Healthcare PACKAGING®

- Bayer Bakes Sustainability into Business
- Cold Shipper Tackles Returns Logistics
- Enteral Feeding Pouch Wins Top FPA Award
- New Products Featured on PP. 52

MARCH/APRIL 2022

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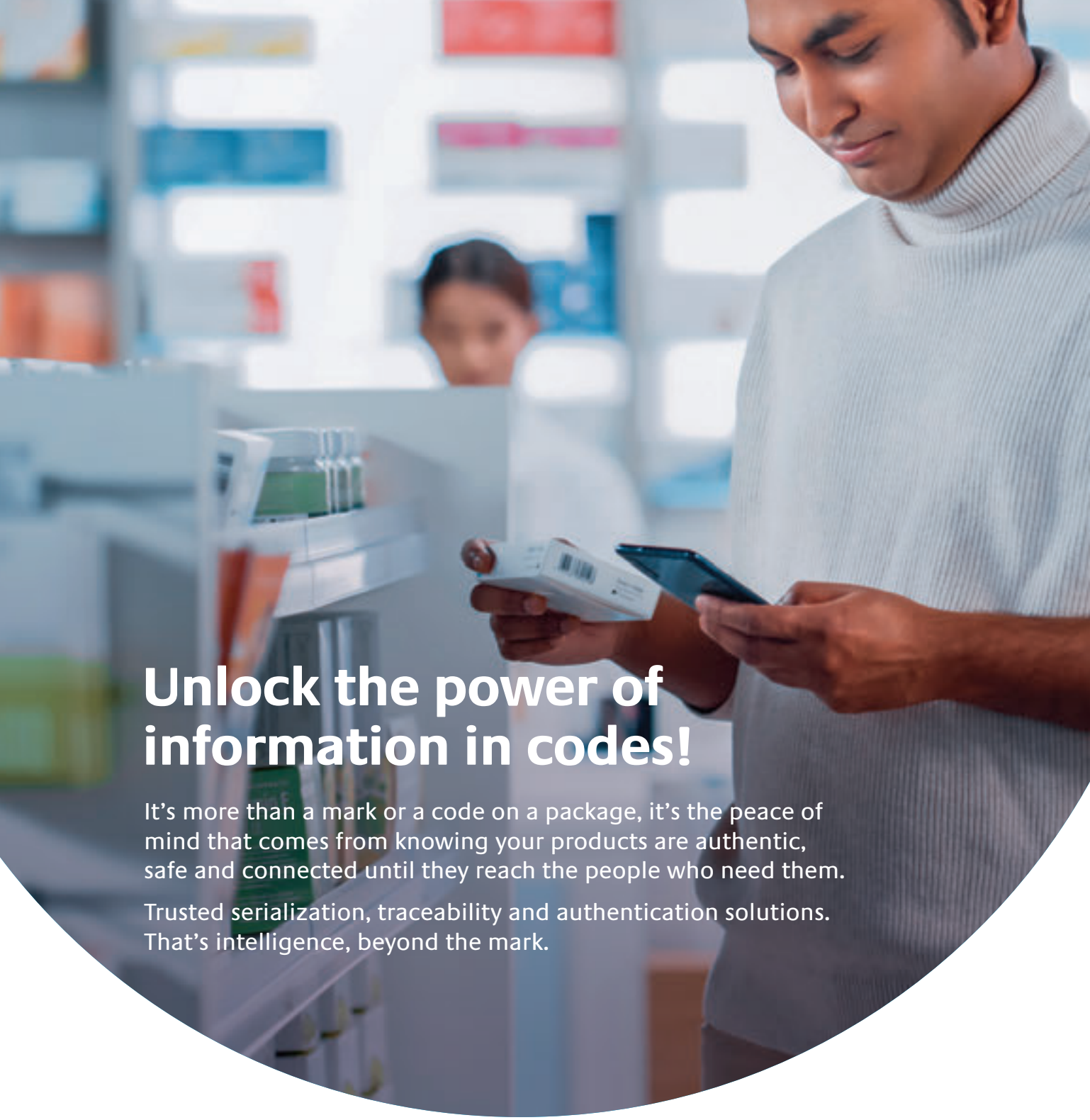

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↑ pp.18

Supplements' Tamper-Evident Label Takes QR Path to Smart Features

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Brand Owners Capture QR's Potential

QR codes link consumers to a plethora of info, all with the point of a smartphone lens. The codes hold promise for right-sizing packaging, brand protection, and educating consumers.

Even if you've been living under a rock, you've likely emerged enough to use a QR code a time or two in your personal life. The 2D code is capable of linking people to a treasure trove of information from a small footprint on packaging, leaflets, signage, and more.

Due in large part to the pandemic, consumers are accustomed to capturing the codes for touchless menus, easy access to info/apps, and more—and brand owners are taking advantage.

In our profile of a high-end nutricosmetic's packaging and shippers, QR codes deliver on consumer engagement, geolocation and tracking, anti-counterfeiting, and brand protection (pp. 18).

Daniella Foster discusses Bayer Consumer Health's sustainability strategy (pp. 22), and highlights that the government-approved use of leveraging QR codes in certain Latin American markets helps the company educate users on a range of health topics. It also allows more dynamic and sustainable content vs. printing educational materials on paper.

Beyond consumer-facing applications, many manufacturers are using enhanced labeling solutions such as QR codes, NFC labels, and RFID markers on tertiary packaging for visibility into production and distribution of products. For more, check out our story on pp. 34.

Finally, the evolution of the connected consumer is leading to innovations that provide insights remotely and conveniently to patients. From smartphone ultrasounds to T-shirt ECGs, pp. 36 features medical winners from the Good Design Awards.

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TIM HAYES,
CONTRIBUTING EDITOR, *HCP*

1 Scientists Use Iron Sensor to Target Deadly Tumors

Tumors that develop due to RAS mutations are extremely difficult to treat, and are responsible for roughly 25% of cancer deaths. A recent *New Atlas* article discussed that researchers at UCSF found that a lot of the tumors linked to RAS gene mutations contain high concentrations of ferrous iron. Beyond that, they discovered a connection between the elevated iron levels and shorter survival times for patients. So, they took cobimetinib, an FDA-approved cancer drug, and modified it with a molecular sensor for ferrous iron to reduce collateral damage to healthy tissue. The drug remains inactive until it encounters ferrous iron in the cancer cells, at which point it activates its anti-cancer effects.

2 New Study Finds Parents Are Clueless About Cannabis

A recent *CNN Health* article discussed C.S. Mott Children's Hospital *National Poll on Children's Health*, which polled 1,992 parents with children ranging from newborns to 18 years old. CBD, short for cannabidiol, is a non-psychoactive chemical compound derived from marijuana and hemp. It is very different from THC, which is the psychoactive derivative of the plant that causes the feeling of being "high." More than a third of parents polled didn't know the difference between the two. Both education and regulation seem to be missing elements. Of the 7% of parents who have given or considered giving their child a CBD product, less than a third reported discussing it with their pediatrician.

3 FDA Releases Drug Recall Guidance

According to a recent *ENDPOINTS NEWS* article the FDA has finalized guidance for industry and FDA staff to quickly and efficiently recall products. The *Initiation of Voluntary Recalls* document offers advice for developing procedures including training, planning, and record-keeping to limit the time a dangerous product is on the market. Since recalls can affect the entire supply chain, the FDA encourages having a procedure in place to quickly notify everyone from downstream suppliers to wholesalers and vendors.

4 Mayo-Backed Nonprofit to Make Cheaper Insulin

A recent *KIMT3 News* article discussed non-profit Civica Rx's aims to make insulin more accessible for Americans, by manufacturing and distributing a variety of insulin products. Consumers will be charged no more than $30/vial and the cost for a box of five pen cartridges will be capped at $55, both significantly cheaper than uninsured patients currently pay. The Mayo Clinic noted that Civica will be able to manufacture a "substantial amount" of the insulin needed in the U.S. Civica is working toward FDA approval by completing applications for clinical trials, and one generic should be available as early as 2024.

5 Drug Cocktail Makes Frog Amputee Regrow Limb

A recent *CNN* article reported that a team of researchers at Harvard University's Wyss Institute were able to trigger the regrowth of an amputated leg on an African clawed frog.

The technique used, which was developed at Wyss and Tufts University, involves applying a cocktail of 5 drugs to the frog's stump before sealing it with a small silicone dome. Although the cocktail is only applied for 24 hours, after 18 months, the frog had developed a limb that could respond to touch, and help the amphibian swim. The limb also grew several toes, but sans webbing between them.

6 Patients Left with Obsolete Implants

Second Sight Medical's Argus II is a retinal prosthesis that provides artificial vision by converting images into electrical pulses that can be read by the brain. Over 350 people worldwide received the implant in the last decade. According to a recent *FierceBiotech* article, Second Sight began phasing Argus II out in 2019 due to financial issues. The process was recently expedited amid the company's plan to pivot and merge with Nano Precision Medical, a drug delivery implant maker. It's left Argus II users without access to upgrades or repairs, as focus shifts to an implant for another use. Without an option for replacement or upgrade, Argus users are left with two options: keep a soon-to-be-obsolete device implanted, or undergo removal.

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$1 BILLION

EASTMAN reported plans to invest up to $1 billion in a material-to-material molecular recycling facility in France, using polyester renewal technology to recycle up to 160,000 metric tonnes annually of hard-to-recycle plastic waste currently being incinerated.

89%

THE PERCENTAGE of pharma industry decision-makers that plan to increase IT spending within the next year, with 42% indicating the increase will be more than 10%. 92% plan to increase IT spending on supply chain monitoring tools.

Source: Zebra's Pharmaceutical Supply Chain Vision Study

April 13, 2022

STERILE PACKAGING DAY, from the Sterilization Packaging Manufacturers Council (SPMC), celebrates those working to deliver innovative, safe, and sterilized devices and supplies.

$6.7 BILLION

PFIZER SIGNED an agreement with clinical-stage company Arena Pharmaceuticals to enter the medical cannabis industry for a total equity value of approximately $6.7 billion.

Source: Forbes

"While we are continuing to analyze the proposed standards, HDA is pleased that FDA has recognized the need for a uniform licensing framework across all 50 states and has reinforced the DSCSA's elimination of the patchwork of state requirements that currently exists."

—CHESTER "CHIP" DAVIS JR., PRESIDENT AND CEO, HEALTHCARE DISTRIBUTION ALLIANCE

"I've spent a lot of time in the ESG space, and oftentimes when we talk about the environment or climate, we're usually just talking about the environment. I think one of the key pieces here that we're really trying to unite and put a focus on is that connection between human health and the environment."

—DANIELLA FOSTER, GLOBAL VP AND HEAD OF PUBLIC AFFAIRS, SCIENCE, AND SUSTAINABILITY, BAYER CONSUMER HEALTH

"We have founded Health Tech Without Borders in response to this ongoing health and humanitarian crisis in Ukraine. [HTWB] is an independent, global non-profit movement providing digital health and telehealth aid where it's needed most."

—HEALTH TECH WITHOUT BORDERS

INTERPHEX 2022 Returns to NY

Coming off the heels of its October 2021 in-person return, INTERPHEX 2022 will take place May 24 to 26, 2022, at the Javits Center in New York, NY, to address challenges faced by the pharmaceutical, biotech, and medical device industries. The event will deliver its 3-day technical conference with educational sessions, PDA roundtables, and networking events, and will showcase technologies and industry expertise. Technical conference tracks include Development/Formulation; Compliance Quality; Processing/Manufacturing; Facility Optimization; Inspection/Distribution; Data/Information Management; and Automation/Process Controls. The Poster Hall highlights new technologies, equipment, methodologies, and innovation.

The 2021 show had diverse attendee demographics with a focus on engineers, bioprocess, biomedical and biochemical professionals, automation, manufacturing, and consultants in the risk assessment and technology implementation space.

INTERPHEX announced that, as of March 7, in accordance with New York State and New York City guidelines, and the updated requirements of the Javits Center, proof of COVID-19 vaccination and face coverings will not be required to attend. "We will continue to monitor the guidance of public health authorities and government agencies going forward to ensure we are creating an environment at INTERPHEX that is as safe as possible for our industry," they report.

For the most up-to-date booth listings and conference agenda, visit Interphex.com.

—Keren Sookne

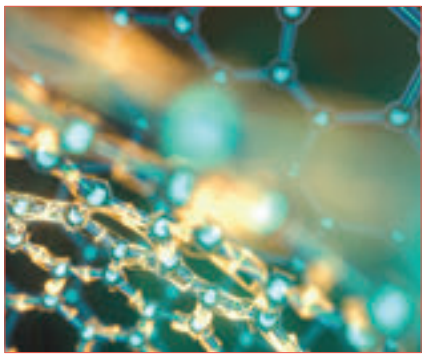
Thwart Foreign Cyberattacks

As conflict continues stemming from Russia's invasion of Ukraine, authorities are warning of imminent increases in state-sponsored hacking attempts to disrupt critical and essential U.S. infrastructure and industries and their supply chains. Threats have been sent and carried out against American organizations, including within the packaging and processing space.

Days after initial threats came in from Russia, PMMI specialists in IT, Andy Lomasky, and in OT, Bryan Griffen, offered the following five steps to keep your company and supply chain secure.

+ Patching and anti-malware—ensure that all of your devices, operating systems, and software are patched and up to date and that all have an anti-malware tool that is capable of detecting sophisticated threats, like ransomware, deployed across your organizations.
+ If you haven't already, implement access protections, such as multi-factor authentication, on as many of your logins and accounts as possible. Make sure your passwords are long and complex to prevent them from being easily cracked. Also remember to only provide access to what employees need to get their jobs done.
+ Scan your network—know what is on it and make sure that you know how to configure it to protect it, especially those hidden devices, like Wi-Fi modems. If you don't know how to locate these devices, ask for help before something happens.
+ Back up everything that's important to the operation of your business and have a good IT disaster recovery and business continuity plan. Know where your backups are stored and test getting your data back before there is an incident.
+ Train ALL of your employees on what cybersecurity threats look like, from phishing and smishing to spoofing to malware. Employees are your first line of defense on the front lines every day!

—Melissa Griffen



HPRC Publishes Advanced Recycling Pilot Project Findings

In 2021, the Healthcare Plastics Recycling Council (HPRC) partnered with advanced recyclers to conduct a pilot project, with the goal of uncovering new recycling opportunities to reduce landfill waste, carbon emissions associated with creating virgin plastic, and reliance on fossil fuels. The findings relevant to medical product manufacturing are (1) plastic healthcare packaging plays an essential role in delivering a safe, sterile, and effective product to the customer in a cost-effective manner; (2) "designing for recyclability" includes avoiding the use of materials that negatively impact yields of advanced recycling processes; and (3) the use of PVC should be limited when possible. *—Morgan Smith*

GAO Makes Recommendations to Improve FDA Foreign Inspection Program

As a result of the FDA postponing most inspections of foreign drug manufacturing sites due to the pandemic, the GAO was asked to update previous work on the FDA's foreign drug inspection program. The GAO recommended the FDA Commissioner should ensure the agency incorporates GAO-identified leading practices as it finalizes plans for implementing pilot programs that will evaluate: the effectiveness and efficiency of unannounced foreign inspections and the costs and effects of using different types of translation services during foreign inspections. Also noted: develop strategies to recruit and retain investigators specializing in conducting foreign drug inspections. *—Morgan Smith*

FDA Publishes Guidance on Reporting Certain Medical Device Shortages

The new draft guidance assists manufacturers in providing timely, informative notifications about a permanent discontinuance or interruption in the manufacturing of certain medical device products. The guidance helps clarify how the agency interprets the notification requirements of section 506J of the Federal Food, Drug, and Cosmetic Act (FDCA), including when and who should submit a notification and the information that should be included. The guidance recommends manufacturers voluntarily provide additional details to ensure the FDA has the information it needs to help prevent or mitigate shortages during or in advance of a public health emergency. *—Morgan Smith*

Open Credentialing Initiative Closes U.S. DSCSA Compliance Gap

The Drug Supply Chain Security Act (DSCSA) mandates that an interoperable electronic system to protect the integrity of the pharma supply chain be fully operational by Nov. 2023. The Open Credentialing Initiative (OCI) has introduced its Early Adopter Program, the industry's first widely available, functional, scalable compliance solution for Authorized Trading Partner (ATP) authentication. Thanks to fully API-based integration of Verification Routing Service providers, ATP authentication can be incorporated into existing processes without disruption. The Program is now available for supply chain companies to test for free. *—Morgan Smith*

Self-Refrigerated, Cloud-Based Shipper Tackles Return Logistics

Ember Technologies and Cardinal Health partnered on the shipper which offers unique 'return to sender' technology. Cardinal Health plans to launch a customer pilot for the Ember Cube in 2022.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

A new digital shipping box, developed by partners **Ember Technologies, Inc.** (Ember®) and **Cardinal Health**, is poised to cut down on waste in the pharmaceutical supply chain while upholding product integrity for 2 to 8°C temperature-sensitive biologics for 48 to 72 hours.

Brian Bejarano, Vice President of Operations, Cardinal Health, reports that the Ember Cube is a cloud-based, self-refrigerated shipping box, which uses GPS tracking technology via onboard cellular radio to communicate its location and real-time temperature at every point in the supply chain using national parcel networks. Data, including humidity levels, can be accessed via Ember's proprietary cloud-based dashboard.

"This technology provides unprecedented assurance of the integrity and security of temperature-sensitive products. In addition, the Ember Cube's return-to-sender technology allows each Ember Cube to be reused hundreds of times, eliminating single-use packaging and potentially eliminating millions of tons of landfill waste," Bejarano adds. Leaders at Cardinal Health and Ember estimate the Ember Cube will save 7 million pounds in medical shipping containers from the landfill annually.

The new Ember Cube will come in multiple sizes and will accommodate payloads from 125 cubic inches up to 900 cubic inches. For each size, the payload space is designed to be greater than or equal to the space in comparable EPS and paperboard shippers used to ship medicines today.

Returns logistics

While returns logistics have represented hurdles to pharma manufacturers in the past, the Ember Cube features a unique "return to sender" technology to essentially ship itself back.

↗ The Ember Cube is a cloud-based, self-refrigerated shipper, which uses GPS tracking technology via onboard cellular radio. A 'return to sender' button automates return scheduling.

"Making the return process simple was part of the product design. Once the healthcare providers have retrieved the medicine from the payload, they simply press the 'return to sender' button and the Ember Cube uses its built-in cellular radio to schedule a pick-up with the shipping service, automatically providing its current GPS location," says Bejarano. "After notifying the shipping service that it is ready for pick up, the Cube generates a new shipping label on its digital screen and is returned to Cardinal Health's distribution center. The return process takes advantage of the same national parcel networks and uses ground transportation to save costs." See it in action at **hcpgo.to/cube**

Upon return, the Cubes are placed back in the warehouse, stacked, and charged using upright charging stations, readied to be reused for the next shipment.

As a major distributor for specialty pharmaceutical products, Cardinal Health will deploy Ember's cold chain technology to patients via hospitals, pharmacies, and physician clinics to deliver life-saving therapies. "The Ember Cube will be a particularly relevant solution for the many cell and gene therapies that are in the drug development pipeline, due to their temperature sensitivity, high value, and need for real-time integrated tracking," said Heidi Hunter, President of Cardinal Health Specialty Solutions.

Cardinal Health plans to launch a customer pilot for the Ember Cube in 2022. Future cryogenic and ultracold versions are currently in development. The companies also aim to codevelop and commercialize additional patented healthcare industry inventions from Ember.

Drone Delivery Pilot

Cardinal Health announced a new pilot program with drone supplier and operator **Zipline International** in November 2021. Drones carrying cargo of up to four pounds will operate from a distribution center in Kannapolis, NC, to deliver pharmaceutical and medical products to local pharmacies within a 10-mile radius in less than 30 minutes. The companies highlight that this program can help mitigate everyday risks in inventory stock-outs or more acute challenges posed by natural disasters and emergencies. Expansion is planned after initial launch.

Global spending on cold chain pharmaceutical products is estimated to grow to more than $21 billion by 2024. [Source: *Biopharma Cold Chain Sourcebook 2020*]

Solving Packaging Format Challenges: Communication is Key

When CPGs and OEMs discussed challenges surrounding packaging formats, designs, and materials, most said improving industry partnerships is the solution.

KIM OVERSTREET, DIRECTOR, EMERGING BRANDS COMMUNITY

As consumers and legislators demand more environmentally friendly packaging, and e-commerce continues to drive new and innovative packaging designs that may require new machinery to implement, the packaging market must be ready to pivot quickly.

A report from **PMMI** Business Intelligence, *Key Challenges for Packaging and Processing Operations*, based on conversations between CPGs and OEMs at PACK EXPO's Top to Top said, "Given the amount of ongoing change, machine flexibility is key, with rapid changeover times and machines that are future-proofed to handle new materials an absolute must."

Top to Top Summit is an annual three-day networking event of high-level executives in the packaging and processing industry, who meet to discuss industry problems and solutions with the aim of improving industry outcome. Sponsored by PMMI, the latest meeting (the 15th annual) was held in conjunction with PACK EXPO Las Vegas.

End users who participated in the discussion plan to work more closely with all suppliers (including OEMs) to better understand the supply chain, as well as with their regulatory teams to better understand new legislation around sustainable materials. End users also reported that they look for OEMs to offer new ideas, and new technologies with creative solutions to problems.

Ensuring that machinery can handle recyclable and/or bio-based materials and new innovative packaging designs is a current operational challenge. One solution is to facilitate communication between OEMs and the end user's own material suppliers and marketing departments. A need for improved market understanding and forecasting around issues such as post-consumer recycled materials was also mentioned by many end users.

Balancing the reduction of a package's environmental impact with a good customer experience—while also keeping new sustainable packaging formats simple and easy to produce—was also mentioned as a key concern, as was the need for standards and definitions of "sustainability."

OEMs spoke about concerns they have that the latest "biodegradable" materials can run on their equipment, as well as issues with the frequency of which new materials are being introduced. Since brand owners hope to run machines for many years, adaptability to as yet untested materials is needed, and OEMs must develop the ability to support troubleshooting surrounding new raw materials.

Lead times and the cost of packaging raw materials were consistently mentioned as one of the largest challenges faced by end users. One end user described unpredictable lead times on raw materials as "their greatest anticipated constraint over the next 12 months."

While this challenge is, to some extent, out of the control of end users, reducing raw material waste is one method to reduce packaging costs, and choosing local raw material suppliers, or on-shoring or near-shoring raw material production, are also possible solutions.

Download a FREE copy of this report to read more about these discussions at **hcpgo.to/399**

Cartoning and Coding Line Delivers COVID-19 Vaccine Vials

Equipment for cartoning, serializing, and case packing vials was designed and delivered in just a few short months.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

↑ A line of this size and complexity would typically take approximately 10 to 11 months to deliver, but this line for cartoning, serializing, and case packing vaccine vials was designed and delivered in mere months. (Image credit: ESS Technologies, Inc.)

With time of the essence, numerous lines for packaging COVID-19 vaccines were installed or reconfigured to meet public health needs. A major pharmaceutical CMO in the U.S. required one such expedited line for cartoning vaccine vials.

They sought out **ESS Technologies, Inc.**—an OEM specializing in health sciences—and **Videojet** because of their long-standing experience in pharmaceuticals and diagnostics. The new line was identical to one that the companies had provided approximately one year prior in 2020. At about the time that first line was up and running, the CMO approached ESS and asked how soon they could procure a second line.

Having been deemed an essential business at the outset of the pandemic, Walt Langosch, Global Business Development at ESS, explains they "were vetted by the Department of Defense, and we were told that this project takes priority over everything else we were doing." ESS sent their quote in Sept. 2020. "Usually, a line of this size and complexity would probably take around 10 to 11 months, but because it was for COVID-19 and it was a priority, we had it installed and running in February 2021," he says.

Cartoning vials

Coming off of a **WLS** (Weiler Labeling Systems) VR-72 labeler at 150 vials/min, capped five mL vials arrive at the ESS VC 30 cartoner where they are placed in a 2x5 pattern into a 10-count carton.

A **Fanuc** SR-6iA SCARA four-axis robot erects the carton and at the next station, a partition is inserted. Cartons and vials are conveyed to the Fanuc LR200iD robotic loader, which places the vials in the carton, followed by an SR-3iA robot that inserts a pre-folded leaflet on top of the vials. See a similar line in action at **pwgo.to/7529**

The system closes the carton's top flaps, and the carton is laser marked with the lot, expiration date, and a 2D barcode by a Videojet 3340 CO_2 laser marking machine. The Videojet 3340 laser system is ideal for high-speed pharmaceutical serialization applications,

providing marking speeds of up to 2,000 characters/sec.

Videojet and ESS worked together to ensure the carton arrived at the coder in the right orientation.An ESS TaskMate® system utilizing a Fanuc LR Mate robot with ESS-designed end-of-arm tooling (EOAT) picks up cartons and shows them to a camera for verification.

"We manipulate the carton to code the end panel because the carton is traveling narrow-side leading down the conveyor," explains Langosch. "When it's on the end panel, we must pick up the carton, code it, read it with the camera, and then set it down in a different orientation to facilitate the case packing operation."

A CEL5 robotic case packer erects the case and places it on a vacuum table as product arrives at the collation station. Cartons then go into the case, and filled cases are labeled with aggregation data by a **Domino** labeler with a **Zebra** print engine. An overhead camera shoots into the case to verify that the first layer is in, then the second, and so forth. Everything is fail-safe and must be proven to be "good." The system visually inspects to ensure there are 10 vials, a leaflet, and a coded carton.

Notably, the Fanuc systems are the only robots that the CMO has at their facility, and ESS uses Fanuc robots exclusively in their applications.

ESS Technologies has been an exclusive Authorized System Integrator for FANUC America since 2000. ESS reports that with the highest meantime between failure of any commercially available robot, FANUC robots offer years of reliable performance in addition to their flexibility and ease of programming. "The wide range of FANUC robots, offering solutions for both light payloads and heavy ones, allows ESS to integrate them for machine loading and unloading, pick-and-place, case packing, palletizing, and material handling," says Langosch. "ESS designs the custom end-of-arm tooling using vacuum and/or gripper technologies to create an end effector that will handle almost any product shape. **Allen Bradley** controls and color touchscreen HMIs make the robotic systems easy to operate."

Coding and marking

The pharma CMO opted to have the code graded, needing to meet the customer's regulatory requirements and pass a certain level of accuracy to be considered good. David Wales, Videojet OEM Sales Engineer, says, "With barcodes, if it's an internal code that's not customer-facing, usually it's read-or-no read versus ABCD grading. However, if the packaging is customer-facing, the manufacturer abides by a certain regulation—usually pharmaceutical GS1 standards—and needs to be a certain grade to pass. If it doesn't meet specifications, it is rejected." Native software and laser firmware help Videojet lasers like the 3340 CO_2 system to meet these requirements with precise, vision-ready codes marked on the packaging.

The CMO is aggregating to the case, and the code is graded at the case level, as well. The facility did not have enough room for an automated palletizer, so cases are hand-palletized. Every case is scanned before it goes out to a pallet.

Results

Once the customer had the system in place, an ESS technician visited the site to check all the connections and test the system. Then there were weeks of testing and validation before the final PQ run.

The line needed quite a bit of flexibility in order to produce other formats and products. "Though the line that we built was dedicated to COVID-19 at the time, they also wanted this line to be able to run the other nine or 10 products that they were running on the first line," explains Langosch. "There were some changes that we made to this second line, because they had been running the first line for six or seven months and they could pinpoint some improvements. Then we went back to line #1 and made the same changes, so they are identical."

With other product formats in mind, a key feature that the CMO is taking advantage of is ESS' commitment to 15-min changeover or less, with no tools. This is important to the customer when they're changing over from one item to the next, which depends on market demands. "All movements of the robot are pre-programmed by ESS. The operator changes to another format via the HMI and the robot motions are changed automatically," Langosch says. Unlike many traditional pick-and-place systems that may require adjustments to multiple axes, the FANUC multi-axis robot only requires an EOAT changeover, which involves loosening thumbscrews, replacing the EOAT, and tightening thumbscrews.

↑ **Videojet and ESS worked together to ensure the carton arrived at the coder in the right orientation. (Image credit: ESS Technologies, Inc.)**

Videojet installation and support teams worked with ESS to take the necessary actions in meeting the accelerated timeline. "Our service team, the largest in the industry, flexed our expertise and team to optimize the installation. We have also expanded our service and support reach into customer locations through our VideojetConnect™ Remote Service. It enables

remote access capabilities for technicians to troubleshoot issues. It's been a good benefit to have during COVID—our technicians don't make changes, but they can view the laser and what the customer is seeing onsite," says Wales. "That's something that we were adding before COVID happened. It just was a huge benefit—a lot of plants weren't letting our technicians in. So, to be able to view that during the pandemic has been a big feature that's helped us out. It helps to diagnose and resolve any issues, and if further functionality is impacted, we can have the right repair components defined and on hand to support a site service call."

ESS also offers remote access with their robotic or PLC programs for customers who want the option. Many in the pharmaceutical industry do not want outside companies going through their firewall, but on occasion, they see the benefit and they can get approval to do so. "If they give us access, we can look at their robotics and PLC and make changes. It gets them running faster, and it's good training experience for their people because they can watch everything that's happening and participate," says Langosch.

For other lines, ESS has a preventative maintenance program in which a series of sensors on motors look for vibration, heat transfer, and other parameters. "They're in the Fanuc robots, as well. We deploy anywhere between 45 and 50 robots a year in similar applications, so their predictive maintenance program and our predictive maintenance program together provide insight for the customer."

With the success of this line, the CMO is already looking to purchase another similar cartoner, case packer, and coding solution from ESS and Videojet for a different product's line.

↙ Cartons are laser marked with the lot, expiration date, and a 2D barcode by a Videojet 3340 CO_2 laser marking machine. (Image credit: Videojet)

Closed-Loop Enteral Feeding Pouch Wins Top FPA Honors

Winning the Highest Achievement Award in the 2022 edition of the Flexible Packaging Associations' annual competition was the EnteraLoc medical device, a flexible spouted pouch with direct connect to the ENFit enteral feeding tube.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

Designed for tube-fed patients, the EnteraLoc™ is an innovative 510(k) FDA-approved enteral device—a flexible spouted pouch with leakproof seal—for direct-connect delivery of nutrition in a safe and convenient manner.

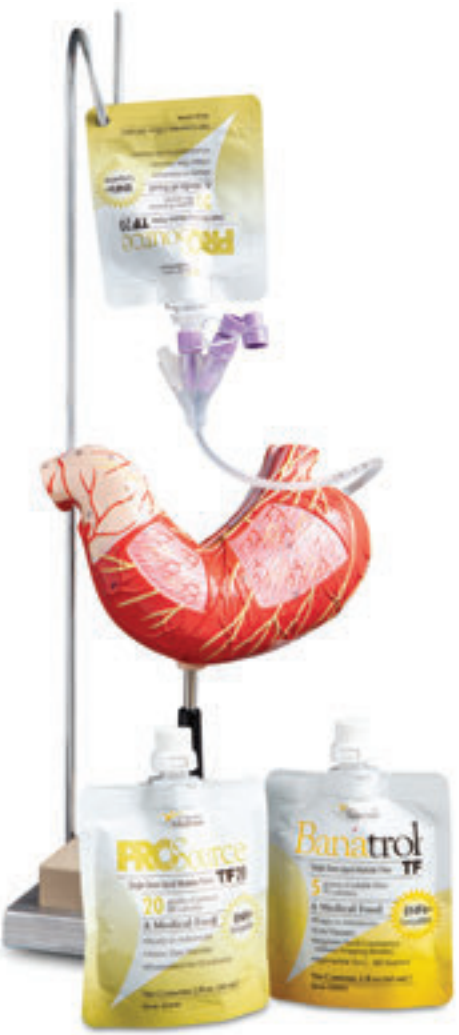
Beyond winning FPA's Highest Achievement Award, the system garnered an impressive four Gold Awards in Packaging Excellence, Sustainability, Technical Innovation, and Expanding the Use of Flexible Packaging.

Marketed by Medtrition, EnteraLoc was developed by **Vonco Products**, with contribution from nutritionDay (in the U.S.), **Hoffer Plastics Corporation**, **Truitt Brothers/Baxter's Foods** (formulation and filling), GEDSA, and Oley Foundation.

The company reports that it is the first seamless, closed-loop system that combines nutritious meals with a flexible pouch, leak-proof seal, custom-designed spout, and direct-connect ENFit® device in one complete enteral feeding system.

In the U.S. alone, more than one million patients are placed on feeding tubes to sustain life and/or improve healing. Vonco sought to improve nutrition/hydration by providing a convenient method of gastrointestinal delivery that is simple, safe, no mess, and portable, eliminating the at-times messy dissolving and mixing steps.

Traditional methods of enteral feeding include bottles, cans, or Tetra-style packs with modular liquid nutrients, and can require measuring cups, syringes, gloves, and towels. Patients and caregivers risk clogged or occluded tubes if the nutrient is not properly mixed or thin enough. Vonco highlights that a common challenge in tube-fed patients is the difference between prescription and administration: "Clinical studies show patients are administered less than 50% of prescribed protein due to the time it takes nursing to prepare and deliver these products."



↑ **For patients and caregivers, the system represents a time-saving and dignified feeding option offering mobility in an easy-to-grasp pouch. As Vonco highlights, feeding with EnteraLoc may only require 25% of the time it used to with traditional feeding components, allowing nurses to concentrate on other tasks at hand.**

EnteraLoc offers a simple connection, then a squeeze of the innovative pouch quickly and safely administers nutrients. EnteraLoc with the ENFit connector—the ISO 80369-3 connector design—results in higher rates of administration for improved compliance and outcomes.

The ENFit connector on the end of the feeding tube will only connect with an ENFit-compatible enteral port. It delivers products including liquid protein and fiber modulars, both blended and non-blended. With a product used in a range of settings—hospital, long term care facility, rehab facility, or home care setting—ease of use is key.

The flexible package allows for near total evacuation of the product, with a leak-proof seal that prevents leaks in transit, warehousing, or use, resulting in less waste.

It eliminates the need for traditional enteral packaging in the form of rigid bottles or Tetra-style packs. When compared with rigid plastic bottles, the

lighter and more portable package uses up to 60% less plastic while requiring approximately 50% less energy to produce. The design requires fewer trucks for transportation compared to rigid containers, reducing carbon footprints associated with shipping.

The system is a contract manufactured medical device sold by brand owners (using their liquid or blenderized formula) direct to hospitals, health systems, and home care patients. As a turnkey solution, EnteraLoc reduces complexity, as well as costs and risks of sourcing, manufacturing, and distributing enteral feeding.

"We've dramatically reduced the risk to brand owners by offering turnkey contract manufacturing services," says Kyle Vlasak, Vice President of Sales at Vonco. "Our enteral feeding system can be fully customized by the brand owner, including preferred formulation, pouch designs, shapes, sizes, hang holes, and spout locations." Products are available in several sizes to meet patient needs (60ml, 250ml, 330ml, 500ml, and 1000ml).

The EnteraLoc spout was designed specifically to accommodate high-speed filling; the caps can be used in the same feeder bowl system, enabling an easy changeover on the filling line.

Customizable for formula brand owners, the pouch features a laminated and custom printed structure suitable for the harsh retort environment, also required for high protein formulations. It features rotogravure retort grade printing in vibrant colors. Available QR codes and peel-off labels can increase patient engagement.

↓ **The flexible package allows for near total evacuation of the product, with a leak-proof seal that prevents leaks in transit, warehousing, or use, resulting in less waste.**

Part 2: Supplements' Tamper-Evident Label Takes QR Path to Smart Features

MATT REYNOLDS, EDITOR, *PACKAGING WORLD*

TOP THREE TAKEAWAYS

1. Nutricosmetic products use a QR code that delivers on consumer engagement, tracking, and more.
2. Two steps: An initial QR code's directions take the user to a second, authenticating (and hidden) QR code.
3. Tracking information offers marketing insights into where products are purchased vs. where they are opened.

↑ **A holographically printed, tamper-evident label with external QR code and die-cut tear strip spans the gap between shipper sidewalls and top.**

Packaging's primary function has always been to protect a product and keep it intact as it travels through the supply chain to reach its end consumer. This foundational duty has been put to the test as packaging originally designed for retail evolves to accommodate the many-touch, multiple-handler world of e-commerce and direct-to-consumer (D2C).

And for high-end, high-margin products that are using these emerging D2C channels, the functional expectations placed on packaging go even further. A product in the luxury space often requires a pack to match in style, aesthetic, and expanded ability to engage with the consumers using smart technology. Plus, if that luxury product is intended to be consumed or applied to the body—as is the case with high-priced personal care products, nutraceuticals, supplements, and cosmetics—packaging is often tasked with additional security and anti-counterfeiting measures.

HEBE LIFE®, a UK-based supplements and nutricosmetics

company, launched in 2019 its SE85® and Core ASX® supplements—rejuvenating products that check all the boxes listed above.

Part 1 of this two-part series covered the primary and secondary packaging choices HEBE LIFE made, including counterfeit-resistant labels by **Royston Labels**, **Clariant** desiccants, **Wrapology** heavy-gauge paperboard cartons, and authentication features from European specialty and secure label maker **Eltronis**. In Part 2, we're delving into the platform behind the QR-coded seals and consumer engagement benefits. For the full article, visit: **hcpgo.to/hebelife**

Software underpinnings smarten up seal

In the HEBE LIFE application, Eltronis' engage™ seal is a circular label with adhesive only applied to its upper and lower quarters. The belly portion of the seal is die cut to create a tear strip that is printed underneath with additional information that remains hidden until the strip can be removed.

As was explained in Part 1, engage has evolved over time to where it is now, having originated from work in helping pharmaceutical companies with the implementation of the European Falsified Medicines Directive (FMD) along with Eltronis' work with several governments looking at authentication labels.

The seal adheres to the side wall and top panel of the printed paperboard shipper to act, at its most basic functional level, as a physical tamper-evident indicator. When the tear-off strip is removed, the remaining top and bottom portions of the label remain adhered to the packaging. If the seal has already been broken, that tells consumers that the package has been compromised. Like the labels used on the glass jars, printing is done with such quality—including the HEBE LIFE logo using holography via rain-

↑ **Primary packaging for HEBE LIFE's two nutricosmetic offerings involve durable, p-s labeled glass jars using a desiccant and metallized foil seal.**

bow cold foil—that counterfeit reproduction should be prohibitively difficult. But the authentication process goes much further than top notch label design.

The engage cloud-based software underpinning the seal's advanced features works with two QR codes. The outward-facing side of the seal is printed with a QR code that's smartphone readable, transforming the seal into a consumer-facing marketing tool. It may also simultaneously serve as a back-end data collection tool, allowing HEBE LIFE to track, trace, and glean market insights from the pack as it travels through the supply chain.

But to the consumer, this external code is the starting line of an interactive path, and it acts as an initial call to action asking them to scan the QR code with a smartphone as a first step down the road toward product authentication. That first QR code will take the customer to a bespoke landing page that tells the customer what to do next, what to expect, how to open the product via the tear strip label, how to authenticate it, and any other pertinent information.

WATCH

Watch this video on three healthcare packaging updates from PACK EXPO Las Vegas at: **hcpgo.to/3hcp**

"In this instance, for all intents and purposes, the landing page is HEBE LIFE's landing page," Pete Smallwood, Business Development Manager, Eltronis, says. "It's there to get the end user to authenticate the product once they open it, but it also can be used to provide additional information. These bespoke landing pages are always a reflection of our customers' branding. We use their logos and we use their marketing rules."

For example, since HEBE LIFE has two products that can be consumed in a complementary fashion—Core ASX and SE85—the first landing page encourages buyers of one product to seek out the other.

But the really neat stuff starts with the second QR code. By following the first QR code's directions, a second, authenticating QR code hidden within is revealed on the inside of the label's tear strip. Having broken the seal and scanned the second QR code, a consumer confirms that this is the genuine, authentic product. In an ideal world, this would always happen.

But in the rare but possible event that the second QR code has already been scanned when the customer first scans it, or if the code doesn't exist in HEBE LIFE's database at all, a brand protec-

↙ **Presentational secondary packaging for the SE85 supplement, which contains a six-month supply of product, is durable and intended to be displayed.**

tion protocol will go into action. The software will recognize the incongruity and instruct the consumer on next steps. This isn't ideal, of course, but it's information that the brand owner is going to want to know, and information exchanged between brand and consumer on these scan errors can help the brand investigate the cause of the problem and prevent a consumer from using counterfeit product.

Depending on the application, brands employing this system might also use the secondary QR authentication step to reveal a hidden bonus for customers. It could lead to discount offers or get customers to sign up for gift giveaways, newsletters, refill subscriptions, or loyalty programs.

"There is also a geolocation element to the software within the second QR code, so a brand can see if the product is being authenticated, where its market strategies have been implemented, and it can align its marketing accordingly," says Smallwood. "That can also be used to identify gray [illegal] import and make sure that your distribution channel has not been compromised."

↗ **Upon tearing open the tamper-evident label, consumers are asked to authenticate the product via QR code, leading to further engagement opportunities while capturing tracking, timing, and geolocation insights for HEBE LIFE. A tamper-evident label is affixed to the secondary packaging for the SE85 supplement variety.**

"The seal isn't just all about security; an equally important role for the seal is in tracking," HEBE LIFE's Ahmad Attar, Marketing Director, agrees. "The outer or external QR code in the system is unique, so in every logistical step in our supply chain, we can track it. We will know that a given box has been tracked to a given location and know where it has been. Since we're dealing with an open market, and dealing with a lot of distributors, it's always good to know statistics on where a given box has been opened."

They noticed, for example, that often boxes are purchased in the U.S., but opened in Canada. Or boxes purchased in the U.K. are opened in the Persian Gulf. This gives HEBE LIFE good, real-time tracking information and informs future marketing.

Finding the right fit

Heba Elshourbagy, Director of HEBE LIFE, and Attar landed on Eltronis and its engage platform after a lot of shopping around, even among some other suppliers purporting to offer the same technology. What tipped the scales in favor of Eltronis' engage for HEBE LIFE?

"Engage was very flexible and we found that their system is very reliable," says Attar. "It's especially easy to manage, and again it's not only for security. For us, if we compare how we use the functionality, the security piece is maybe 30%, but the tracking is 70%."

Also, customization of the bespoke web pages was an easy process. Elshourbagy says she and Attar worked closely together with Eltronis to form and design the landing page templates to improve the user experience with the landing pages served up by the engage platform.

"We work together still now—we have an open communication with Eltronis, too, for feedback and enhancements and to provide better options and solutions for future products," Elshourbagy says.

Adds Attar, "Eltronis' engage has been a very good value-to-money product and this is the key to any recommendation. When you compare the same technology with other technologies, you will find that many ask for a retainer, or minimum orders, even if they don't provide all the tracking services like Eltronis. But if you compare the value of money in a product—even less expensive or lower value items, as this can serve even a £1 product—you will find that engage has real value for these products, combining use of the tracking system, authentication, and all their other IP services. We are already recommending them for everyone."

Bayer Emphasizes Human Health and Environment with +100 Mil Investment

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Bayer is baking sustainability into its business—in packaging, emissions, and more.
2. They are focused on expanding global access to medications and supplementation.
3. QR codes offer multiple benefits for packaging and convenient consumer education.

65% of energy consumed at three Consumer Health production sites—one each in Germany, Guatemala, and Spain—is generated from renewable sources. (Image credit: Getty)

Planetary health may not be what immediately comes to mind when you think of Aspirin, but they're more connected than you might realize.

Bayer AG has initiated several "100 million challenges," including its recent investment in sustainable health products to advance the company's 2030 sustainability commitments. They're pouring in €100 million to further enable sustainable innovation, production, and consumption of Consumer Health products including global brands like Aspirin, Bepanthen, Claritin, and Elevit.

We'll get to the packaging details shortly. But first, it's important to discuss the connection between human health and the environment. "When you think about the environment and climate issues, we're talking about the environment as a social determinant of health," says Daniella Foster, Global Vice President and Head of Public Affairs, Science, and Sustainability for Bayer's Consumer Health division. "Reflecting on the past 20 years, we know that climate change has been a cause behind a growing number of health concerns, and we also know that underserved populations are particularly vulnerable."

Data suggests that approximately half of the world's population does not have access to basic and essential health services, while the same populations are often in communities significantly

impacted by climate, resulting in being hit from multiple sides. "Rising temperatures, poor air quality, pollen counts, all these things are increasing... this leads to heart disease, respiratory illnesses, allergies, etc. For people without access to medical care, they're really having a hard time managing or treating these conditions. This also impacts their ability to work. In some cases, it's perpetuating a cycle of poverty," she explains.

The company is setting out to tackle the inclusive growth challenge and environmental challenge together, looking to protect people's health in both the short- and long-term, while also reaching science-based targets.

Bayer's plan includes (1) prioritizing sustainable brands, products, and packaging, (2) urging collective industry action, and (3) targeting carbon emissions, including net zero by 2050.

One of the concepts that attracted Foster to Bayer is that they no longer separate business strategy and sustainability strategy. "They're integrated and we bake sustainability into our business and how we think about our value chain," she says. "The renumeration of our Board of Management is tied to our sustainability strategy and progress. So, it's a core part of how we operate. We also have an external sustainability council that reviews our plans and progress, and they pressure test us."

↑ A health education program with Mercy Corps Indonesia.

Products and packaging

Bayer has been making headway in improving the sustainability of its products and packaging for a few years, obtaining data to determine where impact can be made and how best to prioritize efforts.

With the €100 million investment, Bayer explains it is "committed to finding new solutions that inspire the sustainable creation and consumption of the company's over-the-counter products and supplements."

The company is targeting that by 2030 (where quality and safety permit), 100% of Bayer Consumer Health's packaging will be recyclable or reusable and all packaging will include consumer-friendly recycling information, and the division's packaging will include an average of 50% recycled content and 100% of purchased paper will be sustainably sourced.

In setting packaging targets, Bayer assessed the recyclability of their portfolio and identified the formats used at highest volumes—paper, plastic bottles, blister packs, and flexible tubes. Next, they evaluated the current recyclability of these formats and the technical and financial feasibility of conversion into recyclable packaging solu-

↑ Bayer presents a health education program with reach52 in Kenya.

tions, setting priorities accordingly. Their progress thus far includes:

- **Shipping boxes included 80% recycled content by the end of 2021.** Many initiatives already taking place at manufacturing sites gave Bayer a baseline toward the goals. Additional transformation has been driven by strong partnership with their supplier network, and continued sharing of best practices among sites. (*Editor's note: Bayer chose not to reveal its packaging suppliers.*)
- **Conversion started for paper packaging across global brands,** including Aleve, Claritin, Iberogast, and Redoxon to use certified paper from responsibly managed forests.
- **A program was implemented to transition to digital marketing and reduce the footprint of the division's printed promotional materials.** Bayer has worked on prioritizing digital marketing for years, which Foster explains "makes sense from both a sustainability standpoint and reaching the consumer where they are. For instance, in some of our Latin American markets at Bayer, the government-approved use of leveraging QR codes helps educate users on a range of health topics. Consumers are getting much more comfortable with QR codes thanks to restaurants and stores incorporating them during the pandemic. Instead of printing brochures or other materials, we can create much more dynamic and sustainable content to help people take better care of themselves."
- **100% of new product development projects are assessed for sustainability performance across health, the environment, and access.**

With partnership and collective action being so powerful, Foster says she was particularly excited for the Q4 2021 launch of the Global Self Care Federation (GSCF) Environmental Charter. The GSCF counts Bayer, Sanofi, GSK, and J&J among its members working across competitive lines to deliver carbon emission reductions and more sustainable packaging. "I think this charter was a really great example of how an industry can come together in this area of environmental action and determine the areas where we all want to see progress and whereby working together, we can get farther quicker," she says. "This is going to be critical. I always say—especially when we're talking about environment—no one company, entity, government, etc. owns the environment. We all have to work collectively and collaboratively to reach the UN sustainable development goals. I see it much more as a team sport."

Similar to Consumer Health, a priority area for Bayer's Pharmaceutical division is to create change within their operations, which includes switching to greener electricity and investing in projects to reduce greenhouse gas emissions in their production facilities. The Pharma division is also working to reduce the ecological footprint of their products, but with prescription drug packaging oriented toward function, there is less optimization potential than on the

Drivers from All Sides

The move to more sustainable practices is driven by company goals, the financial world, consumers, and employees. Bayer's mission is "health for all, hunger for none," and as Foster emphasizes, it's not just the sustainability mission but the company mission.

ESG [environmental, social, and governance] criteria has been in the investor lexicon in different forms for approximately a decade. But the past four years have brought heightened pressure, from Blackrock's Letter to CEOs on climate change to ratings such as the *Wall Street Journal*'s ranking of the most sustainably managed companies in the world (in which Bayer is listed). Foster notes that the pandemic also highlighted the "importance of environment and, two, the importance of human health. They're also completely linked, and you can't divorce the two."

On the employee front, sustainability is less about what you say and more about transparency: what you're doing, why you're doing it, and how you're measuring it. Foster says the whole organization is mobilized, adding, "Sustainability shouldn't just be the job of people like me. If you're embedding it into your business, it becomes a part of everyone's job… and that definitely becomes a driver of retention, of employee satisfaction, and of pride."

Consumers are ever more adept at spotting greenwashing claims—transparency on progress and measurable goals are critical. Bayer's site features a section on the auditing process they go through, and progress and methodologies are shared in their annual sustainability report. "In any journey that's long and ambitious, you're also going to hit challenges, and that's ok. Anything worth doing, you're going to have roadblocks," says Foster. "But that's another place where that full transparency of 'here's what we're seeing and here's where we need to go' is fundamental, and where collective action can help."

↑ **Bayer AG is investing €100 million to further enable sustainable innovation, production, and consumption of Consumer Health products including global brands such as Aspirin, Bepanthen, Claritin, and Elevit.**

Consumer Health side. While too soon to tell, Foster notes that there may be knowledge that comes from GSCF efforts that applies to pharmaceutical packaging: "When you crack that code and get to that solution, which is going to take a lot of time, then that paves the way for solutions to potentially be scaled where it makes sense, where you can ensure safety, efficacy, etc."

Tangibles in cutting carbon

Many companies are looking to reach climate neutrality and net-zero emissions with supply chains responsible for such a large proportion of an organization's global emissions. Bayer has an overarching commitment to climate neutrality by 2030 (Scopes 1 and 2) and net zero across the entire value chain (Scopes 1, 2, and 3) by 2050.

Progress in Consumer Health to-date includes:

- Reduction of carbon footprint across production facilities through energy efficiency and renewable energy projects, contributing to a 30% reduction in carbon emissions between 2019 and 2020 alone. As Foster explains, "When we move, we move fast." This includes upgrading HVAC (heating, ventilation, and air conditioning) systems, representing "very unsexy but really critical updates when you're talking about energy efficiency and reduction," she says.

- 65% of energy consumed at three Consumer Health production sites (one each in Germany, Guatemala, and Spain) is generated from renewable sources.

Bayer has monitored its carbon footprint for some time, so they had a good base understanding of their Scope 1 and 2 footprints. Their Board of Management set the intention to be climate neutral by 2030 and empowered the company to prioritize this across the value chain. Their science-based targets have been reviewed and endorsed by the Science Based Targets initiative (SBTi).

The company also has a partnership with CDP [formerly the Carbon Disclosure Project], which aims to make environmental reporting a business norm. Bayer is also working with suppliers to obtain data and understand some of the biggest opportunities to work on together in reducing their carbon footprints. Approximately 73% of Consumer Health suppliers have submitted their data.

Expanding access

Accessibility to products is a major goal for Bayer Consumer Health—they set the target of expanding access to everyday health for 100 million people in underserved communities by 2030. For various underserved communities, Bayer has spent time researching ethnographies to understand the challenges they face and access gaps that can be bridged, and then overlayed that information with medical needs. This way, Bayer can tailor and design access to products with specific communities in mind. Beyond sustainability criteria, the company has baked the accessibility and availability of products into their innovation pipeline.

In the Pharmaceuticals division, Bayer set a goal to expand access to modern day family planning and contraceptives for 100 million women in low- and middle-income countries. "Some may ask why family planning? We know access to family planning is essential—it improves not only women's health, but it improves overall economic opportunities," Foster says. "It's key in terms of tackling cycles of poverty and breaking down barriers to progress for gender equality. So that's how we start to unite some of these goals." (On a related note, *New York Times* best-seller "Drawdown" on climate change solutions features chapters on family planning and educating girls as key sustainability practices in reducing greenhouse gases over time.)

Foster says that transparency in these "100 million challenges" is key—they keep metrics on their site and display their methodology as they look at improving access now, not just 10 years from now.

Bayer also launched its Nutrient Gap Initiative in 2021, which is focused on expanding access to vitamins and minerals for 50 million people in underserved communities by 2030. They've reached 20 million people globally to date. WHO data shows that one in three people suffer from malnutrition. "We see this being most critical for pregnant women because if you don't have the right nutrition, it impacts all aspects of your life. This can exacerbate the cycle of poverty if you have children that are not born healthy, lacking nutrients," she explains.

Not only is this prenatal focus in line with Bayer's fundamental principle that every child should have the best start in life, but scientific research shows the importance of multiple micronutrient supplementation (MMS), having been recently placed on the WHO's list of essential medicines.

This is not merely a donation program. Bayer has partnered with several NGOs—including Vitamin Angels—and is working to create

systemic change and improve the health outcomes of women via interventions with local community and healthcare workers, with wraparound nutrition and educational programs to boost adherence and meet people where they are.

Things are evolving in real-time, but Bayer is starting to see the unification of sustainable packaging and expanded access. The aforementioned digital solutions, for example, offer a lot of potential. "Data is showing that underserved communities get QR codes—people like them. They're simple and easy to use," she explains. "This is an area where we see potential to unite human health and the environment. On one hand, if you have QR codes, you eliminate the need for things like leaflets and you can probably reduce the size of your packaging. On the other hand, you can also start to build into that QR code things like health education, literacy, and additional tools so it's in one place and easy for the consumer. We're already starting this in some of our regions, including in Latin America."

Industry collaboration

Foster, who is co-chair of the GSCF Environmental Charter committee, says that collective action is key in scaling solutions to big challenges that are truly sustainable. "I also think when you talk about systemic challenges, whether it's waste systems or climate change as a whole, these are not the kind of challenges that one government, company, etc., is going to solve on their own, nor should they. We have to work together," she says.

Beyond the power of working across competitive lines, opportunity also lies in working with suppliers. Reflecting on her previous experience at the State Department, Foster notes that she helped set up their first office of public-private partnership at a time when these partnerships weren't the norm. Some of the most effective public-private partnerships she saw were in the areas of health—including PEPFAR focused on HIV/AIDS—where companies, NGOs, and governments worked together to identify effective solutions.

"Sometimes just making the commitment to come together and having very clear focus areas can be the hardest bit," says Foster. "We're now doing that through the GSCF Environmental Charter, and I think that that is going to open up a world of opportunity as we start to talk about more sustainable solutions and materials, working collaboratively with suppliers."

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Applying Modern Technology to Pharmaceutical Production Facilities

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Robotics, biometrics, and isolator technologies are cleaner, faster, and safer than manual methods.
2. Panelists discussed challenges and solutions surrounding mobile robots and entry to grade D air locks.
3. FDA addressed sanitation guidelines, and noted that isolator technology is an unexpectedly underutilized solution.

Since the FDA released its current good manufacturing practices (cGMPs) and 21st century initiative that includes promoting industry modernization, the majority of industries—including pharma—have gotten onboard the digitalization and Industry 4.0 train.

Though cost and documentation hold some companies back, this has resulted in improvements such as robotics and biometrics initiatives in drug product manufacturing being implemented as well as the adoption of modern, robust aseptic processing technologies that afford tangible safety benefits to sterile products. Three industry panelists and an FDA regulatory expert presented on these subjects at the 2021 PDA/FDA Joint Regulatory Conference:

- James C. Weber, Advisor IT, Digital Manufacturing at Eli Lilly and Company
- Carl-Helmut Coulon, PhD, Head of Future Manufacturing Concepts at **Invite GmbH**
- David Wolton, Engineering Technology Lead at Takeda
- Nicholas A. Violand, Investigator/Drug National Expert at ORA, FDA

Modern tech: cleaner, faster, safer

Benefits of adopting modern technology emphasized between the four panelists' presentations included improved cleanroom capabilities, time efficiency, and product and worker safety. Weber explained that Eli Lilly and Company (Eli Lilly) jumped on the opportunity to seize these benefits through developing a Global Robotics Program and integrating biometric solutions, both of which furthered the company's digital plant aspirations.

"There definitely is an industry opportunity for robotics," said Weber. "That's demonstrated by the fact that most players in pharma are pursuing some type of robotics program. There are a lot of both ergonomic and economic drivers that make it attractive and in terms of regulatory or interaction with the FDA, from where I sit as an engineer, as a practitioner, most of the challenges are very tactical and they come down to risk-based design, validation decisions, and creation of procedures to mitigate risks."

Efforts began in 2017 when the cost of robotics technology started decreasing as the market increased, along with the physical and digital capabilities of the robots. Eli Lilly established central staffing and funding for its new program and used site experts to network and establish partnerships for opportunity identification, prioritization, design, and deployment. These experts focused on projects with the most potential value that could be replicated throughout the company. Eli Lilly's standard sets of equipment, platforms, automation, and IT landscapes allowed it to create a lab for simulating activities across most locations and sites in order to develop solutions.

Weber said the company's solutions ranged from logistics operations with automated warehouse and automated guided vehicles; to drug production manufacturing through loading and unloading of cartridges and vials on production lines, automated cleaning, and flexible aseptic filling; to flexible device assembly and flexible drug product packaging; as well as parts identification, in-process checks, and packaged product unloading, palletizing, and transport.

A specific robotic solution brought up by Wolton and Coulon was autonomous mobile robots (AMRs) which are experiencing increased demand. AMRs work 24/7, do not host viruses or bacteria like humans do, are cleaner as they do not shed skin, and are ideal for repetitive or manual tasks. These robots are commonly used for the delivery and removal of items, such as waste, consumables, gowning materials, spare parts, and reagents for QC labs, and the newest type of AMR that comes with a manipulator can do more complicated and complex tasks, such as repetitive tasks in environmental monitoring, water sampling, and product sampling.

Adopting robotic technology further opens up opportunities to go "deeper" and "broader" than initially expected, allowing the focus to be on processes instead of individual activities. Digital data trail benefits become apparent through the ability to track the chain of custody of a product, its time out of refrigeration, etc. The same thought process can be applied to labs and creating a robotic logistics flow with the digital chain of custody for samples as they're withdrawn for production and sent to the lab, stored and crated in an automated way, or tested in an automated way.

"By deeper, I mean capitalize on the integration of robots with the process equipment," said Weber. "For example, sensor technology integration so they're not just moving material but they're also verifying materials, verifying batch identities, maybe even using vision technology to verify undamaged materials."

Eli Lilly saw similar benefits with biometrics. Previously, the tedious task of operators entering their credentials in the form of signature entries made up of usernames and passwords was an ergonomic risk and needed to be done whenever an operator interacted with a machine. The company used manufacturing execution systems (MES), which have an especially high demand for user entries to support electronic batch records and related documents.

The company ran initial pilots in drug substance manufacturing "control room" settings using fingerprint and iris scanning biomet-

ric devices, then introduced biometric bracelets as options for operator mobility. Operators were given the opportunity to continue using the traditional signature method, yet three months in, data showed 80% of signatures being done with biometrics and 56 of 60 users opting to use the biometric bracelets, which data proved saved a minimum of six seconds per signature.

Similar to robotics, Eli Lilly saw opportunities to go "deeper" and "broader" with a wider-administration process for user enrollment and using the biometric devices for access control and tracking people within operations on the shop floor or production offices. Further abilities the company is pursuing are general-purpose wearables to enable additional capabilities such as alerts and alarms from machines and systems; standard communication to notify maintenance and supervision; safe operations applications, including "operator down"; social distance monitoring; and contact tracing.

Room to improve

Though robotics can prove very beneficial to operations, there is still much to be done to make robotic solutions more efficient. In the case of AMRs, though more sanitary than humans, they are highly expensive assets, often resulting in a company having just one AMR, which will likely traverse all parts of the facility including air locks. Getting through air locks is the biggest challenge keeping the use of AMRs from becoming widespread, panelists noted.

Grade D air locks, in particular, require a specific type of cleaning with IPA wipes, which are difficult for AMRs to use for a number of reasons, so validating the cleaning process is very challenging. A potential solution brought up by Wolton is to automate air locks, having different automation solutions per grade. These solutions would need to disinfect quickly and be retrofittable, cost-effective, and flexible. But between companies, and even within a company, a

↑ **Despite their expense, autonomous mobile robots (AMRs) are experiencing increased demand, and are ideal for repetitive or manual tasks. Airlocks remain challenging.**

solution cannot be agreed on, he said.

Suggestions that have been explored include robots from the semiconductor industry, which have similar requirements to GMP cleanroom class A, as well as cleanable robots, for their compact cleanroom design, powder coating, seals to protect against particle emission, extremely smooth surfaces, and hydrogen peroxide-resistance. But the issue of humans needing to clean these robots keeps arising and Coulon asserted that current requirements for cleaning methods do not reflect automated cleaning but rely on human intelligence and vision.

He concluded that a concept for validating automated cleaning of complex equipment taking into account environmental, equipment, and substance features needs to be developed and to do so, engineers and pharmacists must be connected—in other words people, science, and regulation need to be connected.

Wolton agreed, adding that next steps should include defining specifications for what air locks need to achieve in terms of air quality and surface disinfection—especially if using ultra violet (UV) disinfection—as well as a discussion around the issues of "visually clean." Wolton said, "What we'd like to ask for is a working group to actually debate this topic, but also then recommend a path forward. Now, we believe this will need a collaboration between PDA, ISPE, and BPOG and maybe other organizations as well. But at least if we can agree on what specifications are required, we can actually look into achieving it through automated means."

Common cause of observations

Another important sector, highlighted by Violand, where modern technology applications can have a significant impact is aseptic processing. Violand stated that one of the primary contributors to contamination in drug manufacturing is the personnel. He asserted, "The greater the level of separation between personnel and operation, the greater level of sterility assurance."

Microbiological contamination of drug products purporting to be sterile has continued to be a top 20 observed citation in the drug realm over the last decade according to FDA research, and a solution not as widespread as the FDA expected is the use of isolator technology. This contamination is mainly due to operators not following sanitation guidelines around sterile drug products. Violand explained that isolators, however, create that needed distance between personnel and operation as they don't allow space for operator hands and heads to enter sterile areas, such as under the laminar flow hood, instead using automated disinfecting systems, such as vaporized hydrogen peroxide (VHP).

Typical advantages of the closed isolator design listed by Violand include:

- Fully closed, with personnel completely separated from aseptic operations
- Positive pressure, and no interventions requiring open doors permitted
- Surrounding room can often have lower classification than in traditional aseptic processing
- Increased automation in lines is typical, further reducing opportunities for human error
- Transfer of materials inside is controlled (e.g., rapid transfer ports or transfer chambers)
- Disinfection processes can be more tightly controlled (e.g., VHP)
- Decontamination occurs after initial line setup and any necessary open-door activities

The FDA's *Guidance for Industry, Sterile Drug Products by Aseptic Processing–Current Good Manufacturing Practice, 2004* states that "aseptic processing using isolation systems separates the external cleanroom environment from the aseptic processing line and minimizes its exposure to personnel. A well-designed positive pressure isolator, supported by adequate procedures for its maintenance, monitoring, and control, offers tangible advantages over traditional aseptic processing, including fewer opportunities for microbial contamination during processing."

READ

Watch this video on robotics use in the high-mix, low-volume space at **hcpgo.to/hmlv**

EU Regulators, Recycling, and Healthcare Plastics

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Regulations are key in moving toward more circular ops in packaging and processing.
2. EU regulators are open to hearing from the packaging community.
3. Healthcare plastics may offer good source material for recycled content.

↑ Medical packaging can be a great source of recycled content—packages are composed of high-quality polymers.

The need for environmental regulations should not be downplayed as the healthcare industry cannot ignore its environmental impact. However, it's important that regulators understand the implications of potential legislation to avoid unintended consequences for patients, workers, and the environment.

At the virtual Medical Packaging Conference, Thierry Wagner, Global Director, Regulatory & Standards—Healthcare at **DuPont**, and Dr. Isabelle Jenny, Sustainability Manager at **Amcor Flexibles** Europe, Middle East, and Africa, were asked whether EU regulators are open to hearing from the medical packaging community in cases where proposed rules may be moving too fast and could impact patient safety. This topic can be particularly concerning when it comes to requirements for using post-consumer recycled (PCR) content in new packaging. [*Editor's Note: Answers below have been edited for brevity.*]

Thierry Wagner: "Yes, I think regulators recognize [this issue]. In the packaging and packaging waste directive (PPWD), there is very clearly a rule which allows regulators to make implementing decisions, so that rules that will apply to other types of packaging wouldn't apply to medical and pharmaceutical packaging, because I think they recognize that the need for patient safety is first.

"And the medical and pharmaceutical industry is only a small percentage of plastic usage, but the requirements and the consequences for patients can be huge. I think they recognize that, but at the same time, we all need to advance, and I think they're right to say that.

"Also, medical packaging can be a great source of recycled content—packages are composed of high-quality polymers. So, we certainly have to contribute to that first, but I believe going forward in terms of integrating recycled content, we have to wait a bit longer for the maturity of these emerging technologies because of the EU MDR regulation and the FDA rules for controlling risks. You only can make sure that you are meeting those requirements if you have traceability of these streams and if you have flawless quality control. So eventually it will come—the push is there."

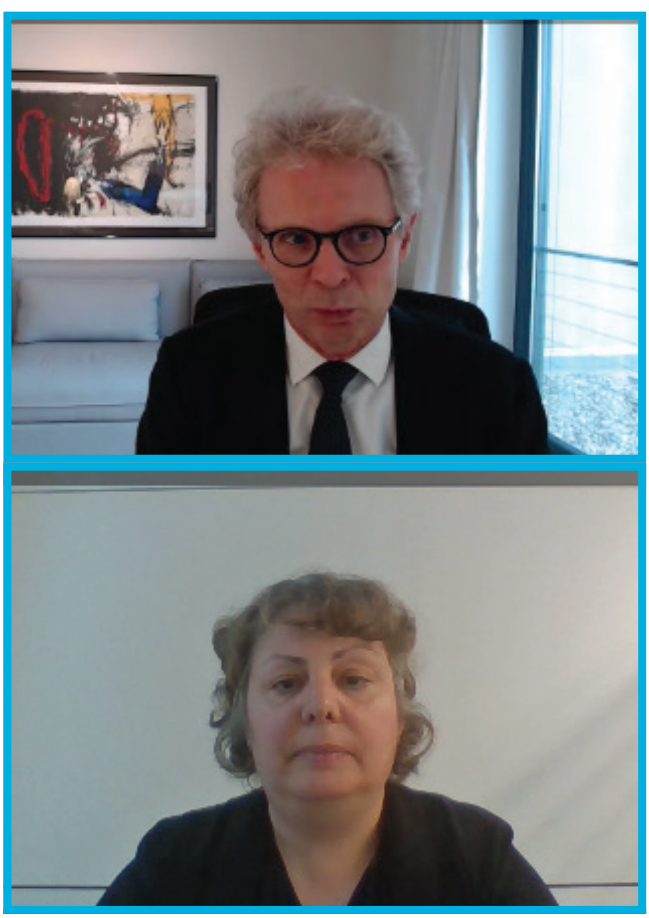
Dr. Isabelle Jenny: "Post-consumer recycled content—which is often what people are looking at coming from mechanical recycling today—is very limited in its use, also in food packaging. You basically cannot get it into food, pharma, or medical packaging currently, but when we look at the future of advanced recycling, as we discussed previously, we see that the PCR content coming from chemical recycling or advanced recycling maybe of use as recycled content for food, pharma, and even medical applications.

"This is one of the future options that we are assessing now when it comes to Amcor. We already use some PCR content in, for example, hygiene product packaging, which is not food compliant. Also, we recently launched one of the first food packages at Amcor which contains 'advanced recycling recycled content' used in a chocolate flow wrap application. So, we're seeing now that advanced recycling recycled content is starting to be implemented for food packaging. We are also expecting that as a next step, pharmaceutical or medical types of packaging would be assessed for the use of recycled content coming from advanced recycling processes, not from mechanical recycling."

Thierry Wagner: "There are good projects out there. We've recently done a project where we upgraded our mechanical recycling processes for our internal recycling of pre-consumer waste. Some of the recycled materials go into other applications than healthcare, but we also use recycled Tyvek® for the manufacture of plastic cores to wind the Tyvek sheet material, which is a great reuse of this material adding circularity to that process."

READ

Read this story on emerging EU sustainability regulations: **hcpgo.to/EUregulations**



↑ **At the virtual Medical Packaging Conference, (from top) Thierry Wagner, Global Director, Regulatory & Standards – Healthcare at DuPont, and Dr. Isabelle Jenny, Sustainability Manager at Amcor Flexibles Europe, Middle East, and Africa.**

READ
Read this story on sustainability trends affecting EOL operations at **hcpgo.to/EOL3**

Demand for Supply Chain Visibility Leads to Labeling Enhancements for EOL Operations

KIM OVERSTREET, DIRECTOR, EMERGING BRANDS COMMUNITY

TOP THREE TAKEAWAYS

1. The need for product visibility in the supply chain continues to increase.
2. This means new demands on end of line operations.
3. Most often the focus is labeling enhancements and vision inspection.

In the end of line (EOL) packaging space, the demand for greater product visibility is driven by a combination of regulations, retailer requests, and manufacturer logistics. These three forces are leading to expanded labeling for end of line packaging configurations, allowing for greater efficiency and accuracy in product tracking through the supply chain. Read on for perspective from **PMMI's** report, *2021 End-of-Line Equipment Purchasing Trends and Design Insights*.

Regulations

In the area of U.S. regulations, the Drug Quality and Security Act (DQSA) and the Food Safety Modernization Act (FSMA) are the primary legislation affecting the pharmaceutical industry and the food and beverage industries, respectively. And the result for both is more visibility of products—particularly bulk bundles and pallets—as they move through the supply chain.

For pharmaceuticals, Title II of the DQSA, the Drug Supply Chain and Security Act (DSCSA), requires the complete serialization of products from the individual product level all the way up to pallets. For food and beverage manufacturers, Section 204 of FSMA requires detailed production and distribution records to be kept in case of a product recall.

Retailer requests

Retailer requests for increased product visibility in the supply chain impact many CPG manufacturers. In order to plan their own inventory management and distribution systems, the largest retailers can dictate new tertiary packaging arrangements and require additional visibility into the movement of products through their own supply chains.

Retailers are driving changes in pallet configurations, coding/marking visibility, pallet labeling, traceability, and the expanded use of direct printing on EOL packaging.

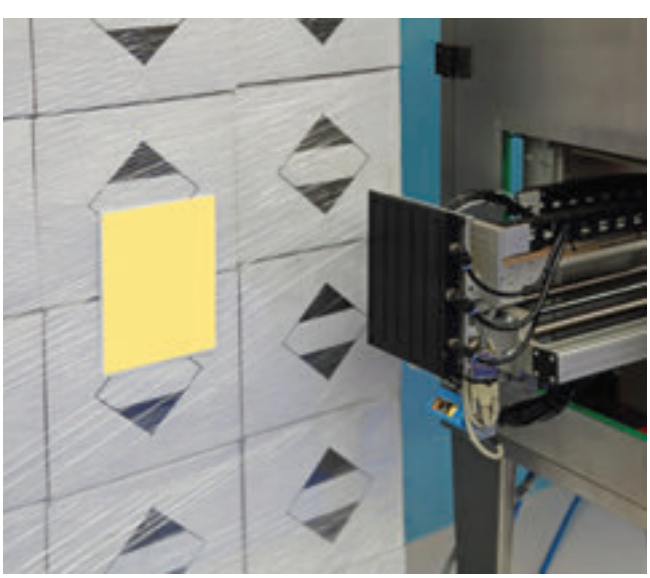
Manufacturer logistics

Supply chain product visibility also enables manufacturers to better track shipments and forecast future production needs, or manage e-commerce and direct-to-consumer solutions—especially when setting up channels for online purchasing. Even manufacturers that outsource portions of e-commerce production and distribution must tightly track product inventories to gauge available supply.

All of these drivers require packaging lines to adjust end of line strategies through more labeling on tertiary packaging, which enables more efficient tracking of bundled products through the supply chain.

EOL operations must also be integrated into a larger ERP system to manage production, track shipments, and predict future distribution needs.

Many manufacturers are using enhanced labeling solutions such as QR codes, NFC labels, and RFID markers on tertiary packag-



ing. These smart labels provide reliable and accurate visibility into production and distribution of products, enabling manufacturers to track shipments in the event of a recall and enabling the accurate management of just-in-time delivery systems.

Enhanced labeling requirements have also created needs for labeling capabilities at the very end of the line, such as label application after the accumulation and final securing of products on a pallet. For manufacturers, this means either new labeling equipment, or the integration of labeling capabilities into existing equipment at the end of the line.

To read labels and log them into a centralized, integrated ERP system, manufacturers are turning to vision inspection equipment to fully integrate their packaging lines. And in some cases, they are combining these capabilities into one machine capable of carrying out multiple tasks, such as an integrated robotic palletizer equipped with vision capability to read and log labels.

Download the FREE PMMI Business Intelligence report *2021 End-of-Line Equipment Purchasing Trends and Design Insights* at **hcpgo.to/EndOfLine21**

Contract Manufacturers and Packagers

The expansion of SKUs, surge in e-commerce, and the growth of CPG industries have all pushed brand manufacturers to rely more on contract manufacturers (CMs) and contract packagers (CPs) to manage expanding production levels. Manufacturers also rely on CMs/CPs to access packaging formats and logistics strategies that they do not have the capacity to handle in-house.

For contract packagers, being able to accommodate a variety of pallet configurations and conform to several different labeling requests is particularly important. 80% of contractors interviewed for the report stated that pallet flexibility is being dictated by their retail accounts, while 60% noted that retail customers were requesting greater coding/marking visibility on EOL packaging.

Good Design Awards Highlight Connected Devices

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Multiple devices won for convenient diabetes care, including insulin pens.
2. Ultrasound and ECG devices offer remote diagnostics convenient for patients.
3. An allergy amulet worn on the neck tests foods in real-time for presence of allergens.

Each year, The Chicago Athenaeum presents its GOOD DESIGN® Awards Program, showcasing cutting-edge industrial, product, and graphic designs produced around the world.

The 2021 awards honored 53 total entrants in the medical category, with products running the gamut from consumer-focused medical devices to diagnostics tools and even mobile COVID-19 units. Here we profile a subset of the winners advancing design in connected devices.

Diabetes care

Sanofi Aventis Deutschland GmbH's AllStar® Connect (1) is a reusable insulin pen injector that connects by Bluetooth to a smartphone, designed by **DCA Design International Ltd**. With frequent adjustments to insulin dosage commonly needed, the pen is intended to help patients manage diabetes by automatically and seamlessly keeping track of insulin usage.

AllStar Connect records the details of each insulin dose delivered and dose records are transferred to the patient's smartphone, where they can be logged and reviewed by the patient and shared with clinicians. Dose details are permanently stored in its memory, so even if the pen is out of range from the smartphone, data will automatically download the next time the pen is used with the phone.

As was reported in the entry, electronic features have been miniaturized so that the size and form factor are just like a regular pen, and "it needs no recharging or battery replacement and is designed to provide a troublefree life of approximately three years for an average patient."

The Sanofi/DCA duo also won an award for the TouStar® reusable insulin pen (2). Intended for delivery of Toujeo®, the pen retains the size and format of the existing AllStar pen, offering familiarity to patients along with new features such as a new dedicated cartridge system developed to simplify cartridge exchange and help to prevent potentially life-threatening insulin mix-ups from occur-

1

ring. With body and cap subtly color-coded to reflect the Toujeo brand, the injection force has been enhanced to deliver extremely precise doses. While AllStar already featured competitive injection force, the efficient new mechanism is beneficial for the comfort of all users, particularly those with low grip strength or limited joint mobility. The pen, which resuled from the desire to offer an affordable insulin pen in developing countries, has been designed for efficient manufacture in India.

The InsulCheck Connect (3), manufactured by **Innovation Zed** and designed by **SHL Medical Design Team, SHL Medical**, is a reusable and compact add-on device to insulin pens. It aids in diabetes management by automatically recording information about the timing of insulin injections.

The system consists of a large screen and mounting mechanism to clip the device to the pen. When properly mounted, an animation indicating successful mounting is displayed on the screen. The device features a patented mode of detection based on an optical sensor that recognizes dose-knob movement at the end of injection. Using Bluetooth technology, data from the device can be shared with connected apps.

Ultrasound technologies

VAVE ULTRASOUND UNTETHERED is a handheld ultrasound device (4) with the ability to wirelessly connect with any smartphone or tablet. Designed in collaboration with San Francisco studio **Box Clever**, the shape and size allow Vave to be balanced in the user's hand and be held in multiple orientations. The battery is an independent element, allowing for it to be swapped out and replaced in a matter of seconds. Materials, including the cast-metal magnesium case, were selected for efficient heat dissipation. A silicone sleeve enhances the grip and control, makes it waterproof, and allows for easy disinfection of the device with hospital-grade cleaning agents.

PulseNmore ES (5) is an ultrasound device for home use, allowing women to remain on bedrest during pregnancy when needed.

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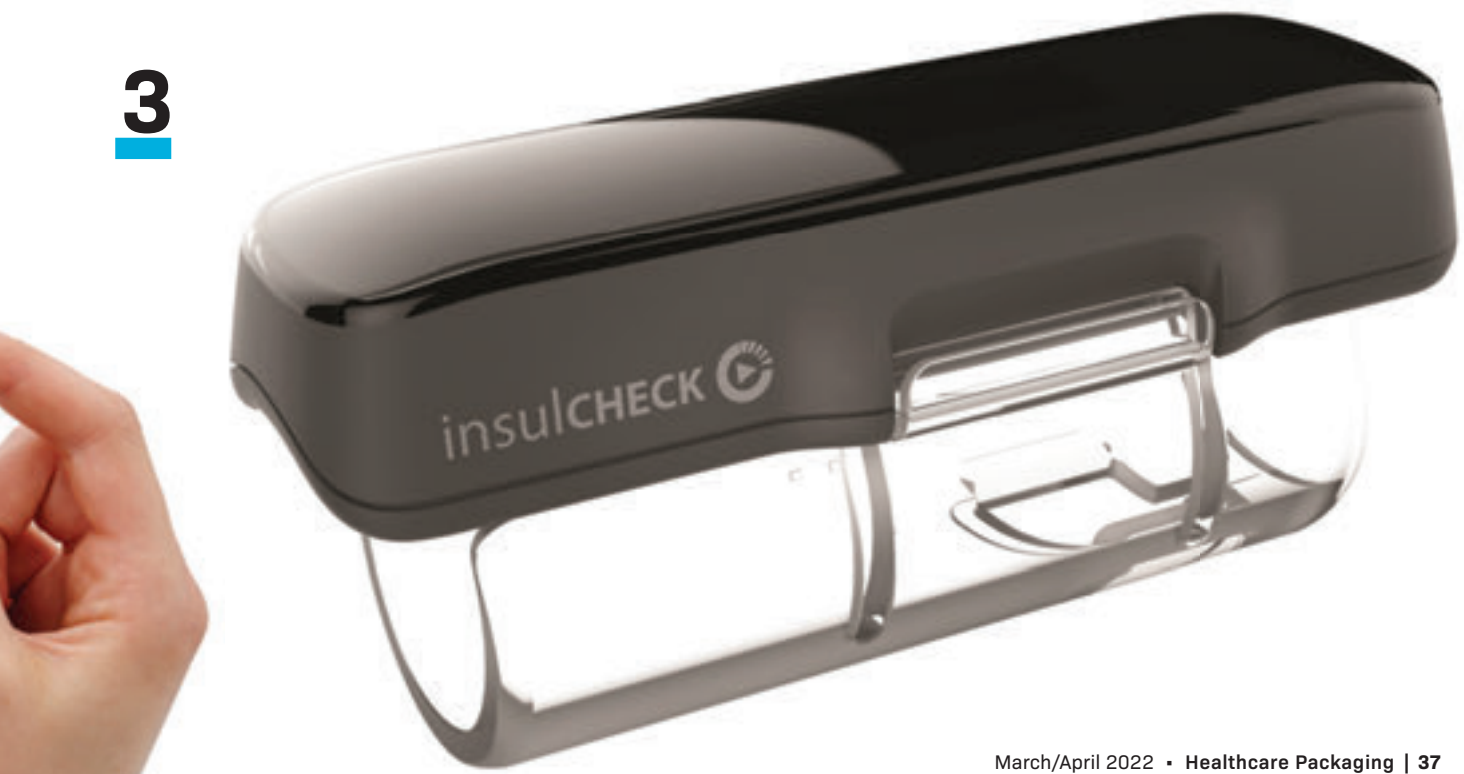

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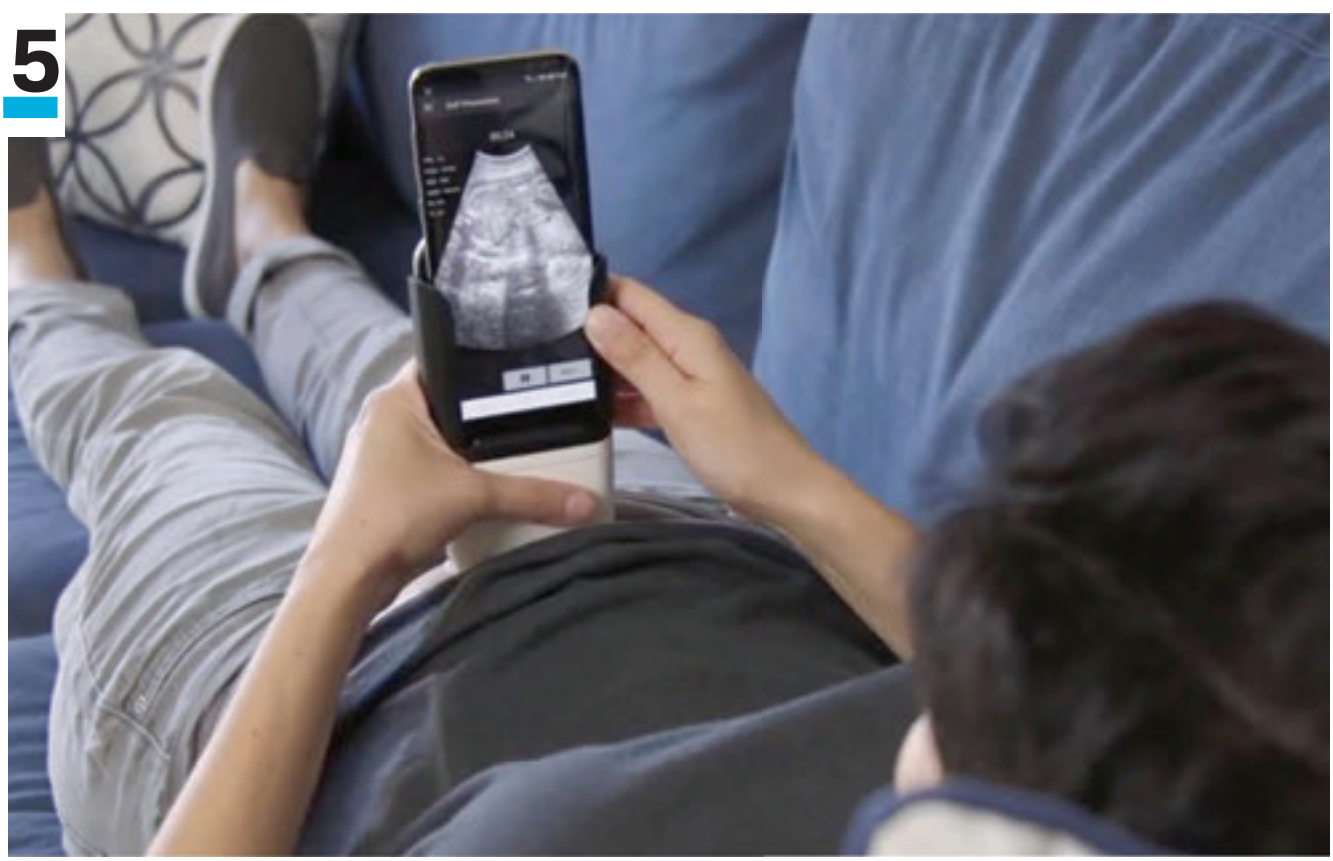

It connects to the user's phone, and an app automatically sends the image directly to the doctor. The disposable device, designed with **Taga Innovations Ltd**, is intended to be provided to the patient by the HMO and features "plug and play" design allowing the user to dock their phone and get started with guidance that accompanies them throughout use.

ECG monitoring

Design Partners won a Good Design Award for their Viscero, a wearable ECG monitoring device (6). The designers note, "A traditional holter is uncomfortable and inhibits natural movement, often making the data it collects unrepresentative of real life, so a wearable that is the same as throwing on a vest under your everyday clothes was designed and engineered."

Its sensor technology is integrated seamlessly into a simple vest resulting in a medical-grade, 6-lead ECG monitoring system that the user can forget about. The system uses dry electrodes that are positioned away from the chest to more peripheral locations, while maintaining consistent compression points. Viscero has compression on the arms and waist that are carefully integrated using lamination and double layer compression areas.

Viscero's "brain" is the size of a matchbox and easily fits into a small pocket. The device can be recharged and can link to a healthcare professional's dashboard that uses AI to segment recordings into pre-arrhythmia and post-arrhythmia. Data can then be triaged for cardiologist review. The patient app is designed to provide peace of mind through interaction and direct connection with their healthcare consultant.

Allergen detection

Allergy Amulet worked with **Loft Design** to deliver this is wearable sensor designed to detect food allergens in real-time (7). "The discreet device consists of three components: the food sampler, the reader, and the app. The user simply drops a small piece of food

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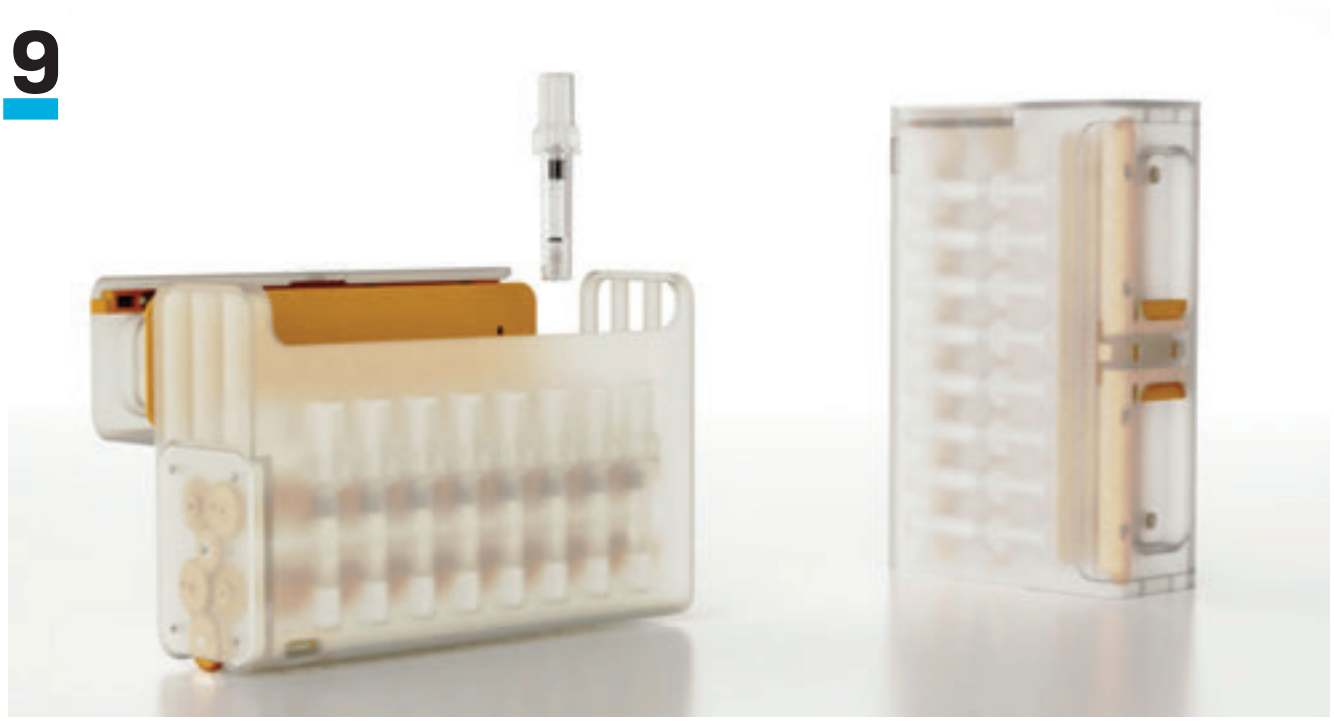

into the sampler chamber and twists the cap closed to activate the testing procedure," explains the company. "In a few moments the food has been mixed and is ready to give a result. The user inserts the reader into a port on the sampler and the results automatically appear on the reader screen."

Users can pair the amulet—which can be worn around the neck outside as a necklace or tucked into the shirt—with a mobile app. Interchangeable sensor strips allow users to test for multiple food allergens.

Smart watch

Empatica EmbracePlus (8) is a health smartwatch with a collection of onboard sensors and algorithms aiming to give users and caregivers the ability to remotely predict and monitor conditions ranging from seizure detection to chronic stress. Designed by personnel at **Whipsaw, Inc.**, the watch automatically measures vital physiological functions and sends them to the cloud. Originally created for epilepsy and seizure detection, the technology can be employed to monitor patients remotely, or enable clinical researchers to collect data in clinical trials.

The low-profile watch can offer a continuous view of how environment, medication, or diet affect a patient. EmbracePlus has a modular wristband with insert-molded physiological sensors and electrical components, allowing Empatica the opportunity to swap out the wristband and tailor the data collected per patient and per condition. Smart alerts and pattern tracking are available to help patients prepare for seizures. Empatica has received the first-of-its kind European CE mark for early detection of COVID-19 for its Aria system.

Syringe dispenser

The **Omnicell** Narcotic Syringe Dispenser (9) is designed to securely dispense prefilled syringes containing narcotics or other controlled substances in a hospital or clinic. The "dispenser box," holds 26 prefilled syringes, and is placed in a cabinet with multiple dispenser boxes. To remove a syringe, a nurse makes a software command in the cabinets' interface, and the syringe is deposited onto a drawer below for retrieval. A mechanical auger configuration is designed to avoid jams while being simple to reload.

The closing date for the 2022 Good Design Award applications is June 1, 2022.

All images for this story are credit: Good Design Awards and The Chicago Athenaeum.

Beyond Connected Devices

Other medical Good Design Award winners include an eye tracking communication system for patients with Locked-In Syndrome, post-mastectomy breast warmers, the FEND nasal mister, rechargeable masks, and more. Check them out at **hcpgo.to/GoodDesign21**

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Label Manufacturer Increases Efficiency and Decreases Labor Hours with Clamshell Packaging

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. A recycle-ready, stackable clamshell container stocks well in hospitals and pharmacies.
2. The container alleviated bottlenecks, reducing the time needed to package labels.
3. The Clamtainer is right-sized for the labels, reducing the amount of packaging materials.

Manufacturers seek to improve efficiency, reduce downtime and bottlenecks, and provide sustainable, reusable packaging to their customers. Oftentimes, the manufacturer finds a machine that increases efficiency or uses a different material and type of packaging that meets company goals.

In 2016, Jeff Hill was appointed Vice President of Manufacturing at **Health Care Logistics** (HCL)—a company specializing in the manufacturing, packaging, and distribution of unique and hard-to-find items for the healthcare industry, including compounding and dispensing products, infection prevention supplies, and unit dosing packaging materials, along with labels for hospitals and pharmacies. HCL labels are applied at its customers' sites to a variety of medical supplies—IVs, syringes, patient charting, pill bottles, and more.

While overseeing manufacturing, Hill realized that the company's print production area was suffering from packaging bottlenecks that slowed down production, required additional manpower to manage, and resulted in increased cost of materials.

Seeing these inefficiencies, Hill decided to reach out to **Jamestown Plastics**—a custom plastic company—that he had worked with on small projects in HCL's cabinets and shelving department. "We were just past due for package improvement for our product line, and I wanted to reduce costs," says Hill.

Stackable, child-resistant containers

The solution proposed by Jamestown Plastics was its Clamtainer™, which is a clamshell designed to open and close easily thanks to the

↑ The clamshell is designed to open and close easily thanks to the company's Click-it Closure technology. After initial use, the container can be repurposed for other applications.

company's Click-it Closure technology. Jamestown Plastics invented the Clamtainer to be restockable at the retail level, reduce labor, increase pack-out efficiencies, and improve downstream satisfaction.

The Clamtainer can also be child-resistant certified, which has opened it up to markets such as pharmaceuticals and aggressive glues. Pharma applications for the Clamtainer thus far include oral medications and topical applications—especially for multiple foil pouches that need child-resistant packaging.

HCL worked with a Jamestown Plastics engineer and settled on a design that would not require HCL customers to replace all their housings. Samples arrived at the facility within three weeks of finalizing the design, and product arrived just over one month later.

Hill says that once the product arrived, he and the operators were very pleased to see their bottleneck issue disappear, reducing the time and labor hours needed to package labels, and making the workers' jobs easier. "[The Clamtainer] hit the floor running, we just changed the assembly line, got rid of a bunch of machines that were no longer needed for packaging. We would put our product into the clam, auto-bag it, and then it was done," explains Hill. "Fast changeover, no training needed."

Hill reports that the Clamtainer has cut packaging time by 35% per single use. He also says, "The print production area has definitely increased every year since 2016."

The biggest benefit to HCL has been decreasing the worker count from six to eight down to two workers to get product out the door. The company's previous system required it to pull workers from their regular jobs to fill large orders, but now all of the employ-

↑ Hill reports that the Clamtainer has cut packaging time by 35% per single use.

↑ The biggest benefit to HCL has been decreasing the worker count from six to eight down to two workers to get product out the door.

ees can remain working on their lines, which has improved workflow. Hill says the operators are also happier with this arrangement.

HCL's customers have also provided positive feedback on the Clamtainer as it is stackable and thus takes up less space, which is often at a premium at hospitals and pharmacies. The transparency of the clamshell containers also allows customers to restock before reaching the last label.

Reduce, reuse, recycle and the clamshell container

Sustainable packaging is high on the industry priority list, and Jamestown Plastics designed the Clamtainer around the Reduce, Reuse, Recycle model. The company reduced the amount of packaging materials that go into clamshells, making its container the size needed for each product. A die-cut Click-it™ card can also be inserted and held in place between the product and lid of the Clamtainer, which especially applies to retail.

As far as reusability goes, Jay Baker, CEO, Jamestown Plastics says, "It's a container that serves the function of packaging the first time it meets the consumer." After that initial use, the Clamtainer is sturdy and versatile enough to serve as a container and organizer for any number of applications, such as office supplies. Baker notes that the Clamtainer should never see the landfill with this flexibility, though if a consumer does decide to dispose of it, the Clamtainer is made 100% of recycled material and can be recycled as PET.

Hill says that HCL places a strong emphasis on providing the best customer service, and it will turn again to Jamestown Plastics the next time a project arises where it needs the custom plastic company's expertise.

READ

Read this story on Desert Harvest's compostable plant-based bags and refillable smart bottles for supplements at **hcpgo.to/desertharvest**

Sharks: From Mortal Foes to Medical Inspiration

MORGAN SMITH, CONTRIBUTING EDITOR

WATCH

Watch this video on a beetle-inspired retrofit poised to save water in the manufacturing plant at **hcpgo.to/beetle**

TOP THREE TAKEAWAYS

1. Shark skin features useful qualities that materials can mimic to prevent/reduce infections.
2. Dermal denticles keep bacteria from attaching and growing on the shark's skin.
3. Shark-inspired tech has applications in foley catheters, wound dressing, and more.

When Peter Benchley released the book "Jaws" in 1974, he made sharks Public Enemy #1. Millions of people stayed out of the oceans—or at the water's edge. But, as it turns out, this much-feared fish had gotten a bad rap. They weren't out hunting people for lunch after all. And now, it seems sharks—or at least a part of their anatomy—can be a valuable example to the medical world. Why?

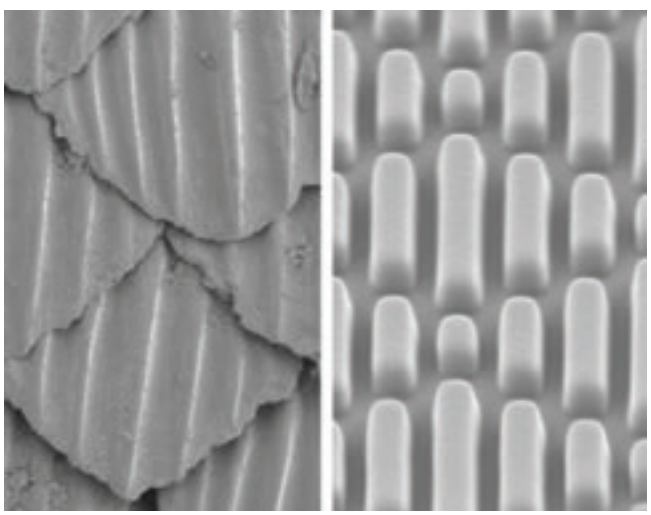
As the Biomimicry Institute has stated in the past, shark skin has some amazing qualities. While many other water species—and even ships—accumulate biofouling as they move through the water, sharks don't. In fact, even bacteria can't adhere to their skin. This resistance comes not so much from the chemical makeup of their skin as its pattern.

While shark skin may appear relatively smooth to the naked eye, it is actually made up of thousands of backward diamond-shaped pointing grooves and ridges. These dermal denticles keep bacteria from attaching and growing on the shark's skin.

Sharks in the medical toolkit

It's this ability of shark skin resisting bacterial growth that inspired Dr. Anthony Brennan, Founder of **Sharklet Technologies** and honorary chair of the company's scientific advisory board, to create Sharklet, reportedly the first surface technology to inhibit the growth of bacteria through pattern alone.

Influenced by the shape and pattern of the dermal denticles of shark skin, the Sharklet surface is comprised of millions of microscopic features arranged in a distinct diamond pattern. The structure of the pattern inhibits bacteria from attaching to it, colonizing, and forming biofilms.



↑ At left, an image of a shark skin denticle. At right, the Sharklet micropattern featuring the similar diamond pattern and ordered feature lengths. (Image credit: Sharklet Technologies)

The effectiveness of Sharklet was proven in a study on preventing/reducing catheter-associated urinary tract infections. In the study, three variations of Sharklet micropatterned silicone rods and a smooth silicone rod were placed between two agar islands to measure E. coli migration. The results?

In tryptic soy broth and artificial urine, Sharklet micropattern surfaces, on average, achieved a 47% reduction in colonization-forming units and bacterial area coverage, plus a 77% reduction in colony size, compared to the nonpatterned surfaces. E. coli migration over the segments was reduced by more than 80% on the Sharklet transverse patterned rod, compared to the unpatterned control rods.

The company now produces the Sharklet Foley catheter incorporating its proven technology.

Shark skin helping human skin

Sharklet also uses its technology's demonstrated effectiveness in its Sharkskin wound dressing, which promotes healing without autologous skin grafting.

Utilizing a new micropattern designed to promote cellular migration, the Sharkskin wound dressing's apical layer accelerates re-epithelialization by as much as 64%, while the base layer uses small pores to promote the formation of new blood vessels and dermal tissue. Consequently, the dermal layer of the skin heals at the same time as the epithelial layer.

As a plus, using additive printing, every Sharkskin full-thickness wound dressing can be rapidly produced and customized to the unique needs of each patient—at the point-of-care.

So, the next time you're at the aquarium staring into the dark eyes of a shark, be not afraid. This creature may be a great marine ally for human health.

Healthcare-Associated Infections

In the *2020 National and State Healthcare-Associated Infections Progress Report*, the CDC reports, "Each day, approximately one in 31 U.S. patients contracts at least one infection in association with [their] hospital care, underscoring the need for improvements in patient care practices in U.S. healthcare facilities. While much progress has been made, more needs to be done to prevent healthcare-associated infections in a variety of settings."

Pitfalls to Avoid in FDA Aseptic Manufacturing Inspections

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. An FDA policy advisor provides an outline of what facilities can improve on.
2. Despite guidance, FDA continues to find observations surrounding aseptic technique.
3. FDA is increasing its focus on line design review, emphasizing smoke studies.

The pharmaceutical industry depends greatly on cleanroom standards to ensure the health and safety of patients, especially during aseptic processes for the production of drugs purporting to be sterile. At the 2021 PDA/FDA Joint Regulatory Conference, Brooke K. Higgins, MS, Senior Policy Advisor, CDER, FDA, presented on recurring deficiencies and safety failures found during FDA aseptic manufacturing inspections, both in the U.S. and globally, along with possible solutions.

As aseptic processing is one of the highest risk pharmaceutical operations, there are severe consequences for lack of control. FDA's aseptic guidance, the European Annex, and a number of other valuable resources list principles to avoid contamination events, yet FDA continues to note inspectional trends surrounding aseptic technique and behaviors; facility, room, and process design; and the use of media fills.

"We know it takes a myriad of meticulous steps to ensure the quality of sterile drug products," said Higgins. "This includes fastidious control over the sterile drug, container closures, and components, and careful and attentive interactions in the processing and surrounding areas."

Higgins emphasized that in control strategy, FDA rule requires manufacturers to run all processes by them to ensure proper protection from microbiological contamination of drug products purporting to be sterile. FDA also insists a current Good Manufacturing Practices (cGMP)-compliant firm must continually assess its systems and take action in a timely manner to ensure that it remains in a state of control—this includes the facility, equipment, and the process. FDA expects companies to assess the effectiveness of controls and measures in place to minimize the risk of contamination.

Causes of contamination

Main causes of contamination in the U.S. and internationally listed in the presentation were:

The personnel—Higgins said, "The major variable in the control of aseptic processing arises not from the sterilization processes,

the cleanroom, or the filtration processes that are so often the subject of technical papers on regulatory guidelines, but rather from the workforce itself." She noted that humans shed almost one billion particles a day, which may land on the aseptic processing line and even inside the sterile drug.

Incorrect actions commonly noted by FDA inspectors are:

- operators placing head and upper torso into filling cabinet over open vials without clearing them;
- operators inadvertently contacting the interior of doors used to access ISO 5 aseptic processing areas;
- failure to disinfect materials before introducing them into the ISO 5 aseptic processing area; and
- sterile drug product leaks on the floor. Filling continues as operators attempt to clean spilled product by placing wipes and other materials over the area with their feet. Aseptic connections are made directly above spilled product.

↑ Brooke K. Higgins, MS, Senior Policy Advisor, CDER, FDA.

Higgins asserted that personnel must be trained and frequently reminded of proper cleanroom procedures and behaviors. Further, a substantial part of environmental control includes management performing extensive observation of operator activities in the aseptic processing cleanroom and the surrounding areas to ensure that situations as noted above do not continue to occur.

Facility, room, and process design—Older facilities can often include "processing lines and facility layouts that are less effective at mitigating various operational variables that pose a risk to sterility," as Higgins put it. "If equipment is not well designed, or is poorly maintained, repeated or extensive manual interventions often occur due to mechanical problems. When production line operators perform manual activities near an insufficiently protected product, they raise the risk of microbial contamination."

↑ Humans shed almost one billion particles a day, which may land on the aseptic processing line and even inside the sterile drug.

Higgins explained that FDA has seen older facilities try to use a curtain or rigid plastic enclosures to separate the critical processing areas from the rest of the facility, but this is done oftentimes without proper risk evaluation. These platforms typically involve extensive manual interactions with the aseptic processing line and its exposed sterile drug product, containers, and closures. Such antiquated techniques often prove inefficient, with unstable lines, and they require frequent starts and stops to correct major problems and to make adjustments. This generates excessive opportunities for interaction between personnel and sterile material.

"I'd like to highlight that these lines that are considered traditional or conventional are not the modern choice. Given the technology available, these kinds of antiquated lines should not be the go-to for new facilities. These lines are at a heightened risk for quality and safety failures. It doesn't make science or business sense to use these lines," said Higgins.

Further design issues noted during inspections include:

- aseptic filling equipment design, room space, protection of the area and filling equipment where connections are made, and the number of personnel present during filling operations are deficient;
- stopper hopper leans diagonally across the filling line during stopper loading thereby blocking first air; and
- interventions require a large door to be opened. When opened, the door is exposed to the ISO 7 area, and when being closed, there is a significant risk of the lower quality room air sweeping into the ISO 5 filling cabinet. Empty, open sterile vials are located extremely close to the door.

Smoke studies—FDA is increasing emphasis on line design review during inspections as well as case review. One means of review that is being continuously emphasized is the smoke study, which verifies the sterility of a line effectively by illuminating design weaknesses that pose contamination hazards when performed properly.

"We observed through smoke studies that when some doors open, the airflow changes profoundly. It causes excessive turbulence within the ISO 5 enclosure," Higgins explained. "Whether it's an isolator or an open system, you must take time to understand the risks associated with your processing. Assess what can go wrong

within each area, watch operations, compare what's being done to what your procedure is saying, compare what you see to what is being simulated in your smoke studies, evaluate the ergonomics of the line in the processing areas, and how operators interact with the line itself. These areas and others can help identify your gaps."

Issues surrounding smoke studies that are commonly found in FDA inspections include:

- Smoke studies not being dynamic
- Smoke studies lacking simulation of multiple critical interventions
- Non-unidirectional airflow being seen in smoke studies
- Inadequate visualization of airflow due to either lack of smoke or the view of the aseptic processing zone being obstructed

"Studies must include dynamic operations and sufficient smoke to visualize airflow as interventions are simulated," she said. "Non-unidirectional airflow must be identified and addressed. Some of the better studies that I've seen have captured the activities and airflow from various angles. This truly helps prevent obstructive views."

Media fills—FDA inspections are continuing to find issues with media fills and needing to perform investigations into media fill failures. The inspections often find that process simulations do not always represent actual aseptic manufacturing operations. To ensure appropriate simulations, Higgins explained that a company could incorporate a retrospective review of inherent critical interventions performed during production and a risk assessment of new interventions that have been performed from previous media fill studies. She further noted that FDA inspections document poor investigations and a lack of understanding of the media fill failures which do not identify root causes or CAPAs.

"Continuous observation of operations and well-documented batch records are critical to developing a robust media fill program," said Higgins.

Common FDA inspection observations are:

- Interventions not being appropriately simulated
- Additional cleaning performed prior to media fills
- Rejection of integral vials without sufficient justification
- Not all operators included in media fills
- Poor investigations into failing media fills which lack scientifically supported conclusions and CAPAs, and which fail to address all potentially compromised lots

The future of aseptic processing

Along with solutions to these issues such as employee training and improving the quality of smoke studies, Higgins highlighted technologies that can better protect product from contamination during aseptic processing. These technologies either improve the separation between personnel and sterile product or eliminate it altogether.

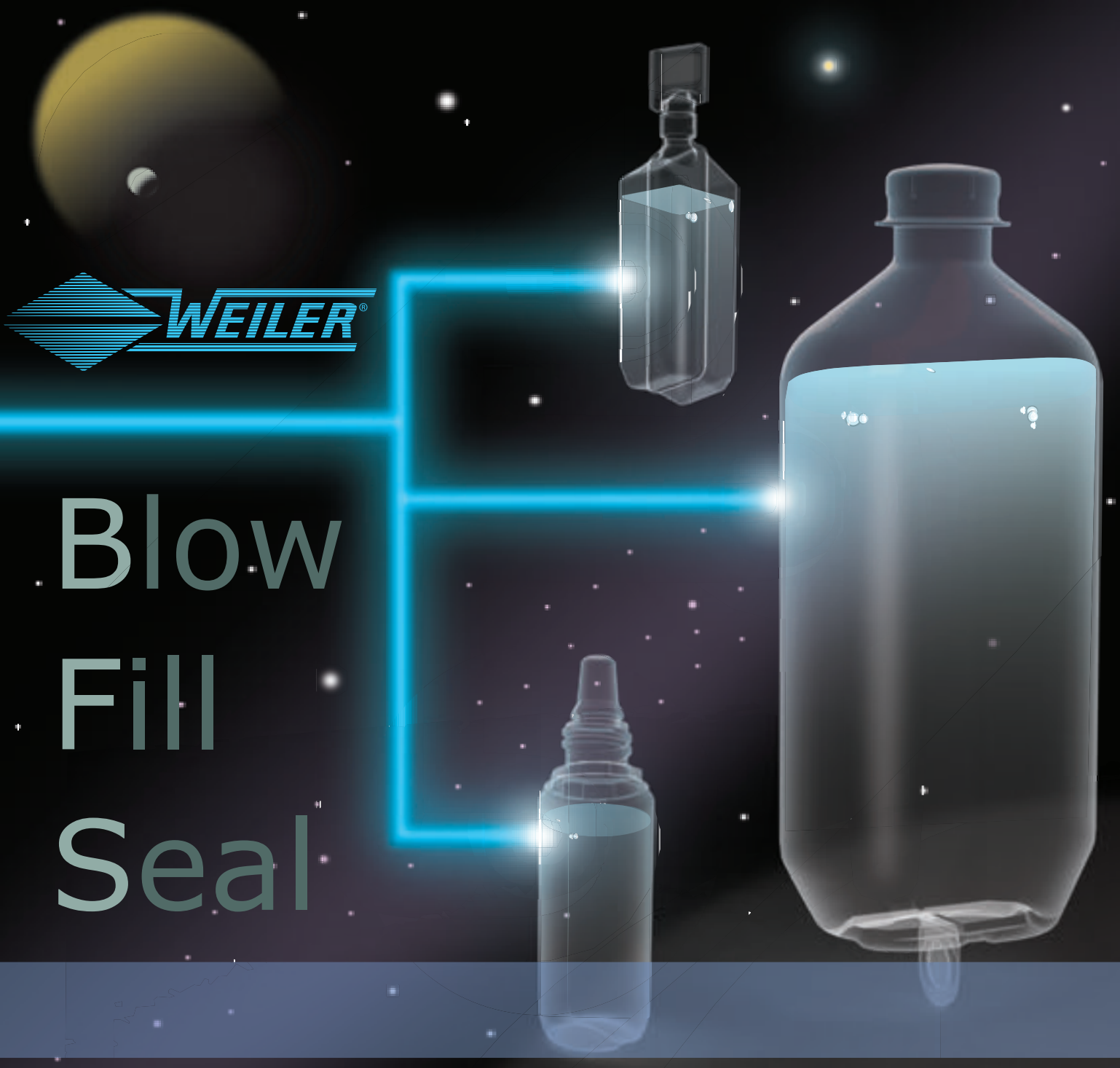
The first solution Higgins noted was gloveless robotic isolators. Isolators already greatly reduce major hazards from personnel activity but gloveless robotic isolators provide the next step which, according to Higgins, profoundly reduces contamination risks. Robotics perform all operation within the system without glove ports that would allow personnel to intervene.

The second solution listed is advanced environmental monitoring technology. In lieu of, or along with, traditional monitoring, this can include technologies such as biofluorescent particle counting systems. As operators do not need to handle the monitoring equipment for such systems or perform certain other tasks, like switching out plates, fewer manual manipulations are needed within the ISO 5 area.

"These systems provide continuous, real-time monitoring and feedback as soon as a potential microbe is collected from the ISO 5 area. However, firms must still ensure these systems are appropriately qualified and that particle limits are still appropriately established. While using this advanced technology, ISO 5 isolate identification still remains essential," said Higgins.

She further highlighted that the amount of investment a company makes into newer technologies, such as automation and isolators, shows how dedicated the company is to sterility and having a strong quality culture. This culture extends beyond the philosophy to the manufacturing infrastructure; investment in properly designed processes, facilities, and equipment; and capable personnel.

↑ FDA representation on assuring sterility of drug products.



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3 Fume Extractors for Laser Applications

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+ They remove smoke and particulate debris generated during the product marking process to help provide a safe, odor-free environment, while keeping the production area clean.

4 Automated Storage and Retrieval System (ASRS)

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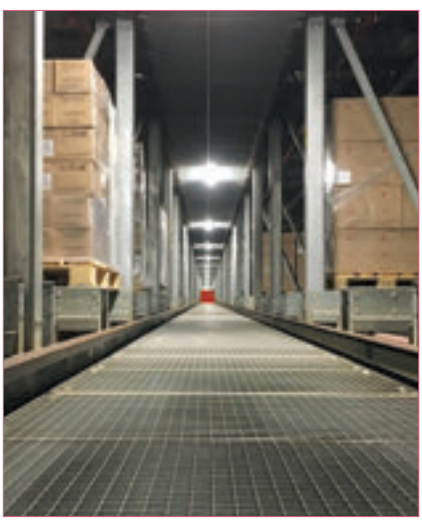
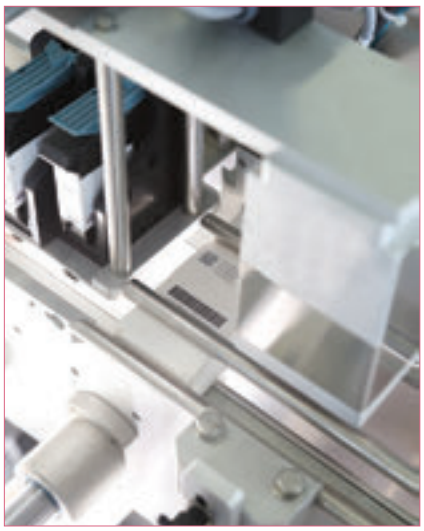
+ Delivering an intelligent logistics management system integrating with order management, warehouse management, and order fulfillment systems, the StorFast ASRS consists of powered carts and lifts that automatically move pallets in and out of storage positions in the warehouse.
+ The customizable system is desgined to enhance throughput to meet demands, optimize operational resources, and improve inventory management.



5 X-ray Inspection System

METTLER-TOLEDO

+ Designed to detect contaminants in small, individual packaged products, the compact X34C X-ray inspection system can operate at speeds up 120 meters/min, with the power and contrast levels automatically optimized for each application.
+ The optimized focal distance of the 0.4-mm diode detector and 100W power generator maximize the probability of detecting small contaminants and helps reduce false reject rates.



6 Global Tracking System Software

ANTARES VISION GROUP

+ Capable of operating both on-premises and through the cloud, the global tracking system manages product recipes, associates printing layouts, and assimilates camera formats based on specific products.
+ Once production has commenced, the system receives data from all lines, as well as statistics, serialized codes, and audit trails, and the information is stored in the site database, where it is accessible via the GTS User Interface.

7 Touchless Temperature Monitoring System

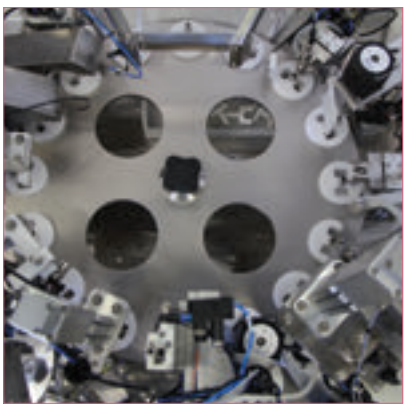
SENSITECH

+ The TempTale® Ultra BLE wireless digital temperature monitoring system can read data without opening cargo packages, providing delivery drivers and receivers with proof of condition at destination.
+ Ideal for smaller packages, the data logger offers an intuitive mobile app for touchless monitor control, clear evidence of alarms, and seamless synchronization to the system of record, speeding product release for receivers and quality managers.

8 Metal Detection System

NJM

+ Integrated with an NJM raised-bed conveyor with a 3rd-party metal detector head, the CMD metal detection system for pharmaceutical and nutraceutical bottles features optional reject and reject verification systems.
+ It eliminates the need for bottle transfers, and has a tablet entrapment-free design to help manufacturers and contract packagers ensure product safety and avoid costly product recalls.



9 Liquid Nasal Applicator Assembly and Filling

TURBOFIL PACKAGING MACHINES

+ The assembly and vial filling machine for unidose liquid nasal devices is available in automatic (up to 80 to 100 pieces/min) or semi-automatic (up to 30 pieces/min) setups.
+ The machine has an accuracy tolerance of +/-0.5% on a fill volume of 100 to 125 ml. Stopper position can be determined down to 0.3 mm.

10 Full Vial Inspection

HEUFT USA INC.

+ Now with Head Space Analysis (HSA), the fully equipped Heuft spotter PHS carries out the optical and radiometric complete inspection of up to 800 full vials/min.
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