manipulation and multiple entries into one container," he said.

Using BFS technology, the syringe barrel is a multi-chamber container that's fabricated immediately, and a company can attach the needle right then—the concept is a BFS container, a connector, and a needle.

"You can fill, form, and assemble in one process step. Because we're using BFS containers, it reduces the weight and if you can remove a processing step, you can get to the market quicker," Pauzer said. Every week or month matters with COVID-19, but for any vaccine or life-saving medication, speeding output means getting to patients in need faster.

Automated Inspection

Q: Would deep learning automatic inspection be an option for BFS? Inspection OEMs are now saying that deep learning would be suitable for difficult-to-inspect parenteral drugs.

Pauzer said that it can assist, particularly for higher density plastics. With lower density resins/plastics, there is more opaqueness making it difficult for automated systems. With the whole container obscured, there isn't a "single blind spot" where comparing images during rotation could help.

If the container is an individual container such as a bottle, deep learning automatic inspection is likely to be more useful. For a strip of five or 10 ampoules on a card joined together, automated inspection would remain a challenge.

Provident Nutraceutical Increases Production Through New Complete Bottling Line

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Provident increased capacity and decreased downtime with a new bottling line.
2. Customer service and augmented reality software allowed for success on the line.
3. Toolless changeover resulted in easier setup, teardown, and cleaning.

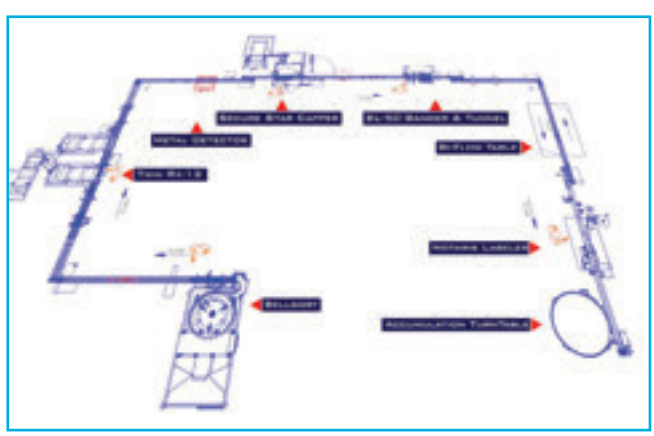
Provident Nutraceutical (Provident), a dietary supplement contract manufacturer, encapsulates powder into a variety of capsule sizes, which are then bottled in counts of 20 to 240. The company previously ran one bottling line for many types of products, such as capsules and tablets, out of its Steven's Point, Wisc., location and sought to expand and increase its capacity. Expansion would allow for the implementation of another bottling line, which would not only increase capacity but also decrease the effects of downtime in the facility if one line were to go down while the other continued to operate.

The company turned to **BellatRx**—a manufacturer of complete lines and packaging equipment for the pharmaceutical and nutraceutical industries—from whom they purchased in the past.

"We did our due diligence of checking out a few different companies when looking into a complete bottling line and, in the end, we liked what BellatRx offered and we knew how they stand behind their product and the service they provide," says Eric Peterson,

↑ The Provident team was pleased with the customer service provided through augmented reality technology.

↑ The company now has two bottling lines running night and day, which has nearly doubled the output of bottles.



Maintenance and Project Manager at Provident.

The company bought a complete bottling line, which included:

- a Bell-Sort unscrambler to orient bottles in the upright position onto the conveyor
- a reject station that removes bottles that are upside down or tipped over
- an Rx-12 high-speed solid dose count system
- a Tablet Elevator for feeding tablet counters, keeping the hoppers on the Rx-12 full
- a metal detector purchased through BellatRx, which they integrated into the line for Provident
- a Secure Star Capper that caps the bottles
- an SL 50 neck-bander against tampering with a shrink tunnel
- an accumulation table
- a BellatRx Wrap Labeler

Provident chose a complete line purchase, manufactured by one company, to ease troubleshooting, part replacement, and other machine concerns. The line was ordered in early 2019 and arrived in late Dec. 2019. Peterson travelled to BellatRx for a Factory Acceptance Test (FAT). The line was then put into full production by early Feb. 2020, completely unaffected by the arrival of the COVID-19 pandemic, seeing as the company was considered an essential business. Rather, the company saw a spike in sales because of the product produced.

Some fine-tuning was required at implementation to fix issues in getting bottles to run smoothly through the Bell-Sort, as well as some minor electrical issues. Peterson explains that Provident was impressed with BellatRx's service and communication, provided with customer care, including the use of software with augmented reality capabilities. BellatRx sent technicians to install the line and troubleshoot, verifying all machinery was properly operational, and to provide team trainings for the Provident operators, such as working new recipes into the machinery. Among the benefits of the BellatRx machinery, Peterson points out the toolless changeover for many of the machines, which allows for easier setup, teardown, and cleaning.

There are also benefits from a busi-

Update: Natural and Organic Market

As consumers seek natural solutions that will boost immunity and reduce stress and anxiety, demand is increasing for functional foods, beverages, and health and well-being products, according to *New Hope Network*'s recent Spark Brand Success event.

- In 2020, the natural and organic products industry grew to $259 billion, an increase of 12.7%, with sales on track to pass $300 billion by 2023.
- Of the total natural and organic products market, food and beverage accounted for 70% of industry sales, growing approximately 13% to $186 billion in 2020. Conventional food and beverage grew 8.6% last year, and both markets saw increases brought on by COVID-19 and resulting quarantine trends.
- New Hope Network acknowledged that consumers continue to seek functionality in the area of food and beverage with the "food as medicine" trend, and sales in this area grew over 9% to $78 billion in 2020. Also, plant-based products are reported to be growing twice as fast as their mainstream counterparts.
- Supplement sales increased 14% to $56 billion in 2020 – $3 billion more than anticipated in pre-COVID estimates. (But conversely, it should be noted, consumer trends also saw an uptick in the consumption of junk food and alcohol.)

—Kim Overstreet, Senior Content Strategist, Alignment, PMMI Media Group

ness standpoint in having two bottling lines running night and day, which has nearly doubled the company's output of bottles. Peterson further says that the machine operators appreciate the toolless changeover and training they received. Provident is in the process of installing an MES system which will allow for further benefits through data recovery off the line, as much of the BellatRx machinery is already equipped with PLCs.

Rapid-Response Packaging Development Aids Distribution of COVID-19 Vaccines and Test Kits

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Trays, inserts, tubs, and lids were developed in mere days, compared to the traditional weeks or months.
2. The companies had to navigate shortages in resin supply due to COVID-19 and severe winter storms in Texas.
3. Over a two-week period, 80 permanent full-time and part-time employees were hired for production, inspection, and packing.

Pharmaceutical companies have not been the only ones scrambling to get the COVID-19 vaccine and testing kits out to millions of people at lightning speed. They may not make the *New York Times*' headlines, but packaging companies are working in parallel to ensure these critical medical supplies are packaged and transported safely and quickly.

What has traditionally taken several months to design and manufacture healthcare packaging has shortened to just weeks due to the urgency of the pandemic and the universal desire to save lives and return life to normal.

So how do packaging suppliers make this herculean task happen? It requires careful orchestration involving everyone in the supply chain, from design and production to HR and logistics.

Rapid development of test kit packaging

In Dec. 2020, a major healthcare company introduced a new fast-response, at-home COVID-19 test kit that would increase testing availability to the public in an effort to slow the virus. With a commitment to

↑ An inspector checks every lid for quality at the end of the production line before packaging and sending to SiO2.

produce millions of kits in just a few short months, the company needed to acquire its packaging very quickly.

The healthcare company reached out to **Prent Corporation** with a big request: produce millions of custom plastic tray inserts to hold their kit components, and do it in record time. Prent, a manufacturer of custom plastic thermoformed medical packaging, jumped at the chance to have an impact on defeating the pandemic. The key to success was to have multiple departments working simultaneously to avoid any delays in the timeline.

Design and piloting: Design Engineer Michelle Rademacher began developing concepts for two different trays: one for kit assemblers using automation and the other for manual kit assembly. The difference is that automation systems need a clear tray so that the vision systems can see the components. The trays inserted manually didn't need clarity and it was important that they look different from the automation trays for fast visual identification by personnel assembling the test kits.

The tray design needed to fit the dimensions of the small kit carton and allow the components to be stacked in the tray. Therefore, the designer took into consideration the order of use for the components to ensure the first item to be used would be on top.

One day after the initial customer request, Rademacher had developed two concepts for the two different trays. Final designs were approved in about 15 days, a process that can often take up to 10 weeks. Tooling engineers used Prent's in-house 24/7 automated machining center to produce the molds, cutting down the typical timeline to just 10 days.

During the piloting program, the Prent team produced sample trays and conducted characterization studies to ensure they met all requirements. The same day the tray samples were created, Sales Representative Mike Sokolik got in his car and drove the samples to the healthcare company to expedite the approval process.

Choosing a plastic: Meanwhile, there was much consideration about which material to use. Prent worked with its plastic extrusion partner, **GOEX**, to determine the best options.

The biggest concern was procuring high resin quantities in a short time period as there was a shortage of various resins due to severe winter storms in Texas that impacted many resin manufacturers. Plus, the increasing use of plastics for PPE had stretched many reserves thin.

"Our biggest problem has been resin supply," says Michael Pregont, Senior VP of Operations at GOEX. "Usually medical packaging takes a while to be developed and validated so there is plenty of time to acquire the resins we need based on a demand forecast. We reached out to some of our suppliers to support the high volumes we needed in a very tight timeframe. Due to the specific material requirements that were driven by the project, many were unable to help us."

For the automation tray, the key needs were to have a clear, lightweight material with slight rigidity that was easily recyclable after the consumer used the kit. Eventually PET was chosen as the best material due to its widespread availability and high clarity.

The manual tray had the same rigidity and recyclability requirements but didn't need to be clear. After considering several options, opaque high impact polystyrene was chosen because it was highly available, fairly easy to thermoform, and would use 30% less plastic than PET in the same footprint.

↑ The lid on the vial tubs was redesigned to stack more securely but still denest smoothly and uniformly.

↑ The new lid has a snap feature that holds it tightly in place because a robotic arm grabs the tubs by the lid at the vaccine filling plant.

Preparing production machines and people: While designs were being finalized, the production manager was preparing for a large demand on the manufacturing floor. Prent was in the process of developing a new certified clean room when the test kit project came in, putting construction on fast forward. The new clean room was ideal for adding production capacity quickly.

Because Prent designs and builds its own thermoforming equipment, they were able to build and validate multiple new thermoformers in the new clean room faster than if they had to wait eight months for machines to become commercially available from an OEM.

"It was an 'all hands on deck' approach," says Mark Rothlisberger, Senior VP of Manufacturing at Prent. "Our employees worked overtime and we brought in employees from other facilities to help us install the equipment. Engineers stepped out of their usual roles to put machines together."

The extra effort paid off. The clean room and its multiple production lines were complete in six weeks, which normally would have taken twice as long.

But who would run the production lines? Over a two-week period, human resources conducted a job fair and the company hired 80 permanent full-time and part-time employees for production, inspection, and packing. Soon the lines were running two shifts. There were 8 million trays produced in the first month, with millions more expected throughout 2021.

Logistics: After inspection, trays were packed into one-way totes, which stack higher in semi-truck trailers than traditional skids, so they can ship twice as many trays in a single truckload. Logistics were a bit more complex because there were 13 different sites assembling the test kits, all with different tray type and quantity specifications. The first batch of trays was sent out to assembly sites within 28 days after the initial call with the healthcare company, which is three times faster than a standard project.

Improved tote lid for vaccine vials

In July 2020, **SiO2 Materials Science** announced it successfully accelerated its manufacturing capacity for COVID-19 vaccine vials and would be producing millions of them in just a few short months. An important aspect of distributing vials to the vaccine producers is ensuring they arrive quickly and safely in an easy-to-use format for the filling process.

SiO2 called its packaging partner, Prent, to ensure they would have the available capacity to keep up with the large project. (For years, SiO2 has been shipping vaccine vials to pharmaceutical filling plants in plastic tubs developed by Prent.) The company successfully increased production of tubs and matching lids to meet the increase in vial production.

Soon, however, it became clear that a new lid design was in order. "The lid snap needed to be stronger because a robotic arm would be grabbing the tubs by the lid at the filling plant," says Prent Sales Representative Marcus Knouse. "Plus, the tubs needed to stack more securely but still denest smoothly and uniformly. SiO2 requested a new lid that would meet these needs."

Design and production in record time

Prent Design Engineer Jason Erickson designed a new lid with a deep undercut so the lid could better grip the tub flange for a more secure fit. Stacking locating features were added to the tub lids so that they could stack without slipping during transit. A PETG medical grade copolyester resin from GOEX was chosen because it retains high rigidity and has a special property for consistent denesting, which improves efficiency in SiO2's automated process.

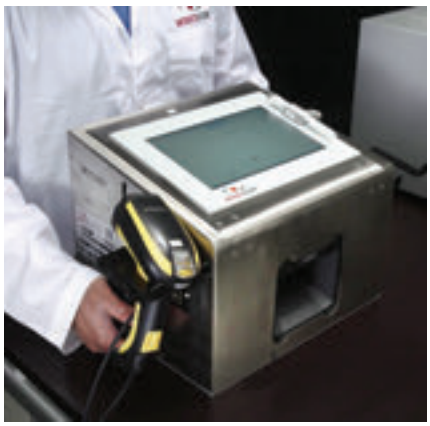
Erickson had two design concepts for consideration the day after SiO2's call, then two lid models the day after that. The process of design, modeling, and approval traditionally takes about three to four weeks, yet it took less than 10 days in the expedited process with SiO2. Next, tooling engineers in Prent's automated machining center produced the mold in 26 days and began the pilot process to develop samples in three days (a tooling and pilot process usually takes about eight weeks).

Once the lid design was approved, sterile production began immediately on a dedicated line in Prent's clean room. The first 60,000 lids were manufactured in just two weeks and shipped to SiO2 in one-way totes. A second batch of 60,000 lids was sent a month later.

In total, the new lids were designed, produced, and shipped in just two months, which was 1/3 of the time it takes in a typical situation. Prent has produced more than a million transport tubs and lids for SiO2 and will continue to do so into the foreseeable future.

In the global drive to defeat COVID-19, companies including SiO2, Prent, and GOEX work closely to do their part to ensure the safe and fast delivery of vaccines and test kits to people everywhere.

Print & Check EVO



Mini Manual Station

Antares Vision Group

1 Whittendale Drive, Suite A, Moorestown, NJ 08057 | **PHONE:** 856.780.3465

EMAIL: sales.us@antaresvision.com | **WEBSITE:** www.antaresvision.com

Compact, Easy to Integrate Serialization Unit Handles 300 Cartons/min

Antares Vision's Print & Check EVO is among the most widely used integrated serialization solutions on the market. Quick and easy to integrate into packaging lines, the unit occupies just 705mm of floor space as it prints and verifies on carton flaps. Upper and lower conveyors keep cartons stable for reliable printing and unsurpassed verification accuracy. The Print & Check EVO can handle cartons up to 120mm wide and 200mm in height at a maximum speed of 300 units per minute.

Mini Manual Station Aggregates Small- to Mid-Sized Batches

Ideal for small- to mid-sized production, the Mini Manual Station maximizes manual aggregation productivity and, among other benefits, efficiently supports post-lot reworking operations in warehouses and distribution centers. Following the situation-specific recipe – for example, the number of cartons per case – the Mini Manual Station aggregation unit issues the upper level, "parent" container label once the preset quantity of items has been scanned into the system. The unit features an ergonomic design for easy, multi-point access and an always-on handheld scanner for fast, reliable code reading.

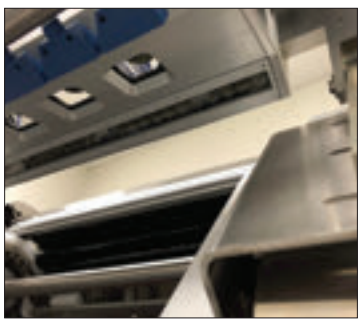
Advanced System for 100% Inspection for Slat Fill Bottling

Designed to ensure the highest integrity slat fills, AV Slat View inspects uncoated or coated tablets as well as mono and bi-color capsules. Compatible with a broad range of OEM slat filler brands, the turnkey, easily integrated unit offers simple setup and unlimited recipe storage. Equipped with an advanced color detection algorithm, the module's complete validation package offers high accuracy and a low false reject rate. A configurable alarm that flags and rejects bottles with potential objects eliminates the need for line stoppage.

Tool for Leveraging Serialization Data to Improve Production Practices

AVionics is a comprehensive software tool designed to monitor equipment performance and efficiency throughout the production process. The solution satisfies pharmaceutical companies' increasing desire to leverage data initially generated to comply with serialization mandates in the US and abroad. By tracking various key performance indicators (KPIs), AVionics streamlines data into a user-friendly dashboard for intuitive operator decision-making. Information collected from production and packaging lines can then be used to improve business processes at all levels.

Our MISSION



Antares Vision Group guarantees protection of products, people and brands through inspection systems for quality control, Track & Trace solutions for anti-counterfeiting and supply chain transparency, smart data management tools for maximized efficiency and digitalization of the supply chain, from raw materials to the final consumer. The Antares Vision Group is active in the pharmaceutical market, Life Sciences (biomedical devices and hospitals), beverage, food, cosmetic and consumer-packaged goods. The Group reaches over 60 countries in the World with complete and flexible solutions, hardware and software. With twenty years of experience in vision technologies, the Antares Vision Group is supplier to ten of the leading pharmaceutical companies, more than 25,000 inspection systems ensuring product safety and quality, 6,500 quality controls and more than 3,500 serialization modules on lines installed around the world. In 2020, Antares Vision Group expanded their capacity services through the acquisitions of Convel, Adents, Applied Vision and Applied Vision.

ANTARES VISION

www.antaresvision.com

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AZCO Corp.

26 Just Road, Fairfield, NJ 07004 | **PHONE:** 973.439.1428
EMAIL: cs@azcocorp.com | **WEBSITE**: www.azcocorp.com

AZCO Corp.'s standard line of products includes tubing cutters, pouch making machines, desiccant dispensers, test strip cutters, cut-to-length knife assemblies, and precision punches. These units are designed to handle all types of flexible materials and give you the ability to automate a process, improve an existing production line, control costs, and increase output.

Just introduced to the market is the new generation HS-250 pouch making machine. This compact system with unwind, heat sealer, and cut to length knife assembly will give companies the flexibility to make pouches on-demand or for inventory. Just by changing the roll width and entering a new pouch length, you can make a large variety of pouches as needed. Optional printer can serialize lot, date, and barcode. This unit can be set up to run on-demand or in automatic mode producing the quantity required.

AZCO's automatic bench top tubing cutter is ideal for processing medical and flexible tubing with a diameter range of 2 – 25mm (0.080 – 1"). Automating your process reduces your risk of contamination by human contact, and increases accuracy, speed and productivity. The tubing is indexed by a dual drive tractor belt system for high accuracy. For easy operator use, the indexing motor is controlled by the touch screen; simply enter the length and number of pieces. Options include material guides, a lubrication system, and a dancer unwind & baseplate package.

The 5D pouch dispenser is most commonly used for dispensing desiccant and oxygen absorbers. This unit is all electric, easy to use, and affordable. The dispensing head is compact in size: only 7" wide x 12" high x 14" deep. The machine is designed to run desiccants from all manufacturers, giving you the freedom of choice to get the most competitive pricing for your material. A touch screen is provided for easy setup, and the unit self-threads with the automatic loading feature. The all-electric design requires only 110vac; just plug it into a standard power outlet.

AZCO's module style units are quick and easy to install and use. Seamlessly integrating our units into an existing line can increase production speed and reduce downtime, ultimately saving you time and money. Please give us a call to discuss your application.

Our MISSION

AZCO Corp.'s mission is to serve our customers and members by designing and manufacturing units and components to feed, cut and place flexible products used by medical device companies. They specialize in providing simple solutions for applications based on a building block concept. Standard modules and units can be purchased alone or in combination to build a solution that meets your unique needs. AZCO Corp. helps companies worldwide and is ISO 9001:2015 certified which ensures that you are receiving high quality products.

www.azcocorp.com
See our ad on page 25 of this issue

Columbia Machine, Inc.

107 Grand Blvd., Vancouver, WA 98661 | **PHONE:** 360.694.1501 | **FAX:** 360.750.9221
EMAIL: pallsales@colmac.com | **WEBSITE**: www.loadtransfer.net

Reduce Contamination in Production Areas
The Load Transfer Station (LTS) product line, offered by Columbia Machine, helps to reduce contamination from entering production areas, streamlines operations & reduces costs. Columbia manufactures a complete line of pallet transfer solutions including stand-alone stations to fully automatic solutions that allow pallet load transfer to be completed in less than one minute, without requiring the operator to leave the safety of the forklift.

Industry Leading Standard Safety Features
Columbia Machine's LTS solutions come standard with the latest safety features. These include Category 3 electrical safety components, up- stacker guarding with A-B SensaGuard RFID interlocked door switches, multiple emergency stops, and muted light curtains on the automated systems. Every Columbia Machine LTS has been engineered to exceed the requirements of pharmaceutical processors who are working to meet FSMA regulations.

Flexible Product Handling
Columbia's LTS is capable of transferring products that are packaged in cases, super sacks, glass vials, pails, barrels, drums and bags from one pallet type to another, including Plastic, Chep and GMA pallets that are commonly used in both receiving and shipping applications.

System Integration
To ensure that all Columbia equipment works smoothly with upstream and downstream machinery, complete systems integration services are available—including project management, controls, installation, wiring, commissioning and preventive maintenance plans. As a family-owned company with a total commitment to customers, employees and a long-term financial perspective, Columbia is your premier partner for load transfer solutions.

Columbia Machine, Inc.
The Load Transfer Station (LTS) product line is part of the Palletizer Division of Columbia Machine, a leading American palletizer manufacturer. For more than 80 years, Columbia has manufactured complete palletizing and material handling solutions.

Our MISSION

The mission at Columbia Machine is to be the preferred supplier of engineered product solutions in the targeted markets we serve. We provide exceptional customer value through strategic marketing, innovative product development and unparalleled customer service. We value safety, integrity, trust, fairness, professionalism and teamwork in relationships with our customers, employees, business partners, suppliers and shareholders. We "always" see our business through "the eyes of our customers," and provide them with superior solutions through innovation, quality, reliability and continuous improvement.

Columbia

www.loadtransfer.net
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This total manufacturing solution includes converting and heat seal pouching.

Delta ModTech

8445 Bunker Lake Blvd NW, Ramsey MN 55303
PHONE 800.279.3358 • 763.755.7744
PHONE (EUROPE) + 46 706 97 24 34
WEBSITE www.deltamodtech.com

For over 40 years Delta ModTech has been a leader in web converting and packaging innovation. We are dedicated to providing flexible automation solutions for converters and manufacturers worldwide.

Delta ModTech systems feature a variety of processes including 4 side seal pouching, rotary die cutting, laser die cutting, multilayer lamination, sheeting, conveyors, coating, drying and subsystem integration.

Seal to print registration

The packaging solution for process applications where speed, flexibility and consistent seal quality are important. For the manufacturing of:

- Heat-seal/Cold-seal pouches
- Resealable pouches
- Liquid dispense pouching
- Sachet filling

Improve your capability with seamless integration

We've developed several solutions to meet the pack- age and pouching needs of our customers and their end users. Our experience with building machines to meet the demands of the most stringent specifica- tions will give you confidence in meeting your production goals.

Common options:

- Mod-Track® Vision Inspection – Part-in-pouch, closed loop registration, date/bar code reading, rejecting
- Reject conveyors/marking equipment
- Part handling Conveyors for: stacking, shingling, sorting, turning, etc.
- Printing for date, lot and bar codes - inkjet, thermal transfer, laser, etc.
- Case packing and cartoning

Packaging and Pouching Machine Specifications

- Max Web Width: 10" (254 mm), 13" (330 mm), 18"
- (457 mm), Custom Widths Available
- Max speed – Reciprocating Packager: 13" 80 ft/min
- (24 m/min)*, 18" 55 ft/min (16.75 m/min) *
- Seal Repeat – Reciprocating Packager: 24" (609 mm)
- Unwind/Rewind Mandrel Diameter: 3" (76 mm)
- standard, other sizes available
- Control System: Delta ModTech INTELLI-MODTM
- control system
- Drive System: Servomotor Control
- User Controls: Touchscreen HMI Pendant Arm
- Footprint: 8' x 6' x 7.65' (Packager Base Platform) Cabinet Construction: Welded Steel Frame,
- Aluminum Front Plate

** Process Dependent*

Now with Frontier Coating Technology

Frontier designs and builds coating and drying equipment for batteries, capacitors, printed electronics, display compo- nents, transdermal drug delivery, test strips, fuel cells and more. Frontier coating and drying lines can be integrated in-line with Delta ModTech systems.

Our MISSION

We deliver web converting and packaging systems for the most complex demanding jobs in the medical, pharmaceutical, label, RFID, electronics, automotive and cosmetic industries. Our systems are designed to meet your application requirements, improve your profitability, and reduce your risk.

Service and Support

Serving our customer's has always been Delta's highest priority. We focus on quick efficient solutions to keep your machines running to their full potential. To back up this philosophy, we have a full service staff on call, made up of Engineers and Technicians. We have the process knowledge and proven modules to ensure the longevity of your machine.

EQUIPMENT SOLUTIONS FOR A VARIETY OF PRODUCTS:

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Domino North America

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Since 1978, Domino has been a leading global product identification and traceability specialist for the Pharmaceutical and healthcare industries. Our technology enables manufacturers to comply with the validation requirements of Good Manufacturing Practice (GMP) and emerging global legislative standards, such as the DQSA, helping to secure the supply chain from Product to Pallet. As a result of this philosophy Domino has supported some of the worlds' largest pharmaceutical manufacturers and original equipment integrators.

Domino's printers are designed to print the highest quality alphanumeric and graphic codes including bar codes, 2D data matrix and QR codes onto a variety of diverse substrates.

Global traceability initiatives, such as the DQSA, are designed to hinder the production and distribution of life-threatening imitation or counterfeit pharmaceuticals. These initiatives can require identification and authenticity features on primary, secondary and tertiary packaging levels typically in the form of unique, non-predictive, serialized and machine readable codes. This level of product identification aims to impair the ability of counterfeiters to successfully replicate pharmaceutical products and packaging.

Selecting valuable, trusted partners is a primary objective for pharmaceutical companies as they prepare for the challenges that will come with serialization. Now is not the time to be experimenting…the planning required for the November 2017 deadline should already be in the works, but if you have not yet begun, rest assured that Domino, and trusted partners, can guide you in the right direction.

Put your trust in the experts. Domino brings 39 years of experience for coding compliance.

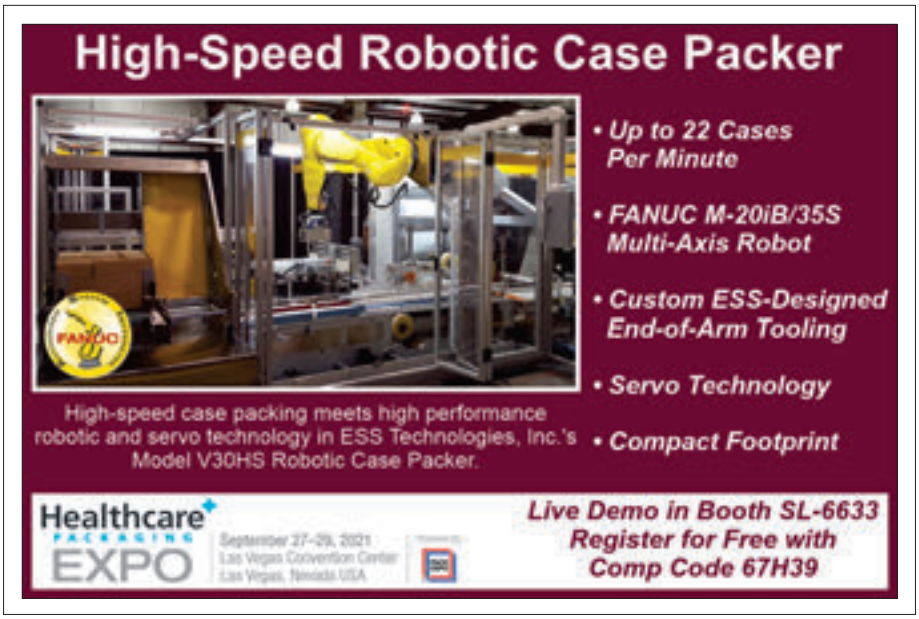
Our MISSION

The pharmaceutical industry demands highly reliable products and services that satisfy the stringent quality and production requirements of modern processes. Aligning yourself with right partner who has the experience to meet these specific requirements effortlessly, including support for DQSA federal serialization requirements, is paramount.

As the Sector Development Manager for the Pharmaceutical industry in North America, my role is designed to support seamless partnerships with the Manufacturers, CMOs and OEMs, to understand and support your serialization needs. While our technology is more than adept at supporting the DQSA requirements, the experience behind our name makes the difference. Put your trust in the experts.

DOMINO

For more information, please visit us at: www.domino-na.com



ESS Technologies, Inc.

3160 State Street, Blacksburg, VA 24060 | **PHONE:** 540.961.5716
EMAIL: info@esstechnologies.com | **WEBSITE**: www.esstechnologies.com

ESS Technologies, Inc., founded in 1993, designs, manufactures and installs automated packaging machinery. ESS is an authorized FANUC America robotics system integrator and Strategic Relationship Partner for secondary packaging and palletizing systems. ESS designs custom end-of-arm-tooling (EOAT) for integrated FANUC robots, which allows the precise handling of components and packaging materials. Our full product line includes:

- **Fillers / Cappers, Inline or Monoblock — up to 250bpm**
- **Horizontal Cartoners — up to 150cpm**
- **Vertical Cartoners — up to 100cpm**
- **Top, Bottom and Side Load Case Packers — up to 22cpm**
- **Wrap Around Case Packers — up to 30cpm**
- **Robotic Pallet Cells — up to 40cpm**
- **TaskMate Robotic Systems®**

ESS engineers work with customers to understand the level of automation required, equipment specifications, OSHA requirements, flexibility, and future expandability. The end result is an ergonomic and cost-effective production line that requires minimal operator training and can be easily retrofitted for future applications. ESS has expertise in the areas of project engineering, project management, system integration, electrical design, mechanical design, robotic end-of-arm tooling, and more. As a system integrator, ESS Technologies handles every detail of packaging line design, manufacture, and installation. ESS also offers packaging machinery with integrated serialization systems to meet pharmaceutical serialization mandates. In this area, ESS has extensive experience integrating our cartoners, case packers, and palletizers with serialization systems, aggregation cameras, barcode readers, and labelers from today's industry leaders in off-the-shelf serialization track and trace equipment.

The ESS team has designed packaging lines for the following industries: Pharmaceuticals, Diagnostics, Medical Device, Cosmetics, Nutraceuticals, and Consumer Products. Our robotic systems, cartoners, case packers, and palletizers are engineered to meet all applicable standards and production requirements.

Our MISSION

***President* — Kevin Browne**

***Vice President* — Linda Browne**

***Director of Operations* — Paul Landers**

***Director of Engineering* — Michael Morgan**

***Global Business Development* — Walter Langosch**

***Southeast Regional Sales Manager* — Matt Kentfield**

***Midwest–West Coast Regional Sales Manager* — Mike Witowicz**

***Mechanical Engineering Manager* — Steven Easter**

***Electrical Engineering Manager* — Brian Stuck**

Founded in 1993 by Kevin and Linda Browne, ESS Technologies engineers and manufactures fillers/cappers, automated cartoners, case packers, and palletizers for the Pharmaceuticals, Diagnostics, Medical Device, Cosmetics, Nutraceuticals, and Consumer Products industries.

ESS Technologies, Inc. defines corporate responsibility as action we take which positively impacts our customers, employees, suppliers and the communities around our company, and which includes and goes beyond our legal or regulatory obligations. We engage with business and non-business interest groups alike to ensure that we fully understand their expectations of us and to ensure that our policies and programs address relevant issues.

ESS Technologies, Inc.
Packaging Machine Design & Integration

www.esstechnologies.com
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Formost Fuji Corp.

19211 144th Avenue NE, Woodinville, WA 98072 | **PHONE:** 425.483.9090 | **FAX:** 425.486.5656
WEBSITE: www.formostfuji.com

As a market leader in flexible packaging, Formost Fuji has been providing horizontal wrappers and baggers that are EFFICIENT, RELIABLE, and SIMPLE to operate for over 55 years.

Our **Horizontal Flow Pack Wrappers** are built with the end-user in mind having an easy to operate HMI that includes graphics and step by step instructions. The HMI can be customized for simplicity with icons or photos representing each product for a one touch changeover. This innovative flow wrapper has a simple to thread film process that saves time and a shortened film route that saves money. The center fin seal unit tilts down allowing easy access for sanitation and maintenance.

B16 Box Motion End Seal Technology offers four times the sealing pressure and longer dwell time with improved design. This provides high performance hermetic seals on difficult to seal films.

The **Swing Arm Rotary End Seal Option** for Horizontal Wrappers provide increased dwell time and seal quality at high speeds, allowing flexibility for a wide range of product and film sizes.

The **Formost GTS Bagger provides** performance proven technology with speed, versatility and dependability. Built to run up to 90 bags per minute, it is ideal for gently bagging a wide range of products including medical drapes.

Proven superior design and engineering are combined with the latest technology to bring you the **High-Speed Box Motion** horizontal wrapper. Capable of packaging speeds up to 400 per minute (application dependent), the high-speed box motion wrapper boasts high efficiency, tight wrapping, low vibration, and direct drive servos.

Formost Fuji provides **sustainable, and efficient packaging solutions** for the healthcare industry. Items such as masks, IV bags, inhalers, blister packs, syringes, tube sets, and many other medical and pharmaceutical products are wrapped and bagged on performance proven Formost Fuji equipment.

Our MISSION

First and Formost, we strive to put you the customer first. Meeting and exceeding your expectations is our gold standard. Whether it be in design, manufacturing, or service, you can expect Formost Fuji to deliver a solution you are proud of. Throughout 55 plus years in this business our ideals have remained the same; build it right and deliver on time, all at a value to our customers.

Our team of experienced people listen to you, and understand your needs.

- **Horizontal Wrappers**
- **Baggers**
- **Automation Solutions**
- **Special Applications**

FORMOST FUJI

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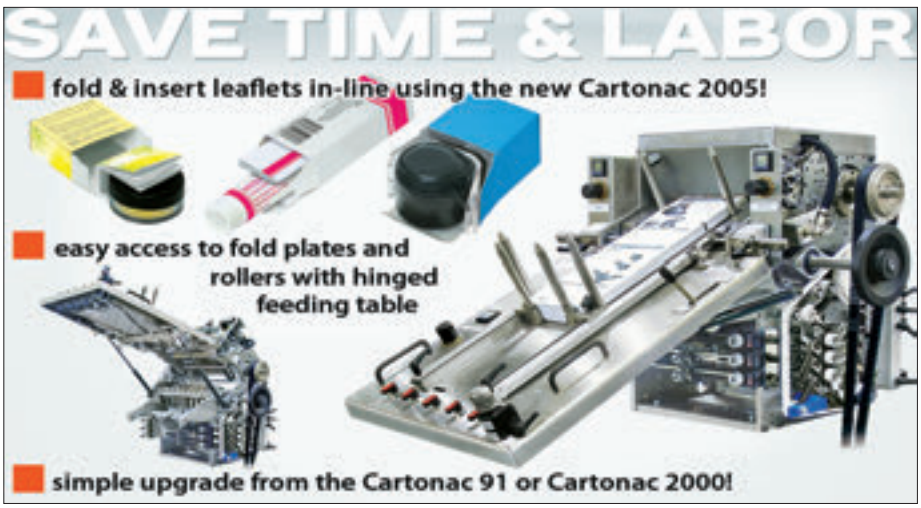

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OPTIMIZE PACKAGING PRODUCTION
GUK packaging-line equipment runs on the packaging line's drive or can be equipped to run independently.

In-line leaflet folding enables immediate insertion of leaflets into product cartons, along with the product. The **NEW** servo-driven **GUK Cartonac 2005** has a hinged feeding table for easy access to the fold plates and rollers, and improved suction rollers and air blasts on the feeder table allow efficient feeding of folded products—up to 3 panels thick. It is a simple upgrade from the Cartonac 91 or Cartonac 2000. The **Cartonac 2003DS** is PLC controlled for quicker, easier setup, and the feeder and folder is servo driven for better control and greater speed.

The **GUK–Sigma Pick & Place Station** precisely tips flat or 3-dimensional (and difficult-to-handle) items onto products in production lines.

GUK PA21 Leaflet Feeders feed inserts (and outserts) in-line for insertion into or cartons, handling leaflets up to 8 mm thick, depending on the model. The **GUK PA15 Leaflet Feeder** feeds leaflets, turned 90º, and can be mounted parallel to the packaging line to save space. It is also used with gluing or tabbing equipment in off-line leaflet/outsert bundling systems.

GUK RS Roll-Fed Folders offer economical leaflet production, as roll printing saves paper, cutting, and labor costs—while minimizing probability of leaflet mix-up.

BOOKLET / LEAFLET / OUTSERT PRODUCTION
Make spine-glued booklet leaflets on the **GUK FA53 Folder**. Fold up to 28-3/4 inch sheets for larger med-guides on the **GUK FA73 Folder**. Choose from a number of **G&K–Vijuk Outsert Systems** with varying capabilities of folding outsert leaflets with from up to 90 panels to up to 350 panels.

Meet **TRACK & TRACE** requirements with the **G&K–Vijuk CTM Coding and Serializing Station** on MV Outsert Systems. Print industry standard 1- and 2-dimensional codes using black or UV inks. A 3-camera system verifies the dimensional qualities of outserts, and verifies and logs the printing and print quality of the codes.

Save time and labor with the **GUK–Sigma PPM Auto Stacker**, which automatically collects outserts and packs them compactly into trays that move in, then move out when full, in continuous production.

Our MISSION

World leader in outsert-producing machinery, G&K–Vijuk has been specializing in miniature-leaflet folding solutions for over 40 years.

Member of the GUK Group headquartered in Germany (manufacturer of folding machinery since 1949), we continue to assess the needs of the pharmaceutical industry, as shown by recent developments in machinery to fold a greater number of panels and fold wider sheets—both for more print space on a single leaflet—and machinery for bundling leaflets for dispensing even more information on two to four leaflets.

GUK recently acquired MB Bäuerle, manufacturer of automated folding and inserting systems in Germany, and Sigma Engineering, manufacturer of pick and place product-handling machinery in the Netherlands, to further our goal to provide innovative, time-saving equipment to improve our customers' efficiency in providing products and services for their customers.

G&K-VIJUK® INTERNATIONAL

www.guk-vijuk.com
See our ad on page 89 of this issue

Greydon

391 Greendale Rd., York, PA 17403 | **PHONE:** 717-848-3875 | **FAX:** 717-843-6435
EMAIL: Greydon@ProMachBuilt.com | **WEBSITE:** www.greydon.com

Since 1992, Greydon has delivered innovative printing systems for a wide variety of flexible packaging applications and materials. Our quality inline and retrofit printing and coding solutions are perfectly suited for form fill and seal machines – such as Ossid and Pharmaworks – that support medical device, pharmaceutical, and food packaging operations.

Greydon has successfully integrated standard or custom solutions across a full range of print technology, including digital printers, flexographic rotary printers, thermal transfer printers, thermal inkjet printers, and wet ink reciprocating imprinters. Our range of flexographic printers provide the perfect solution for printing nutritional facts, high quality barcodes, or total product information directly onto your packaging.

Greydon's Genesis – our flagship digital ink printing solution – delivers optimum performance and return on investment for medical device and pharmaceutical manufacturers who require high quality labeling and coding for product validation, tracking, identification, and branding.

Boasting the smallest machine footprint on the market, the Genesis produces high-definition output on paper, Tyvek®, and flexible webs by utilizing best-in-class ink chemistry to match specific application needs. Utilizing non-contact printing with one, two, or full-color capability, the Genesis prints complete graphics and variable coding information that can be quickly and easily changed for different products and applications – perfect for UDI and DSCSA compliance.

Greydon is part of ProMach's Labeling & Coding Group, which includes well-known brands such as EPI, Panther, Code Tech, and ID Technology, the leader in labeling automation in North America. Greydon systems also integrate with Ossid and Pharmaworks, key ProMach brands that provide packaging solutions for the medical and pharmaceutical industries.

ProMach is an industry powerhouse providing integrated packaging and processing solutions for food, beverage, consumer goods, pharmaceutical, and other diverse companies.

Our MISSION

Greydon's mission is to provide every customer with the most effective printing solution for their specific application. Our dedicated team of passionate individuals listen closely to develop solutions designed to exceed each customer's expectations. This approach provides unique insight and allows us to apply best-in-class solutions across every industry we serve.

Our primary focus has been integrating printing system solutions within horizontal form, fill, and seal packaging machine applications in the medical and pharmaceutical industries. Our solutions eliminate the need for preprinted materials, cutting operating costs and maintaining the highest print quality of logos, text, lot and date codes, and other variable data – all while meeting UDI and DSCSA compliance.

GREYDON

www.greydon.com
See our ad on page 88 of this issue

Heat and Control, Inc.

21121 Cabot Boulevard, Hayward, California 94545 USA | **PHONE:** 510.259.0500
EMAIL: info@heatandcontrol.com | **WEBSITE:** www.heatandcontrol.com

Providing safeguards that help ensure your products match the prescription.

Metal Detection

Anywhere along the line, protect your consumer and your equipment. Efficient detection of foreign objects is critical to consumer safety, brand survival, and will also protect machinery and prevent downtime. We offer a complete line of metal detectors, checkweighers, and X-ray inspection systems from our strategic partners: CEIA® and Ishida.

CEIA, is a world leading innovator of industrial metal detection systems for products such as powders, capsules, tablets, and liquids. CEIA recently expanded the line to include three new systems to ensure pharmaceutical, nutraceutical and healthcare manufacturers have the safeguards they need for their customers:

1. THS/FBB for plastic tubes and sanitary packages inspection
2. THS/FBB for effervescent tablets inspection
3. THS/MBB for vertically oriented products

The systems have high sensitivity to all metals, integrated controls for line speed and rejection, digitally adjusted belt speed, and high immunity to environmental interference.

X-Ray

The latest Ishida X-ray (IX) series raises the bar in performance and usability with a global range that meets all local territory standards. Offering customers easy maintenance and stress-free operation, the range includes a robust fail-safe system that prevents a contaminated product reaching the consumer in the event of a power outage or breakdown, helping to minimize the potential for costly recalls.

All models offer exceptionally sensitive foreign body contaminant detection and additional benefits such as the ability to identify damaged and missing products or components, helping the pharmaceutical industry achieve a rapid return on investment. Quick commercial returns are also achieved by ensuring that high quality product leaves the factory gate, safeguarding reputations.

Checkweighers

Ishida also offers high-precision weight checking you can depend on. Checkweighing is key for delivering what your consumers expect by providing accurate verification of a package's weight or count and detecting missing components. Rely on a range of features to handle different products and incorporate new functions to meet the latest requirements. Promote quality control and customer satisfaction with Ishida's extensive know-how in weighing technology.

Our MISSION

Rising to the challenge, advancing processes, and helping to bring the best products to the world using science, technology, and creative thinking.

We are process and product technologists committed to advancing pharmaceutical and other industries with science and imagination. Whether you measure success by efficiencies, improvement, or innovation, count on us to deliver results.

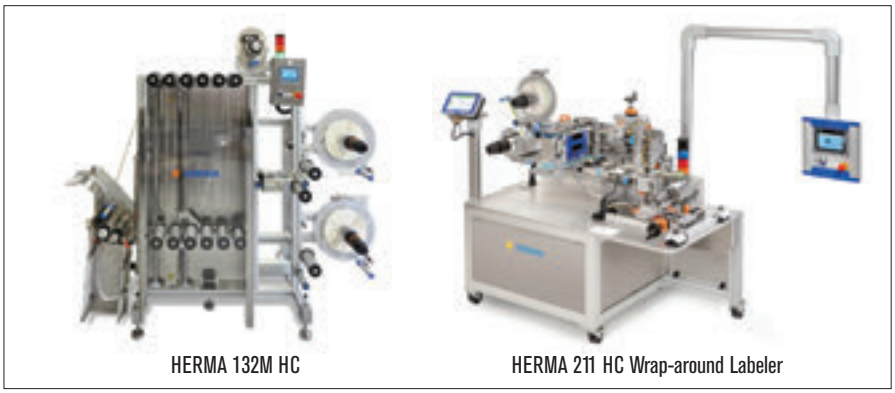
Providing sales, service and spare parts expertise across the globe for metal detection, X-ray and checkweighing anywhere along a production line, Heat and Control works closely with strategic partners to bring new technologies and solutions that meet the strictest of quality standards.

To view the entire line up of pharmaceutical solutions offered please visit: www.heatandcontrol.com/solutions/pharmaceutical

HEAT AND CONTROL

www.heatandcontrol.com

See our ad on page 27 of this issue



HERMA 132M HC HERMA 211 HC Wrap-around Labeler

HERMA US, Inc.

39 Plymouth Street, Suite 300, Fairfield, NJ 07004 | **PHONE:** 973.521.7254
EMAIL: info-usa@herma.com | **WEBSITE:** www.herma.us

At Pack Expo Las Vegas Booth #SL-6608, HERMA US will be exhibiting a variety of labeling machinery solutions, including:

COVID Vaccines and More: Continuous Labeling for Premium Wrap-around Labeler

HERMA has introduced continuous labeling capabilities for its 132M HC Wrap-around Labeler. Adding speed without sacrificing accuracy, the offering comes amid the dramatic push to produce billions of doses of COVID-19 vaccines at an unprecedented pace. The continuous operation is made possible by two new modules – EasySplicer and EasyCutter – that can be retrofitted onto existing machines.

The new add-ons allow label and backing paper reels to be changed or disposed of without production interruption. Considering that reels on high-speed labelers such as the HERMA 132M HC require replacement approximately every 10 minutes, the result is significantly improved output through downtime elimination. With the new EasySplicer and EasyCutter modules, label reels can be changed, and the backing paper reels disposed of, without the machine coming to a standstill.

Ultra-Compact Labeler for Small-batch & Biopharm Production

The HERMA 211 HC Wrap-around Labeler is designed to meet demand for a fully FDA-compliant labeler in a highly compact footprint. The semi-automatic unit is particularly helpful in the transition from clinical trials to full production, as well as for the smaller-batch manufacturing typically found in biopharmaceuticals settings. The HERMA 211 HC is suitable for labeling a wide range of cylindrical products including syringes, tubes, glass vials and ampoules. Capable of applying approximately 30 labels per minute, the HERMA 211 HC can handle webs as wide as 80mm, and products ranging in diameter from 10-120mm.

Next-generation IOT-enabled Label Applicator

The HERMA 500 Label Applicator is an IOT-enabled machine utilizing real-time metrics to optimize production efficiency and consistency, even in a multifactory setting. Capable of achieving labeling speeds up to 200m/min, the HERMA 500 can handle label widths between 80-320mm and roll diameters from 300–600mm. HERMA has enjoyed impressive sales of its signature HERMA 400 Label Applicator, selling more than 4,000 of the label applicators in 2018 alone – half of which were provided to original equipment manufacturers (OEMs). The HERMA 500 is a next-generation label applicator that builds upon its predecessor's best features and integrates Industry 4.0 connectivity. Exceptionally fast, the HERMA 500 has a maximum speed of 650ft/minute, and also offers short make-ready time and industrial-grade Ethernet connection.

Our MISSION

CEO
Peter Goff

HERMA US Inc. is a subsidiary of HERMA GmbH, a Germany-based provider of labeling machinery and self-adhesive labels and materials to the global packaging marketplace. HERMA GmbH's comprehensive range of products spans the labeling production process to include labeling machinery, a variety of adhesive materials, and finished self-adhesive products.

In the United States, HERMA is best known for its equipment. HERMA's flexible labeling machines are designed, developed, and built for integration into industrial processes, while its self-adhesive paper and film compounds are manufactured with unsurpassed precision. The company's range of finished adhesive products includes labels for a broad set of industries, including healthcare and pharmaceuticals, automotive and electrical, chemicals, food, cosmetics and logistics. The company's three divisions comprise nearly 1,000 personnel.

HERMA

www.herma.us

See our ad on page 9 of this issue.

James Alexander Corp.

845 Route 94 Blairstown, NJ 07825 | **PHONE:** 908.362.9266 | **FAX:** 908.362.5019
EMAIL: info@james-alexander.com | **WEBSITE:** www.james-alexander.com

Stemming from an uptick in demand, James Alexander Corp. is currently adding manufacturing space to its facility, a project scheduled for completion in Q2 2022. The expansion will provide additional capacity for servicing the company's key markets, including pharmaceutical (OTC & Rx), medical devices, health & beauty products, first aid and diagnostics.

James Alexander Corp.'s patented single-use plastic ampoules, which have undergone a series of enhancements since their initial market introduction, are available in a variety of colors and with an array of applicators, offering singlehanded activation in a customizable format. Meanwhile, the company's glass ampoules can be filled and assembled in single-use swab or dropper packages.

The company also recently introduced a winged device, "The Activator," which provides easier activation for these glass formats. Other services include autoclave sterilization for glass ampoules, blister packaging and formula compounding.

Plastic Unit-Dose Dispensing Systems
James Alexander Corp.'s revolutionary plastic ampoule combines style and ease of use through single-handed activation. With just a gentle squeeze, the inner membrane ruptures, allowing the contents to be dispensed by the user. The plastic ampoule is available in sizes up to 5ml, as well as a range of colors and applicators.

Unit-Dose Glass Swabs
James Alexander Corp.'s unit-dose swabs offer the stability of glass in one- or two-part systems allowing for convenient application of pharmaceuticals and health aids. JAC also produces single-use glass ampoules for inhalation and dropper tip assemblies for the dispensing of liquids.

The DuoDispersion System® Tandem Package
James Alexander Corp.'s DuoDispersion System® is a refinement to the company's well-regarded tandem swab package. Safe and easy to use, the tandem dropper or swab can be customized to hold two separate liquids, or a powder and a liquid; each individual formula is hermetically sealed in its own ampoule. The DuoDispersion System® can hold a combined volume of 1.2mls that are kept separate until the point of application. Two versions of the DuoDispersion System® are available: a dropper tip and a swab for topical application.

Our MISSION

CEO
Francesca Fazzolari

PRESIDENT
David Robinson

Located in northern New Jersey, James Alexander Corporation (JAC) is a leading contract manufacturer and custom filler of single-use crushable glass and plastic ampoules. Founded in 1976 by Francesca Fazzolari and Alexander Davidson, JAC is a privately-owned, ESOP company that still services several of the same customers it originated with 45 years ago.

James Alexander Corp.'s manufacturing facility features unique, company-designed equipment and produces its patented plastic ampoules, among other product offerings. The company makes great efforts to ensure that most of its components are made in the USA, aligning with its goal of investing in local communities, regional job markets and the American manufacturing sector at large.

DISPENSING SOLUTIONS.®
JAMES ALEXANDER CORPORATION

www.james-alexander.com
See our ad on page 19 of this issue

KOCH Pac-Systeme GmbH

Dieselstrasse 13, 72285 Pfalzgrafenweiler • GERMANY | **PHONE:** +49 7445 181-0
EMAIL: info@koch-pac-systeme.com | **WEBSITE**: https://koch-pac-systeme.com/

Since 1969, KOCH Pac-Systeme GmbH has built up an outstanding reputation around the globe as a leading manufacturer of high-quality blister forming and packaging machinery for the cosmetics, consumer, healthcare, Medical, and Pharmaceutical industries worldwide.

As an expert for custom packaging solutions it is KOCH's basic understanding to develop and offer innovative and individual packaging solutions for customers. With new innovative concepts and customized solutions, KOCH sets new standards and continuously improves associated processes.

At this year's PACK EXPO, KOCH highlights its innovative strength doubly: On the one hand KOCH will present sustainable packaging solutions for consumer goods and on the other hand its in-depth expertise in the field of medical technology.

Package the Sustainable Way – This is the motto of KOCH's trade show presentation about consumer goods with a focus on the American market. Visitors will experience how to comply with future US regulations already today or step by step: with intelligent machine technology for reduced material usage even of disposable plastics and always best blister quality.

With sustainable packaging solutions KOCH is shaping the future today: With Blisters made of sustainable film, **cyclePac®** or **cycleBox®** mono-material packaging. Or – the latest innovation and highlight – **cycleForm®** made of formable paper.

Safe and optimized packaging of medical products – This is what the brand KOCH medplus stands for. High-quality packaging machines and solutions, with special expertise in the validation-compliant packaging of the most sensitive products such as medical devices, liquida, solida or diagnostics. The latest example of packaging technology can be seen in live operation for the first time in Las Vegas: the blister machine KBS-C medplus with innovative processes for reduced film consumption and perfectly formed blisters.

In additon visitors can experience more about the advantages of an individualized KOCH packagingLine for primary and secondary packaging on Stands 6364 and 6601. And about the K 4.0 smartpacks - digital service packages for reduced downtime and permanently lower maintenance cost.

Our MISSION

Shaping the future – with sustainable packaging solutions

For more than 50 years and with approx. 400 employees KOCH Pac-Systeme has stood for top quality and efficient custom blister packaging technologies. A specialist in meeting complex demands, when it comes to the development and implementation of custom blister machines and packaging lines featuring modular designs.

According to the principle "Package the sustainable way", KOCH focuses on all-in-one solutions comprising packaging design and packaging technology: Innovative processes and technologies for a reduced product-pack ratio and an optimum utilization of the machine format. KOCH's portfolio is suitably rounded off by comprehensive service support and perfectly combined digital K 4.0 smartpacks.

Shaping the future:
With sustainable packaging solutions
CONSUMER PACKAGING
LOWER SOUTH HALL, Booth #6364

Safe and optimized packaging of medical products: with KOCH medplus
HEALTHCARE PACKAGING
LOWER SOUTH HALL, Booth #6601

KOCH
UHLMANN GROUP

https://koch-pac-systeme.com/
See our ad on page 50 of this issue

Marchesini Group USA

43 Fairfield Place, West Caldwell, NJ 07006-6206 | **PHONE:** 973.575.7445
EMAIL: sales@marchesiniusa.com | **WEBSITE:** www.marchesini.com

We are a leading supplier of primary and secondary packaging solutions to the pharmaceutical, biotech and cosmetic industries. Established in 1992, our 23,000-square-foot North American Headquarters supports the USA, Puerto Rico, and Canada and is backed by 2,300 Marchesini staff members worldwide. This modern facility is equipped and staffed to meet the ever-increasing demands of today's sophisticated and quality-conscious packaging clients.

In today's high-tech global marketplace, you need the right people and a commitment to providing the highest level of innovation, craftsmanship, reliability and service. Our years of collective experience are at the service of our clients every day. Each person at Marchesini Group USA is here to satisfy our clients' packaging requirements in the most effective way possible.

Our sales team comprehensively analyzes and defines the customer's packaging requirements to translate technical challenges into effective unique solutions. By combining the most-advanced technology with our knowledge and understanding of the pharmaceutical, cosmetic and consumer products industries, we have made solving packaging challenges our specialty.

All precision packaging machinery available through Marchesini Group USA has been manufactured to meet the highest level of quality certification using established production benchmarks and testing procedures. No single element of our business is as important to our reputation and our success as quality… and it has never been compromised.

A full range of equipment is offered including Blister and Deep Draw Thermoformers; Bundlers; Horizontal & Vertical Case Packers; Depacker; Form/Fill/Seal Machines; Jar Fillers; Labelers; Track & Trace/Serialization Solutions; Aseptic Fillers for Vials and Disposable Syringes; Liquid Fillers/Cappers; Palletizers; Filling-Stoppering-Closing of Vials, Ampoule, or Carpules; Washing, Class 100 Sterilization/Depyrogenation Tunnels; Strip Machines; Tray Packers; Tube Fillers; Wrapping/Banding/Overwrapping Equipment; Wallet Packaging; Needle Safety Device Assembly; Turbo-Emulsifiers; Melters; Filling and Closing Machines; Stickpack Machines; Sachet Machines; Electronic Counting & Filling Machines; Pharmaceutical Inspection Systems; Stainless Steel Product Containers and Tanks for Pharmaceuticals and Cosmetics.

At Marchesini, customer service is not a department. It is a commitment to our company philosophy and a realization that our steady growth can only be maintained through customer care. Whether our customer's packaging solution requires a new installation or a modification or retrofit, we are here to help optimize productivity and maximize uptime to get the best results and the highest output. Quality control and testing procedures are maintained at every stage of product development and manufacture.

Our customer care service, like our custom packaging solutions, is tailored to fit our customer's specific requirements. Staffed by experienced, factory-trained technicians, customer care provides machinery and line rebuilds, servicing and integrations, outstanding quality, unquestioned dependability and the highest level of performance. Our computerized customer care spare parts and shipping office is in direct communication with HQ to forecast the demand for critical parts and equipment.

Our MISSION

"Forty-two years have gone by since my father, Massimo, developed the first cartoning machine branded Marchesini.

He started his business in his garage at home, in Pianoro, just outside Bologna, but soon expanded thanks to the abilities of a man who had worked for years as a skilled technician for a leading manufacturing company of automated machines.

Will power, the ability to face ever challenging enterprises and Italian passion for the fine tailoring of the product are the reasons that have always inspired our company in facing ever important and committing projects of expansion.

The packaging industry is indeed one in continuous evolution and to remain competitive we have to constantly deal with technological innovation.

We are the right partner where customers will find the best cutting edge solutions for their specific needs. Because You are our mission"

Maurizio Marchesini
Chairman, Board Member

MARCHESINI GROUP USA

www.marchesini.com

See our ad on page 52 of this issue

Material Master™
Bulk Bag Discharger

PowerFill®
Bulk Bag Filler

Material Master™
Bulk Bag Conditioner

Material Transfer & Storage

1214 Lincoln Road, Allegan, MI 49010 | **PHONE:** 269.673.2125
EMAIL: sales@materialtransfer.com | **WEBSITE**: www.materialtransfer.com

Material Master™ Bulk Bag Conditioners – Quickly and safely return hardened materials to a free-flowing state.

Our newly enhanced Material Master® Bulk Bag Conditioner leverages our patented design and unique feature set to bring customers the most advanced conditioning technologies at reduced price points.

Flexible programming and touch-screen operator interfaces ensure consistent material conditioning, eliminate unnecessary labor, and reduce costs associated with bag breakage, production bottlenecks and compromised employee safety.

Material Master™ Bulk Bag Dischargers – Feature patented technology for clean, dust-tight discharge of your materials.

Container & Drum Dischargers – Discharge any size container at heights to 40', dust-tight Lift & Seal System™ or open discharge. Patented Control-Link Rotation System™ for 180° rotation. Container and drum discharging systems are custom-designed to meet each customer's specification requirements.

Material Master PowerFill® Bulk Bag Fillers – Material Transfer Bulk Bag Filling Stations offer a complete range of filling solutions, from a simple durable unit for low volume filling, to a highly sophisticated, automated system for high-volume production.

The new **PowerFill® Pro** and **PowerFill® Select Bulk Bag Fillers** set the standard in reliability and high performance at price points that make the technology both more affordable and more valuable. Well-designed and solidly built with rich feature sets, they are easy to use and maintain. A broad range of options make custom-designing solutions for specific customer applications easier and more cost-effective than ever before.

Integrated Systems – Are available to meet specific customer application requirements.

These products are supported by the highest standards of excellence in service. Our service doesn't end when our products ship. From operator training to equipment evaluations, service contracts, remote equipment monitoring and more, our teams are focused on doing what's right for each of our customers: keeping their equipment up and running efficiently and safely.

Our MISSION

Material Master™
Drum Discharger

Material Transfer has always held itself to a higher standard. That is how we have earned our reputation for the highest quality powder and bulk material handling equipment and systems in the market. Focused on serving the customer well, all of our products are built the way they should be built: robust in design, elegant in operation, simple to use and easy to maintain. This guiding principle has fueled our growth for more than 30 years.

TECHNOLOGIES:
More than 98 percent of the equipment Material Transfer manufactures is custom designed for a customer's unique application requirements. Material Transfer utilizes talented engineers and the latest 3D computer software for equipment design, experienced metal fabricators and machinists with the latest fabrication and CNC machining technologies, as well as an experienced team of machine assemblers to build its products.

MATERIAL TRANSFER

www.materialtransfer.com
See our ad on page 6 of this issue

METTLER TOLEDO

1571 Northpointe Parkway Lutz, FL 33558 | **PHONE:** 813.889.9500
EMAIL: pi.marketing@mt.com | **WEBSITE**: www.mt.com/pi

METTLER TOLEDO is your single source for product inspection solutions offering Safeline metal detectors and x-ray inspection systems, Hi-Speed inline checkweighers, CI-Vision machine vision systems and PCE Track & Trace, serialization, and aggregation solutions. Our broad product inspection line ranges from very basic and economical systems to sophisticated, state-of-the-art systems with customized material handling solutions. Depending on your specific requirements, our systems can ensure perfect product presentation, create codes, verify package and label integrity, ensure weight range compliance, provide tamper-evident sealing, detect physical contaminants and inspect contents inside the closed package.

Track & Trace
METTLER TOLEDO PCE Systems are available to mark packs with individual serial numbers for full traceability of the production or packaging process and collect critical corresponding process data. All packaging formats from single cartons and bundles through to shipping cases and ready to ship pallets can be marked and verified.

Machine Vision
METTLER TOLEDO CI-Vision inspection systems ensure that products consistently meet manufacturers' quality standards and specifications resulting in perfect product presentation every time.

Metal Detection
METTLER TOLEDO Safeline metal detection systems prevent costly recalls by ensuring your products are free of ferrous, non-ferrous and stainless steel contaminants which can be introduced during processing.

X-ray Inspection
METTLER TOLEDO Safeline x-ray inspection systems can detect ferrous, non-ferrous, stainless steel, glass and stone contaminants, detect mass and check for missing or damaged product inside closed packages.

Checkweighing
METTLER TOLEDO Hi-Speed dynamic checkweighing systems ensure 100% quality control, minimize costly giveaway and give you total peace of mind.

Connectivity & Service
We also offer connectivity and data management solutions and global service support for increased productivity and profits brand protection, and regulatory compliance.

Our MISSION

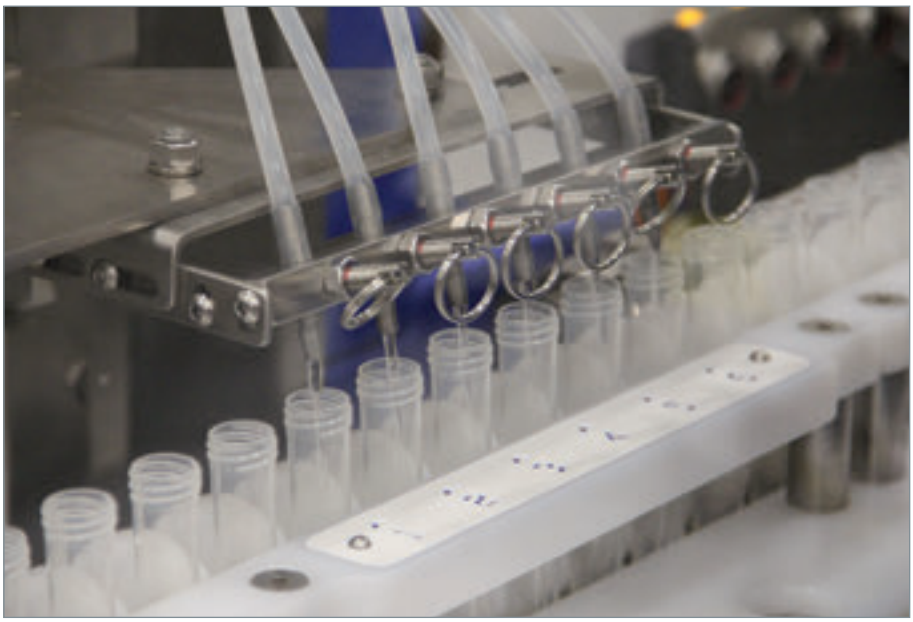
METTLER TOLEDO
Product Inspection Division
813-889-9500
www.mt.com/pi
pi.marketing@mt.com

Key Pharmaceutical Contact:
Robert Conrad
Sales Director Pharma
813-889-9500
Robert.conrad@mt.com

Manufacturing Facilities:
1571 Northpointe Parkway
Lutz, FL 33558

METTLER TOLEDO

www.mt.com/pi
See our ad on page 53 of this issue



Morrison Container Handling Solutions

335 W. 194th Street, Glenwood, IL, 60425 | **PHONE:** 708-756-6660
EMAIL: info@morrison-chs.com | **WEBSITE**: www.morrison-chs.com

Morrison Container Handling Solutions designs innovative packaging solutions for your unique container handling needs.

Innovation, in the pursuit of greater line efficiencies, has kept Morrison Container Handling Solutions the leading manufacturer of custom container handling equipment for over 50 years. Our services are all backed with design expertise and our legendary Support Built In®, our customer service philosophy, for any questions you have or technical support you need before, during, and after installation.

Our mission is to utilize our experience and design innovation to provide flexible and responsive solutions to the packaging industry. We strive to be the industry standard by providing an exceptional work environment that allows us to meet our customers' needs and exceed their expectations with our promise of Support Built In®.

Utilizing a variety of our product lines to create custom integrated systems or single solutions that solve container handling challenges, we approach every line with a unique opportunity to improve throughput and container handling.

As the leading manufacturer of timing screws in North America, we custom design not only screws but also drive units, change parts, down bottle reject integrations, can openers, and Auto Adjust Rails® . These solutions address a variety of line related productivity issues from the perspective of your container. For customers looking for robust solutions, we can provide turnkey systems that handle their containers for a variety of packaging applications complete with controls.

With PMMI Certified Trainers on staff, as well as a team of Field Service Engineers and Container Handling Experts, we back all our products with Support Built In®, so every step of the way, you'll have a partner, from design, to install, to spare parts, and maintenance.

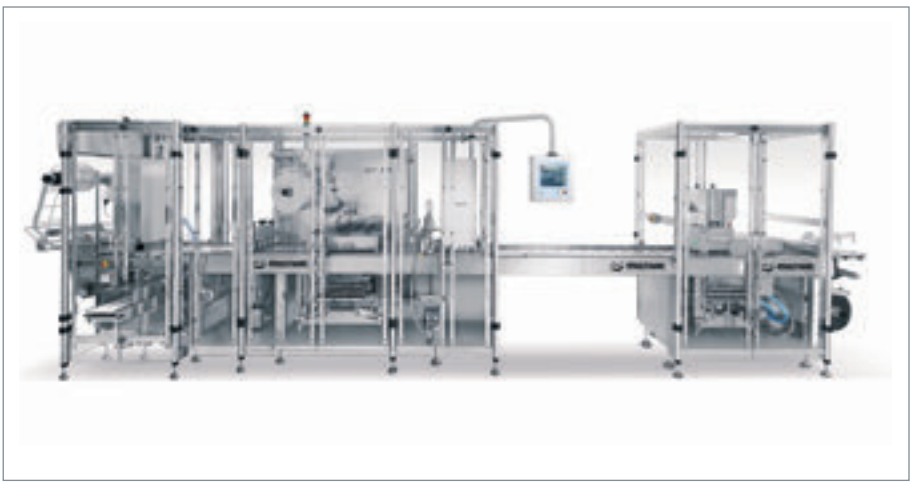
We know moving your containers efficiently is key to packaging success. Our objective is simple: perfectly move your container for the application you need every single time. No two containers are the same, so your handling systems shouldn't be either. We expertly move containers to make filling, capping, labeling, check weighing, metering, indexing, code dating, and just about everything else - easier.

Before arriving at your plant for installation, each custom designed has been tested and approved. So, you can have peace of mind throughout the whole process that our service, commitment, and support starts day one. Leading the industry in fast service and expert follow up, when you work with Morrison, you're working with a team of dedicated solution providers that are excited to enhance your plant productivity and container throughput.

We look forward to being a partner in your productivity. With over 50 years of knowledge and experience, we are determined to analyze problems and provide solutions for your container handling needs – with Support Built In ®.

MORRISON
CONTAINER HANDLING SOLUTIONS

See our ad on page 28 of this issue



MULTIVAC, Inc.

11021 N Pomona Avenue, Kansas City, MO 64153 | **PHONE:** 800.800.8552 | **FAX:** 816.891.0622
EMAIL: muinc@multivac.com | **WEBSITE**: us.multivac.com

The thermoform packaging machines with MULTIVAC Clean Design™ are solutions for sensitive pharmaceutical and biotech products, such as combination packs, pre-fill syringes, ampoules, vials and injectors. This machine concept separates the process area and machine equipment from each other to the greatest possible extent. This GMPcompliant machine design supports reliable line clearance. Furthermore, the machine is characterized by high flexibility in terms of the packaging materials being processed. Simple, quick and reproducible format changes also make the machine attractive for small and medium-sized batches.

Flexibility

The thermoform packaging machines with MULTIVAC Clean Design™ provide a high level of flexibility in terms of formats, packaging materials and modified atmosphere packaging. The quick conversion of the machine, even for small batch sizes, can be achieved by a simple format change.

Modular construction

The modular construction makes a high level of flexibility possible in the machine design.

Sensitivity

The innovative machine concept allows the process area to be strictly separate from the machine equipment. Transparent enclosures with large-area doors guard against direct access and environmental influences. At the same time, they provide perfect visibility and cleanability.

Process reliability

The thermoform packaging machines with MULTIVAC Clean Design™ are equipped with the proven MULTIVAC IPC control to guarantee reliable and reproducible packaging outcomes. The aim of the design in all machines with MULTIVAC Clean Design™ is maximum visibility and the avoidance of cross contamination.

Accordingly, particular emphasis was placed on a machine design with the following features:

- Strict separation between the product processing area and the machine technology area
- Visibility of all process-related machine areas
- Deflector plates in the inside of the machine
- Widest possible avoidance of hidden voids
- Minimum gap dimensions
- Cable and pipe work routing in enclosed ducts

Our MISSION

MULTIVAC is the global leader in horizontal thermoform fill-seal packaging machinery. Our thermoform machines package a wide range of products efficiently and cost-effectively, including medical and pharmaceutical products, food products and industrial and consumer goods. Our product range is the broadest in terms of size, performance and equipment: compact machines for small volumes, high-speed machines for large volumes and specialized machines for producing applications including FormShrink and MultiFresh™ packaging.

The worldwide MULTIVAC organization is comprised of more than seventy subsidiary companies serving countries on every continent.

Additionally, MULTIVAC agencies ensure the most advanced packaging machinery is available to medical and pharmaceutical, food, consumer and industrial product manufacturers virtually anywhere in the world. No matter where a MULTIVAC machine is purchased and installed, our sales and technical service professionals are committed to helping our customers achieve their goals with the world's most innovative and reliable packaging solutions.

MULTIVAC
BETTER PACKAGING

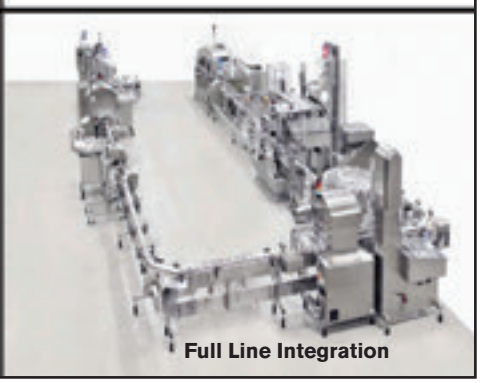
us.multivac.com

See our ad on page 37 of this issue

Dara Filling/Closing for Vials in Nest

Cremer CFS-622*4 Tablet Counter

NJM Courser® 230 Vial/Syringe Labeler



Full Line Integration

NJM Packaging

5600 Kieran, Montreal, QC H4S 2B5 Canada
PHONE 800.811.6990
EMAIL info@NJMPackaging.com • **WEBSITE** NJMPackaging.com

NJM Packaging is a trusted automated packaging systems manufacturer, integrator, and support resource. We offer a broad range of technology, specializing in the needs of packagers in these industries:

Pharmaceutical
Biotechnology
Nutraceutical
Vitamin
Personal Care

For over 100 years, NJM has been the proven packaging systems resource, unmatched for the innovation and quality of our equipment manufacturing, solid dose solutions, expertise in labeling, complete line integration and truly exceptional support. We are a one-stop packaging solutions source offering expert knowledge and experience from the earliest stages of planning through implementation and production. Our deep understanding of the entire production line, processes, and logistics allows us to supply quality packaging line equipment from other leading manufacturers, providing fully integrated lines and serialization solutions. NJM provides custom design build, engineering and research & development capabilities through the ProMach Innovation Center (PMIC). Our equipment and services include:

Aseptic Filling/Stoppering/Capping
Cappers
Cottoners
Inspection
Integration
Labelers
Print & Apply
Serialization
Tablet Counters
Unscramblers

By offering both stand-alone machines and integrated systems, NJM has grown our standing as a trusted comprehensive packaging systems manufacturer.

Our MISSION

PROMACH Pharma Solutions

NJM, part of ProMach Pharma Solutions, is a world-class supplier of packaging systems for solid-dose and liquid pharmaceuticals, biopharmaceuticals, nutraceuticals and more. We design, manufacture and provide line integration services, backed by exceptional support and over 100 years of customer success. NJM equipment includes but is not limited to:

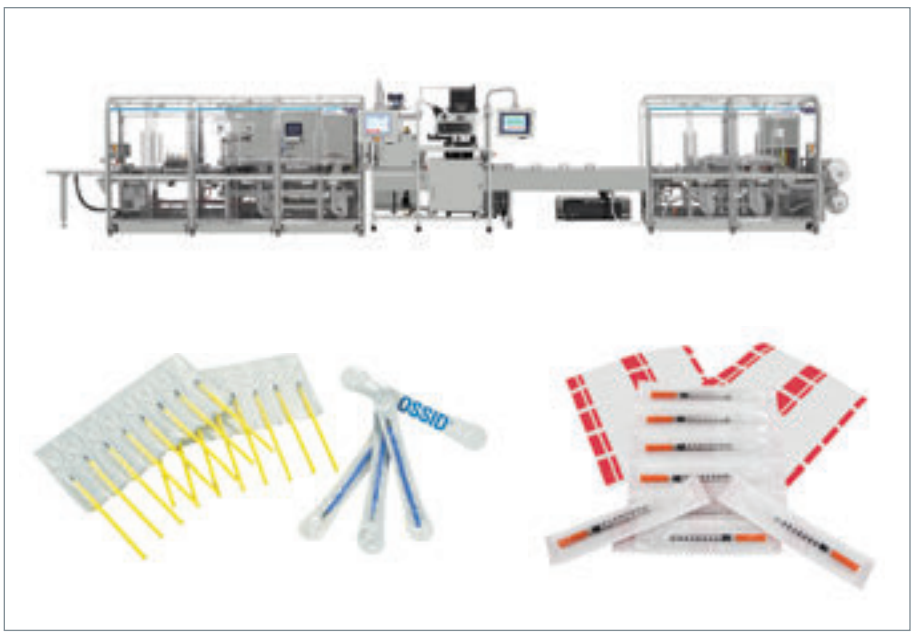
- **Beltorque®** – A hi-speed, in-line capper that rivals the throughput of complex rotary cappers but with simpler mechanics, faster changeovers and gentler handling.
- **Courser 230** – A compact, dual-purpose labeler that handles both vials/syringes.
- **Complete Turnkey Solid Dose Line Integration** – Build and install turnkey systems at the customer's plant and offer in-plant training documentation, and validation support.
- **Cremer CFS-622*4** – A modular tablet counter and filler integrated with CountSafe inspection and ejection system.
- **Dara Pharmaceutical Packaging** - Aseptic filling and closing solution for syringes, vials and cartridges in nest. Ready-to-use disposable syringes provide security, hygiene and dosing accuracy for medical injections.

Beyond pharma and biopharma, our customers include food, beverage, chemical, personal care product and cosmetic manufacturers and contract packers.

NJM

www.NJMPackaging.com

See our ad on page 5 of this issue.



OSSID

4000 College Rd, Battleboro, NC 27809 | **PHONE:** 1-800-334-8369 • 1-252-446-6177
EMAIL: ossid@promachbuilt.com | **WEBSITE:** www.ossid.com

Ossid LLC, a ProMach brand, is committed to providing our customers with a superior line of machines. Ossid is the leading manufacturer of high speed packaging and labeling equipment, including tray overwrappers and sealers, flow wrappers, weigh price labelers, case scales, and horizontal form fill seal machines. Working with customers in the medical industry, Ossid provides sterile, safe, and effective packaging solutions.

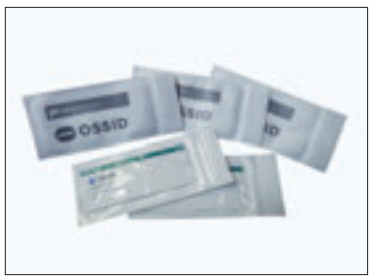
There's nothing standard about medical devices. Ossid understands the unique and complicated requirements of the medical industry and strives to meet those needs with precision and safety at the forefront of the design. That's why Ossid's line of horizontal thermoform fill and seal machines are flexible to fit your specialized needs, no matter the specifications. If you can imagine it, our team of engineers, with a combined 75 years of experience, will work to design it.

Ossid's medical machines are versatile; packaging both flexible and rigid medical package types and are built in accordance with UL 508A standards. In addition to medical devices, Ossid's FFS machines are ideal for packaging medical and dental kitting, disinfectants, pharmaceuticals and other products.

Ossid medical machines offer many additional features and benefits including an auto web aligner, static eliminator, hinged upper tooling, servo actuated presses, and a robust framework and guarding package. The unique machine design offers multiple stations for efficient and consistent output.

Our comprehensive customer service program, including service technicians, parts and training teams know how to help you keep your equipment running at maximum efficiency. Ossid helps its packaging customers protect and grow the reputation and trust of their consumers. ProMach is performance, and the proof is in every package.

Our MISSION



Our mission at Ossid, LLC is to provide our customers with cost-effective packaging and labeling solutions. Ossid works to give our customers a complete flexible packaging solution. Providing customers with excellent service nationwide, we can respond quickly to customers experiencing downtime needs and offer preventive maintenance programs to reduce overall downtime concerns.
Our goal is to build long term relationships with our customers. Our committed sales, service and aftermarket parts teams work collectively to quickly and effectively assist customers with their needs. As part of the ProMach Flexibles & Trays business line, Ossid helps our packaging customers protect and grow the reputation and trust of their consumers. ProMach offers end to end capabilities nearly everywhere on the packaging line. ProMach can offer solutions for any customer project or application needs by providing best in class stand-alone equipment from industry leading product brands, partial line integrations, and complete large multi-brand turnkey packaging line integrations. ProMach is performance, and the proof is in every package.

OSSID

www.ossid.com

See our ad on pages 55 of this issue

Packworld USA

539 South Main Street, Nazareth, PA 18064 | **PHONE:** 610.746.2765 | **FAX:** 610.746.2754
EMAIL: info@packworldusa.com | **WEBSITE:** www.PackworldUSA.com

Packworld USA offers a complete line of precision controlled heat sealing equipment engineered with the advanced TOSS Technology – The Optimum Sealing System. Designed specifically for today's medical device, bio-tech, and pharmaceutical markets, Packworld machines produce validatable, repeatable seals on all types of medical pouches and related polymeric products. To complement their line of straight bar heat sealers, Packworld also offers machines equipped with Vacuum & Purge and Seal & Cut capabilities for a variety of materials and pouch shapes. High temperature applications (over 300°C) can be accommodated.

Unlike conventional impulse heat sealers that attempt to use thermocouples to control the temperature of the heat seal band, all Packworld machines are equipped with the advanced TOSS Technology which relies on Variable Resistance Control (VRC) of the heating element itself. Similar to an RTD which measures temperature via a change in resistance, TOSS Technology VRC measures and controls the resistance of the heat seal band to deliver precise temperature control over the entire length and width of the heat seal band up to 500°C.

With TOSS technology, there is no need to worry about thermocouples that don't stay in place, burned up thermocouples, or the inherent inconsistencies of thermocouple controls. With Packworld and TOSS, customers are assured of consistent, repeatable seals from one machine to another as well as from the first pouch to the last.

Packworld USA has continued to expand on its TOSS Touchscreen line of machines. The various series in the line now includes the PW3300, PW3400, PW4400, and PW5500. All of these new series provide graphical display of time/temperature/pressure, password protection, recipe storage, data logging and built–in multiple point temperature calibration. Machines are able to run in 21 CFR Part 11 compliance with the Touchscreen controls.

Along with its full line of validatable pouch sealers, Packworld USA also specializes in the design and manufacturing of custom heat seal tooling for applications requiring contoured shaped heating elements.

We are so confident in the quality of our machines that Packworld USA's entire line is backed with a 30 month warranty.

Our MISSION

From the start, Packworld USA's sole mission has been to redefine conventional impulse heat sealing by employing the advanced, Variable Resistance Controlled (VRC), TOSS Technology in every machine it builds. Today our entire company is committed to the design and engineering of precision VRC heat sealing machines that are fully validatable and capable of producing "Perfect Seals…Every Time".

Our entire team is driven by Packworld core values: quality, trust, honesty, integrity, respect for the individual, teamwork, partnerships, and a striving for excellence.

Added all together, Packworld USA has quickly become one of the most recognized brands of heat sealing machines in today's medical device, bio-tech, and pharmaceutical markets.

Packworld With T·O·S·S Technology

www.PackworldUSA.com
See our ad on page 2 of this issue

PAXXUS

Americas: 320 South Stewart Avenue, Addison, IL 60101 • **Asia**: 9 Tuas Avenue 4 | Singapore 639365
Europe: Ballyvourney | Macroom | County Cork P12 PX72 | Ireland
PHONE: +1 630.628.1700 | **WEBSITE**: www.PAXXUS.com

PAXXUS is a leading supplier of flexible packaging for the global healthcare market. With over 85 years in the packaging industry, PAXXUS' team of material science experts, packaging engineers, and chemists have created an extensive portfolio of engineered flexible materials to draw from. Providing a wide range of options from off-the-shelf to custom, PAXXUS is known for collaborating with their partners to ensure requirements are well understood and considered every step of the way.

PAXXUS has been recognized and awarded by several industry organizations for technological advancements in flexible material design. Many of PAXXUS' best innovations have been directly inspired by the complex regulatory requirements of the medical device, pharmaceutical, diagnostic, and life sciences industries. PAXXUS provides state-of-the art solutions to meet compliance and regulatory requirements around the globe.

In addition to expertly designed products, partners of PAXXUS greatly benefit from the company's comprehensive manufacturing capabilities alongside agile and responsive service. Better quality control, shorter lead times, and real-time project updates are direct results of choosing a vertically integrated supplier like PAXXUS. From project start to finish, the team at PAXXUS is dedicated to providing the highest-quality flexible materials and best-in-class service.

Our MISSION

MISSION:
Improving the quality of life – now and for future generations – through engineered flexible materials

CHIEF EXECUTIVE OFFICER:
DHUANNE DODRILL

CHIEF TECHNOLOGY OFFICER:
DOUG DODRILL

MANAGING DIRECTOR, PAXXUS ASIA:
EDDY CHAN

MANAGING DIRECTOR, PAXXUS EUROPE:
CIARAN FOLEY

CHIEF STRATEGY OFFICER, VP OF SALES & MARKETING:
DWANE HAHN

VP OF RESEARCH & TECHNOLOGY:
HENK BLOM

PAXXUS
GLOBAL FLEXIBLE HEALTHCARE PACKAGING

www.PAXXUS.com
See our ad on page 14 of this issue

Perlen Packaging

135 Algonquin Parkway, Whippany, NJ 07981 | **PHONE:** 973.887.0257
EMAIL: info.us@perlenpackaging.com | **WEBSITE**: www.perlenpackaging.com

Perlen Packaging is a Swiss based international company in the field of thermoformable blister film manufacturing. With locations in Switzerland, Germany, USA, China and Brazil, we operate on a global basis and create win-win Situations for SMEs and multinational pharmaceutical companies.

At Perlen Packaging, people, processes, facilities and products are geared to the needs of the pharmaceutical industry. Our factories are equipped with state-of-art machineries fulfilling the needs of our pharmaceutical customers like clean room class 8, GMP Zone concept, 100 % film inspection and many more. Our experience in the pharmaceutical blister market started more than 60 years ago and since then we are constantly further developing our quality products and are convincing our customers with our service capabilities.

Our wide PERLALUX® product portfolio covers a full range of solutions for primary packaging from Mono PVC films up to high barrier films, in which we are one of the leading suppliers globally, for highest product protection.

Perlen Packaging was the first company to enter the ultra-high barrier segment with PVdC based blister films. In 2006 Perlen Packaging took the market by surprise with the successful launch of PERLALUX® - Tristar ultra, the first PVdC based high barrier film and cost-effective alternative to PCTFE. In 2012 a new generation, PERLALUX®-Ultra protect was launched in the market. A further development with the highest water vapour and oxygen barrier, which gave Perlen Packaging a further competitive advantage. The most important pharmaceutical companies worldwide are using these high barrier films today.

Perlen Packaging has now succeeded in expanding the product line with the highlight PERLALUX® MultiLayer ultra 280. "MultiLayer ultra 280 combines an increased water vapour and oxygen barrier with optimised processability. The product perfectly completes our range of ultra-high PVdC barriers," said Lars Kirchhoff, Chief Sales Officer of Perlen Packaging.

Our MISSION

In our company, the customer is always at the center of our work - protecting their pharmaceutical products is our purpose. Our employees and our worldwide sales-network are our most important success factors. We focus on innovations and developments in order to meet the market requirements with our high-quality product range and to achieve sustainable growth. Our customers can rely on us because we do what we say.

By continuously improving our processes together with our partners, we aim to be **"always one step ahead".**

perlen
packaging

www.perlenpackaging.com
See our ad on page 13 of this issue

ProSys Servo Filling Systems

422 E. Fountain Rd., Webb City, MO 64870 | **PHONE:** 417.673.5551 | **FAX:** 417.673.7971
EMAIL: info@prosysfill.com | **WEBSITE**: www.prosysfill.com

ProSys is a premier manufacturer of manual, semiautomatic, and fully automatic equipment for filling Cartridges, Squeeze Tubes, Syringes and Rigid Containers. A global supplier of filling equipment since 1985 with U.S. sales, manufacturing and customer service facilities located in Southwest Missouri.

GLOBAL INSTALLS

- **Pharmaceutical**
- **Cosmetic**
- **Chemical**
- **Adhesive**
- **Sealant**
- **Grease**
- **Food**

FLEXIBLE COMBINATION FILLING SYSTEMS

- **Plastic & Metal Tube Filling Systems**
- **Tube & Airless Pump Filling Systems**
- **Tube & Cartridge Filling Systems**
- **10, 14 & 30 oz. Cartridge Filling Systems**

Squeeze Tube Filling Machines-
speeds from 15 to 300 per minute.

Syringe Filling Machines-
speeds from 20 to 300 per minute.

Airless Pump Filling Machines-
speeds from 15 to 300 per minute.

Cartridge Filling Machines-
speeds from 10 to 250 per minute.

Custom Filling Systems

FEATURES & BENEFITS

- **Fill Accuracy to +/- 0.5% by Volume**
- **Turnkey & Custom Designs**
- **Air-Free Filling**
- **Vertical Bottom Up Filling**
- **Color Mix Solutions**
- **Drum & Pail Presses**
- **Explosion Proof Controls**

(Class 1 Division 1&2, ATEX 0&1)

Our MISSION

Building Quality, Integrity & Value In Our Team, With Our Customers, and in The Equipment We Design, Build & Deliver.

- **Tool-free Release System for Simple Changeovers**
- **"Digital Readout Indicators" for Fast & Accurate Adjustments**
- **On-line Service & Support**
- **Recipe Storage & Recall**
- **Creams, Lotions & Viscous Pastes to 3 Million Centipoise**
- **Designed & Built in the U.S.A.**

PROSYS® SERVO FILLING SYSTEMS

MADE IN USA

www.prosysfill.com

See our ad on page 49 of this issue

Spectrum Solutions

12248 S. Lone Peak Parkway, Draper, UT 84020 | **PHONE:** 801.569.0465
EMAIL: info@spectrumsolution.com | **WEBSITE:** www.spectrumsolution.com

Fully-Integrated, Forward-Looking, and Scalable End-to-End Medical Device Products, Services, & Solutions

The difference between designing and delivering a good or industry-transforming medical device that advances your product program, even in the throes of a global pandemic, actually hinges more on the talented experts behind the scene. It's identifying, recruiting, and building the industry's most talented medical device manufacturing dream team to successfully deliver a new saliva diagnostic solution, so innovative, it changed industry testing protocols worldwide. **That's Spectrum**.

Advancing your medical device product program means choosing the right outsourcing partner with the superhuman ability to handle the complexities of mass-scale medical manufacturing and global fulfillment. Medical device outsourcing is a vital component of the life science industry.

Sometimes a fresh perspective on something we thought we understood, can open the door to new possibilities we hadn't even considered. Focused on pioneering medical device innovation, Spectrum Solutions commissioned the break-through saliva study that dared to suggest a complete transformation in viral PCR testing protocols to an easier, pain-free, noninvasive, 99.998% accurate, and infinitely safer option using saliva (spit).

Saliva's recent MVP status is a new development even though saliva's been used in diagnostics for more than 2000 years. Analysis of the properties in saliva using biochemical and physiological methodologies are traced back to at least a century ago. Unlike blood, saliva analysis looks at the cellular level (the biologically active compounds), making it a better representative of what is clinically relevant.

Years from now, the medical community, patients, and history books will look back on 2020 and COVID-19 testing as the diagnostic turning point in favor of saliva.

Spectrum offers dedicated internal resources at each stage of its fully integrated custom product manufacturing process. From concept to device manufacturing, all the way through to an order and direct-to-user product fulfillment. Our all-star team of medical, design, engineering, and manufacturing experts leverage the ideal combination of Six Sigma, Lean Manufacturing, Theory of Constraints, and FEMAs to deliver the products and services crucial in supporting a global healthcare system.

Our MISSION

SPECTRUM™ SOLUTIONS

- **Medical Product Design, Development, CAD, & Concept Prototyping**
- **R&D Scientists and Engineers Including Quality, Design Controls, & Process Validation**
- **Injection Molding & Expert Tooling with Rapid Prototyping Capabilities**
- **Microfluidics Chemical Formulation Development**
- **Custom Packaging, Unique Barcode Serialization, and Specialized Kitting**
- **Direct-to-User Global Fulfillment with SaaS biosample chain-of-custody & customizable track-and-trace notifications**

www.spectrumsolutioncom

See our ad on page 57 of this issue

Starview Packaging Machinery, Inc.

1840 St. Regis Blvd, Dorval, Quebec H9P 1H6 Canada | **TOLL FREE:** 888-278-5555
EMAIL: sales@starview.net | **WEBSITE:** www.starview.net

Starview Packaging Machinery, Inc. is the leading manufacturer of packaging machinery for high-visibility packaging with over 30 years of supplying standard and custom packaging systems to our customers and distributors.

Providing the Medical Device and Pharmaceutical Industry with innovative packaging machines for:

- **Medical Device Packaging**
- **Pharmaceutical Packaging**
- **Blister & Clamshell Packaging**
- **Customized Packaging Equipment**
- **Systems with Automation and Integration**

We design, engineer, and manufacture a comprehensive line of manual, semi-automatic, and automatic sealing machines. Available in shuttle, rotary, carousel, and inline conveyor configurations, a variety of standard and custom sealing areas are available to meet the specific requirements of customers and maximize productivity. Machines are configured to suit the specific application such as retail-carded packages, sterile medical device packages, or pharmaceutical wallet packages.

With over a century of combined experience, Starview's management team strives to continuously exceed our customer's needs and expectations. Our distinct competitive advantage is in providing a complete range of both standard and customized quality packaging systems backed by solid machine designs, robust machine construction, and superior service.

Starview offers many value-added features for our machines such as product sensing, printing and/or verification, hydro-pneumatic cold seal presses, robotic product loading, automatic packaging materials loading, automatic inline fold-over, finished package unloading with reject feature for non-compliant pack- ages, RFID tooling identification and all-electric machine models.

Additional features can include process controls for third party validation, direct access with on-screen adjustments for critical value calibration, and an ethernet connection for real-time data acquisition. Quick-change mechanisms for tooling sets, on-screen sealing press adjustments, machine performance tracking, and ANSI Class 4 safety make Starview machines an excellent choice.

Machines are offered worldwide through a network of Authorized Distributors who provide sales and service as well as the packaging materials used in conjunction with our machines.

Our MISSION

The owners, management, and staff of Starview are dedicated to designing and manufacturing packaging machines in North America with the highest quality fit, and finish backed up with industry leading customer service.

Starview's directive is to produce a full range of sealing machines for medical device packaging, pharmaceutical packaging and retail high visibility packaging. We offer standard machines with an array of custom and pre-designed options to provide our clients with machines to match their manufacturing requirements. Starview offers to design, manufacture, and integrate many value-added features including materials verification, custom automation, and robotics for its clients.

www.starview.net

See our ad on page 87 of this issue

Weber Packaging Solutions, Inc.

711 West Algonquin Road, Arlington Heights, IL 60005 | **PHONE:** 800.843.4242
EMAIL: info@weberpackaging.com | **WEBSITE**: www.weberpackaging.com

Weber Packaging Solutions, an ISO2001:2015 certified company, is an experienced innovator in meeting the needs of the healthcare industry. We provide the latest in pressure-sensitive labels, labeling systems and continuous ink jet systems and back them with a nationwide network of direct sales, service, and technical support.

Labels

Weber understands that the healthcare industry requires unequaled quality, consistency and traceability in its labels. We demand the same of our products and our processes, ensuring that your insistence on the highest-quality standards will be met.

Our wide-ranging label converting and printing capabilities are too numerous to detail here, but here's a sampling that's particularly germane to the healthcare industry:

- Vision inspection systems both on-press and post-press that ensure superior label quality
- Label adhesives, topcoats, and inks compatible with autoclave, ETO, gamma, and e-beam sterilization processes
- Expanded-text, multi-ply label constructions that handle the growing demand for increased text
- Intricate label die-cutting capabilities and adhesive zone-coating to permit one-step labeling for product kit combinations and recordkeeping
- In-line, variable code dating, bar coding, and messaging using on-press laser etch or UV inkjet
- Sequential, back-of-liner numbering for superior inventory control
- ISO 9001-registered, with label manufacturing processes that can assist your cGMP compliance to 21 CFR Subpart G (Packaging & Label Control)

Labeling Systems

Weber Packaging Solutions also manufactures a complete line of labeling equipment for the in-line printing and affixing of pressure-sensitive labels. We offer a broad selection of automatic label applicators that rapidly apply decorative, pressure-sensitive labels to all types of products and packages.

In addition, we design and build an exclusive selection of label printer-applicators. These self-contained systems combine high-resolution print engines with automatic label applicators to print and apply labels that help you comply with UDI regulations.

Ink Jet Coding Systems

Weber has a complete line of small-character continuous ink jet and high-resolution thermal ink jet systems available for high-speed, reliable coding on almost all substrates. Our BestCode and Markoprint ink jet coders are affordable and easy to use. These systems are the best way to print dynamic variable information like lot codes/date codes on packages or bottles.

Our MISSION

We Identify Your World

Since 1932, Weber Packaging Solutions' sole focus has been the development and improvement of labels, labeling and coding solutions. And we believe that focus has enabled us to thoroughly understand the needs of our customers.

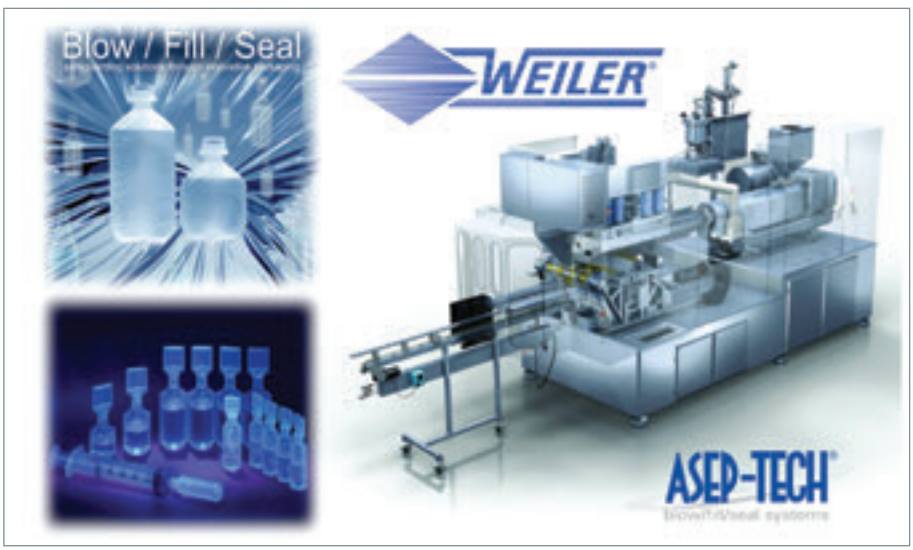
Weber's Corporate Mission Statement asserts that our success derives from helping our customers grow. Further, our commitment is to bring technologies to market that improve packaging automation, product identification and brand recognition. To underscore those efforts, we have assembled a team that is agile, creative, responsive and conscientious toward our customers, our community and our environment.

We believe that our Mission has helped us to become a knowledgeable partner to the healthcare industry.

Weber Packaging Solutions

www.weberpackaging.com

See our ad on the Back Cover



Weiler Engineering, Inc.

1395 Gateway Drive, Elgin, IL 60124 | **PHONE:** 847.697.4900 | **FAX:** 847.697.4915
EMAIL: solutions@weilerengineering.com | **WEBSITE:** www.weilerengineering.com

Weiler Engineering, Inc., a leading provider of aseptic custom Blow/Fill/Seal liquid packaging equipment for pharmaceutical and healthcare applications, is committed to the highest standards of excellence and to further expanding products and systems to enhance patient care. Weiler's proprietary ASEP-TECH® B/F/S packaging machines produce shatterproof, durable, aseptically-packaged products in one uninterrupted operation. This hands-free manufacturing process ensures that parenterals, ophthalmic solutions, and respiratory drugs reach the marketplace sterile, in the most cost-effective manner possible - every time. The ASEP-TECH® System is the culmination of 60 years of innovation in machine design and sterile process development, producing the most advanced aseptic liquid packaging process machinery available today.

The Weiler design incorporates the three-step process of blow molding, aseptic filling, and hermetic sealing of liquid products in one sequential operation on a compact machine frame. Weiler's patented electronically controlled fill system, automatic sterilization system with integral data collection, and filter integrity test system are provided as standard equipment for each machine configuration. Each machine is also equipped with a HEPA air shower to ensure a Class 100 environment under dynamic conditions in the nozzle shroud area.

Weiler's latest innovation is the NEW compact ASEP-TECH® **LAB+** Blow/Fill/Seal machine, which is ideal for Stability and Clinical batches for pharmaceutical products and/or small development batches using advanced aseptic technology. This revolutionary small footprint design focuses on ease of change-over and product range flexibility.
The versatile ASEP-TECH® **LAB+** machine features servo-driven motion controls and a modular platform that offers options such as Single-Use Technology (SUT) or conventional Clean-in-Place (ClP) and Steam-in-Place (SIP) technologies, a new patent pending Grade A filling zone and Particulate Matter Removal (PMR) system.

ASEP-TECH® Blow/Fill/Seal machines are proudly manufactured in the USA, designed and built by Weiler Engineering, Inc. in a 140,000 ft^2, state-of-the-art manufacturing plant. Weiler's manufacturing facilities and corporate offices are conveniently located near Chicago's O'Hare International Airport.

ABOUT US

INNOVATION DRIVEN BY SCIENCE!

FACTS:

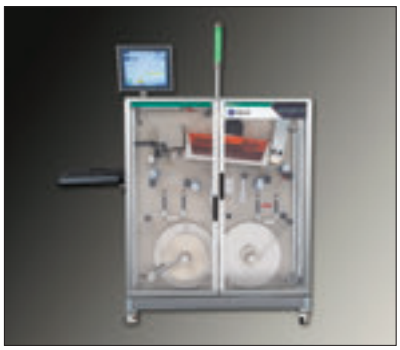
- Recognized as an advanced aseptic technology by the USFDA
- 60 years serving global markets
- Experience gained from 25 years operating a captive pharmaceutical CMO
- Close operation with regulatory authorities – compliance is key!
- Quality + Operational Know-how + Integrity

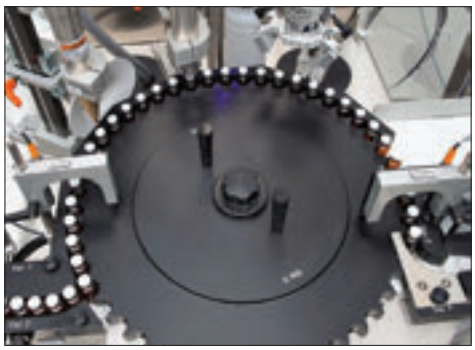
GOALS:

- Focus on the science of the technology for maximum customer benefit
- Simplicity of design to maximize product flexibility and minimize footprint
- Optimum service support throughout the markets we serve = high customer satisfaction!

WEILER®
ASEP-TECH®
blow/fill/seal systems

www.weilerengineering.com
See our ad on page 43 of this issue


Autonomy® Digital Label Printer


VCV Vial Coder


VR-72 Trunnion Labeler


RL-420 Rotary Labeler

WLS

1256 N. Church Road, Moorestown, NJ 08057, USA | **PHONE:** 1-856-273-3377 | **FAX:** 1-856-231-9883
EMAIL: WLS@ProMachBuilt.com | **WEBSITE:** WeilerLS.com

As part of ProMach, WLS has been designing, manufacturing, integrating and supporting some of the most sophisticated and advanced pressure sensitive labeling solutions, and now label printing solutions, in the marketplace. Our clients include companies across the following sectors:

- **Pharmaceutical**
- **Medical**
- **Nutraceutical**
- **Household and Personal Care Products**

WLS has long been known as a manufacturer of the industry's most robust and sophisticated labeling systems. With more than 450 active machine installations worldwide, WLS has one of the most extensive field support networks in the industry built around an unwavering service-driven culture. In addition, WLS also offers an industry-leading two-year warranty.

WLS also supplies the following equipment and services:

- **X-5 labeling heads with continuous print and inspection capabilities**
- **Label coding or printing platforms**
- **Serialization and product code association on a labeler**
- **Integration of RFID tags into labelers**
- **Bright-stocking platforms**
- **Integration**
- **Complete documentation services (i.e. DDS, FAT, IQ/OQ)**

ProMach Pharma now offers sales and service capabilities through our European office.

Our MISSION

PROMACH Pharma Solutions

About WLS

WLS is an industry-leading designer and manufacturer of high-speed rotary and in-line labeling machines and serialization, coding and label printing solutions for the pharmaceutical and medical packaging markets as well as the food, beverage, personal care, and consumer markets. With over three decades of experience, our mission is to improve our customer's labeling capabilities and ensure that our labelers provide them with the highest possible OEE. We strive to provide the most innovative labeling technologies with a culture of unwavering customer care. As part of the ProMach Pharma business line, WLS helps our packaging customers protect and grow the reputation and trust of their consumers. ProMach is performance, and the proof is in every package.

Learn more about WLS at WeilerLS.com

WLS™

WeilerLS.com

See our ad on page 11 of this issue

1 Enhanced Serialization Platform

COVECTRA

+ The ATLAS Repackaging System was designed to simplify the repackaging of pre-serialized pharmaceutical products
+ Licensed repackagers can cost-effectively relabel previously serialized products, rework products damaged in the warehouse, or account for products removed after packaging for quality control processes

2 Enhanced Heat Seal Coating

AMCOR

+ Amcor introduced its ACT2100TM heat seal coating for medical grade DuPont™ Tyvek® and paper packaging applications
+ Speedier ethylene oxide (ETO) sterilization cycles are made possible by the material's improved porosity, a fiber-free peel, and a bright, white adhesive that does not yellow

3 Serialization and Aggregation Systems

METTLER-TOLEDO PRODUCT INSPECTION

+ The T60 Integrated 360 Series offers serialization and aggregation of bottles and vials, enhancing quality control and traceability of products with 360-degree image capture
+ The technology uses a unique camera configuration of six image sensors that deliver a 360-degree image of the bottle; users can choose between a Liquid Lens that allows for 0.35mm module size inspection, or a Fixed Local Lens that allows for 0.2mm module size inspection

4 Beltorque Capper

NJM PACKAGING

+ The beltorque BT-ICL linear, continuous-motion capper handles a wide range of bottle shapes and sizes, as well as a variety of closure types, with simple mechanics that speed changeover and reduce maintenance
+ The BT-ICL uses two pairs of belts to gently rotate and tighten caps; by synchronizing the speed of the bottle with the rotating speed of the closure, the design applies precise torque that eliminates damage and minimizes cap skew and slippage

5 Full Service First-Opening Indication for Prefilled Syringes

SCHREINER MEDIPHARM AND PLAS-TECH ENGINEERING

+ Cap-Lock is Schreiner MediPharm's security concept for prefilled syringes combining a cap adapter and label; it irreversibly indicates whether a syringe has been previously opened, ensuring the integrity of the primary container, and preventing its undetected opening
+ Plas-Tech Engineering's cap is precisely adapted to the syringe and ensures accurate interlinking with the primary closure to equalize the diameter differences between the syringe body and closure

6 Capsule Filling Machine

SYNTEGON TECHNOLOGY

+ The GKF 60 capsule filling machine features a piezo station that fills small quantities starting at 0.1 milligram filling weight; also available are dosing modules for dry powder inhalation (DPI), pellets, tablets, or liquids
+ Each dosing station can be optionally equipped with a gravimetric 100% weighing system for each component dosed

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Healthcare PACKAGING EXPO

GET READY TO EXPERIENCE INNOVATION

Whether you're scaling up production, ramping up e-commerce, streamlining operations or increasing usability, the **most efficient way to find the solutions you need is attending Healthcare Packaging EXPO** with co-located PACK EXPO Las Vegas—***in person***.

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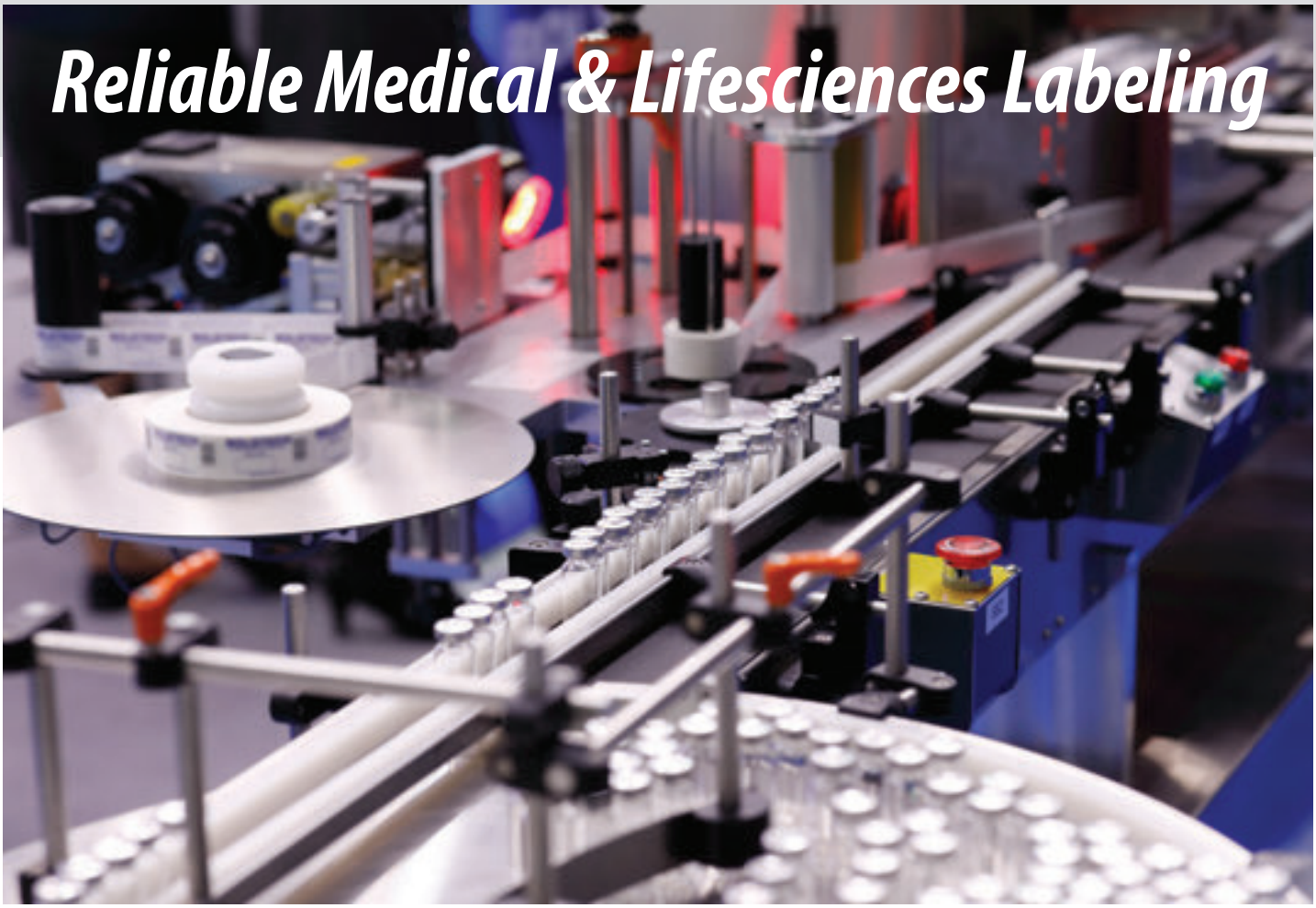

We Identify Your World.

When you need mission-critical labels and labeling systems that will be reliable, cost-effective, and easy to use, you need a one-source partner that you can trust.

Weber can help you with a wide range of medical and lifescience labeling and coding systems including cold-storage labeling, security labeling and track & trace labeling.

Weber Packaging Solutions is a family-owned labeling company that has been helping customers look their best for over 85 years.

We provide turn-key labeling solutions that, whether locally or globally, can add reliability to your production. With experience in just about every industry, we make sure you succeed in getting your product labeled correctly.

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