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RECYCLE-READY BLISTERS CONTINUE TO GAIN STEAM

SEP/OCT 2021

+ 9 Use Cases for IoT Stickers
+ Dry Ice Feeding for COVID-19 Vaccines
+ Sustainability-Minded E-Comm Supplement Kit
+ Previewing INTERPHEX 2021

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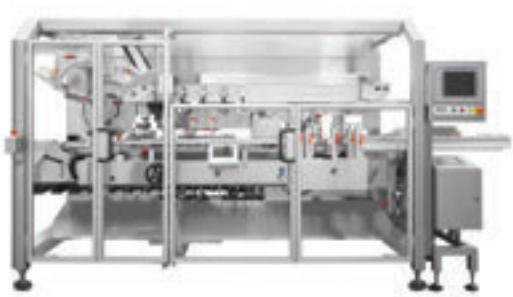

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↑ pp.16

9 LIFE SCIENCE USE CASES FOR IOT STICKERS

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Brand Owners and Consumers Eye Sustainable Packaging

Recycle-ready offerings continue to grow in the healthcare packaging community, but more work is needed on the recycling infrastructure front.

From a personal standpoint, I'm excited to see demand soar for practical, recycle-ready blisters and other life science packaging. Most of us are aware that we can't keep consuming resources—and disposing of them—at our current rates. Brand owners are coming around to the idea that you don't have to sacrifice barrier properties when implementing primary and secondary packaging with alternative materials or end-of-life stories.

While I interviewed a source about a recycle-ready blister package (pp. 14), she put things in perspective: it's critical that the blister *actually gets recycled* after folks put in all this design work. So it's encouraging to see packaging suppliers collaborating with organizations as well as recyclers, sorters, and hospitals to tackle the massive of issue of ensuring packages end up in the proper waste streams. (We'll need much more investment from municipalities.)

For another waste reduction angle—of which there are many—our story on pp. 20 profiles a subscription supplement's e-commerce starter kit and pared down refill mailers. They really left no stone unturned, down to the algae-based ink and recyclable tape.

Of course, sustainability goes far beyond recyclability—from materials to energy to water usage and more. What is your company doing to cut waste from your operations? If you have ideas you'd like to share, or hurdles you've run into, write me at the email below.

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 Packaging Issue Leads to Massive Moderna Vaccine Recall

A recent *AP News* article discussed the late August recall of Moderna's mRNA coronavirus vaccine due to contamination. The vials that house the vaccines were found to contain tiny particles of stainless steel. Though health ministry officials believe the high-grade stainless steel poses no health risks, the company was still forced to suspend 1.63 million doses. An investigation, led by Moderna and its Japanese partner Takeda Pharmaceuticals, concluded that the contamination occurred on the production line at the point where stoppers are added to the vials.

2 Smart Dental Implants Resists Bacteria

A recent *MedicalXpress* article discussed a new high-tech dental implant with two novel features from a team of engineers at the University of Pennsylvania School of Dental Medicine. The first is a biofilm material infused with nanoparticles that resist bacterial colonization, and the second is an embedded light source for phototherapy. The latter is powered by the mouth's natural motions like chewing or brushing teeth, and it promotes the health of the surrounding gum tissue. The tech earned the team a finalist position in the University City Science Center accelerator program, which links them with commercialization experts and a chance to receive $200,000 in funding.

3 Veterans Want Medical Marijuana in the South

A recent *Stripes* article discussed a new effort from U.S. Military veterans to legalize medical marijuana, specifically in North Carolina. North Carolina is home to one of the largest veteran populations in the country thanks to its eight military bases. The effort is led by a Wilmington resident, Chayse Ross, a former Marine sergeant who served multiple deployments to Iraq, Afghanistan, and Pakistan. The goal: legalize medical marijuana for veterans living with debilitating conditions such as post-traumatic stress disorder. Ross has banded together with other vets to form NC Families for Medical Cannabis.

4 New Breath Test Determines Epilepsy Drug Regimen

Patients with epilepsy need a tailored drug regimen because the difference between a therapeutic dose and a toxic one is very small. A recent *Medgadget* article discussed a breath test that can quickly determine the optimal drug treatment approach. Developed by researchers at Switzerland's University of Basel, it helps outline metabolic hallmarks to help clinicians determine the efficacy of a medication. The technology is based on a system that measures breath metabolites in real time without the need for laboratory analysis.

5 Counterfeit Gilead Drugs Found in Authentic Packaging

A recent *FiercePharma* article discussed unsettling news about Gilead's HIV drugs sold at pharmacies in the U.S. According to Gilead, Biktarvy and Descovy have been swapped out for fake versions. Unauthorized distributors were selling counterfeit versions of the drugs in genuine Gilead bottles. The company alerted the affected pharmacies and is working with FDA officials to remove the fake tablets from circulation and prevent future incidents.

6 FDA Modernizes Social Media Voice

It's not uncommon to see a pun or humorous reference on the highway. Dynamic message signs are intended to increase compliance. A recent *FiercePharma* article said the FDA has enlisted its own wordsmiths to help relay their messages to get peoples' attention and combat dangerous viral misinformation. In one example, the FDA's Twitter account read, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." The post linked to an article discouraging people from using veterinary ivermectin to treat COVID-19. "Historically, we've used our social media platforms to communicate about a lot of important public health issues in fairly straightforward ways, but as the platforms have evolved, we've embarked on an effort to find creative ways to deliver our messages," noted Brad Kimberly, Dir. of Social Media for the FDA's Office of External Affairs.

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October 22, 2021

THE DEADLINE for entries to the 2022 Flexible Packaging Achievement Awards Competition.

$612 MILLION

THE NORTH AMERICAN PHARMA SACHET PACKAGING MARKET is expected to surpass this figure by 2027, offering pre-measured, single-dose packages designed to reduce product waste.

Source: Coherent Market Insights

225,978

THE NUMBER of new COVID-19 cases in children reported from Sept. 9 to Sept. 16, 2021, per the American Academy of Pediatrics.

50%

THE PROJECTED GROWTH in global biopharma sales for cold chain products, growing at approximately twice the rate of non-cold chain products (see pp. 10).

$470 MILLION

THE NATIONAL INSTITUTES OF HEALTH (NIH) has created a research initiative awarding grants totaling roughly $470 million to study long COVID-19. The research will include children, adults, and pregnant people.

"The MedAccred program is a demonstration of commitment to absolute quality among elite medical device manufacturers, and provides a competitive edge for those who have worked hard to achieve accreditation."

—CONNIE CONBOY, MEDACCRED PROGRAM DIRECTOR

"The laboratory at the CPT Jennifer M. Moreno Primary Care Clinic began using heat sensitive labels on the urine collection cups. This initiative allowed the cups to be recycled while protecting the patient's personal information. This effort reduced the clinic's regulated medical waste costs by 30%."

—LORI NEWMAN, PUBLIC AFFAIRS SPECIALIST AT BROOKE ARMY MEDICAL CENTER

"We saw the public narrative moving from robots taking jobs to robots saving lives and rebooting the economy. Manufacturers, unions, and policy-makers need to figure out how they can really leverage the vast amount of innovation...because many of the biggest issues holding back robotics innovation are... related to societal, cultural, and business barriers."

—FADY SAAD, CO-FOUNDER AND VP OF STRATEGIC PARTNERSHIPS, MASSROBOTICS

Survey: Manufacturers Must Step Up the Sharing of DSCSA-Required Transaction Data

In September, the HDA Research Foundation published its inaugural *EPCIS Implementation Benchmarking Survey*, gauging the current state of industry adoption of GS1 Electronic Product Code Information Services (EPCIS), as well as trading partner plans for exchanging DSCSA-required data. Results offered some startling statistics. 59% of manufacturers report they are not currently sending data to distributors; manufacturers cite "delays due to either past or potential future enforcement discretion" as the top obstacle to implementing EPCIS (43%). Most distributors are not connected to manufacturers in production today, and no connections in a production environment currently exist with distributors' dispenser customers. Visit HDA's Resource page for the FREE report download at hda.org. —*Keren Sookne*

DHL Express Aims at Sustainable Aviation

DHL Express announced that they were the first to order 12 fully electric Alice eCargo planes from Eviation, a Seattle-based global manufacturer of all-electric aircraft. This represents a pioneering step for DHL, with sights set on building an electric Express network. Eviation's Alice is reportedly designed to enable airlines—both cargo and passenger—to operate a zero-emission fleet.

Alice can be flown by a single pilot and carries 1,200 kilograms (2,600 lbs). Eviation expects to deliver the Alice electric aircraft to DHL Express in 2024. "We firmly believe in a future with zero-emission logistics," says John Pearson, CEO of DHL Express.

—*Keren Sookne*

Global Economy Passes Pre-COVID GDP; Risks Remain

In the second quarter of 2021, the global economy surpassed the pre-pandemic GDP from fourth quarter 2019, according to *PMMI State of the Industry: U.S. Packaging Machinery Report* by **PMMI** Business Intelligence. The Asia-Pacific region completed its recovery in late 2020, while the U.S. likely peaked in May 2021. Africa and Middle East regions are expected to follow suit in the third quarter, with Europe and Latin America completing recovery in the fourth quarter. COVID-19 remains a risk to economic outlooks in places where vaccination rates are lagging, including emerging and developing countries where vaccine campaigns are just beginning and will extend into 2022.

The rebalancing of severely disrupted global supply chains will take time. In May, supplier delivery times were the longest in survey history, according to the IHS Markit PMI™ global manufacturing survey, contributing to the steepest rise in input costs in over a decade and record inflation in selling prices. Semiconductor shortages have also disrupted several industrial sectors, including automobiles and parts, household goods, and technology equipment.

—*Kim Overstreet*

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Cold Chain Logistics: Poised for Growth with Lessons Learned from the Pandemic

As more complex, innovative specialty pharmaceutical products reach the market, including cell and gene therapies, there will be a growing demand for cold chain storage, transport, and distribution solutions.

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

By 2024 experts predict that five out of the top 10 best-selling drugs will require refrigerated storage and handling. Between 2018 and 2024 there is a projected 50% growth in global biopharma sales for cold chain products, growing at approximately twice the rate of non-cold chain products.

At August's HDA Distribution Management Conference, Ann Pham, Director of Business Development at third party logistics provider **ICS**, discussed cold chain considerations from a 3PL's point of view. She said that COVID-19 caused significant disruption to pharmaceutical supply channels, but the pandemic alerted the entire industry to become better prepared in the event of a future incident. "At the 3PL level, refining and renewing previously developed supply chain, risk management, and business continuity planning strategies became a focus, as well as storing product across multiple locations to decrease the risk event," said Pham.

As temperature-controlled logistics increase in both importance and complexity, evaluating the supply chain or distribution strategy, analyzing solutions and associated costs, and identifying channel partners can seem daunting. And according to the Institute for Human Data Science (IQVIA), the biopharma industry loses approximately $35 billion annually due to failures in temperature-controlled logistics. "Temperature excursions or deviations from required storage and shipping conditions are a major concern for pharmaceutical manufacturers," said Pham. "This was especially critical as we looked at the COVID-19 vaccine and associated therapy rollouts because of the widespread concern that improper cold

chain storage and handling would add to the pandemic crisis. But we saw tremendous collaboration amongst government agencies, manufacturers, 3PLs, and other supply chain partners to build rigorous yet flexible logistic strategies that enable the safe and secure distribution of vaccines and therapies around the world. The strategy collaboration in conjunction with the significant investments 3PLs have made in recent years to build out their cold chain storage and distribution capabilities made the vaccine rollout successful."

Pham added that the collective experience and capabilities to support temperature sensitive products was in place, but alignment was needed on a plan to support rapid-scale distribution with complex means. For example, if products with ultra-frozen requirements weren't distributed until after the vaccine doses thawed and the doses then needed refrigerated storage, it enabled supply chain partners to distribute vaccines at a more common temperature range, but it also required precise execution and coordination amongst all stakeholders to ensure that vaccines and therapies were delivered in a timely manner and administered within their short shelf life. She said, "We're taking the lessons learned from the COVID-19 vaccine and therapy rollout and applying them to our strategy as service providers. We understood the need to pivot quickly due to new demands on experience and capabilities, and to support these temperature sensitive products. Now more than ever the need for collaboration and communication across stakeholders throughout the product journey is key."

Temperature excursions

An excursion event involves a Time Temperature Sensitive Pharmaceutical Product (TTSPP) being exposed to temperatures outside the range(s) prescribed for storage and/or transport. What to do in the event of an excursion, and processes and tools for handling cold chain product, are both critical factors in successful management of a cold chain logistics program. The key to avoiding temperature excursions is knowledge of the product and product journey, and pre-planning for the most common challenges that occur along the way. "By engaging 3PLs early in the commercialization process, pharmaceutical companies and their partners can design and execute a robust supply chain strategy that leverages flexibility, storage across different areas, and the right packaging solutions to maintain product integrity across all conditions," Pham said.

Read this story on dry ice feeding for COVID-19 vaccines in this issue's OEM Application Note, pp.12.

Pack-out solutions: qualified vs. validated

There are multiple pack-out solutions, or shippers. A qualified pack-out includes a container and supplies specifically designed for use when packing product for transport and is "qualified" through International Safe Transit Association (ISTA) testing on minimum and maximum temperature ranges—often referred to as allowable excursions—which are supported by stability and other studies. This testing under controlled conditions ensures the shipper can achieve and maintain desired temperatures for a set amount of time.

Validation is taking a qualified pack-out and validating the actual temperature range time. Validation is typically performed by the manufacturer's quality team, which evaluates the duration or the time that it takes the completed package to be closed and sealed at the point of departure, until it is opened at the point of arrival. "Using a custom pack-out versus one that your 3PL can provide," Pham explained, "oftentimes comes down to understanding the product specific handling and temperature requirements. Cost is also a consideration. Your 3PL's standard qualified pack-out will be a less expensive solution than a custom pack-out. There is also a myriad of temperature-controlled transportation options as well, whether it's by truck, air, or larger container. Temperature loggers also operate to give clear evidence of temperature stability throughout the transit of your package."

"NOW MORE THAN EVER THE NEED FOR COLLABORATION AND COMMUNICATION ACROSS STAKEHOLDERS THROUGHOUT THE PRODUCT JOURNEY IS KEY."

–ANN PHAM, ICS

Monitoring

Monitoring innovations such as GPS and GSM technology allow for real-time shipment tracking and can also be utilized through loggers with live transmission and location reporting, providing immediate availability of data. Metrics typically include temperature, light, pressure, and shock. Pham said that 3PLs should be able to provide standard tracking information for all outbound shipments that leave their facility, providing full visibility to when a shipment was picked up by a carrier, status updates, and proof of delivery. A 3PL should also have the ability to provide these options and the various costs associated with them to aid in your analysis from both a dollar and quality perspective, said Pham.

Dry Ice Feeding for COVID-19 Vaccine Distribution

Equipment for dispensing dry ice into insulated containers holding COVID-19 vaccines had to be designed and produced by this OEM in just eight weeks.

PAT REYNOLDS, EDITOR EMERITUS, *PACKAGING WORLD*

Material Transfer & Storage (MTS) is a provider of custom design and manufacture of bulk bag filling, conditioning, and discharging systems for dry powders and bulk solids. When they were called upon to design and build customized equipment that would dispense dry ice into insulated containers carrying COVID-19 vaccines, the MTS team worked faster than ever before to meet the tight deadlines and compliance requirements of this vital project. Leveraging the talents of its experienced, committed staff and trusted vendors, MTS produced the dry ice discharging systems in just eight weeks.

Designing and building customized equipment so rapidly involves a strong level of knowledge and experience, says MTS President Scott Nyhof. "It's also good to have suppliers like **Eriez** that we can trust."

When it came to vaccine distribution, MTS needed to maintain ice pellet size consistency, meter ice evenly to protect each vaccine, and monitor ice discharged during packaging—and the process had to be automated. The integrated process MTS came up with includes a crusher, a scale system, and customized feeder and controls required to report diagnostics to the vaccine manufacturer operating the system.

An essential part of the success of the MTS dry ice unloading/feeding system is the integration of a vibratory feeder, the Eriez 65B Electromagnetic Feeder. The rush to move the vaccine to distribution centers around the globe demanded that Eriez respond swiftly and effectively.

Eriez created engineered drawings and CAD models for MTS within days. They delivered a custom-engineered system to meet the demanding timeline for the project. It helped tremendously that MTS and Eriez have a long history of success together.

The Eriez feeder was required to handle the sub-zero temperature of dry ice to protect the new vaccine, and precise feed control was critical. Just as vital, this feeder model handled the specific capacity and proprietary requirements of this application.

"The customization includes an over-tray electromagnetic drive configuration for maximum clearance below the feeder tray and closed-loop control to maintain precise tray vibration under

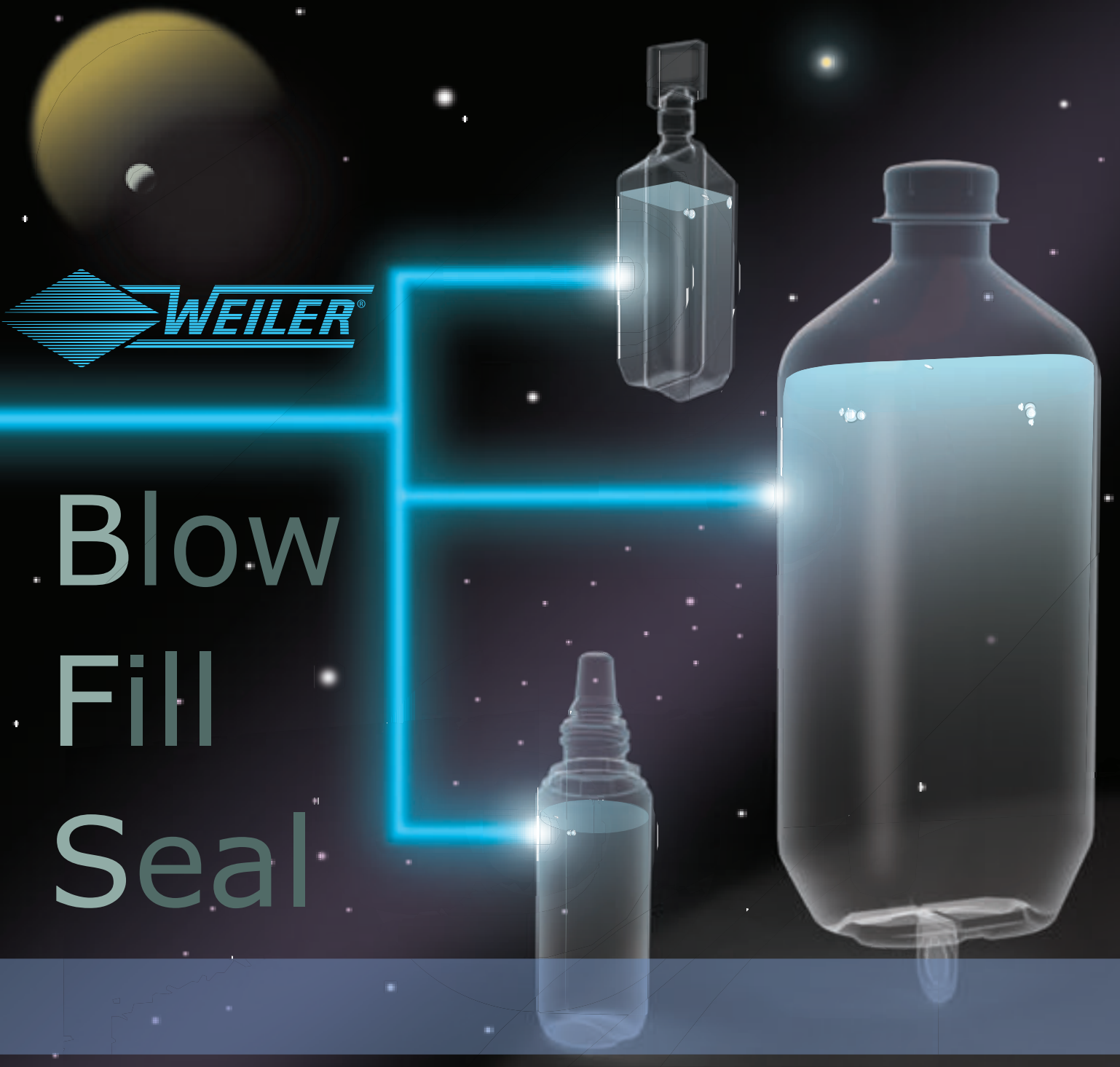
↑ The integrated process MTS came up with includes a crusher, a scale system, and customized feeder and controls required to report diagnostics to the vaccine manufacturer operating the system.

temperature conditions that are cold but not exactly constant," says Rob Yandrick, Eriez Product Manager-Vibratory/Screening. "The Eriez feeder design also provides excellent vibration isolation, that is, its vibration does not transfer to the other important components of the overall MTS system." Considering that there are other things going on—like load cells measuring weighments—it's good to keep the vibrations of the Eriez unit isolated from these other critical activities taking place in the overall system.

Eriez feeders and solid state controls integrate readily with MTS's master controller, which is supplied by **Rockwell**. According to Yandrick, electromagnetic feeders as opposed to those more mechanical in nature that are driven by motors are ideal for packaging applications because they can be rapidly cycled on/off and feed material quickly, evenly, and consistently.

MTS built a system that also includes a customized touch-screen control panel to monitor system performance and send diagnostic reports back to the vaccine manufacturer.

"We have always held ourselves to a higher standard, believing that doing things right and serving others well are the most important things that we do," says Nyhof. "We are humbled to play a role in delivering the COVID-19 vaccine to millions of Americans.



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Stream #1 Recyclable Pharma Blister: New Blister, Same Machines

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. PET blister launches for pharmaceutical, nutraceutical, and consumer health companies.
2. 'Plug and play' blister can be incorporated for recycle-readiness without redesigns.
3. kp is working on industry collaboration with recyclers and sorters to bolster infrastructure.

Major market segments have made a shift toward more sustainable packaging choices which include recycle-ready and recycled content options. The pharmaceutical industry is not immune to this movement and in fact has been challenging packaging suppliers for more sustainable options for blister packaging.

Klöckner Pentaplast (kp) has been working to provide pharmaceutical customers with viable options to meet those goals. New on that front is kpNext™, kp's blister packaging film that is designed to be recyclable in the RIC (Resin Identification Code) 1 stream.

The company set out to create a PET blister that could be recycled in the most established stream globally, with the goal of changing user behavior and the environmental footprint of the industry, says Tina Jächel, Product Manager, Pharma at kp.

For the entire package to be a recyclable solution, the lid stock must also recycle in the RIC 1 stream. With its partner **Huhtamaki** (HUH), a recyclable lid stock has been developed which solves that issue. The newly developed lidding material also has the same clarity as the blister film.

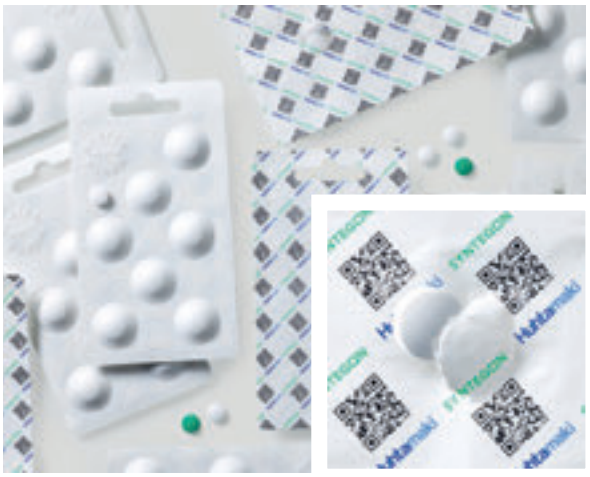
kp, together with Huhtamaki, is working on a washable ink system for the lid stock, so recyclability is not compromised when branding and dosage information are printed on the lid. "You can also change the lidding film color to a certain extent," says Jächel. "For example, in the PET recycling stream, you can enter with either clear, clear-blue, or green lidding material. Any colors outside of these three standard color options would require a workaround to ensure recyclability."

The patent-pending technology has been in development for three years, and it serves as a next step in kp's long-term sustainability journey. (The company's kpVantage®, launched nearly a decade ago, was reportedly the first to market with a vinyl-free solution, representing an early step in the journey towards a recyclable solution.) kp launched a new sustainability initiative, Investing in Better, which includes a sustainability roadmap for 2021 and beyond. One key target is making 100% of packaging recyclable by 2025, and as kp's Close the Loop sites notes, "That means making it clear what can be recycled and how, while ensuring there are enough disposal and recycling facilities available."

A 'plug-and-play' blister

One of the goals in the development of kpNext was to ensure it was a "plug-and-play" offering, meaning customers can use the same blister design, packaging lines, and equipment, and they do not need to slow line speed to accommodate the new material. "Some

↗ **The newly developed lidding material also has the same clarity as the blister film. One of the goals in the development of kpNext was to ensure it was a 'plug-and-play' offering. This means customers can use the same blister design, packaging lines, and equipment, and they do not need to slow line speed to accommodate the new material.**



Paper Blister Wins German Packaging Award

"Blister meets Paper," developed in partnership with **Syntegon** and Huhtamaki, offers an alternative to plastic blisters for tablets and capsules. The German Packaging Institute awarded Syntegon with the German Packaging Award this summer in the "Sustainability" category for the innovation.

"While eco-friendly and health-conscious customers can already find sustainable packaging solutions for a wide range of products, an environmentally friendly alternative for push-through packaging for tablets and capsules was not available to date," Torsten Sauer, Sustainability Project Manager at Syntegon, explains. Seeking to change this, the paper-based blisters are particularly suited for nutraceuticals. In the submitted version, each blister has seven cavities equating to one tablet per weekday.

Matthias Klauser, Sustainability Expert at Syntegon, says, "Thanks to the combination of our TPU 1000 form, fill and seal machine for paper packaging, the 3D formable FibreForm® paper from **BillerudKorsnäs**, and the sealable barrier coating from Huhtamaki, we have succeeded in forming paper with the geometry required for tablets in cavities of three to four millimeters," so the tablets can push through the barrier layers without breaking. They will be available for tablets six to ten millimeters in diameter to package larger tablets such as pain killers in the future.

The paper blister can be printed on both sides, and both base and lidding are recyclable. A Euro hole can be punched in the upper area of the blister, which conserves packaging material compared to conventional blisters in folding cartons.

—Keren Sookne

sustainable upgrades require the customer to redesign the package to accommodate the new material being utilized," explains Jächel. "We wanted to be sure companies didn't need to use additional materials or invest in new lines or new facilities because those are resource-intensive."

kp has been working with multiple customers prior to the launch to gain market feedback, develop product features, work on consumer studies, and more. Jeff Cole, Director of Marketing Communications, Pharma, Health & Protection, and Durables at kp, says, "I think a lot of companies realize that if they're going to make the jump to a sustainable solution, they probably have to sacrifice something," so the aforementioned "plug-and-play" aspect has garnered positive customer reactions because it does not require end users to retool, slow production, or purchase new machinery.

As customer interest builds, ramp-up is happening more quickly than was initially expected, as most pharmaceutical projects are long-term. Jächel is already stocking material at strategic locations to produce samples for incoming customer requests.

Beyond pharmaceutical applications, the recyclable blister is of interest for nutraceutical and consumer health products in which the consumer has more choices. Jächel notes that consumers may opt for the more environmentally friendly option if a given OTC medication—a cold and flu drug, for example—is from a brand known to employ a more sustainable packaging option.

WATCH

Five years in the making, Amcor's new recycle-ready AmSky PE-based thermoform blister packaging is designed to meet stringent pharma requirements. Watch this new PACK EXPO Las Vegas interview on AmSky by visiting hcpgo.to/392.

Beyond materials

Of course, designing for recyclability and a package *making it into* the appropriate recycling stream are two different matters. "We're doing all this hard work to ensure it's a sustainable and recyclable solution, so it's imperative the blister is actually recycled," says Jächel. That's why kp also has its sights set on industry collaboration to raise the range of Stream 1 recycling within the recycling industry. "As a producer, we are talking about much more than just product development. I'm working with different recycling groups and sorting companies, such as the EPBP and PFE, to find out what a collection system could look like, how we can develop infrastructure that works and really make an impact," she explains. "I think that's really integrating into our vision of 'investing in better.' It's not just having a sustainable product, but really using our position, our knowledge, and our connections in the industry to change things for the better."

9 Life Science Use Cases for IoT Stickers

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. From asset tracking and authentication to adherence and disposal, IoT stickers hold promise for healthcare products.
2. The disposable sticker gives insights that weren't possible before and works with smart devices.
3. Low-cost energizer devices are emerging that use commodity radios. They can provide LoRa and other kinds of Bluetooth energy.

"I think if we're honest with ourselves, when we look at true IoT [Internet of Things] technology, connectivity, and intelligence, it has really been focused on the internet of expensive things," began Steve Statler, Senior Vice President at **Wiliot**, at a recent AIM webinar. While industries have achieved a lot in connecting products to the internet, Statler feels the real opportunity is in connecting food products, medicine, and supplies where the volume is in the trillions and the impact—on the way we live our lives, how efficient we can be—is much more significant.

Wiliot is a provider of "sensing as a service" anchored on smart/IoT stickers. The sticker is a disposable form factor without batteries that can give insights that weren't possible before. It doesn't rely on expensive scanners, but works with devices like smart speakers, wifi access points, micro gateways, and phones.

Statler said that over the next few months, low-cost energizer devices will emerge that use that use commodity radios. "These devices will cost on the order of $10 or $20 and can provide LoRa and other kinds of Bluetooth energy to energize tags that talk to the cloud via these devices," he explained. "At Wiliot, we're focusing on access control, privacy, sensing, and flow control that will allow a hospital with potentially millions of tags to have a view of where doctors, patients, equipment, supplies, and medicine are, and to also extend that architecture forwards and backwards in the supply chain."

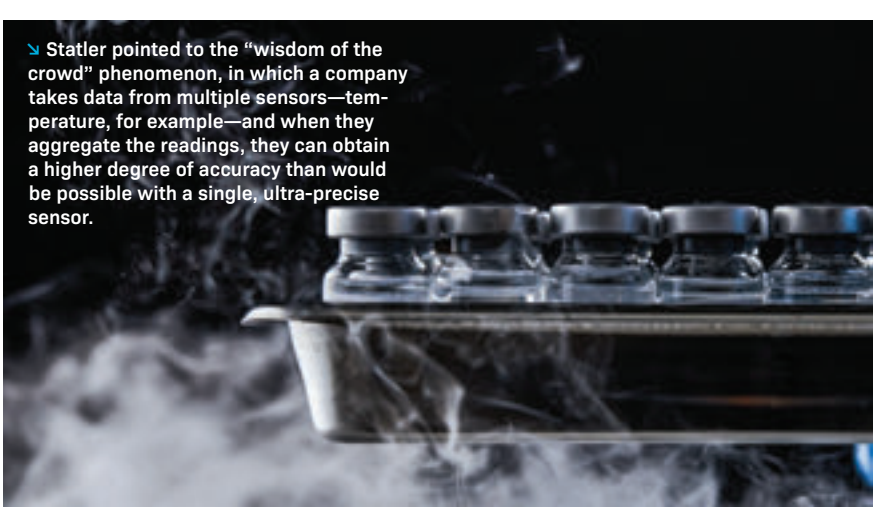
The company is currently transitioning from version one of its product to version two. Statler gave some examples of projects they're working on:

- A proximity sensor measures when a person's finger comes in proximity with a tag, and they receive a read-out on their dashboard—useful for measuring engagement or adherence.
- Tags are being used as high-water and low-water marks to detect consumption.
- Applied to plastic crates, the stickers can sense large amounts of produce items of all kinds. He said, "And we're seeing the ability to sense whether those crates are full or empty, but also the change in products over time. The water content is changing as these zucchinis are aging, and we can detect that."

Statler pointed to the "wisdom of the crowd" phenomenon, in which a company takes data from multiple sensors—temperature, for example—and when they aggregate the readings, they report they can obtain a higher degree of accuracy than would be possible with a single, ultra-precise sensor.

Watch this video on digital transformation in pharmaceuticals: **hcpgo.to/digitaltransformation2021**.

He referenced the demand chain—an evolved supply chain that is much leaner and more responsive in getting the right products to the right place. Ultimately, this can lead to considerable savings and meeting future regulatory requirements. The company says that wo key facets of a demand chain are that:



↘ Statler pointed to the "wisdom of the crowd" phenomenon, in which a company takes data from multiple sensors—temperature, for example—and when they aggregate the readings, they can obtain a higher degree of accuracy than would be possible with a single, ultra-precise sensor.

- There is a continuous view of item locations rather than a snapshot that has been facilitated by a handheld scanner. This requires more fixed readers and telematics devices looking at where things are.
- There are demand signals, e.g. the use of a medical product in a hospital or clinic, or the consumption of a product by a patient or consumer in the home.

Use cases

1. **Asset tracking**: Statler shared one project in a pharmacy with their partner **Blyott**, a location-based tracking and monitoring provider in the healthcare industry. They had conventional battery-powered beacon technologies but wanted to use the smart tag label/IoT stickers to get a real-time view of where drug containers are in the facility.

"Applying a sticker means that you can actually use existing containers and the existing automatic dispensing machines… and the reality is not all of the containers are in that machine, they're spread around the pharmacy," said Statler. The stickers offer trilateration (giving X and Y coordinates) so pill containers can be located both within the **BD** dispenser, but also throughout the area where work is being done.

2. **Grey market**: As a logical extension of asset tracking, tagging products offers the ability to detect gray market diversion, where real products are being used where they shouldn't be. "The opportunity to address unlicensed sale and usage of products is very significant," he said.

3. **Cold Chain**: Cold chain traceability is, of course, not a new concept. While there are many solutions for monitoring large shipping containers for location and temperature, Statler said there is still more opportunity for tracing conditions to the item level so that when products are left on a shelf or a loading dock, and temperature compliance is breached, it can be detected.

Wiliot engaged in a project with several partners—**Verizon** for connectivity, **Avery Dennison's** atma.io, the **Cloudleaf** team on the application side, and a number of converters—to create a vaccine vial for a major pharmaceutical company that could track the temperature of the vial in real time.

He showed video in which a pizza box of vials was being tracked and traced, with box and vial temperature being measured. A vial was removed and diluted, and a frequency shift was detected with the tag. "There's a smart gateway on the desk reading those labels. That then allows us to understand whether the medicine is good to use or whether you're having something put into your arm that either has been out of temperature compliance or has not been diluted," he said.

4. **Consignment management**: Statler said there's a great opportunity around consignment deliveries where clinics and hospitals are increasingly not taking ownership of the products that are delivered to them until they're actually used—until a nurse takes the medicine or the appliance out of the cupboard. He noted, "There's a trend to that ownership being fleeting, as it's being passed on to the patient or the insurance company. We believe that smart labeling has a great role to play in reducing the costs for a hospital stay by streamlining that, making sure that products don't disappear and that there isn't a financial burden on the venues that are enabling the use of these products."

5. **Engagement/trust**: Augmented reality can be used so that the consumer's phone recognizes a package or pill bottle with machine vision. The user can then tap on that image, its cloud data is pulled down, and they receive not only the item-level information about when this product was made, its distribution path, but also its temperature history. "So this is an example of the way consumers could be provided a way of interacting with medical products—it could be a knee brace—where we can give advice on how to use it," he said.

6. **Anti-counterfeiting/serialization**: Around the world there are huge problems with counterfeit medicines. Having a smart tag with embedded encryption as a default could allow companies to authenticate what's real and what isn't, and potentially the industry can save lives in that way.

Read this story on RFID-embedded vial labels: **hcpgo.to/rfidbenefits**.

7. **Adherence**: "One of the things that never ceases to amaze me is the challenges that we have around the fact that people don't take their medicine. We have Nobel laureates inventing drugs and efficacy is significantly reduced, not because the drug doesn't work but because we're not taking it very often… for the very human reason that we forget," Statler said.

Wiliot is working with **CCL** on a smart label project for autoinjectors. Beyond ensuring a drug is the right temperature level to administer it, they are measuring the position of the plunger to

↑ Augmented reality can be used so that the consumer's phone recognizes a package or pill bottle with machine vision and leads them to product information and instructional content.

know whether the autoinjector has been fired or not. This will be critical as clinicians look at outcomes and evaluate if a medicine is truly not working, or if it's not being taken properly by the patient.

8. **Replenishment**: Related to adherence, smart labels can also play a role in auto-replenishment when containers are empty or nearing a certain level. Higher value from the financial sector is placed on companies who adopt subscription business models vs. one-off deliveries.

9. **Disposal/end of life**: Companies may be able to track product and package disposal. "We can use AR to interrogate the labels and pull the data from the cloud to understand what the state of the item is. You've taken your medicine. What do we do about disposing what's not been used? This is a huge issue and we see it not just in medicine, but in verticals like apparel as well," said Statler. "We're in the early stages of work with consortia that are trying to address that with smart collection and sorting, using automation to detect what used medicine is so that we can know how to dispose of it correctly."

Aggregate ROI

With so many use cases, Statler reiterated the "wisdom of the crowd," that the technology will really gain momentum as there is more and more default enablement of the smart speakers and the wifi access points that provide the infrastructure to read smart labels that are already there. He noted, "We think the key is multiple use cases that can build on each other so that the ROI is the aggregate."

This means a platform approach will be necessary. Many of the applications of the technology in manufacturing, distribution, use at home, recycling, and more have been evaluated as individual or coupled cases. "It's logical to do that, but in our opinion, this is like having an app store with one or two apps. It just doesn't make sense. It's hard to get critical mass," said Statler. "The only way this really scales and the only way people are willing to invest what it will take to put intelligence into everyday things is if you can amortize the cost of that throughout the life of a product. And if you really do that, the impact can be quite profound."

Interphex 2021: Return to New York

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

International Pharmaceutical Expo (INTERPHEX), the event dedicated to pharmaceuticals, biotechnology, device innovation, and technical knowledge makes its in-person return to the Javits Center in New York City, October 19 to 21, 2021.

After an almost 2-year absence without the ability to hold a live event, the show will offer technical education, networking, and over 550 global suppliers to source products and services. INTERPHEX offers a 3-day technical conference as well as INTERPHEX Live—a moderated panel with speakers to develop a year-round video series—available on-demand, 24/7/365. This year, INTERPHEX Live sessions will be streamed live and broadcasted during the show on RECONNEX 365—the repository for industry content and supplier sourcing.

Health and safety are paramount. INTERPHEX producers reported that on August 3, 2021, the city of New York announced that it will be putting in place requirements for full COVID-19 vaccination verification at New York City events, and the event will require masks as well.

"We're closely monitoring these changes and working closely with the Javits Center to update our health and safety guidelines," said an announcement on INTERPHEX's site at press time. "We are fully prepared to comply with state and local requirements and public health guidance at the time of the event to enable our industry to get back to business at INTERPHEX 2021. Please continue to monitor our website for the most up-to-date information about our evolving health and safety protocols."

For the most up-to-date booth listings, visit Interphex.com>Show Info>2021 Exhibitor List.

Conference Sessions

Here's a look at just a few of the educational sessions. For full schedule visit Interphex.com.

OCT. 19, 11:15AM - 12:00PM
Three Practical Examples of Pharma 4.0 Technologies in Manufacturing Operations

OCT. 19, 2:15PM - 4:15PM
RX360: Enhance your Organization's Expertise in Quality and Supply Chain Security

OCT. 20, 3:15PM - 4:00PM
Facility & Building Robotics: Capturing Reality & Delivering Solutions

OCT. 20, 4:15PM - 5:00PM
Driving Robust Container Closure System Optimization for Risk Mitigation Through Big Data Analytics

OCT. 21, 11:30AM - 12:15PM
How Mobile and Collaborative Robots Create New Opportunities for Laboratory Automation

The inside of the corrugated shipper is laminated with a printed top sheet that conveys the upbeat, quippy brand messaging. Stacked shippers illustrate how little space is wasted in this packaging system.

Subscription D2C Supplement Brand Makes Sustainable Impression at Unboxing

MATT REYNOLDS, EDITOR, *PACKAGING WORLD*

TOP THREE TAKEAWAYS

1. With an underwater origin story, a new-to-science fatty acid nutraceutical is designed to improve longevity.
2. Seraphina Therapeutics created a sustainability-minded D2C packaging and unboxing experience.
3. An impressive starter kit is followed by sleek, pared down refill mailers, complete with water-activated tape.

The founders of nutraceutical company Seraphina Therapeutics, producer of the new Fatty 15 essential fatty acid supplement, come with an origin story that's fit for a Bond movie. Dr. Stephanie Venn-Watson, the CEO, is a veterinary epidemiologist with a host of degrees and credentials across disciplines. Dr. Eric Venn-Watson, her husband and COO, is a Navy physician that spent years internationally deployed as a military orthopedic surgeon and aerospace medicine specialist before entering the private sector. Recently, the two have been featured in publications like *Forbes*, *Authority*, and *Worth* as examples of an entrepreneurial power couple.

But here's a wrinkle that could be straight from a comic book: the Seraphina pair discovered their first product—a new-to-science variety of healthful fatty acid—by working on a long-standing project studying Navy-raised and -trained dolphins. The discovery was corroborated with the aid of 60 years' worth of Navy-collected

experimental dolphin data and cell samples. You read that correctly, military dolphins.

More specifically, the discovery is of a trace fatty acid called C15:0, eventually to be branded as Fatty 15, that Seraphina says has evidence of significantly promoting cellular resilience and general health. The company claims this fatty acid boosts human longevity by strengthening cell membranes, supporting mitochondria, and activating receptors in our bodies that regulate metabolism, immunity, mood, sleep, and appetite.

I'll have to take their word for it, but the discovery was impressive enough for lauded scientific journal *Nature* to publish Venn-Watsons' findings. Luckily, Fatty 15's packaging origin story is a good one as well. The C15:0 ingredient itself spent more than a decade in research and development. But as promising as it appeared to science and academia, Seraphina knew that C15:0 wasn't going to sell itself to consumers.

"It's our intellectual property, we've published on it, and we now have 28 patents on this technology, nine of which are issued," says Eric Venn-Watson. "We finally had to ask ourselves how would we bring this discovery to the masses? How could we improve global health? More practically, we asked ourselves how we would manufacture this. And what kind of packaging would we need?"

More freedom in packaging

There are regulatory guidelines on safely getting the ingredient into a capsule and safely getting the capsules into a package to protect it. Once those capsules are safely sealed in a suitable pack, they can be packed in non-food-contact secondary packaging, which affords the brand a lot more freedom for artistry and latitude for brand positioning. (Considering its target market of health- and sustainability-minded Millennials and Gen Xers, Seraphina also must certify that the product is both vegan and sustainably sourced.)

↑ **The branded 'pill pattern' is used on the tape and various decorative spots on the pack. The design is meant to recall the C15:0 chemical name for Fatty 15.**

↑ **An exploded view of the Fatty 15 starter kit demonstrates the use of corrugated inserts to safely handle a glass bottle through the many-touchpoints of the e-comm channel in a compact format without extra space or the need for dunnage.**

↑ **This elegant, silkscreen-printed durable glass bottle with bamboo closure doesn't need to be hidden away in a medicine cabinet with your other white HDPE pill bottles. It's designed to be display-worthy.**

At the time of the January 2021 launch, C15:0 was (and still is) a Direct to Consumer (D2C) distribution play using the Shopify D2C logistics software platform. This e-comm-based go-to-market format meant consumers' first physical interaction with the brand would be by way of a shipper arriving on their doorstep. To maximize its impact at this critical point, the company enlisted L.A.-based creative and brand design agency **Phenomenon** (which goes by phno) to work out brand positioning, naming, identity guidelines, and the sourcing and implementation of the packaging. Ali Filsoof, Design Director at phno, led this process.

He was involved in an early, tenor-setting brand decision to move away to the clinical-sounding C15:0 ingredient name to the more engaging Fatty 15. The name plays on the juxtaposition between consumers' historical vilification of fats and the fact that certain fats, like C15:0, are required for life (putting the "essential" in essential fatty acids). The name Fatty 15 is a bold attention getter and conversation starter to the brand's health-aware target market.

Another branded design element that would end up being reused across the packaging is a "pill pattern" graphic depicting alternatingly oriented horizontal and vertical capsules. One half of each capsule is represented by an unbroken "C" shaped line, the other half consists of 15 dots outlining the same, but inverse "C" shape. The design is meant to recall consumers to the C15:0 chemical name.

As Filsoof's brand strategies and designs began to crystalize, he brought in Erin Moharita, CPP, Principal of boutique packaging agency **EKM**, to make sure they were on point on the technical and procurement side of packaging. Moharita's specialty is connecting entrepreneurs—many of whom are unfamiliar with the packaging supply chain or lack enough volume to meet their MOQs—with her extensive network of larger or premium packaging suppliers that

↑ Metallized pouches, with an FSC-certified, printed paper layer exterior, carry the capsules through the supply chain while providing a moisture and oxygen barrier. These pouches easily fit into a small kraft mailer for the subscription-based refills.

might not otherwise engage with smaller, emerging brands.

Balancing sustainability with product protection, shelf life

Health and wellness consumers that are likely to be drawn to Fatty 15 tend to value sustainability and seek to protect the environment. "That's why one of Seraphina's early directives on packaging was to be as environmentally friendly as possible. When I think about packaging in general—particularly in e-comm, D2C, and Amazon though they're working to change things—I think of a box, in a box, in a box, in a box," Filsoof says. "I challenged the team and myself to practice what I'm calling un-packaging. We're not putting beautiful graphics on a box that's bound to go into a plain shipper filled with unnecessary extra material like padding. We thought about what materials we could use that are unconventional but more sustainable. We researched for weeks on what those possibilities could be and then we started designing different packaging options."

The team arrived at a dual-pronged packaging strategy that consists of a sustainability-minded starter kit shipper, designed to impart a carefully conceived aesthetic during unboxing. The centerpiece of the starter kit is a durable glass bottle designed to contain the product—eventually. The bottle is delivered empty. Also within the starter kit are three metallized film pouches that each contain a month's worth of Fatty 15 capsules (30).

"The pouch is a laminate foil—we needed that for shelf life, for the capsules to survive the warehouse setting prior to getting to a consumer, and then opening, and then being used," says Moharita. "We wanted to make sure it had the longest shelf life possible."

While multi-layer metallized films aren't recyclable themselves, they accomplish the essential logistical task of getting the product into homes safely, and carry necessary oxygen and moisture barriers. The lightweight pouches have some sustainability pros of their own—the top layer of the lamination is made from post-consumer recycled (PCR) paper that is 100% FSC (Forest Stewardship Council)-Certified. This paper layer is flexographically printed in three colors: white, green, and blue.

Consumers are meant to open the starter kit, open the first three pouches, and fill the durable bottle with the 90 capsules. Thereafter, a quarterly, subscription-based e-comm delivery of three of the same three metallized film pouches incrementally restocks consumers. After the initial starter kit, only a kraft-style flat mailer envelope is needed to deliver the refill pouches. The stakeholders involved

declined to name their packaging suppliers.

Durable glass bottle

If you've ever been to a GNC retail location, you know that nutraceuticals and supplement capsules are largely packed in white plastic bottles, often HDPE, adorned with shrink or p-s labels. While these formats can be recycled, they often are sold almost comically underfilled. This also is endemic to OTC pharma capsules. Consider that a 25-pack and a 100-pack of ibuprofen might use the same size of HDPE bottle—it may be simpler for a brand to limit pack formats, but it's perceived as wasteful. Also, though they tend to carry decoration, these bottles aren't exactly artistic.

Fatty 15 takes a different tack with an elegant, durable glass bottle meant to be displayed in full view on a bathroom counter instead of hiding in a medicine cabinet. The easily recyclable bottle is sprayed in the brand color specified by Phenomenon, similar to seafoam green, then decorated with simple messaging via silkscreen printing directly on the bottle, one color—dark blue, bordering on black.

Direct decoration on the bottle—which would hold up better than a label in a bathroom setting—needed to be high-quality considering that the bottle would be handled multiple times.

Since the capsules are primarily packaged in metallized foil pouches, all regulatory information and instructions for use need only appear on the pouches. The durable show piece of a bottle is allowed to remain simple and uncluttered.

What really makes the bottle pop is its bamboo closure. A wood closure was originally specified in the design briefs, but there were some problems marrying the bottle threading to the closure. After expanding a closure search, bamboo's advantages quickly became evident. First, bamboo is a plentiful, fast-growing grass, so the material's renewability profile is strong. "And from a shipping and environmental standpoint, bamboo is a lot lighter than the wood, so I think in the end it was a better choice," Moharita says. "I think the wood cap still was a great avenue that we explored, but the end result with the bamboo cap, in my opinion, is better."

The lone piece of decoration that isn't directly printed on the bottle and closure combination is a piece of recyclable pressure-sensitive tape. It provides tamper evidence, but also affords a narrow strip of billboard space to reinforce the "pill pattern" design.

The bamboo closure does have an inner polypropylene (PP) fitment to accept the bottle's thread that is made out of 100% PCR material. "Anywhere we could, we were as environmentally friendly as possible in terms of the material we're sourcing as well as the lifespan," Moharita says. "Durability and lifespan of the piece was really important as well."

Based on estimated sales, the company says that in 2021 alone, the use of a durable glass bottle instead of a typical HDPE pill bottle will save 9.24 tons of plastic.

Secondary packaging's strong sustainability profile

Fatty 15 uses a shipper made from 100% PCR kraft corrugated, adding a circular quality to what already was recyclable. Instead of printing directly on corrugated, the Fatty 15 team decided to print a top sheet and laminate it to one side, the inside-facing corrugated wall. The top sheet is also recyclable and is made out of FSC-certified paper.

"We didn't print directly on the kraft since we just felt that the top sheet gave a little bit of a cleaner look. The color was a little more vibrant going down this route, and we just could get better quality. Also, I find that when you print on these top sheets, you're getting less corrugated 'dust' coming from the shipper as it travels through the supply chain. That was really important since we feature a beautifully decorated glass bottle with no carton protecting it," Moharita says.

A corrugated kraft insert is used to hold the glass bottle in place, and to orient it toward consumers as they unbox the product. This bottle-holding insert rests on a second corrugated insert, this one seamed and erected to be a 3D, shelf-like structure that forms a collar around the inside bottom of the shipper. This corrugated collar cradles three pouches' worth of capsules, three packs at 30 days each. To maintain a small footprint, the box was custom-designed with only enough room to hold the inserts, while inserts are laser cut to the bottle size to eliminate the need for padding.

As we've seen with other successful subscription-based D2C personal care plays (see Grove and Truman's), text printed on the top sheet is punchy, upbeat, and implies a wink. The design uses infographic-style visual cues and the brand's "pill pattern" graphic, flexographically printed in two colors, the brand's green and blue. Of note, the inks used here are vegetable-based, thus more sustainable.

The final top sheet-printed flourish appears on the inside bottom flap, intended to be read as a consumer removes the last of the three pouches of capsules. There, dark blue text on sea green paper reads, "Okay, now you can recycle me," serving both as a closing remark on the brand's sustainability profile, and practical reminder to the user.

The company is using a recycled kraft paper, water-activated tape that's custom printed with the brand name and capsule pattern. What's particularly interesting about it is that it is fully recyclable while still stuck to the corrugated shipper—no need to remove it, unlike tapes that are reinforced by fiber crosshatching.

"As much as you might not think about tape when you're looking at the whole package, with the careful branding, beautiful packaging, and everything we designed in the brand, I think that the tape was a really huge win," Moharita says. "Because of the weights, and how we designed everything in consideration of how these ship, we were able to use this type of unreinforced tape, which is really cool."

Refill packs

Since the starter kit contains 90 days' worth of capsules, about three months pass before the next delivery arrives at consumers' doorsteps. The brand calculated that it'd be favorable for customers to have enough time to really start feeling the positive effects of the supplement before they started the subscription portion of their account.

The next delivery looks nothing like the dramatic starter kit, instead focusing on minimal design and limited packaging usage.

"We're just using a mailer envelope that is fully recyclable. On top of the mailer envelope, all the printing on there is done with an algae-based ink which is really interesting, it's kind of a newer product in the industry that's highly renewable," Filsoof says. "I started investigating it a little further and we found a vendor. We're really proud of the mailer as well because it's as small as it can be to hold the three pouches [90 capsules] and it's fully recyclable, and the algae ink is unique."

The PCR padded kraft paper is FSC-certified, features quippy copy, and uses a fiber-based padding that's also recyclable, unlike bubble mailers. It uses the aforementioned recyclable tape, as well.

What's next?

The brand is currently looking into other channels, retail and otherwise, that will be able to accommodate their current pack format, and is also considering new packaging formats tailored to the channel. One step—that Eric Venn-Watson thinks might really blow the doors off of this discovery—is FDA recognition as GRAS (Generally Recognized as Safe) categorization for C15:0 as a food additive or food ingredient. This takes the fatty acid outside of the capsule, and into the food ingredient category for healthful foods. "And I think from the Seraphina Therapeutics and Fatty 15 standpoint, and the ingredient FA15, our goal is to just really improve global health. This is important and we want to get this out to people and dolphins," he says. Wait, dolphins? Bringing the story full circle, Eric adds that, "This supplement's going to go back to the dolphins as well, to continue to improve their health, which is neat."

Attract and Retain a Quality Workforce: Insights with Gardner Carrick at PMMI's ELC

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Since 2010, there has been an increase of nearly a million and a half jobs in manufacturing.
2. A key manufacturing business challenge in 2021 is attracting and retaining a quality workforce.
3. The Manufacturing Institute, NAM, and PMMI are launching new programs to diversify and grow the manufacturing workforce.

At the 2021 Executive Leadership Conference (ELC) from **PMMI**, The Association for Packaging and Processing Technologies, Gardner Carrick, Vice President of Strategic Initiatives at The Manufacturing Institute (MI) and National Association of Manufacturers (NAM), presented technical workforce development trends, both in connection to and beyond COVID-19.

Results show that since 2010 there has been an increase of nearly a million and a half jobs in manufacturing. This number decreased when the pandemic hit, but recent studies suggest jobs have rebounded and are returning to previous counts.

Beyond COVID-19, the second key business challenge of 2021 is the continuing struggle of attracting and retaining a quality workforce in manufacturing. Research proves that this issue is systemic and not transitory. There's not a "strong enough pipeline of individuals desiring to go into a career in manufacturing, and not enough breadth of training programs to prepare them with skills to be successful in those careers," said Carrick.

MI and NAM prioritize the success of manufacturers and their workforce, whether it be through fighting for manufacturer rights, providing news and intelligence about the industry, or through initiatives to support the diverse American workforce by providing skilled training programs.

The MI and NAM efforts, presented at ELC, are:

1. Creators Wanted, which exhibits in towns to invite high school students to enter the manufacturing field post-graduation. MFG Day—when facilities open their doors on the first Friday in October—has been combined with Creators Wanted. It includes virtual tours and 3D maps, as well as an MFG Day webinar series.
2. Military and veteran recruitment, which starts these brave servicepeople on their next career. Individuals on their last six months of service can start training in the MI programs, which have recently been modified to include networking days with manufacturers. In addition, both non-commissioned and commissioned officers have shown increased interest in leadership roles in manufacturing. These programs are available at five U.S. military bases.
3. The STEP Women's Initiative, which includes training women to be role models in their community. More than 800 women have been recognized so far with hundreds of companies participating.
4. The NAM Pledge of Action, which ensures broad-based recruiting strategies "to cast as many nets as wide as possible in order to fill the roles that we need," said Carrick. This allows for greater diversity in the workforce by reaching out to minority communities.
5. The Second Chance operation, for those with criminal records. Studies done on retention routes and productivity of individuals show that those in the Second Chance program have a competitive drive to keep their positions.

Apprenticeships and credentials

Once a workforce is obtained, however, training is indispensable in making each individual's manufacturing career a success. Manufacturing-related positions focus on keeping machines working, which requires technical skillsets that go beyond the abilities of technical colleges. Carrick emphasized that companies, with their up-to-date knowledge, need to be involved in the learning of future

generations and the development of scholastic programs every step of the way, including apprenticeships. This is also a great opportunity to offer debt-free education and show the new workforce that the company is invested in them, which Carrick said will help gain their trust.

An apprenticeship program that Carrick highlighted is FAME, the Federation for Advanced Manufacturing Education—created by Toyota. FAME is a multi-skilled maintenance technical program operated by a group of companies, which further promotes professional behaviors in dress and speech, and educates workers on the culture of manufacturing, or in other words, how to think as a maintenance employee.

Another aspect of forming a quality workforce is credentialing. The credential market has been filled with credentials that are lacking, creating confusion on industry standards. NAM and MI have created tools to evaluate individuals and credentials in an attempt to rectify this confusion. States are already lining up to back this standardization.

PMMI's efforts to build the workforce

PMMI has invested in a single employer model with Amazon to develop an apprenticeship program. Amazon wanted to develop a program to upscale current employees, which would build a baseline to allow individuals to fully make a career in the industry. The company had been looking for different models and certifications to provide standards to align to. PMMI's mechatronics' certification program became the base of Amazon's apprenticeship program, which allows individuals to not only finish the program but obtain certifications as well.

PMMI saw a huge increase of 223% in utilization of the certification program throughout 2020. This increase is expected to continue as more schools offer the certification program thanks to the Amazon apprenticeship program. PMMI is also attempting to get involved in efforts to make the military aware of the industry and become properly trained.

As research shows that the majority of students who study in manufacturing programs do not end up in the manufacturing workforce, PMMI created its Skills Fund for the future workforce. It allows companies to work with local education programs and donate money or equipment—PMMI then matches company donations up to $50,000. This helps companies build stronger relationships with their local education programs.

Learn more about PMMI's workforce development programs at: hcpgo.to/PMMIworkforce.

4 New DSCSA Guidances: Are You Up to Date?

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

TOP THREE TAKEAWAYS

1. DSCSA guidances were released in June 2021 to bolster industry understanding of requirements.
2. Topics include suspect and illegitimate product, product identifiers, and enhanced drug distribution security.
3. An expert warns that the guidance for enhanced drug distribution security at the package level is dense and complicated.

At the HDA Distribution Management Conference, Tish Pahl, Principal at Olsson Frank Weeda Terman Matz PC, discussed four FDA DSCSA guidances that were issued on June 3, 2021. And as Pahl said about the following information, "this is the DSCSA advanced seminar."

Identification of suspect product and notification

This guidance provides updates, and finalizes the 2016 guidance, without many changes and should be familiar to most in the industry by this point. Said Pahl, "It provides very helpful information to trading partners on the suspect and illegitimate product systems and processes that you need to have in place in order to comply with section 582 of the act.

Definitions of suspect and illegitimate product

A revision to a previously issued draft guidance, this guidance updates definitions of suspect and illegitimate product. It updates definitions such as "stolen" to be product that's in your possession or control that you have reason to believe was stolen, or product that you have credible evidence that was stolen. Either of these would trigger suspect and illegitimate product obligations under section 582. Pahl noted, "FDA gives examples of 'stolen' in the guidance, including product that's taken in a cargo warehouse or carrier theft. It also includes any packaging that's been stolen, and any product that's been removed or taken. An example of this would be a bottle of controlled substance where pills are taken out and replaced with acetaminophen. These would all trigger the suspect, illegitimate product requirements of section 582."

The guidance also addresses a part of the definition of suspect and illegitimate product, which includes "unfit for distribution." Expired product, damaged product, and recalled product are not necessarily suspect or illegitimate, but they shouldn't be going to patients. Pahl said one helpful clarification is that product that's awaiting reverse distribution is not going to be considered unfit for distribution for purposes of suspect and illegitimate product obligations, under section 582.

Product identifier Q&A

This guidance is intended to assist manufacturers and re-packagers in developing standardized formats for the human and machine-readable information that is contained in the product identifier. There is some question about this guidance, and if products using GS1 global standards are aligned with the new FDA recommendations. The statutory date for the draft guidance of a fixed product identifier—which includes both a 2D data matrix (machine readable barcode) and a human readable interpretation of that barcode on each package, passed (originally Nov. 27, 2017, with an extension to Nov. 27, 2018), and this final guidance is now presented two and a half years after the deadline.

The DSCSA requires that the product identifier conform to the standards of an international standards development organization, and the industry-aligned GS1 standards for product identifiers. In this guidance, the FDA recommends a format for the human readable portion of the product identifier, and Pahl pointed out that the final guidance eliminates the flexibility that was in the 2018 draft guidance, which had said that the GTIN could be used in the human readable identifier so long as the NDC was elsewhere. Also, manufacturers and re-packagers should be affixing product identifiers to the smallest individual saleable unit.

Enhanced drug distribution security at the package level (EDDS draft guidance)

This draft guidance sets out the FDA's recommendations and interpretations of what's necessary for compliance with the DSCSA requirements that go into effect on Nov. 27, 2023. Pahl said, "I'm going to caution you that this is a complicated and dense guidance," and encourages reaching out to the agency with questions or

concerns (though the comment period on this guidance ended Sept. 2).

According to the guidance, the enhanced system is the interoperable electronic package level product tracing systems and processes required by section 582-G. Although each trading partner should have its own individual validated systems and processes for managing its product and data, the FDA recommends that the enhanced system enable the interoperable integration of such systems to allow for appropriate access, information sharing, and data security.

The type of data collected, and the data validation policies and standards that govern how data is used, stored, and managed, and how it's integrated within and between organizations and individual systems, is the "data architecture" of this enhanced system. The FDA recommends that the enhanced system use appropriate data security standards and protocols that are developed by a widely recognized international standards development organization, and plans to address these standards for secure interoperable data exchange in a separate guidance.

Pahl added that the draft guidance expects trading partners to maintain the confidentiality of product tracing information. The DSCSA emphasizes confidentiality protection because the disclosure of highly confidential commercial information in TI and TS to improper parties could result in competitive harm from its disclosure. Establishing those business-to-business connections for seamless transfer of transaction data should take place with an EPCIS file format, a global GS1 standard for creating and sharing visibility event data to all users, within and across enterprises.

For links to the guidance documents, visit the digital version of the article at **hcpgo.to/4guidance.**

2021 AmeriStar Awards Honor Med Device Packages

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

The Institute of Packaging Professionals (IoPP) announced the winners of the 2021 AmeriStar Package Award competition. We present the three winners in the medical device category, plus a couple of related winners, in no particular order.

1 Deep Blue Hernia Mesh Strand Package for Sutures

Inspiration for this suture packaging by **Merrill's Packaging Inc.** came from research at Bass Pro Shops and the sewing industry. As IoPP reports, "Prior to this device, doctors would have to thread several sutures through several needles for one surgery, taking a tremendous amount of time and risking puncture injuries. This package and device, of which the PETG package is part of, aids the doctors in effortlessly extracting the sutures and needles during hernia surgery by organizing the mesh suture strands and needles in a logical fashion, making the device and package of extreme value in the operating room." Other benefits of the package: extensions are tucked in until the surgeon needs them, and strands are actually less destructive to organs due to being distributed over a wider area.

2 Medical Device Card-Hoop Assembly and Packaging Optimization by Medtronic

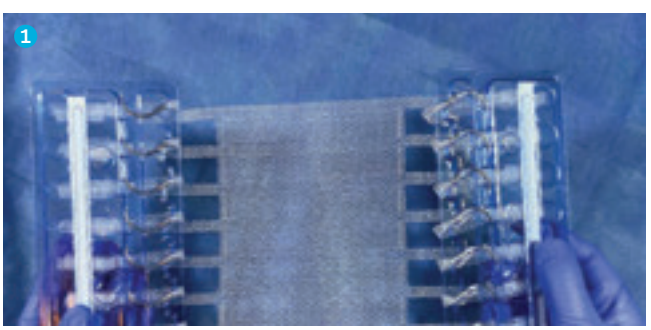
By integrating material, "poka-yoke" design, and customer-focused features, ClosureFast™ from Medtronic enables the package to act as a value-add to the overall therapy for RF ablation treatment of varicose veins. The packaging is designed to accommodate both 60 and 100 cm lengths. "A single card-hoop assembly was created to contain and protect both 60 and 100 cm devices, with a 47% smaller footprint and an 80% reduction in weight. Additionally, a switch was made from the PET to Natural HDPE," says IoPP. The card-hoop assembly reportedly improves device protection and containment while offering the surgeon the ability to temporarily contain the device in the card-hoop assembly while in the sterile field.

3 Miltenyi CliniMACS Prodigy Set

Nelipak Healthcare Packaging created an innovative package for a blood management tubing set for its customer, Miltenyi Biotec. "The thermoformed carrier allows the product to be shipped securely with all the components assembled in the correct order, in the correct place, without damage during transit," Nelipak says.

With an integrated handle, a single person can remove the entire tubing set with one or two hands, while packaging provides clear application to the CliniMACS Prodigy Instrument for efficient preparation. Parts that need to be removed before use have a different color than the other blister packs.

Engraved instructions for tubing connection allow the packaging to be recycled. Seal width is minimized to reduce the amount of plastic and weight, decreasing the system footprint.



2 WINNER OF IOPP'S 2021 PEOPLE'S CHOICE AWARD AT PACK EXPO LAS VEGAS!

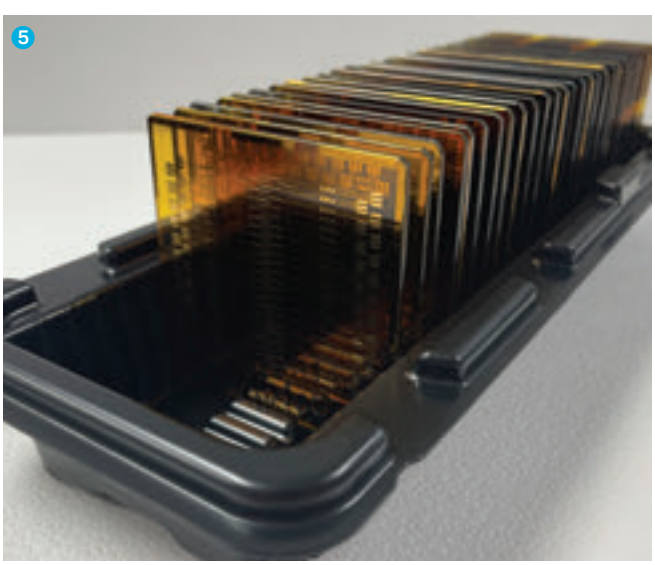
4 GSK 100% Plastic-Free, Recyclable Secondary Packaging

Winning the Sustainable Packaging Award this year was GSK Consumer Healthcare's 100% plastic-free, 100% recyclable secondary toothbrush packaging launch. Winners of this award are evaluated based on efficient energy usage; recycling efforts; and effective use of reusable, recyclable, and eco-friendly packaging materials. As IoPP notes, "This toothbrush twin pack consists of a color matched, thermoformed PaperFoam tray that is compostable and recyclable in the paper waste stream. It is heat sealed to a printed, SBS NatraLock® UltraSeal top card engineered to be used as a plastic clamshell replacement, while maximizing shelf appeal and enhancing sustainability. The top card has a die-cut window glued with clear, heat-sealable compostable cellulose transparent film, allowing the consumer to see the product. Finally, on the back of the cellulose tray are two paper-based labels, also plastic free."

5 Medtronic Glass Component Automation Tote

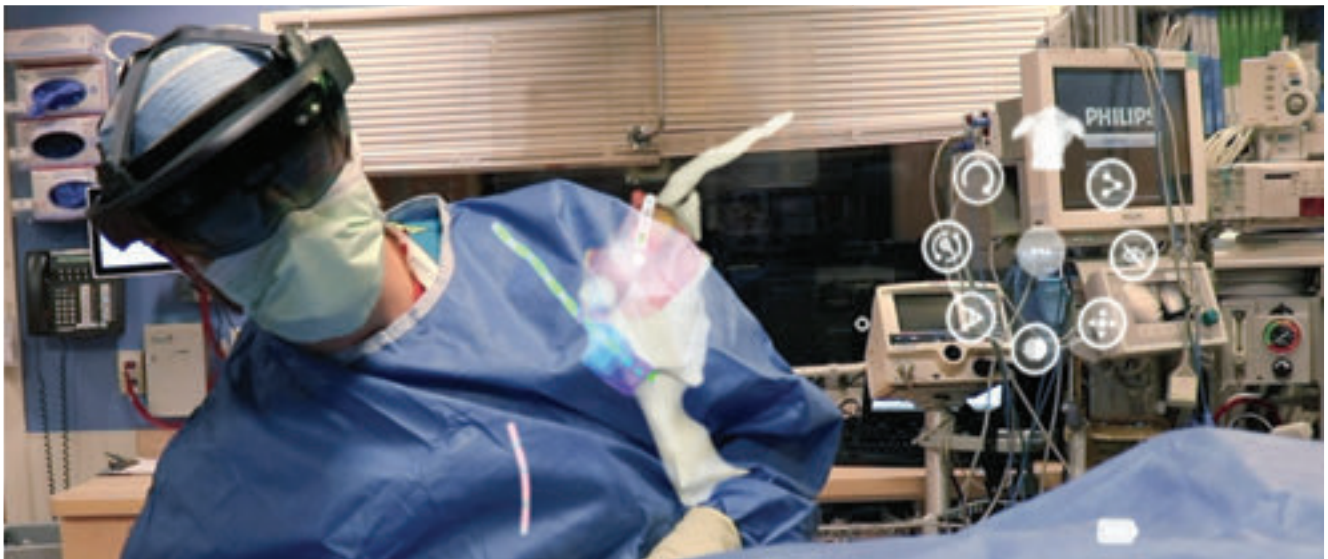
In the electronics category, this Medtronic tote was designed by **Prent Corporation** to replace an outdated transportation and automation tote made from a three-piece, injection-molded system. The new system needed to safely transport 30 fragile glass components and integrate into the existing automation process. "The solution was one single part that could function as either the top or bottom of the tote; plus, when interfaced with itself, provided a safe and effective tote," says IoPP. "The single asymmetrical part, when reflected onto itself, is snapped into place, safely housing the fragile glass components. Utilizing tight-fitting radii and challenging drafts, the tote provides sufficient protection for the glass components."

To view the full list of winners, including personal care, sustainability, and student winners, check out: **iopp.org**.



2020 IoPP Technical Committee of the Year

The IoPP named its Medical Device Packaging Technical Committee the 2020 IoPP Technical Committee of the Year. Congratulations to committee chair Amy Stewart, Product Development Manager for **Printpack Medical**, and the entire team.



The SentiAR Wearable Command Center is an interprocedural augmented reality (AR) system—with the user interface built off the Microsoft HoloLens—that enables the electrophysiologist to model the heart. (Credit: HS Design, Inc.)

Medical Product Changes Stemming from User Centered Design

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Interacting with end users improves medical device and machinery designs.
2. User centered design helps manage technical and marketing trade-offs.
3. In one case, feedback led a tabletop system to become a floor-standing model.

At this year's MD&M BIOMEDigital, industry experts held a discussion on the role of user centered design (UCD) in next-gen medical product development.

As Tor Alden, Global Design, Engineering and Human Factors lead at **HS Design, Inc.** (HS), explained, UCD is a methodology that focuses on gaining a deeper understanding of the product end user. It outlines the phases throughout a design and development lifecycle to help create a product that fits within the user's environment. Some of the key benefits are:

- User needs are clearly communicated.
- It provides a clear framework for documentation for the FDA.
- It helps capture and translate user needs early in the process to allow for product pivots.
- It helps manage technical and marketing trade-offs.
- It allows early feedback from the users to see if products are actually responding to them.

The panelists discussed how they approached the UCD process in their various fields and how it led to success in development.

Lab automation equipment

Aleksandar Vacic, Chief Operating Office and Co-Founder of Selux Diagnostics, Inc., presented a case in which they were new to UCD. They brought in advisors from HS who started embedding it into their culture and process at the outset of developing the Selux Next Generation Phenotyping Platform, which aims to transform the treatment of infectious disease by fast-tracking targeted patient therapies within 24 hours. "When done well, UCD can turbocharge your development process. It's really kind of meant for agile development because it brings you closer to the users, and shortens that feedback loop which is very important," said Vacic.

He noted some key actions that led to their success. From the beginning, when introducing voice of customer studies, contextual inquiries, and usability and formative studies, they encouraged engineering team members to visit the labs, and participate with the end users in real life.

They also hired potential users who were in the clinical labs, bringing on "internal customers." This helped in bridging the gap between marketing and development teams. Third, they developed good relationships with industry leaders both for immediate insights but also to have perspective on where the market is headed in five years to stay ahead of competitors.

Three key learnings: Architectural learnings were really important as they had initially envisioned a tabletop system. "As we started interacting with users, exploring their workflows, we realized they want higher throughput, higher capacity, and walk-away capabilities," said Vacic. They pivoted to a floor-standing, two-floor system to save lab space and footprint.

The second example was in user touchpoints. There's a lot of potential for use errors in today's labs as medical technologists are incredibly busy.

"There's a shortage of labor. There's hundreds of samples that need to be processed per day, and they are stretched between different departments," he explained. "So really the goal is to load the machine and let it run and then move their focus toward results, and sending those results to the people who make clinical decisions: infectious disease doctors and pharmacists." They decided to reduce the number of reagents, for example, into a single pack that is enough for a full shift's operations allowing for a 24-hour walk-away system.

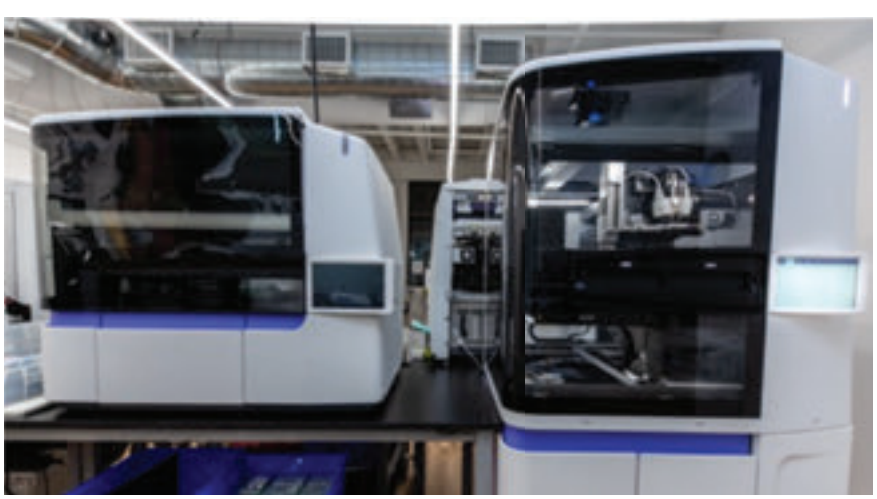
The third point was related to aesthetics. They originally used plexiglass to cover the prototype since they had it in the lab. Users were really pleased to be able to see what's going on inside the system. "It helped them create a good mental picture of what's going on, and medical technologists are very curious, very capable," he said. They worked with Alden's team to keep the "see-through" capabilities.

The system earned FDA Breakthrough Device Designation in September. Vacic highlighted how important it was to balance internal requirements with user needs, and look at all of the stakeholders: medical technologists who use the system, clinicians who use the data generated by the system to make therapeutic decisions, and the financial decision-makers in the hospitals.

AR helps cardio tech

Offering a consultant's point of view, Mary Beth Privatera, PhD, Principal, HFE/research, HS Design, Inc., presented the SentiAR Wearable Command Center that she worked on for her startup client. The device is an interprocedural augmented reality (AR) system with the user interface built off of the **Microsoft** HoloLens.

"What it enables the electrophysiologist to do is to model the heart, to understand where the catheters are relative to one another and relative to the target nodes. It takes the onerous activity that the physicians have—pulling all of the information on the monitors in the background—into a three-dimensional model with which they can interact and view while their hands are on catheters and they can go ahead and perform their procedure. So it was really something that was unique and different," Privatera said. She noted that AR is used often in medical training and medical education but in this case, it's really aimed at use during the case to provide additional information to make the overall procedure safer and more accurate. The system was created by clinician Dr. Jennifer Silva, who worked with her husband Dr. John Silva, a biomedical engineer.



↑ Selux Diagnostics, Inc. pivoted from a tabletop version (left) to a floor-standing, two-floor system (right) based on user feedback. (Credit: Selux/HS Design, Inc.)

Key learnings: This product required a very collaborative approach with the users. A major challenge they faced was how to even model a system when there's nothing there to touch or interact with. It was so new that they had to interact with clinicians directly to understand their framework. "It's not as if it's a traditional piece of software, or a piece of hardware that's driven by software, where you can take some of the design principles that we know and love—I have [CFR] 1875 near and dear to my heart," she said. They had to develop tools so they could get feedback from more clinicians for a broad perspective throughout the design process. The began by observing the various environments to design around. Privatera

noted, "One of the big things for this particular product was that there were no two environments that were exactly the same, which meant that we had to pay attention to the contrast of the menu and the display," to ensure users could view the elements.

They worked directly with the electrophysiologists—and tackle the (seemingly daunting) task of looking at all of the displays, taking all of the 2D information, and putting it into three dimensions. Privatera added, "We're talking about the heart. And we're at a pediatric hospital and we're talking about kids. This is a life or death potential situation," so accuracy was key.

They had to get in the weeds with the user and simulate things in order to make decisions. Users can interact with the HoloLens with either their hands or their eyes, and in one case, they realized the user had to take their hands off the catheter to interact with the device. "We didn't want that. Getting into some of those tools and simulations can be super helpful, but we have to enable those users to really highlight and say what's going to work and what's not going to work," she said. They used a combination of methods—including workshops of "multidisciplinary design-by-doing sessions"—to arrive at a design that would translate seamlessly into the operating theater and cath lab. "At the same time, there's a regulatory imperative because we know we have to do user centered design in order to be successful in our submissions," she explained. So they strived for the "right fidelity, the right number of formatives, the right number of explorations so that at the end of the day, when we do our summative evaluation, we can prove and demonstrate that the design actually does what we want it to do.

"In this particular case, it's a wonderful example of something that never existed before that we were able to explore using our knowledge of traditional methods, apply it to this new technology, work with the users... and then revise the design in a very iterative manner, coming up with prototypes and simulations that would reflect it. It's super important to really hone in on making the user the center of the overall design process, and that's especially true for these next generation devices where you don't really have [an existing model] to go by and you're going to be putting it into situations where they are critical to life, critical to the health and success of the clinical outcome."

Bringing it to your organization

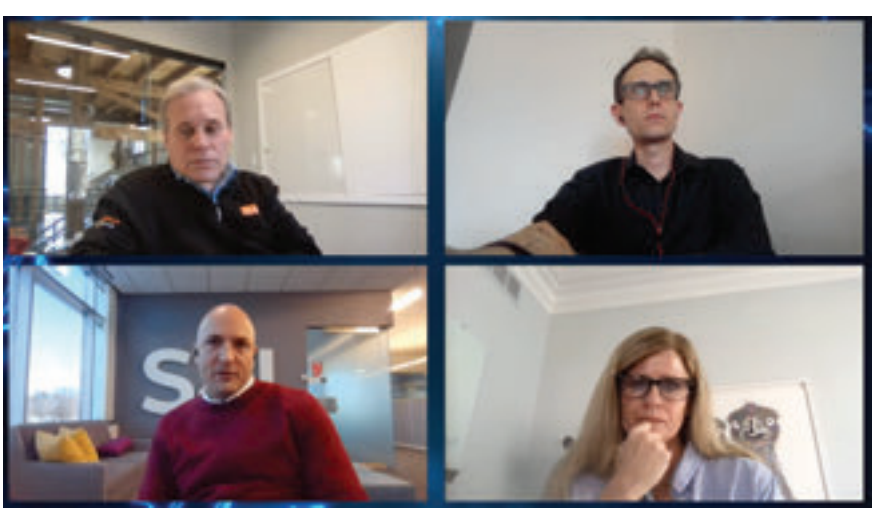
These concepts may be more or less difficult depending on your organization. A larger company may have more resources to devote, but may differ from the consulting or startup side in terms of remaining consistent across a large portfolio of products in development.

"I think that what's really difficult is bringing the internal stakeholders along for the ride—the engineering teams, the marketing teams, the quality, and packaging teams and so forth, giving them an opportunity to understand the process," said John Anastasiadis, Director, Human Factors + Design at Smith + Nephew. "Not many companies employ or embrace an official user centered design process. So it's really important to be able to drive that, get the mindset right, and the value into the process."

Anastasiadis advised attendees to bring designers—whether they're industrial designers, information designers, user interface designers—into the conversation and keep them engaged throughout the process.

He also noted that it's key to have a "champion of the user" present to make sure that your design intent is carried through to production. Bringing a medical device to life, in order to manufacture and commercialize it, there will undoubtedly be trade-offs and compromises. It's important to have the designers there to help solve problems as they come up. "Make sure that you have an understanding of the entire pathway of care. As we're moving into the future here—or maybe we're already living in it... many more users are involved in many more types of devices," Anastasiadis said.

Devices are now including analytics and algorithms with AI. "So it's really important to be able to include all of the designers that are involved in that process, along with the stakeholders within your business to understand that larger image," he added.



↑ **Panelists, clockwise from top left: Tor Alden of HS Design, Inc.; Aleksandar Vacic of Selux Diagnostics, Inc.; Mary Beth Privatera, PhD, of HS Design, Inc.; John Anastasiadis, Director, Human Factors+Design, Smith + Nephew.**

1 Infusion Bottle Labeling

Schreiner MediPharm

+ To simplify international clinical trials, Schreiner MediPharm equips hanger-labels for infusion bottles with booklets, allowing detailed product descriptions in multiple languages
+ The specialty label provides research-based pharma companies and contract research organizations (CROs) with a marking option that offers flexibility and reliability for clinical trials—especially those conducted in multiple countries or languages

2 Test Strip Production

AZCO Corp.

+ Systems from AZCO Corp. enable companies to produce their own test strips or improve current test strip production processes
+ Designed with flexibility and speed in mind, available options include unwinds and rewinds, lamination, coating and drying, and a cut-to-length module

3 Fully Integrated Syringe Inspection Line

Syntegon

+ The AIM 5 fully integrated syringe inspection line not only features a de-nester and a re-nester, but also comes with an Artificial Intelligence (AI) function by default
+ The line is designed for gentle handling: the robotic de-nester removes syringes from the nest and places them precisely in a single infeed lane, while the re-nester gently replaces them into the nest after inspection

4 RFID Labeling Solutions

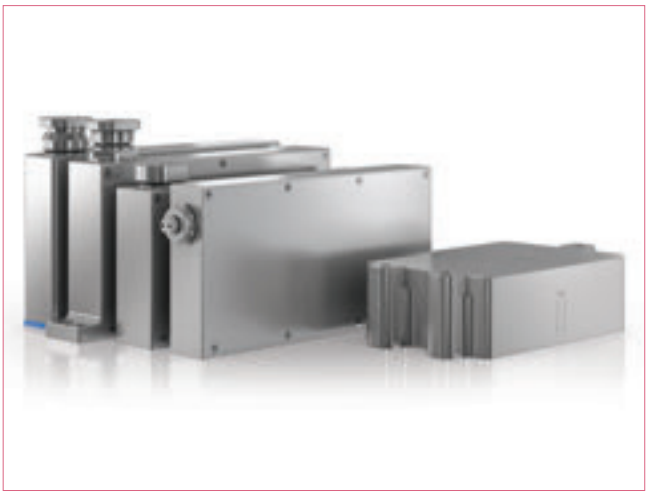
Weiler Labeling Systems, LLC

+ Systems are designed to apply RFID labels at high speeds to vials, bottles, tubes, syringes, and medical devices; options include Labelers, Label Application Systems, and standalone Print Stands
+ The RFID-Ready Labelers are designed to apply p-s labels embedded with RFID inlays from the converter; labels are read, written (encoded), locked or unlocked (as required), verified, applied to the product, and re-verified (as needed)

5 Pierceable, Chemically Resistant Lidding

PAXXUS

+ AccuPierce pierceable foil lidding is a composite material consisting of a highly controlled aluminum foil paired with PAXXUS' chemically resistant, high-barrier Exponent™ sealant
+ It allows for a clean, quick puncture in sensitive testing environments, can contain the often-aggressive chemicals used as reagents, and will seal to a wide variety of materials



6 Modular Multi-lane Weighing System

Wipotec

+ The MMS 2 is a weigh cell for production lines in a variety of settings, including quality control scenarios for vial and syringe filling and other scenarios necessitating customized inspection
+ Its space-saving design allows lane modules to be arranged side-by-side and eliminates the need for an additional cabinet

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Formulated Solutions LLC	www.FormulatedSolutions.com	5
Heat and Control, Inc.	www.heatandcontrol.com	29
Multivac Inc.	www.multivac.com	40
NJM Packaging	www.NJMpackaging.com	2
Nutra-Pack Systems	www.nutra-pack.com	18
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