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+ Colgate's Innovation in E-Commerce, Recyclability, and More
+ 3 Flexible Packaging Awards in Healthcare
+ Tips on Remote Auditing Contract Organizations
+ Fewer Ampoule Rejects with Automated Inspection

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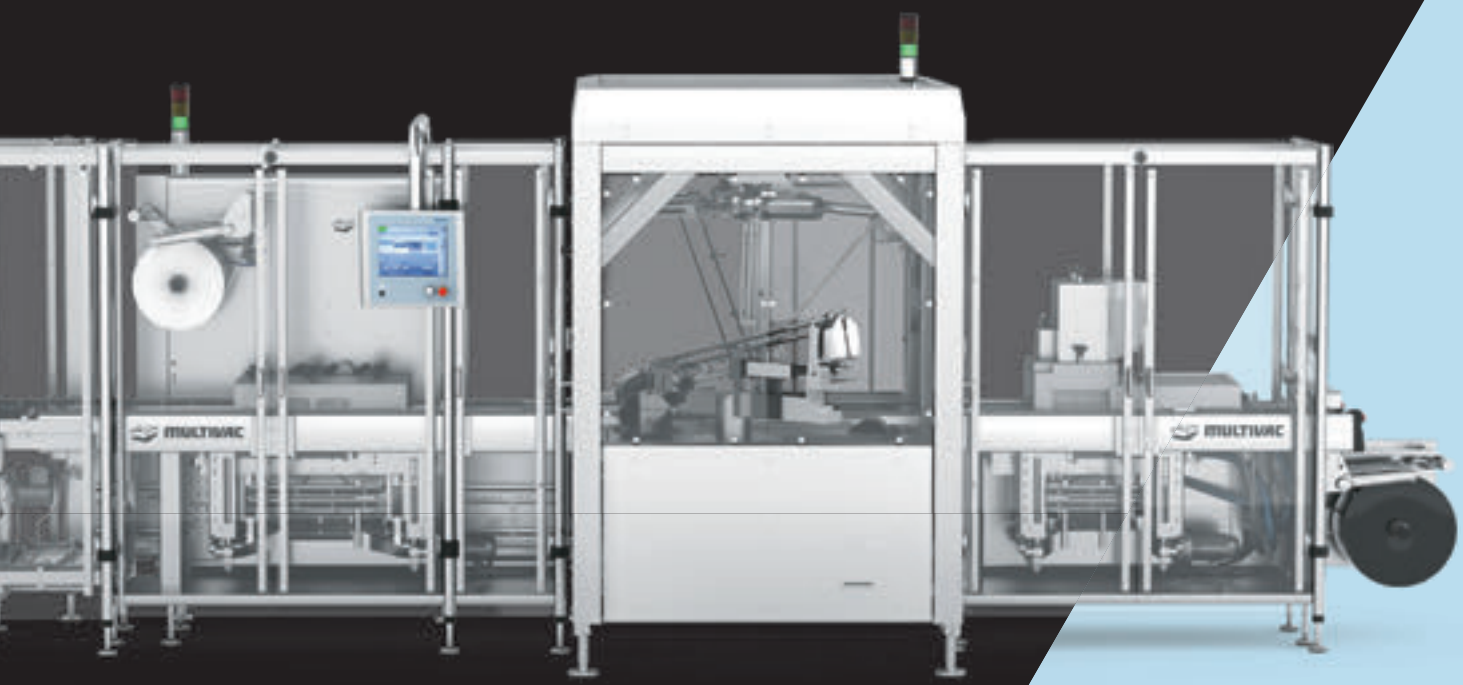

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↑ pp.20

Colgate's Innovation in E-Commerce, Recyclability, and More

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Inventory Management in the Hot Seat

RFID labels are changing the way hospitals track and dispense drugs—will the benefits cause a demand surge for connected packaging?

The pandemic has highlighted or magnified all sorts of pros and cons about the healthcare supply chain. One thing has become abundantly clear—it's more important than ever to know your supply levels, locations, and how fast you can move these products.

This means different things to different people. As a life science manufacturer, your concerns may be upstream, with longer lead times for certain packaging components and raw materials. For hospitals and health systems, tracking medications from the pharmacy to the crash cart is critical to patient safety and preventing waste in the form of expired drugs.

On pp. 16, we cover a new offering in the connected packaging space—RFID-embedded vial labels that manufacturers can implement without artwork changes. A manager of pharmacy operations explains why demand for RFID-labeled vials at health systems is increasing, and how RFID may change the world of inventory management and dispensing.

From drugs to components, avoiding shortages is key. As Colgate discovered in the pandemic, they couldn't procure as many soap pumps as they needed, so they quickly qualified a different closure to keep production going. On pp. 20, they also talk about several exciting new packaging innovations, offering details from e-commerce to recyclability.

If you're looking for even more packaging releases, check out the Flexible Packaging Association's award winners on pp. 26.

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TIM HAYES,
CONTRIBUTING EDITOR

1 'Bacteria Cocktail' Could Add Sustainability to Plastic Packaging

Pharmaceutical packaging is adding to the amount of plastic in the oceans. Luckily, a recent *Yahoo! News* article reported on a new development that could add some sustainability to single-use plastics. A team of scientists in Hungary created a "bacteria cocktail" that consumes plastic in just seven weeks without any additional processing or chemical treatments. Though the ingredients are top secret, Poliloop CEO Liz Madaras says if it can be mass produced, it can significantly reduce global plastic waste. The article contains an interview with Madaras, and a video can be seen at poliloop.com.

2 Don't Like Endoscopies? Swallow a Camera Instead!

The Guardian reported on new medical device, PillCam, that allows patients to easily check for bowel cancer at home by swallowing a pill loaded with a miniature camera. It captures images at 2-6 frames/second. Patients visit a nurse who fits their waist with a belt and receiver that takes pictures. They then go home and clear their bowels with the help of a laxative so that the cameras can get clear images. The entire process takes 5-8 hours, and the photos are sent wirelessly from the capsule to a cancer specialist for analysis.

3 What Will Roche Do with an Unsellable Irish Plant?

A *FiercePharma* article discussed a conundrum Roche faces with one of their non-operating plants. In 2015, the company decided to close four small-molecule plants. The company sold three, but couldn't find a buyer for the one in Clarecastle, Ireland. So they decided to demolish the site. The project will demand more than 90,000 metric tons of backfill to patch 40,000 metric tons of waste now on the land. The process is expected to commence in June of 2021 and wrap near the end of 2024, followed by over three years of evaluation.

4 Democrats Look to Legalize Marijuana This Year

According to a recent *Marijuana Moment* article, marijuana reform is becoming a priority in the new Democratic Senate. Senate leaders intend to release draft legislation to begin the process of policy change on a federal level. Senate Majority Leader Chuck Schumer, Senate Finance Committee Chairman Ron Wyden, and Senator Cory Booker released a joint statement saying that ending cannabis prohibition "is necessary to right the wrongs of this failed war and end decades of harm inflicted on communities of color across the country." On top of that, the Senators will make moves to absolve citizens who were unfairly targeted in the War on Drugs.

5 Pulse Oximeters Have a Fatal Flaw for Some Patients

Pulse oximeters are vital in the fight against COVID-19. However, a recent *CNN Health* article says the FDA is warning that the devices may yield inaccurate results for different skin pigmentations.

The *New England Journal of Medicine* found that in White patients, pulse oximeters produced misleading numbers 3.6% of the time, while the number jumped to 11.7% in Black patients. Pulse oximeters work by sending red light through the finger and reading it on the other side to detect the color of blood to determine the oxygenation levels. Bright red is highly oxygenated, and blue or purplish blood is less oxygenated. But if the device isn't calibrated for darker skin, the pigmentation will affect how light is absorbed.

6 Are Freeze-Dried Vaccines the Future?

A recent *VICE* article discussed an innovative way of preserving vaccines that could simplify the cold chain process significantly by freeze-drying the essential components of a vaccine so that they can be rehydrated with a drop of water and administered in just one hour.

The process is called iVax, and according to the co-author of the study and professor of chemical and biological engineering at Northwestern, it's not too different from freeze-drying fruit. The cellular extracts will remain stable for months without temperature control. They can then be purified and administered for about $1 a dose when needed.

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

Mar 10, 2021

THE INAUGURAL STERILE PACKAGING DAY, from the Sterilization Packaging Manufacturers Council (SPMC), celebrated all who work to deliver medical devices in a sterilized and safe manner to healthcare professionals and ultimately patients.

7

THE NUMBER of common downtime causes in packaging machinery. The top three: general wear and tear (26.3%), product changeover (22.1%), operator error (21.1%).

Source: PMMI's Packaging and Predictive Maintenance

$4.5 BILLION

THE AMOUNT the pharma industry is projected to spend on digital transformation by 2030, as manufacturers look to track, optimize their operations, and boost productivity.

Source: ABI Research

60

PFIZER'S AVERAGE CYCLE TIME is approaching 60 days from start to vial-ready, down from 110 days originally. The company has the potential to produce up to 2 billion doses globally by the end of 2021.

Source: John Kelly, Pfizer Global Supply

"There are, in my knowledge base, six or seven of these [UV] masks at different stages of research and development... **Some are being done extremely well in terms of technology and understanding and R&D**, and others are kind of being rushed out there. And are rubbish."

-DR. JAMES MALLEY, UNH PROFESSOR AND INTERNATIONAL ULTRAVIOLET ASSOCIATION EXPERT (SOURCE: MASHABLE)

"With the White House's renewed focus on manufacturing policy, this bipartisan supply chain legislation comes at the appropriate time to continue the conversation and **establish an Office of Supply Chain Preparedness** to ensure our country is ready to respond appropriately to future scenarios and codify a lasting regulatory framework."

—JOHN WILCZYNSKI, EXECUTIVE DIRECTOR AT AMERICA MAKES, ON SENATE BILL 869

"The investigation conducted by BioNTech found that there were **problems in the crimping process** at the German site that provided batch 210102 and 210104."

-KATHLEEN MAGRAMO AND ELIZABETH CHEUNG, SCMP, ON COVID-19 VACCINES IN HONG KONG

The Global Outlook for the Pharma Contract Packaging Market

The global pharmaceutical contract packaging market size—valued at $28.2 billion in 2019—is expected to grow at a CAGR of 7.1% from 2020 to 2027, to reach $47.7 billion according to a report from Grand View Research, Inc. Drivers include the desire of pharma companies to reduce their overall cost of production and to increase speed to market; the lack of in-house packaging capabilities and expertise along with budget constraints by smaller pharma companies; the need for pharma companies to meet serialization regulations; and the overall growth and increasing competitiveness of the global pharmaceutical industry. Primary packaging accounted for the largest share of revenue in 2019, at 40.2%.

—Anne Marie Mohan

Police Crack Down on Fake COVID-19 Vaccines

According to a recent *BBC* article, international police are working to break up counterfeit COVID-19 vaccine manufacturers. The discovery of 3,000 fake doses led to the arrest of 80 people at a factory in China, and 2,400 ampoules were seized in South Africa along with fake 3M masks. The Chinese ministry of public security announced a targeted campaign to combat vaccine-related crimes. In February, police uncovered a multi-million dollar scam where a man had recreated real vaccine packaging and made 58,000 fake doses filled with saline solution and mineral water. Six people were arrested in Mexico for trafficking fake vaccines and selling them for the equivalent of $2,000 a dose.

—Tim Hayes

COVID-19 Test Kit Cartoning Line Met Urgent Testing Needs

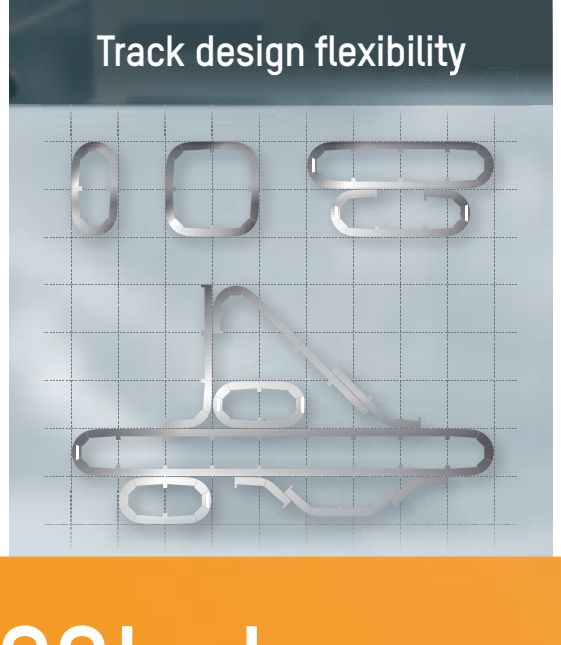
A major manufacturer of fast-response COVID-19 test kits enlisted **ESS Technologies** to design and build a cartoning line to automate the packaging of pouched test kits. By integrating a variety of **FANUC** robots with ESS-engineered automation, ESS designed and delivered three Model VC30 cartoning systems in a fraction of the normal delivery time. The equipment increased production efficiency and OEE. Automating the process also allowed the manufacturer to re-assign valuable human resources to other important functions. Two systems picked pouches and spaced them into lanes at 150 pouches/min. The third VC30 packaged loaded cartons from the first two lines into a larger auto-bottom carton to complete the final test kit shipper.

—Keren Sookne

Also in the News

- RPA's Excellence in Reusable Packaging Award is open through June 1.
- The **Antares Vision Group** expanded its software capabilities through the acquisition of **Rfxcel Corporation**.
- **PTI** announced the acquisition of **Leak Detection Associates** (LDA).
- Sovereign Pharmaceuticals became the first manufacturer to earn all GS1 EPCIS Trustmarks for the FDA DSCSA Interoperability Mandate.
- The Alliance to Modernize Prescribing Information (AMPI), an effort to reduce prescribing label waste, added Bristol Meyers Squibb and Fresenius Kabi.
- **Stevanato Group** leads the first industry discussion paper on primary container traceability published by ISPE.
- PDA's most prestigious award, Honorary Membership, was given to Martin VanTrieste, CEO of Civica Rx. He was recently named a "Champion of Change" on The Medicine Maker's Power List.
- **Tive**, provider of in-transit supply chain visibility, acquired **MyTrackingDevices**, a UK-based shipment and asset tracking company.

—Keren Sookne



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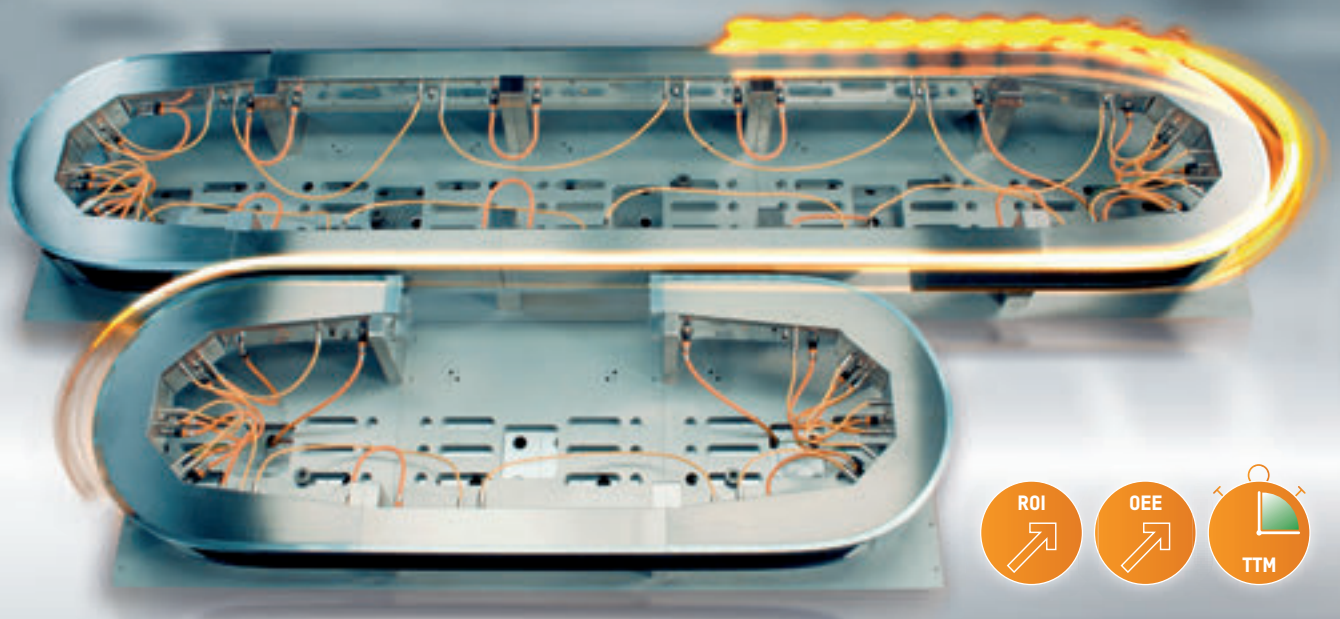

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Vaccine Freezers Powered Partially by Solar, Wind Power

For ultra-low temperature (ULT) storage and transportation, a new entry in the cold chain market can power freezers off the grid. In related news, ULT freezers were purchased for Puerto Rico and U.S. Embassy vaccines efforts.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

A new company in the temperature-controlled sector has a unique offering that powers ultra-low temperature (ULT) freezers partially with solar and wind power.

With temperature control critical to the global vaccination effort, Kansas City-based **Vaccine Pods** was launched by a former firefighter to provide pharmaceutical companies, government organizations, and NGOs with systems to support cold chain logistics efforts.

The power source

The company's technology, developed in partnership with HCI Energy, is designed to boost capacity and power for ULT storage and transportation, allowing the user to ship a container with the vaccine in a freezer powered by the container's integrated power source.

The pod, which measures approximately 20 ft long, is powered by batteries that can be recharged with solar power. Wind turbines and a generator serve as back-up power sources.

The power system leverages sustainable energy to minimize reliance on the electrical grid or fossil fuels, per the company, with the goal of enabling uninterrupted cold chain management and delivery of vaccines and future biologics anywhere in the world. This technology has been designed for use with **Stirling Ultracold's** SU780XLE vaccine freezers.

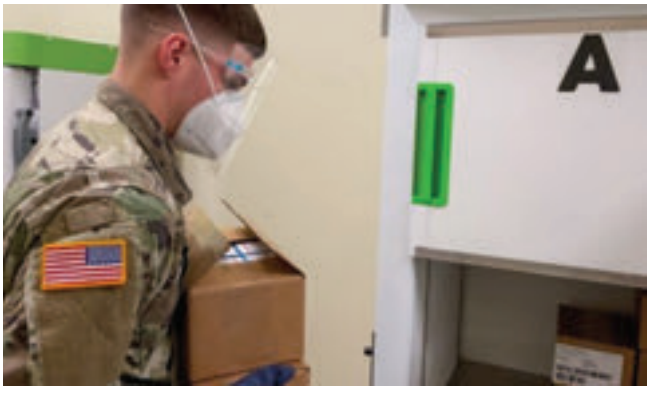
Tracking and monitoring conditions are key in ensuring safe vaccines. The power system offers real-time data visibility including:

- Temperatures of freezers located anywhere in the world
- 24-hour monitoring of location
- Security and remote access permissions
- Solar array and deployment status with real-time weather tracking to deploy or retract the solar panels in the case of inclement weather
- Power system performance and status
- Fuel levels

One focus area for Vaccine Pods is to help power freezers in rural areas and developing countries that may lack access to modern cold chain storage and rely on corrugated boxes and dry ice.

The World Health Organization reports that roughly 50% of all vaccines must be discarded worldwide each year due to improper handling and failed temperature control.

"With recent COVID-19 vaccine approvals, the life sciences industry, in conjunction with government agencies and supply chain partners, is aiming to deliver 300 million doses in the U.S. alone in early 2021. Depending on the manufacturer, these vaccines must



↑ National Guard with a Stirling Ultracold Freezer. For story, see sidebar. (Credit: Business Wire)

↑ A Stirling Ultracold freezer sits inside of a Vaccine Pod. (Credit: Vaccine Pods)

be kept at temperatures between -20°C to -86°C at all times. This has created a new and significant challenge that existing ULT cold chain storage technology is not currently equipped to support," said Edward Collins, CEO and Founder of Vaccine Pods. "To help solve this public health crisis, we have engineered a cost-effective, energy-efficient technology that increases ULT cold chain storage capacity and power while working completely off the grid, enabling organizations to safely distribute more vaccines at reduced expense. Because of its cost savings and continual energy supply, this technology will not only help densely-populated localities, but also rural areas and developing countries that traditionally have not enjoyed the same access to these resources."

"Vaccine Pods' charging station technology is a gamechanger," explained Dusty Tenney, CEO at Stirling Ultracold, as it allows companies to "ramp up capacity and accommodate growing energy requirements of our ULT freezers, guaranteeing that we can maintain vaccines at constant ultra-low temperatures until point of use. This is a major step forward that will help supply chains meet the urgent need for COVID vaccines."

↑ **The pod features retractable solar panels and a wind turbine. (Credit: Vaccine Pods)**

Supplying Puerto Rico and U.S. Embassy Locations

In related news, Stirling Ultracold will be the exclusive ULT freezer provider for the island of Puerto Rico, as well as all U.S. embassy locations around the world:

- The Puerto Rico National Guard has partnered with Select Gases of Atlanta and Bionuclear of Puerto Rico to purchase and distribute four of the company's SU780XLE upright freezers, 20 SU105UE undercounter freezers and 20 ULT25NEU portable freezers to support vaccination on the island of Puerto Rico.
- The State Department has purchased and received a shipment of 210 portable freezers to thermally protect and move vaccines to all U.S. embassy locations in order to safely vaccinate government employees and officials around the world.

Traditional methods for ULT storage, like dry ice and liquid nitrogen, are both currently in short supply and require specialty personal protective equipment (PPE) and training for proper handling.

The company's portable ULT unit can be plugged into universal power sources, like wall plugs or any vehicle outlet, in order to maintain efficacy while in transit. Each portable ULT freezer can hold up to seven of Pfizer's pizza boxes, and nearly 7,000 vaccine doses overall.

Major General Jose J. Reyes at the Puerto Rico National Guard said they "are doing everything in our power to get the vaccine to communities around the world. We are very aware of the challenges associated with last mile delivery and can rest easy knowing we have the ULT infrastructure in place to support the historic global COVID-19 vaccination."

The drive across Puerto Rico is approximately six hours, making safe transport to more rural communities critical. The company reports that the Puerto Rico National Guard plans to "use the upright freezers as a central repository, or hub, on the island, while its undercounter will be for the vaccination centers, and portable freezers will be used to transport vaccines around the island for local vaccine administration."

The State Department plans to load vaccines into the portable freezer units in the U.S., power them onboard aircraft, and deliver them directly to the embassy doorstep where they will then be plugged into power and ready for vaccine administration. Universal power sources, batteries, and vehicle outlets will be used all along these delivery routes to keep the freezers powered, ensure thermal stability, and limit any exposure the vaccines may have to ambient conditions.

Film Technology Protects COVID-19 Diagnostic Test Strips

The new QuickVue SARS Antigen test from Quidel incorporates active packaging technology to protect from moisture and other environmental conditions that could otherwise impact accuracy.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

The QuickVue® SARS Antigen test is a point-of-care rapid antigen test developed by Quidel® Corporation, a leading manufacturer of diagnostic healthcare solutions. The new rapid diagnostic, which delivers test results in 10 minutes, received Emergency Use Authorization (EUA) from the FDA in late December 2020.

The visually read test requires no supplemental instrumentation and offers expanded access to affordable and accurate COVID-19 testing that will help meet the urgent testing needs of the global economy, including for those in school systems and rural areas.

To protect the kit against moisture and other environmental conditions that could impact accuracy, the company integrated

↑ **To protect the QuickVue kit against moisture and other environmental conditions, the company integrated Aptar CSP Technologies' Activ-Film technology.**

Aptar CSP Technologies' Activ-Film™ technology. As Aptar reports, "Activ-Film leverages Aptar's proprietary 3-Phase Activ-Polymer™ technology, which provides a broad spectrum of custom-engineered protection in a variety of configurations, such as Activ-Vial™ for housing diagnostic dipsticks and Activ-Tab integrated within diagnostic cassettes."

The active packaging technology is currently used to protect a range of electrochemical, lateral flow, and molecular diagnostic test kits on the market today. The company also offers systems to protect drug delivery solutions and consumer products.

For more in material developments, check out the Flexible Packaging Awards in healthcare on pp. 26.

↑ **Beyond COVID-19 applications, Activ-Film is used to protect a variety of test strips including tests for strep throat.**

Easy-Application Tube for Veterinary Products Wins Gold

The Tube Council awarded **Hoffmann Neopac** a gold award in the "Best Pharmaceutical Tube" category for its convenient, high-barrier single-use tube with a simple, no-mess applicator developed for Aurora Pharmaceuticals, Inc., a U.S.-based manufacturer and distributor of animal health medicines.

Aurora chose a customized version of Neopac's Twist'n'use™ tube for its prescription Revolt™ topical antiparasitic solution. The product is a small-volume single-dose solution that, once the cap is twisted, is irrevocably opened. In addition to tamper-evidence, the tube's permanently affixed cap emphasizes simplicity for the consumer and offers accurate product application to the treatment area.

The Twist'n'use tube features Neopac's Polyfoil® technology–a proprietary blend of materials providing advanced barrier properties for products requiring ample protection against moisture, oxygen, and other potentially harmful substances.

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Barcode Readers Aid in Serialization

Packaging machinery OEM Packaging Efficiency Solutions found just the right barcode scanners for a system that inspects all angles of the bottle or label at speeds up to 100 bottles/min.

PAT REYNOLDS, EDITOR EMERITUS, *PACKAGING WORLD*

Packaging Efficiency Solutions (PES), which specializes in equipment for the pharmaceutical, nutraceutical, and food and beverage industries, was approached by several customers seeking a reliable system for reading barcodes on bottles or labels to improve serialization and verification. The target customers for this system were pharmaceutical manufacturers and contract manufacturers engaged in serialization activities, as well as producers of consumer packaged goods products using the system to allow label and print verification on all bottle sizes and shapes.

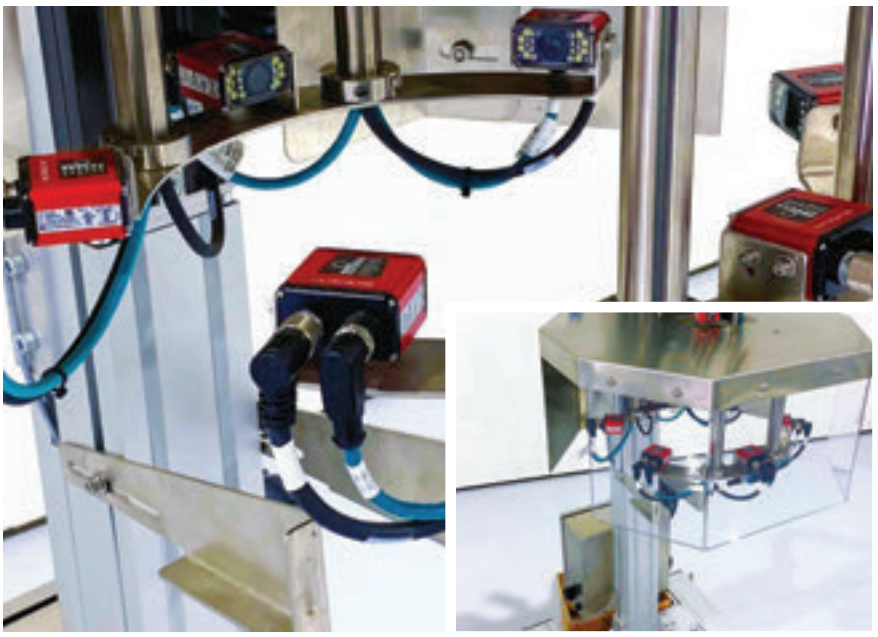
As with any automated system meant to work for a variety of end users, flexibility was paramount. To make the new system accessible to the broadest possible range of customers, PES needed to keep the overall machine footprint small and invest in highly intuitive technology that would minimize installation and maintenance needs. Finally, PES was hoping for a system that would exceed the level of reliability currently being used by its customers.

PES tapped **Omron** to design the new system, dubbed the PES-360, and Omron selected its popular MicroHAWK barcode readers as the key technology. Omron partnered with **Saddle Brook Controls**, a distribution partner based in New Jersey, to help with integration and testing. As a local company, Saddle Brook has been able to provide quick support with respect to implementation and optimization.

The new system needed to reliably inspect all angles of the bottle/label at speeds up to 100 bottles/min, says PES General Manager Andrew Smith. "The goal is to decode the data in the 2D bar code—lot number, expiration date, serial number, GTIN—and associate that code with a code on the top of the bottle, which also gets scanned by a MicroHAWK barcode reader," Smith continues. "So when that bottle reaches the end-of-line equipment, you can scan it from the top and know exactly what's in the case without having to see the entire bottle sidewall."

In addition to keeping the footprint small—the PES-360 adds no more than 34 in. to the length of a packaging line—PES wanted to reduce the amount of integration and line modifications required for installation. Makers of comparable solutions were offering systems that were fairly large and quite expensive, so PES was hoping Omron would be able to come up with a compact and cost-effective solution.

Reliability was also a key requirement. Some of PES's customers were already using automated bottle inspection systems, but these didn't use enough cameras to be fully reliable. Since they took just a single image per camera per bottle, they had an elevated occurrence of false rejects or no response. The PES-360 needed to make



↑ The compact machine adds no more than 34 in. to the length of a packaging line. It reliably inspects all angles of the bottle or label at speeds up to 100 bottles/min.

sure that every point on the circumference of the bottles would always be seen by at least one of the system's cameras, regardless of bottle orientation.

To combat the issue of false rejects, Omron used seven cameras—initially MicroHAWK ID-40 cameras but transitioning to V430 cameras as the latest technology—to achieve maximum performance. The MicroHAWK Series is known for small size and easy installation, and the family's compact design allowed Omron to integrate six cameras situated around the conveyor and one above.

The PES-360 takes advantage of the cameras' ability to capture images in bursts as opposed to a single image per trigger, which provides more chances to successfully inspect and decode the data.

The MicroHAWK readers are easily integrated into the current control system, where the standard/configurable I/O offers greater flexibility in machine logic setup. In addition, the system's ability to communicate data match strings via TCP/IP messages minimizes hardware requirements, and the use of self-contained smart cameras reduces the need for more skilled technical resources to interface with traditional PC-based camera systems.

More than 30 PES-360 systems have now been integrated into customers' packaging lines, and the system has helped PES become a leading resource for serialization and inspection systems. The MicroHAWK cameras work wonders when it comes to giving PES more flexibility. Depending on the application, Omron has a wide variety of MicroHAWK resolutions to choose from without having to change the overall system's mechanical design. There are many options for internal lighting, but there's also the option to utilize external lighting when required. PES is currently using SXGA (which is a 1.2MP sensor) with integrated lighting.

Another benefit of the MicroHAWK ID-40/V430 cameras is that their barcode reading capabilities can be easily upgraded to a machine vision smart camera without requiring any mechanical changes to a customer's equipment. Based on the success of the PES-360 and the ease of collaborating with Omron, PES is looking into partnering with Omron for a variety of other vision inspection and code reading applications.

Advancements in automation, both machine and software, are moving manufacturing toward a smarter factory. Technology that will enable new levels of operational excellence and production intelligence is being implemented now. Learn more in PMMI's *Automation Timeline* report: hcpgo.to/timeline.

From Drug Supply to Staffing: The Benefits of RFID Integrated into Vial Labels

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. A new partnership allows pharma manufacturers to implement RFID-embedded vial labels on existing lines.
2. A manager of pharmacy operations talks about the benefits he's seen from automated inventory management, and COVID-19 effects.
3. Customers' continuous improvement from data they've gathered includes saving drugs at risk of shortage and justifying staffing levels.

Automated inventory management solutions are used for a variety of different products, including medications and equipment. Their popularity continues to grow in tracking drugs for efficiency benefits across health systems.

We talked with Eric Schaefer, PharmD, Manager of Pharmacy Operations at Allegheny Health Network, about how using label systems from **Kit Check** and **CCL Healthcare** has opened doors, increased efficiency, and more.

Before we get into the benefits—and Schaefer explains there are many—we'll go over the technology that makes this possible. Kit Check and CCL Healthcare have partnered to deliver labels embedded with RFID tags to pharmaceutical manufacturers.

RFID inlay for small vials

Until recently, flag labels with RFID tags were manually applied to individual vials at the hospital system. The labels could not be applied at the manufacturer due to the time-consuming nature of the process. "Additionally, pharmaceutical companies use specific adhesives which are tested against migration and anything that can affect the drug," says Karl Hoelper, Director of Marketing at CCL.

CCL has integrated the RFID inlay into the existing vial label that they print for the manufacturer. Vials then arrive at the hospital pre-tagged, eliminating the flag-application workflow at the hospital.

"Because we're producing the label already, we can take a transfer tape and match that adhesive so there are no qualification issues for the pharmaceutical company, which is a pretty big hurdle—it could be a year or two years to qualify," explains Hoelper. "This mitigates the risks of any chemical migrating off the label and into the drug."

Glass, liquid, and small vial/syringe sizes—including the traditional 2 mL vial—all pose challenges for RFID functionality. In addition to these challenges, the RFID inlay needs to be rotated 90 degrees in order for the antenna to fit properly on the 2 mL vial.

To make integrated RFID labels a reality on small vials, CCL custom-built a machine to orient inlays so that manufacturers wouldn't have to change any aspects of their label artwork. The machinery allows them to remove each RFID inlay from the reel, pick it up, rotate it, and space it properly.

The process requires extreme precision with multiple sensors and camera systems on the line to ensure the tag fits behind the label. The labels undergo numerous quality checks before they are released.

The result is that manufacturers receive labels with RFID inlay that appear identical to their existing label—they don't require artwork changes and new FDA approval—and do not affect packaging lines. "We're working within the constraint of the current label, which is key for that 2 mL vial," says Hoelper. "We wanted to make sure we made this work with their current adhesive and current label so that adding RFID is as painless as possible."

DoseID

With the goal of ensuring the quality, performance, and interoperability of RFID-tagged drug products as they move through the supply chain, DoseID launched in August 2020. CCL and Kit Check are founding members of this self-governing consortium established to unify the industry around an approach to serialized, RFID-tagged pharmaceutical products. "Creating pharma specific RFID labels is irrelevant unless there is an interoperable supply chain that sees the value of RFID. DoseID substantiates that value" says the consortium. They report that it takes serialization beyond DSCSA, from the unit of sale to the unit of use. DoseID uniquely serializes every dose, container, or device to track every action taken upon it during its entire lifecycle.

The consortium takes a practical approach to ensure that the system works in the rigors of the real world. DoseID drugs and hardware devices are compliant with existing standards like RAIN and GS1. They are tested to ensure (1) performance (the best inlay is chosen for the application), (2) interoperability so that the drug will read in real-world scenarios, and (3) complete and accurate data in which the evolving record of a drug's attributes and event history is stored in the cloud and accessible to all parties.

"In recent years a variety of different RFID solutions have come into the healthcare market to track drug products, instruments, and supplies without any industry-wide standards having been established to ensure quality, performance, and interoperability between them," says DoseID. "With industry-wide support of a comprehensive set of RFID standards for healthcare, players along the pharmaceutical supply chain can work together to solve these issues proactively rather than reactively."

↑ With the CCL/Kit Check partnership, manufacturers receive labels with RFID inlay that appear identical to their existing label—and don't require artwork changes, new FDA approval, or changes to packaging lines. ● Right: To make integrated RFID labels a reality on small vials, CCL custom-built a machine to orient inlays by 90 degrees to make the process as painless as possible for pharmaceutical manufacturers.

With that explanation in mind, we sat down with Dr. Schaefer to hear about what attracts health systems to RFID solutions adopted by pharmaceutical manufacturers.

Healthcare Packaging (HCP): To start, how have you been using automated inventory management for drugs at your facility? I understand companies are transitioning away from flags into seamless systems with embedded tags.

Eric Schaefer: When you look at how people select automated inventory management, there's one mindset of "I'm going to use it to check this tray or this kit."

Then there's also the mindset of "I'm going use this to check those items and reduce the time it takes to check or use pharmacy time. However, I see the other benefits that are available: the analytics, the inventory pieces, the recall pieces, and shortage management options with the tray."

At my prior facility, I did a major implementation for two systems. We converted part of the facility to Kit Check for crash cart trays

of the facility to Kit Check for crash cart trays and anesthesia trays where they do a tray drop, in which they take the used tray out, place a new tray into that drawer, and then it's 100% stocked. Those are going to be items that are usually higher value vials—they lend themselves well to this use.

Most facilities that implement this are probably going to start with a crash cart because turnover in that cart isn't daily, so it's something where if you have an option to know electronically where stock is, and what's expiring, you're able to manage those and rotate those out rather than opening every cart every month.

That was the case here at Allegheny General Hospital, and at the previous facility I worked at. We started with crash carts and then expanded into other areas, but really you're looking at those kitted items for emergency kits, trays, and operating room (OR) based items.

I GET EXTREMELY EXCITED ABOUT KIT CHECK—I THINK RFID TECHNOLOGY IN GENERAL IS GOING TO CHANGE THE WORLD OF INVENTORY MANAGEMENT AND DISPENSING.

—Eric Schaefer, Allegheny Health Network

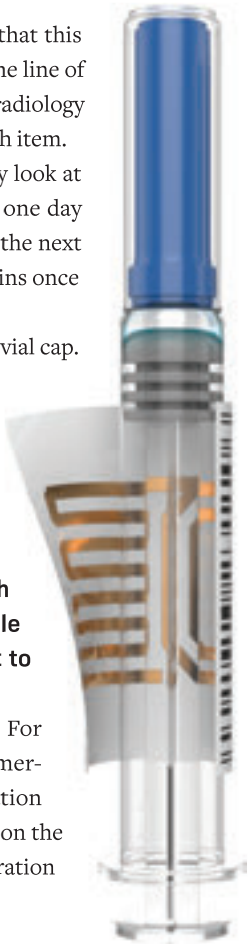
HCP: What is the importance of the ability to scan vials without a direct line of sight?

ES: There's a big time difference between scanning RFID versus 2D codes. If I needed a line of sight to scan a 2D barcode for a box or a bagged kit of drugs, if the label is on the side, I have to stand all those vials up or twist them so that the barcode is showing.

With Kit Check the nice thing is that I'm confirming that this drug is inside using RFID, without necessarily having the line of sight. I can use it to scan trays and scan boxes, such as radiology reaction boxes, without physically having to look at each item.

With 2D barcoding, I'm still going to have to physically look at every vial in that area. Many places will spend about one day every six months doing outdates and pulling drugs for the next six months. With an RFID system, I can now scan my bins once a week, or it may even be more frequent.

The 2D barcode is usually going to end up being on the vial cap. What I had found is when they pop that off, it's still attached and the lid will sometimes fall back down, so it looks like it's an unopened vial. Whereas with RFID, the tag is attached to the side and I can tell when that top is off or when it's used.



HCP: One feature is that information associated with an RFID tag isn't static. Can you provide an example of additional or updated information being sent to RFID tags?

ES: We have a prime example of syringe shortages. For several years, there's been an ongoing shortage of emergency syringes and even FDA updates to their expiration dates. The nice thing is I can validate that information on the FDA website, log into the system, and update the expiration on that lot number.

I can see the history of the tracking. I can see that for some of the syringes, I had to update the lot numbers two or three times because they were performing testing and allowing extended dating due to shortage. We can update expiration dates automatically without having to replace the tag.

HCP: So it's both a patient benefit, a cost benefit, and a sustainability benefit because you're not necessarily getting rid of something that's already in short supply? If an expiration date has been updated, then somebody isn't mistakenly thinking it's expired and tossing it?

ES: Right. So a user looking at the vial doesn't see the old expiration printed on the tag (maybe they do on the carton) but we know that when we're releasing that drug, it has had an updated expiration in the system.

HCP: Let's talk KPIs and metrics. Should an ongoing monitoring system be established for continued improvement? How do you take action based on the data?

ES: There's a few different areas where you could look at this.

Overstocking kits: When we are developing out these kits and trays, the stock inside that tray is going to be based off of what the end user—the anesthesiologists or nurses—had experienced. They may have had a case where they once needed 10 vials, so there's a sense that they needed 10 in this tray.

At first, I didn't have any data to show necessarily

that that was incorrect. But as time went on scanning that tray, it got to the point where I had emergency medications that totaled about $200 to $300 per tray times 120 trays. Everybody insisted that they needed those 10 vials. Over six or seven months, I was able to show data that that was only used maybe one or two times out of thousands of tray expenses.

So I was able to actually show that the vast majority of the time, they don't need these medications, and pull some extra out of that tray. We adjusted stock with the idea that this is a fairly expensive medication and 90% of the time, they only use two in a case. You can work with the providers to start to decrease the stock that's in there and then it also allows you to work with them to place another item that they want. Space is limited. You can start to pick and choose what really is important to have in there and the right quantity, and save money in the carrying cost of that drug and in your pharmacy stock. I found times where there was an emergency kit—they used it one out of a thousand times. I had thousands and thousands of dollars' worth of inventory sitting there that, at that usage, would have been five years' worth of stock. The drugs would sit there until they expired. We were able to make adjustments.

Inventory reporting: I can see the inventory in a given area and see what the average uses are. I can start to decrease inventory amounts in the actual bins themselves. And then when I have to do a physical inventory each year or twice a year, I can just pull the report because they're scanning these bins more frequently than doing a visual inspection of every vial. So it's seconds and it's more accurate than a manual check.

Ordering: Also when you look at cost savings, if you don't have the ability to scan bins, then it's going to be a staff member looking in a bin and thinking it looks empty and ordering more. But if it's something you don't use a ton of, perhaps you don't need to order until you're down to one or two.

If you don't have the data to support that, people are just going to order what they want. So I've seen inventory reductions and reallocations since implementing.

Staffing: I don't look at saving time in terms of eliminating staff hours but to reallocate that time to more meaningful activities. But a lot of places are still driven off of volume for their staffing models. For ORs in my facility, I never had data to show the number of items we were dispensing. Once I had Kit Check implemented, I was able to show the volume of tags and I was able to relate that to the staffing algorithm to prove that the staff that I had was adequate.

Using items close to expiry: You can locate drugs close to expiration, pull them from that tray, and then utilize them in your IV room instead of wasting them. That's very difficult to do if you have to physically look at every vial or physically scan every vial, it's just too cumbersome to actually do that.

↑ Users can confirm a drug is in a tray using RFID, without having a line of sight for each vial.

Benefits in Light of COVID-19

Eric Schaefer: Even in the aspect of non-COVID-19 times, there are facilities such as surgery centers that don't have a pharmacy on-site. I can fill their trays at my hospital and I courier them over, and then they just send back the used trays for refilling.

Pre-COVID-19, people were looking at how to centralize tray processing. Now instead of requiring a pharmacist and technician on-site, it's just the center's technician changing out the tray. We use courier services daily, so why not courier a completed tray or completed kit?

If I have a facility that decreases staff because of COVID-19, I can process and build those trays and then send them over.

If things shut down, with Kit Check being cloud-based, I can remotely look at a tray configuration without rebuilding the entire tray in my system. Staff can be moved to positions where they will do the greatest good.

At a smaller facility, they may have only a few staff and now they don't have to maintain that inventory. They don't necessarily have to have the scanner there, so it's something where I think even outside of COVID-19, we're going to see more of a system approach, as people try to conserve resources and reallocate expiring medication to places with higher usage rates.

Maybe Hospital A needs a significant amount of one medication and Hospital B does not use much. When those trays come back, I could start to move some of that and talk to those providers at Hospital B about decreasing… and I have data to support this.

I can also track a cart's location remotely (or track its lock if it has one), which is helpful if a site has to decrease on-site staff due to COVID-19.

Additionally, for the trays that come back, there is functionality to document the cleaning of a tray so that can be monitored. I would be able to see that this tray hasn't been cleaned in two days, then I can prompt it to be cleaned. You can even then use that data to show attempts to improve infection prevention.

Colgate: Packaging's Day Has Come

PAT REYNOLDS, EDITOR EMERITUS,
PACKAGING WORLD

TOP THREE TAKEAWAYS

1. Colgate-Palmolive has made sustainable packaging a key priority.
2. From recyclable toothpaste tubes to aluminum bottles for mouthwash, Colgate is eliminating plastic waste.
3. Colgate's oral care or personal care tube is the first to earn recognition from the Association of Plastic Recyclers.

"Packaging is a field whose day has come."

That simple and straightforward statement by Colgate-Palmolive's Chief Technology Officer Patricia Verduin neatly sums up the views shared by all five of the Colgate executives I talked with recently in preparing my *View from the Top* feature.

"It's always been viewed as an applied engineering field, if you will," Verduin continues in her assessment of packaging's status. "But I think this is an age where packaging changes the way the world buys products, whether it's making E-Commerce a great experience or it's addressing the whole plastic waste issue. More than ever before, it's changing the way people engage with our brands. From Colgate to Tom's of Maine to Fabuloso to Hill's, the packaging has to deliver against the promise of our brands and our company purpose as a caring, innovative growth company reimagining a healthier future for all people, their pets, and our planet."

Working out of Colgate's Piscataway, N.J., Global Technology Campus, Verduin oversees global R&D, Packaging, and Design. "These are the arms and legs of innovation, the people who are really doing innovation with their pencils and CAD drawings and knowledge," says Verduin. Noting that this organizational structure has only been in place for a few years, she says it's really been powerful to have all three of these functional groups together.

"It's all about having the product formulators, the brand designers, the user experience people, and the packaging engineers and developers all in the same room at the same time and all developing against a common brief," says Verduin. "Too often in the past the practice was to make the formula and throw it over the wall to the packaging people, who, when they'd come up with a package, would toss it over to the design team for graphics. It just doesn't work that way anymore. The formulas are too complicated and the delivery mechanisms too varied."

↗ **In a category where the plastic blister pack is the dominant packaging format, the launch of Colgate Keep in a wet-fiber thermoformed package made of sugarcane and wood fiber was notable to say the least. Shown here is the front of the starter kit and the back of the two-count refill pack.**

Colgate-Palmolive is a global company that competes in the oral care, home care, personal care, and pet nutrition categories. With sales of nearly $16 billion, the company supplies products to more than 200 countries and territories and has 40+ manufacturing facilities worldwide, each with its own team of engineers. Like most Consumer Packaged Goods companies, Colgate places a premium on both innovation and sustainability. Somewhat atyp-

ically, however, the firm doesn't have one director of packaging innovation and another of sustainability. Instead, it has a Director of Global Packaging Innovation and Sustainability, the title held by Greg Corra. When asked why things are organized this way, he has this to say: "We believe packaging innovation is the key to achieving Colgate's purpose of reimagining a healthier future and that our sustainability strategy needs to underpin all aspects of our packaging strategy."

"Underpin" is a bit of an understatement. The extent to which sustainability shapes all things packaging at Colgate is evident if we look at some of the packages recently introduced by the New York-based firm. Many of these are packages for oral care products, which should come as no surprise. Colgate's largest category, oral care represented 46% of the firm's sales in 2019. Let's start with toothbrushes, since Colgate sells about 3 billion of them every year, two-thirds of them made in-house.

Replaceable heads

Just reaching U.S. consumers in winter was Colgate Keep, a line of replaceable-head manual toothbrushes featuring an aluminum handle that's designed to be long lasting for 80% less plastic waste. A new replacement head can be snapped on when bristles are worn. Colgate is launching both a starter kit, which has the aluminum handle with two brush heads, as well as a two-count refill pack sans handle.

The concept of a more permanent and reusable handle made of aluminum is in itself a significant step toward putting less plastic into the solid waste stream. But our interest here is in the fiber-based packaging, which, in a category dominated almost exclusively by plastic blister-packs, is a profound departure.

"The first challenge in our brief was 'Hey, guys, we need to get out of a plastic blister,'" says Senior Global Design Manager Jadalia Britto. "That led, of course, to a series of questions about the options. How can we use fiber? Can we use recyclable paper? How do we still get premium finish and color? We really had to challenge our external partners to help us find the answers."

Britto says that her particular responsibility in projects like this is the look, tone, and feel of the package. "It's all about how to treat the master brand," she notes. "Then I work closely with our industrial designers to execute on the design intent."

The package that emerged for the Keep starter kit is a peggable all-fiber tub and lid that stands 229 mm tall, 70 mm wide, and 26 mm deep (9.01 x 2.75 x 1.02 in.). Sourced from sugarcane and wood fiber, the tub is wet-fiber thermoformed by China's **LVHE Packaging Technology Co. Ltd.**, an impressive specialist in researching, manufacturing, and marketing biodegradable materials and products. The lid, a 400 gsm paperboard containing 60% recycled content, is heat sealed to the tub. Graphics are printed UV offset in six colors plus a matte varnish. As for putting the products into the packs, this is done for now by an outside contractor in a semi-automated process. The starter kit sells for $9.99 and the replacement pack for $4.99.

"From start to launch, including the time we had to spend exploring material options, it took about eight months," says Britto. "We're getting faster with getting these things out the door."

Elsewhere in the oral care category is another brand new product called Optic White Overnight Teeth Whitening Pen. The product itself is a 2.5-mL aluminum and plastic cylinder in an injection-molded stand. Packaging, once again, is entirely paperboard, including an inner tray made of 100% compostable **PaperFoam**. Based in the Netherlands but with manufacturing facilities in coun-

↑ **Key contributors to the work Colgate has done on the monomaterial recyclable tube project include (left to right): Tom Heaslip, Worldwide Director, Category Packaging; Jennifer Noll Waxman, Director E2E Program Management; Jennifer Boada-Rodriguez, Senior Technical Associate; Anne Bedarf, Packaging Sustainability Manager; and Jun Wang, Senior Technical Associate.**

tries including the U.S., PaperFoam mixes four bio-based ingredients into a thick paste that is then injected into a custom aluminum mold and baked at about 400° F. The manufacturing process is said to be energy-efficient, and the resulting part provides the cushioning properties of plastic foam alternatives but is TUV-certified as compostable in home or industrial settings and is UL-validated as recyclable.

The other packaging component for the whitening pen is a 24-point SBS sleeve with two locking tabs. The inner tray holding the pen and stand slides into this sleeve. Supplied by **Multi-Pack Solutions**, it's offset printed in seven colors with a foil stamp plus varnish. "We definitely focused on a recycled paperboard," says Britto. "And the cold foil accents bring a nice element of premiumness without interfering with recyclability."

When asked if the team ever thought about a clear package for the whitening pen, considering how consumers respond to product visibility, Britto says, "I wouldn't say we never considered it, but from the perspective of graphic impact it would have had its limitations. This printed paperboard says Colgate Red. Also, when I thought about E-Commerce, I wanted the package to stand out in a sea of blues and whites. I really wanted that color. And I wanted that curved shape, even though it complicates a number of things compared to a simple rectangular carton. We almost bailed on the curve at one point, but we pushed ahead and solved it because it delivers on the premium experience that we were after."

'Ships in Own Container'

Since the whitening pen debuted as an E-Commerce item, Colgate Director of E-Commerce Bruce Cummings was a key contributor on the team behind its development. "Early on, we considered a carton into a corrugated box," says Cummings. "But by launch we'd come up with the red mailer, which is lighter and has that easy-open tear strip. Then comes the Colgate-Red sleeve, out of which the inner foam tray smoothly slides out. Compact and compelling, it's an experience that resembles an elegant process of unboxing."

Cummings says the team would have gone with a paper mailer

↗ Colgate's Whitening Pen debuted in E-Commerce channels. A good example of a SIOC (Ships in Own Container), its packaging is entirely paperboard, including an inner tray made of 100% compostable PaperFoam.

↑ Swish mouthwash in its impact-extruded aluminum bottle stands out from the ubiquitous clear plastic bottles that dominate the category. Messaging on the sidewall emphasizes that the package is a 'forever recyclable aluminum bottle.'

rather than the polypropylene air-filled wrap had COVID-19 not messed with the supply chain as it did. "The idea is that once the unboxing experience is complete the consumer can put all of the packaging into the paper recycle stream," notes Cummings. He adds that the paper mailer is now in the works.

This package is an example of a SIOC (Ships In Own Container) that is sent from Colgate's contract manufacturer to the Amazons of the world in a corrugated case of 24 units. Each unit, of course, consists of pen in holder, inner foam tray, instruction booklet, outer paperboard sleeve, and mailer. The Amazons apply the last piece of packaging onto the mailer: a thermal-transfer-printed pressure-sensitive label that has all the information needed to get the unit to the consumer.

Another nice example of a Colgate SIOC for the E-Commerce channel is what Cummings refers to as the Smile Box. Like the mailer used for the whitening pen, both Colgate Red and the smile component are used prominently on this corrugated packaging that holds three cartons of toothpaste. Currently the package is a single-wall B-flute corrugated printed flexo in one color Colgate Red by **WestRock**. This represents a downgauging compared to the original structure, which was a C-flute. And according to Cummings, a third iteration is currently being evaluated. This kind of ongoing optimization, he notes, is fundamental to Colgate's approach to packaging regardless of which channel it's designed for.

"I like to say that we need to continue versioning so that we can arrive at better solutions," says Cummings. But as much as downgauging and cost-optimization are vigorously pursued, he emphasizes this: "We never compromise where quality standards are concerned. We don't want people getting a tube that leaks or a dog food pack that's been punctured."

Aluminum bottle

A very different kind of container was developed by Colgate for a brand new mouthwash called Swish. It's an impact-extruded aluminum bottle from **Trivium Packaging** with a 38-mm threaded closure. It's designed to stand apart from the ubiquitous plas-

tic containers in which mouthwash is so typically found, and the messaging printed on the sidewall proudly proclaims "Refreshingly thoughtful: forever recyclable aluminum bottle." Available in stores and online, the 16-oz bottle sells for about $6.00.

"We are filling this on an existing line used for plastic bottles in our factory in Tennessee," says Jose Luis Molinar, Global Packaging Director Personal & Home Care. "But two things have to be done differently. The automated unscrambling and feeding system used for plastic could damage the aluminum bottles, so we are feeding them into the filling system manually. Also, because the bottle won't withstand the top-load pressure of the rotary capper that was on the line, we needed to install a new capper." The ROPP rotary capper is from **Zalkin**.

The push for monomaterials

Intriguing as the above initiatives may be, the area of emphasis staked out by Colgate that may be the most fascinating—not to mention challenging—is the development of monomaterials that score sustainability points because they fit neatly into an already established recycle stream. Notable progress has been made in toothpaste tubes.

When the Tom's of Maine brand reached store shelves earlier this year in a monomaterial recyclable tube, it was the culmination of a five-year effort. The Colgate technology represents the first oral care or personal care tube to earn recognition for recyclability from the Association of Plastic Recyclers.

Popular in a variety of product categories, laminated tubes for toothpaste alone number an estimated 20 billion annually around the world. In most of these tubes, a layer of aluminum is included in the multilayer lamination to protect the toothpaste's flavor and fluoride. It's this laminated combination of dissimilar materials that makes it just about impossible to cost effectively recycle through established methods.

To make a recyclable tube, Colgate first eliminated the layer of aluminum, says Corra. "The other innovation," he says, "was changing the resin specification from a mix of LLDPE and HDPE to mostly HDPE. The tricky part was getting the specs of the resins for the multiple layers to work well to make a flat sheet... And then on the shoulder of the tube it was a matter of switching from a much higher melt index to a lower melt index so that we're compatible with the well-established HDPE recycle stream." As in the past, the injection-molded shoulder is heat sealed to the tube body.

The development team at Colgate's Piscataway Global Technology Center tested a dozen different combinations, using from six to 20 layers, to find the recipe that allows people to comfortably squeeze out all the toothpaste, protects the integrity of the product, and meets the demands of high-speed production. The product protection component, now that aluminum has been eliminated, is EVOH. Corra notes that either of two approaches can be taken. The entire tube material can be coextrusion blown in a single pass or multiple layers of blown HDPE can be extrusion laminated to a blown coextrusion that includes EVOH.

When asked about the relative cost of the recyclable tube, Corra says that parity is the goal. "We have a long track record of cost-optimizing tubes and we fully believe in our ability to get the cost of this one where we need it to be," he says. "That was always in the design brief, as was scalability. Remember, in time we'll be making billions of these."

Colgate chooses to share its technology

Notably, so will the competition. In spite of all that Colgate has invested in bringing this tube to market, it is sharing the technology openly with any and all who choose to use it. John Standish, Technical Director at the Association of Plastic Recyclers, applauds this move. "With Colgate sharing technology, others will be able to offer recycle-compatible tubes faster and at lower development time and cost," says Standish. "It's a great pioneering effort from Colgate that shows real industry leadership."

Corra and colleagues believe that sharing the monomaterial tech-

Impact of the Pandemic

As for COVID-19, Corra notes that some of the course corrections required by the pandemic highlighted the resiliency of Colgate's packaging supply chain. "As the virus hit we started discovering that we couldn't get as many pumps as we needed, so we quickly qualified a different closure that was more of a flip-cap style to keep liquid hand soap in full production," he points out. "And look what we did and how quickly we did it with the bar soap we donated for the World Health Organization's #SafeHands Challenge."

Molinar says that one change brought about by the pandemic will remain a permanent fixture at Colgate: expanded use of remote connectivity. "At the height of the pandemic, we had to install in a facility in Brazil a new shrink sleeve labeler fabricated in the Netherlands," he says.

"So we relied heavily on teleconferencing and virtual reality goggles to get the factory acceptance test done. It was fantastic the amount of information we were able to exchange. We all agreed it was one of the best FATs we'd ever experienced. We'll be sure to build on this in the future."

Also fixed in Colgate's future are the challenges it will face in an era when E-Commerce will continue to grow briskly and consumers are increasingly vociferous in their demand for more sustainable packaging. "We have a million challenges, but I think those are the two big ones," says Verduin.

↑ First to appear in Colgate's monomaterial recyclable tube was the Tom's of Maine brand, but now Smile for Good in Europe and Natural Extracts in Latin America have also been converted. By end of this year, Colgate Optic White in sizes above 3 oz will take advantage of this technology. The goal is to have all of the firm's toothpaste in this recyclable tube by 2025.

nology is the best way to ensure the long-term market viability of this solution. "Having gotten a recyclable tube over the finish line, it only makes sense to help others get there," says Corra. "If our tube is going to be recycled, it's going to be because all tubes are recyclable. We get that. We also understand clearly that developing sustainable packaging is a marathon, not a sprint. We have a lot of work to do, and it's not just in changing consumers' behavior so that they are actively engaged with the idea of recycling these tubes. We also are working with the Municipal Recycling Facilities so that when consumers do put packaging materials into the correct bin, those materials actually find their way to the right place so that they can in fact get recycled."

Since the Tom's of Maine launch, Colgate now has brought the monomaterial tube to a 75-mL Colgate Smile for Good brand in Europe and both 90- and 120-g sizes of its Natural Extracts brand in Latin America. By the end of this year North America will see the new material in the Colgate Optic White brand in sizes above 3 oz and in the 4.2-oz Colgate Kids Zero brand. Corra says the firm has started up this technology in five of its manufacturing plants and continues to adapt its manufacturing and supply chains so that by 2025 it can achieve its goal that all of its toothpaste will be in the recyclable tube.

FPA Awards Applaud Innovative Healthcare Designs

Flexible packaging accomplishes a wide range of tasks, whether in-transit, on the shelf, or in an end user's hands. The diverse 2021 Flexible Packaging Association (FPA) Award winners, announced March 10, 2021, reflect an array of flexible functionalities—we profile those in healthcare.

Dual Chamber Pouch Keeps Medical Devices Safe

The FPA honored **Amcor** with a Gold Award in Technical Innovation for its Dual Chamber Pouch, a specialty multi-layer pouch consisting of a peelable medical device chamber and a non-peelable desiccant chamber. The desiccant is kept separate from the device with a symmetric coextruded vented nylon film.

This system is used by Boston Scientific, and Amcor reports that it is particularly suited to "moisture-sensitive products such as drug-coated products which may be adversely affected by reacting with various gasses found within the atmosphere of the package and is suitable for Ethylene oxide (ETO) sterilization," as well as radiation sterilization.

Providing easy aseptic access to the product—along with tamper and peel evidence—Amcor created this multi-layer system uniting the gas, moisture, and light barrier of 70 gauge foil with nylon in the three webs for high levels of abrasion/puncture resistance. Linear low-density polyethylene (LLDPE) provides strong lock-up seals to prevent access to the desiccant. The Laminate of FM Peelable (LFM) sealant layer is peelable and offers a broad sealing window and visible seal evidence when opened, while a 1059B Tyvek® patch offers breathability between the two chambers allowing the head space between the two to come to equilibrium.

The film is available in clear or pigmented formats. Amcor uses flexographic and rotogravure printing processes depending on the application needs, with the capability of printing in up to 10 colors. For the application in the entry, flexo printing was used.

—Keren Sookne

Colorful Seal Assurance Supports EU MDR for Device Packaging

The FPA awarded **PAXXUS** a Gold Award in Expanding the Use of Flexible Packaging for its Chameleon™ for Tyvek. The product was designed to address the requirements of the European Medical Device Regulations (MDR) going into effect in May of 2021 that the integrity of a package is "clearly evident to the final user." Additionally, ISO 11607-1 further clarifies that the inspection takes place immediately prior to aseptic presentation. This presents a challenge for uncoated (or coated) Tyvek sealed to PET/PE of Ny/PE which shows minimal contrast at the seal, making it difficult to identify anything but gross seal defects. Chameleon allows the user to readily evaluate the quality of a seal when used with uncoated Tyvek.

"Prior to opening, the seal shows as a darker color when

viewed through the film side. Once the package has been peeled open, a vivid colored seal indicator presents on the Tyvek with a contrasting white seal indicator on the film," says the company. Designed specifically to work with uncoated Tyvek pouches, Chameleon consists of an oriented nylon film co-extrusion coated with PAXXUS' moisture resistant Green Chameleon™ peelable sealant. The cohesive peel allows for a consistent, smooth, fiber-free peel thanks to its unique modified-polyethylene sealant technology. The bright color of the seal allows the end user to identify any seal defects quickly—which appear in white or a lighter color—even in fast-paced, dimly lit healthcare environments. The seal color can be customized to user branding or for different product sizes or formats.

Beyond the point-of-use evaluation, the system provides the manufacturer an obvious visual distinction between sealed and unsealed areas when visually inspected through the film side in a quick, non-destructive manner. In terms of sustainability, the uncoated Tyvek (spun-bonded HDPE) can be mechanically recycled in the HDPE stream. Additionally, because the system achieves performance without heat-seal coating the Tyvek, the Tyvek side of the pouch uses 15 to 20% less material than coated options and requires one less manufacturing step.

In what the company calls the "next generation of cohesive peel technology," seal strength is consistent over a large operating window and the system's price generally aligns with traditional polyester/poly pouches. The technology has been adapted from its Allegro®T proven film technologies, so support data is available. The technology is designed to be adaptable to varying thicknesses—the entry product was 76 µm/0.0030 in and featured Tyvek 1073B.

—Keren Sookne

Partnership Creates Infused Face Mask to Counter Dreaded "Maskne"

Amidst the COVID-19 pandemic, some of the most important personal protective equipment are masks, but not all are created equally. The FPA awarded **Karlville** and **The Packaging Lab** with the Gold Award in Shelf Impact for their Infused Face Mask. Karlville is a provider of converting and packaging machinery systems for shrink sleeves, flexible packaging, pouches, and tape multipacks while The Packaging Lab is a provider of custom packaging systems.

This face mask is copper-infused and impregnated with Shea Butter moisturizer as doctors, first responders, and millions of people are dealing with redness, irritation, or "maskne" caused by masks. Nufabrx, the product's end user, says of the masks, "Skin care enthusiasts, dermatologists, and even some A-list celebrities, were thrilled to learn that wearing a mask no longer meant sacrificing their skin care routine."

For the packaging, the pouch is digitally printed CMYK on white film using an HP Indigo 20000. The pouch is laminated on a Karlville PackReady machine and pouched on a Karlville pouch machine. The entire process from loading film on the press to finished pouches in a box takes less than five hours, which the companies say is previously unheard of in the flexible packaging market.

A 1.2 mil film of matte BOPP gives a moisture barrier and is thermally laminated to a white 3.5 mil PET/EVOH/PE prelaminate. The PET provides structure through the print and lamination process, while the EVOH provides the barrier to keep moisture from transferring through the film. The total thickness of the material is 4.7 mil. To avoid future outgassing from lamination adhesive, this pouch was also produced without using any adhesive in the lamination process. *—Melissa Griffen*

Med Device Market Shifting Business Models to Automation and Technology

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

TOP THREE TAKEAWAYS

1. Four out of five medical device companies believe automation is one of the biggest changes to manufacturing.
2. New technologies are creating efficiencies throughout the supply chain, from wearables to cloud-based analytics.
3. Research and development has seen delays to clinical trials and new product development, with some R&D left in limbo.

According to *Pharmaceutical & Medical Devices - Trends & Opportunities in Packaging Operations*, a new white paper from **PMMI**, medical device companies are streamlining processes and adding more flexible solutions to their operations with a continued focus on ROI, cutting costs, reducing waste, and investing in machinery that can meet several needs at the same time.

Connecting with customers and patients through a variety of different services and technologies has reinvented how the medical device market operates, while also giving some companies a competitive advantage in the market.

New technologies are creating efficiencies throughout the supply chain, and technologies such as wearables, smart devices, IoT, and cloud-based analytics are all becoming more widely used in the industry, requiring medical device companies to adapt. Said one director of packaging engineering, "We continue to invest in capital, plus we see growth in our business. We hit thresholds where automation has good ROI and challenges the industry."

According to the report, competitive technology advantages in the U.S. include:

- Microelectronics (very small electronic designs and components, typically made from semiconductor materials)
- Telecommunications
- Instrumentation
- Biotechnology (genetic manipulation of microorganisms for the production of vaccines, antibiotics, hormones, etc.)
- IoT (a network of physical objects embedded with sensors, software, and other technologies to connect and exchange data with other devices and systems over the Internet)
- Software Development

There are also specific trends and opportunities that the report identifies for development in the medical device market:

- Increased need for diagnostic testing kits
- Increased use of plastic packaging (polycarbonate)

- Need for longer shelf-life packaging
- Increased need for sterile medical packaging
- Supply chain disruptions due to COVID-19

COVID-19 has, of course, impacted the market in the last year, according to a report by Tata Consultancy Services Ltd (TCS). Research and development has seen delays to clinical trials and new product development, while some future R&D has been left in limbo due to budget-driven constraints or reduced productivity attributed to work-from-home orders.

Manufacturing and the supply chain have also been impacted by lockdowns, social distancing, and work-from-home orders, as well as delays due to diversion of resources or limited movement of freight, and travel restrictions. These issues—supply chain chal-

lenges, shorter lead times, and staffing issues related to COVID-19—highlight the need for more automation and connectivity in the market.

Said one associate director of equipment engineering, "There's a greater demand for certain commodities, but some are not manufactured at the rate you need, or you can't scale up. For example, we need more syringe barrels, more glass, more aluminum for caps, and more corrugate."

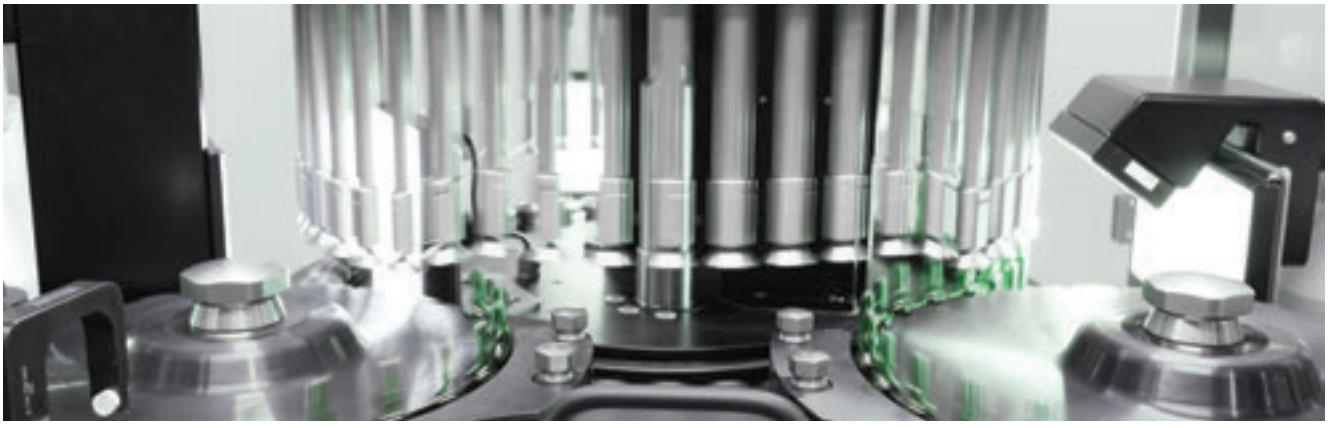
There is also a declining demand for devices in non-COVID-19 segments of healthcare, as well as a decrease in healthcare spending on non-COVD-19 treatments, and a decrease by more than 50% for elective surgeries.

Key changes due to COVID-19

Almost two-thirds of medical device companies who responded to the report say that new equipment will be the largest investment in packaging and processing due to COVID-19. "We've seen huge upticks in demand in areas such as PPE, syringes, swabs, and diagnostics. In some cases, all of a sudden, we need more capacity and can justify more automation with those. Everything pushes us in that direction in driving higher output at lower cost," said one director of packaging engineering.

Although some operations have been delayed, most manufacturing facilities have been granted exemptions for their critical systems. Dealing with challenges related to restrictions for on-site staffing have affected plant operations, however, particularly those that require on-site evaluations. Said one packaging engineer, "Some of our new product development projects have slowed down because of restrictions. When we try to get a new product line up at the plant, if we are not there in person to evaluate the plant situation, it makes it harder. We have a virtual meeting, which is not always ideal, or we can't go there unless it gets approved by higher management levels."

Download PMMI's *Pharmaceutical & Medical Devices - Trends & Opportunities in Packaging Operations* at **hcpgo.to/trends2021.**



↑ CDM Lavoisier implemented new inspection technology. All images courtesy of Syntegon Technology

Fewer Ampoule Rejects with Automated Inspection

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

TOP THREE TAKEAWAYS

1. A manufacturer automated its inspection process for injectable glass ampoules for more than 30 products in four different formats.
2. They implemented the AIM 3000, with a combination of visual inspection and container closure integrity testing.
3. Armed with new data from the system, they have adapted crucial sections of their filling and sealing processes.

Because the increasing variety and complexity of parenteral drugs calls for new dimensions in quality assurance, CDM Lavoisier recently changed their inspection processes for more than 30 products in four different packaging formats to the new AIM 3000, a fully automated technology with a combination of visual inspection and container closure integrity testing (CCIT). A long-term partner, CDM had previously implemented several inspection machines, filling, and packaging technologies with **Syntegon Technology** (formerly **Bosch Packaging Technology**).

Founded in 1888, CDM Lavoisier is a family-owned manufacturer of injectable drugs. "Since the beginning, we have developed products according to the needs of healthcare professionals and sick people. We are committed to top quality for the safety and efficiency of our products. It is with this state of mind that we regularly develop new packaging and formulas," says Philippe Truelle, CEO of CDM Lavoisier, in the company's mission statement.

Ensuring process consistency, speed, and cost-effectiveness

The pharmaceutical manufacturer had previously been working with a combination of automated and manual inspection, so one of the requirements of the new system was to fully automate the inspection process for cosmetic defects like the so-called black spots originating from the ampoule closing process, or non-moving particles within the containers.

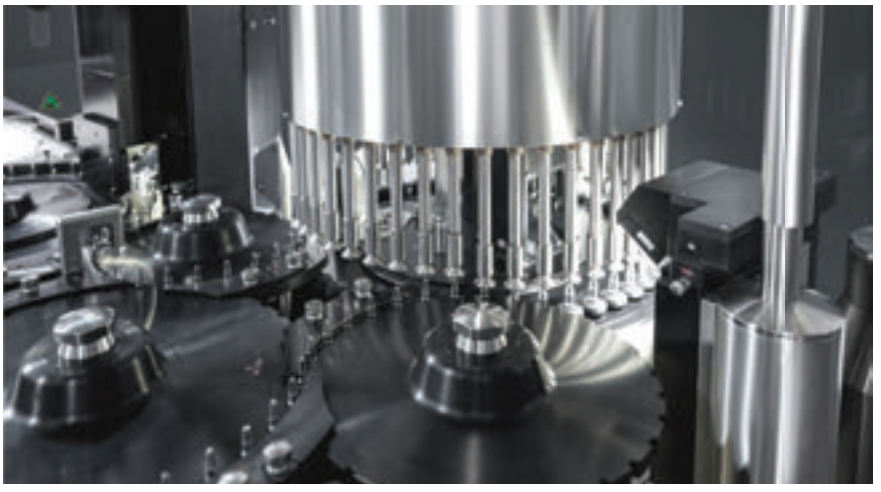
"Fully automated visual inspection offers several advantages, such as process consistency, speed, and cost-effectiveness," says Truelle. "Nevertheless, the main challenge was to optimize particle detection rates and reduce false reject rates within the system." Since many different parameters such as viscosity, density, fill volumes, or the presence of bubbles can affect process performance, it was crucial to evaluate the performance of the system based on a wide range of process parameters and solution properties, in order to qualify a robust and consistent visual inspection process. Once this challenge was overcome, a large variety of inspection recipes had to be implemented and fast changeovers ensured for approximately 30 different products in four packaging formats.

Compact platform for visual inspection and leak detection

The first model of the AIM series was developed by Eisai Machinery some 40 years ago. In 1985, the KLD series was introduced

by Bosch Packaging Technology using high-voltage leak detection (HVLD). It detects leaks by measuring the electrical resistance of containers with conductive solutions. Today, both technologies are an integral part of Syntegon Technology's inspection portfolio, and the AIM 3000 combines the enhanced visual inspection from the original AIM series, and HVLD from the KLD series. The new platform inspects ampoules and vials containing solutions and suspensions at an output of up to 450 containers/min.

To sort out damaged containers before they enter the main inspection turret, the AIM 3000 is equipped with a pre-inspection station. The core module features a high-resolution CMOS camera with high-speed interface for particle and cosmetic inspection, as well as a built-in re-inspection function. The customizable platform can be retrofitted on site to add further visual inspection stations or the HVLD module – which is what CDM Lavoisier opted for. "The AIM 3000 not only offers us high speed, but also a reduced footprint thanks to its integrated HVLD module," explains Truelle. It also equips CDM Lavoisier for the current and upcoming requirements of EU GMP Annex 1.



↑ AIM 3000's HVLD inspection turret.

↑ The AIM 3000 inspects ampoules and vials containing solutions and suspensions at an output of up to 450 containers/min.

Technology and project milestones

For Truelle, the highlights of the new technology are multiple: "First, the HVLD module really works for all products, including Water for Injection (WFI). And second, the mechanical aspect of the equipment leads to significantly reduced glass breakage rates during the process."

Syntegon's transportation technology relies on the Bernoulli principle instead of transporting containers via a starwheel using vacuum grippers. This principle allows for contactless handling of glass containers without mechanical stress. In the unlikely event of glass breakage, no glass splinters will be sucked into format parts

↑ The system allows for contactless handling of glass containers without mechanical stress.

or the pneumatic system.

Despite the sophisticated technology, several steps were required to implement the AIM 3000 with the ideal settings for CDM Lavoisier. "The Syntegon team tackled each challenge. It was a real partnership between our two companies," says Truelle. The first major milestone consisted of selecting both good and bad samples for each of the 30 plus products. The Syntegon inspection experts tested all of them offline and developed suitable inspection recipes. Next came the machine layout validation, the Factory Acceptance Test (FAT) in Germany, followed by the re-installation and machine instruction training at the CDM site in France, including Installation and Operational Qualification (IQ/OQ). "Finally, it was time to see whether the new equipment really is more efficient and effective than the previous combination of automated and manual inspection," says Truelle.

End-to-end quality control

For CDM, the AIM 3000 project not only had a positive outcome on the efficiency of inspection processes, but another important optimization was discovered as well. "The more sensitive and sophisticated the inspection process, the more you learn about your prior production processes," says Truelle. "Thanks to the information we obtained from the AIM 3000, we were able to systematically identify and adapt crucial sections within our filling and sealing processes, to make them more stable and to reduce the number of unnecessary rejects even further. In fact, our performance is increasing from week to week."

CDM Lavoisier has successfully managed the technology shift in its inspection of glass ampoules. "We are still in a continuous improvement process. But we can definitely confirm that the Syntegon inspection technology and the entire AIM 3000 project has led to major improvements. After 25 years of successful cooperation, we were already familiar with the professional and future-oriented working methods. This very demanding project with its thorough project management and efficiency has once again convinced us of their qualities as a reliable partner," says Truelle.

5 Tips on Remote Auditing Contract Organizations

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Remote and hybrid audits gained popularity during the pandemic.
2. Partners can reduce personnel exposure with remote viewing, filesharing, and more.
3. Social distancing measures may not always be possible for an auditor on-site.

Onsite audits have always been the cornerstone of a good relationship between healthcare brand owners and their contract service partners. But with employee, animal, and product safety being of the utmost importance in the pandemic, companies have been switching to remote or hybrid audits.

At a recent joint webinar hosted by PDA Southern California and OCRA (Orange County Regulatory Affairs), representatives from **The Jackson Laboratory** (JAX) and an auditor from **IVR Clinical Concepts, Inc.** (IVRCC), shared how they handled a remote audit from a client across the country, allowing for some local "boots on the ground" at the JAX location in Sacramento.

A hybrid audit is where a portion of the audit takes place remotely, with a local auditor visiting the facility to reduce travel and exposure. In this hybrid case, the client on the East Coast was able to perform a document audit, and Angela Bazigos, CEO of **Touchstone Technologies Inc.**, in association with IVRCC, conducted the onsite audit in California.

At first, the client had asked about an in-person audit. Dr. Aaron Rose, Senior Program Manager for JAX In Vivo Services, said that after holding discussions internally, they made the decision that bringing someone in from the East Coast—where COVID-19 was exploding at the time—and risking the health of staff didn't make sense. Karine Lux, Senior Manager, Quality Systems Initiatives at JAX, explored the options and worked to bring in Bazigos.

The trio discussed operations and shared some lessons learned and tips for the future. They also expressed opinions that fully remote or hybrid audits may be here to stay for a number of reasons.

1. Use of existing filesharing

JAX was already using Box as a tool for cloud file management, and they used it to share documents with remote auditors due to security and versatility. "Early on, we were looking at a few different examples of filesharing—some that were actually specifically designed for sharing documentation between organizations when you're having either an audit or a negotiation," said Rose. "We landed on Box because our IT group had already vetted it from a security perspective. And, because we needed to move quickly, we wanted to work with a solution that we had that rather than starting that process from scratch."

Lux added that they have a signed HIPAA Business Associate Agreement (BAA) with Box which was important, and that "files are encrypted in transit as well as at rest. You can easily turn on filesharing and then remove permissions for editing or viewing."

2. On-site local auditor accommodations

For her visits, Bazigos would arrive and fill in a health questionnaire before entry to the facility. Of course, there were also temperature checks, masks, social distancing, and copious amounts of hand sanitizer.

Anyone entering the lab had to change out of their street clothes

and gown up, leaving all personal effects in a locker to reduce the potential for spreading particles.

To some degree there were enhancements from COVID-19, said Rose, including wearing face masks in the corridors inside the lab. But gowning and degowning are already routine procedure for entry for the protection of both people and mice in the facility.

Of course, social distancing can be tough in certain areas. The necropsy lab was crowded, so everyone relied on gowning and masks for protection. In order to view procedures, Bazigos said she was given a stool to stand on due to her shorter stature. Ensure there are adequate tools and adaptations in place for auditors on-site to observe as safely as possible.

3. Cameras

JAX made use of their existing ceiling-mounted cameras, installed for personnel safety. "These became very useful as we brought on remote audits. Auditors can see and zoom into the study animals," said Lux. A step further, auditors remotely observed cell culture procedures in-depth via JAX laptop cameras.

When asked about camera control by an attendee, Lux explained, "We [at JAX] have control of the cameras. We can log on remotely through our VPN to activate the cameras, but they are used from a safety and security perspective, so we don't give control of the cameras to an auditor or clients."

Bazigos advised auditors: "Being in the labs was like being in a Faraday cage. There was no connectivity, I would have had no bars on my cell phone—and I did not have my cell phone with me since I had to leave it at the locker. With the setup, you wouldn't be able to use your own camera, you had to use the lab cameras."

One audience member in the chat noted that his company has been able to use iPhones compatible with their teleconferencing software, after being vetted by their IT department. Bazigos said she would be interested, though it may have to be a lab iPhone as they weren't able to bring their own phones into the labs.

Future Use

Lux said that remote or hybrid audits will continue and are becoming the norm. "We've been able to successfully share documents ahead of time. The auditors come in with their questions rather than having to review documents during the audit. Then we can give them the virtual tour via camera, and offer a side-by-side view during procedures through the laptop cameras."

Rose agreed that remote auditing might be incorporated into general practices post-COVID-19. The practice opens up who can attend and cuts down on travel time and costs. "We were forced into a hybrid in this situation, but I buy what Angela is putting forward here with regards to the idea that you could have an auditing hybrid in general: an audit group that's already part of or hired by a client to look at what a [contract organization] is doing and then a person local to where the CRO operation is happening to go into the facility so that folks don't have to fly quite as much, save on expense, and save on jet lag. I think it's pretty viable. If anything was going to [cause this shift] quickly, I think COVID-19 was the mechanism."

4. Budgeting prep time

"Give yourself plenty of time to get everything set up for the remote audit," said Lux. "It takes time to upload all the documents in Box. Start thinking about the questions that you'll be asked. If you don't have cameras, take pictures (if you can) of the areas that somebody would normally be able to step into but can't right now."

Remote auditors and brand owners/clients may benefit from a facility plan. "I think having a visual picture of the contract facility and the flow before you start looking at the SOPs and so on might be helpful… as well as a very preliminary meeting to discuss how the facility is laid out," added Lux. Whether you are the client or the contact service organization, plan for extra meeting time. Lux said she was glad they had set up another meeting two days after concluding, in case there were questions or additional requests for information that came up at the end.

5. Critical takeaway

Lux offered another can't-miss recommendation: do not forget to schedule in breaks. "Audits go for the full day and you cannot sit there all day trying to sit up straight in your chair because you're on video," and not get up and get a drink. Build in space for bio-breaks and also consider lunch times in various time zones—lunch hour in Sacramento is 3 p.m. in Florida. Breaks also give people a chance to retrieve any documents that may be needed.

1 Modular Small Batch Systems for Liquid Pharmaceuticals

Syntegon

+ Versynta Flexible Filling Platform (FFP) is an individually configurable machine with an integratable isolator for filling aseptic and highly potent liquid active ingredients
+ System can be easily converted to different container types such as vials, syringes, and cartridges, as well as different filling systems including single-use solutions; processes up to 3,600 containers/hr and comes with 100% in-process control

2 Real-Time Visibility for End-to-End Distribution of Temperature-Sensitive Drugs and Biologics

Cold Chain Technologies with Cloudleaf

+ Cold Chain Technologies Smart Solutions enables real-time, holistic, and actionable insights into location and condition of temperature-sensitive drugs and biologics, including COVID-19 vaccines
+ Cloudleaf's Digital Visibility Platform is sensor-agnostic and enables containers with a prescriptive analysis of vaccine conditions down to unit level

3 First-Opening Indication Label for Pre-Filled Syringes

Schreiner MediPharm

+ Syringe-Closure-Wrap delivers clear first-opening indication of the label with one flick of the wrist, protecting the integrity of prefilled syringes and thus enhancing patient safety
+ When the user pulls off the upper part of the label, the integrated first-opening indication is triggered; special security die cuts render label irreversibly destroyed
+ For added protection, overt, covert, or digital authentication features can be integrated into label

4 Continuous Labeling Capabilities

HERMA

+ Suited for expedited, high-volume vial production, HERMA 132M HC Wrap-around Labeler can be retrofitted for continuous operation with new EasySplicer and EasyCutter modules
+ Offering comes amid dramatic push to produce billions of doses of COVID-19 vaccines; considering reels on high-speed labelers require replacement approximately every ~10 minutes, result is improved output through downtime elimination; EasyCutter vacuums empty backing paper, chops it into shreds, and collects for recycling

5 Artificial Intelligence Platform for Detection

Stevanato Group

+ Based on Deep Learning (DL) models, platform is designed to leverage benefits of human-like decision-making in automatic visual inspection equipment; particularly beneficial when applied to difficult-to-inspect and high-value biotech drugs
+ Microsoft Azure platform, machine learning, and AI features deliver "smart" equipment compliant with strict data management and security requirements, while improving inspection performance and reducing costs related to production reparametrization

6 Smart Label and Mobile Authentication

Covectra

+ Next Generation Stellaguard brings mobile product authentication to consumers worldwide; combines two methods of simultaneous authentication with a serialized QR barcode and random patterns/numbers of holographic stars
+ Combines with AuthentiTrack for comprehensive track-and-trace; Secure, cloud-based mobile authentication system
+ Using any smartphone, consumers can scan the product's barcode with a free mobile app to verify product's authenticity

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