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↑ pp.16

HOW AND WHY PHARMACEUTICAL MANUFACTURERS ARE APPLYING ARTIFICIAL INTELLIGENCE

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Brands Serve Patients and Customers Empathetically

Caring about patients has always been central to the healthcare packaging community; COVID-19 brought renewed focus.

While we focus on packaging design for pharmaceuticals and medical devices, the personal care segment also offers examples on empathy in the development process. Take Matt Reynolds' story on Degree's inclusive deodorant packaging on pp. 12—the company partnered with multiple organizations to invite 200 people with disabilities to trial the design and offer feedback in advance of the commercial launch.

Accessibility also received some renewed spotlight due to the pandemic. Unfortunately, one recent study noted that 57% of Americans with chronic conditions delayed healthcare and experienced a gap in care due to COVID-19. On pp. 32, read how Aetna shipped curated kits with over-the-counter items to Medicare Advantage members to help supplement "simple self-care at home."

Inclusion and accessibility are, of course, not just for product and package design. The pandemic has shifted long-held beliefs about the workplace, and this could be an opportunity to make some needed adjustments. As Sara Minkara, U.S. Special Advisor on International Disability Rights, said in a webinar from the American Foundation for the Blind on the future of work, the really important part to bring forward is "curiosity through the lens of compassion, don't make any assumption of what that person needs to be fully included. Really, ask and have that space for them to bring forward their own experience and journey."

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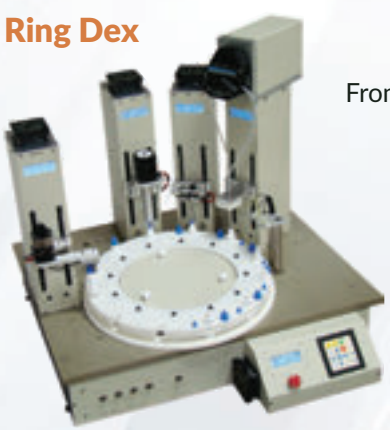

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TIM HAYES,
CONTRIBUTING EDITOR

1 Scientists Create Thermostable Insulin

Insulin is categorized as a cold chain product because it loses potency when exposed to heat or when frozen. The delicate nature of the peptide hormone can be inconvenient for people with diabetes who must constantly monitor their insulin levels and the temperature of their insulin supply. *The Times of India* discussed a new thermostable insulin that was developed by two scientists at the Bose Institute and the Indian Institute of Chemical Biology. The key was introducing a matrix of four amino acid peptide molecules inside insulin molecules, which prevent solidification of the insulin molecules regardless of temperature.

2 New Low-Cost Ventilator Features 3D Printed Origami Tube

The pandemic created a shortage of ventilators that sparked a lot of innovation in the market. A recent *Medgadget* article discussed one such device that replaces the conventional air bag with a 3D printed origami tube. The device was conceived by researchers at Canada's Simon Fraser University who wanted to create a low-cost portable ventilator to help in low-resource or remote regions where healthcare is scarce. The 3D printed origami component consists of interlocking plates that form a tube that is smaller and stronger than the equivalent part on a conventional ventilator, but costs around $1,800 less.

3 Vaccine Patch Outperforms Injection

Over 6 billion COVID-19 vaccine shots have been administered worldwide, which is great, but a recent *News Medical* article says a 3D printed microneedle patch may be more effective. Researchers at Stanford University and the University of North Carolina at Chapel Hill developed a vaccine microneedle patch that's loaded with immune cells that vaccines target. Studies showed that the immune response from the patch was 10 times greater than the traditional needle jab. The patch is painless and can be self-administered. It also doesn't have to be stored in the freezer, which could speed global distribution.

4 Faulty Abbott Labs COVID-19 Tests Lead to Recall

In early September, Abbott announced that some of its COVID-19 tests produced false positives. According to a recent *FierceBiotech* article, the FDA has upgraded the test issue to a Class I recall. The issue stemmed from problematic software employed by processing equipment at the lab. The software automates the mixing of chemicals with samples from patients, but when excess liquid causes overflow into adjacent wells, this can lead to negative samples yielding false-positives. The automated software is being corrected.

5 A BBQ Lighter Inspired This Vaccine Injector

Many new COVID-19 vaccines contain DNA that's encased in lipid nanoparticles. But these special lipid particles increase the cost of the vaccines and require cold storage, which isn't ideal for rural areas and developing countries. *Medgadget* reported that a team of researchers at Georgia Tech repurposed a BBQ gas lighter to administer vaccines via electroporation, which is a microbiology technique that uses an electrical field to make cells more permeable and capable of receiving drugs, arrays, or DNA. The team combined microneedle technology with the piezoelectric sparking mechanism to create what they call the ePatch.

6 Honda is Developing a Navigation Tool for Blind People's Shoes

GPS technology has made getting around a breeze. According to a recent *KNOVHOV* article, Honda is working to bring the technology to shoes in order to help visually impaired people navigate the world. The "in-shoe navigation system" is a device that's connected to the user's shoe and works in unison with their smartphone to help them find a predetermined location. The system consists of two separate motion sensors that vibrate to indicate direction. If the left foot vibrates, it wants you to turn left and vice versa on the right. If both feet vibrate, the user is to continue forward motion.

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41%

LESS THAN HALF of packaging industry professionals surveyed are able to identify production bottlenecks in packaging production. Almost one third use manual systems to identify problems or monitor their KPIs.

Source: PackIOT Digital Maturity Study

$22 BILLION

THE ESTIMATED VALUE of the medical waste management market by 2031, due in part to increasing hospitalization rates. Non-hazardous waste management is expected generate 70% of revenue.

Source: Fact.MR

38%

THE PERCENTAGE of respondents in an HDA poll that cited "lack of trading partner understanding and/or commitment" as an obstacle to building, integrating, or adopting EPCIS for pharmaceutical traceability.

$4.9 BILLION

THE ESTIMATED MARKET for printed sensors by 2032, driven by demand for connected sensor networks. The market includes biosensors, skin patch and medical electrodes, temperature sensors, and force and piezoresistive sensors used in some medical devices.

Source: IDTechEx

DSCSA: INTEROPERABLE ELECTRONIC PRODUCT TRACING TO THE PACKAGE LEVEL

"We can't state enough that we know this is going to be challenging. We know there's a lot of work to be done, but **we are optimistic that we will have enhanced drug distribution security as of November 2023**. This is going to be across the entire distribution supply chain."

—CONNIE JUNG, RPH, SENIOR ADVISOR FOR POLICY, FDA

"Global data shows that consumers across the board have sustainability as a top three choice criteria now, which was not the case a few years back. Even [those with] lower incomes, despite the affordability issue, find it extremely important."

—KONSTANTINOS APOSTOLATOS, MANAGING DIRECTOR AND SENIOR PARTNER OF THE BOSTON CONSULTING GROUP

"A really good mentor is more than happy to **share their mistakes**... Everyone makes a mistake and it's not that the mistake was made. It's more **how you handle it** and how you recover from it."

—CEO TRACEY NOONAN, AT THE PACKAGING & PROCESSING WOMEN'S LEADERSHIP NETWORK (PPWLN)

CDMOs Expected to See Boom in 2022

Driven by the pandemic and record investments in the discovery pipeline, contract development and manufacturing organizations (CDMOs) are experiencing growth and a record number of acquisitions, which are expected to increase over two to three years. This is according to the *2021 CPhI Annual Report*, which notes that "booster vaccines and capacity constraints during a period of record R&D investment are driving up prices for specialized facilities, advanced therapies, and biologics." Co-author Adam Bradbury, Analyst at GlobalData PharmSource noted, "COVID-19 vaccine developers signed contract manufacturing agreements at an unprecedented rate during 2020/21 because many of these sponsors are small companies or non-profit institutions that lack manufacturing capabilities. Even the largest companies require extra capacity to supply billions of doses."

—Keren Sookne

Point to Ponder: Extra Hurdles in Employment

While leadership programs can offer undeniable benefits, it's important to think critically about whether employees from marginalized groups are being required to take them while others are not. Says one biotech director, "Though I've led successful teams for over 10 years and oversaw 40 individuals at my previous organization, I was selected for an emerging leader program. I'm excited about the content and networking, but I did the same program at [previous company] and in my master's program. I'm being told I need this before I can move up into a leadership position, yet my male counterpart was promoted without leadership classes. How do we move the needle as women to achieve equality in a male-dominated industry?" More on the broken rung at **hcpgo.to/rung**

—Keren Sookne

COVID-19 Vaccine is Now in Antarctica

A recent *BBC* article discussed the long-awaited arrival of the AstraZeneca vaccine in the Antarctic. Nine months after the vaccine was released, it was flown in and administered to the 23 staff members conducting research at the British Rothera Station. Rothera has been in lockdown since March, when only a skeleton crew remained at the base to wait out the polar winter. Deployment involved a near 10,000-mile trek where guardians were required to maintain the 2-8°C storage temperature with the help of a special transport container. First doses were administered by the on-site doctor, with second doses planned for four weeks after.

—Tim Hayes

Suppliers in the News

- **UPS Healthcare**'s **Marken** has expanded its global network to support increased demand for its clinical drug supply chain services, particularly for cell and gene trials.
- **Rondo-Pak** announced a major solar energy project at its Camden, NJ, headquarters—the $4M investment is expected to generate 60% of the facility's electricity needs.
- **Aptar CSP Technologies** was awarded a $19 million government contract to expand production capacity for its Activ-film™ technology used in COVID-19 test kits.
- **Tjoapack** acquired **Pharma Packaging Solutions**, which provides services such as commercial packaging and cold chain storage.
- In 2021, **Koehler Paper** switched to 100% green energy for its new production line, saving 45,000 tonnes of CO_2 per year.

Two New Systems Win 2021 Drug Delivery Innovation Awards from PDA

The Parenteral Drug Association (PDA) announced the winners of the 2021 PDA Drug Delivery Innovation Awards during the Universe of Pre-Filled Syringes and Injection Devices conference. Awardees were recognized for their technical innovations in advancing the field of bio/pharmaceutical manufacturing.

The Innovation Award was presented to Roche Genentech for the Port Delivery System with ranibizumab. The drug delivery device is an innovative, investigational, permanent, indwelling, ocular delivery system that includes a surgically placed implant for continuous delivery of a customized formulation of ranibizumab into the vitreous. After implantation, the device uses a refill exchange process to replenish the fresh drug.

The Partnership Innovation Award was presented to **Syntegon Technology GmbH** and **Vetter Pharma-Fertigung GmbH & Co. KG** for the Versynta microBatch, a system based on a gloveless isolator cell with a versatile robot, responsible for filling, line set-up, and environmental monitoring. With the focus on flexibility, a broad range of pre-sterilized packaging components including pre-filled syringes, cartridges, or vials made of glass or plastic can be handled with virtually no product loss. A comprehensive monitoring system and 100% fill weigh checks allow for continuous process control, with an output of 120 to 500 containers/hr.

—Parenteral Drug Association

6 Sustainability Drivers in Temperature-Controlled Logistics

Why it's easier to choose more sustainable options in temperature-controlled logistics than it was just a few years ago.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

There are so many reasons to make more environmentally friendly choices: personal goals, company goals to be seen as a leader, concerns over future regulations, and more. Some merely don't want to be left behind because this is the way the industry is moving.

First, a note: sustainability means different things to different people. There are so many ways to measure it—there are goals around energy and water use, cutting carbon emissions, switching to renewable energies, material choices, and more. Health systems may look at cutting the use of certain gasses in favor of more environmentally friendly ones. Some life science manufacturers look at electric vehicles for local sample transport, find ways to recycle internally, or measure compressed air usage in the plant and make cuts based on those measurements.

Another way to cut down on consumption lies in switching to reusable or greener single-use transport packaging where possible, including shippers, data loggers, totes, tubs, and phase change materials (PCMs). The following are six reasons why it's easier to make this switch now than ever before.

↑ Returns logistics remain a challenge for the healthcare packaging community.

↑ A reusable MilliporeSigma cooler features a return label showing the simple procedure for shipping the cooler back, making the process easy for busy lab managers and techs.

1. The financial sector is onboard.

Making sustainable choices is no longer just for the "green set." Investors are increasingly looking at environmental factors such as ESG Ratings, which are designed to measure a company's resilience to long-term, industry-specific environmental, social and governance (ESG) risks. There are certainly semantic and practical details to be hammered out in this arena, with some European fund managers dropping the "ESG-integrated term" perhaps due to Europe's anti-greenwashing rules. The bottom line is investors are seeking meaningful climate-friendliness.

In the Reusable Packaging Association's article, *Climate Change Interest Isn't Ideology, It's Economics*, they highlighted a peer-reviewed

article where researchers found that in a survey of 439 investment professionals, only 7% of institutional investors said they had done nothing to manage climate risks in the last five years. Sustainable initiatives are everywhere, including in the financial sector.

READ

Read this story about logistics questions to ask in light of a changing climate at **hcpgo.to/364**

2. More and more, we're seeing guidance from end users on selecting products from manufacturers making sustainable choices.

For example, there's Kaiser's Environmentally Preferable Purchasing (EPP) Initiative and Practice Greenhealth's sustainable procurement guide for health systems. This means that those who are making sustainable choices can be seen as having a competitive advantage for purchasing decisions, because this is what end users are being guided toward.

3. There are trusted industry associations leading the charge to help life science manufacturers.

The Reusable Packaging Association covers an array of topics and industries, with the goal of boosting reusable transport packaging.

ISTA's Pharma Committee is a collaborative group (end users, suppliers, and service providers) working together on industry standardization for reusables in temperature-controlled life science products. They produce practical guidance documents to help companies implement reusable packaging specific to the unique needs and challenges of healthcare products.

To avoid painting an overly rosy picture, the industry is still figuring returns logistics. It can be hard to get customers to send materials back. However, the broader the adoption of reusable packaging, the more routine it will become for customers to send packaging and components back. Tactics such as including return labels, easy instructions, and pictograms (*see image, left*) may boost success.

4. COVID-19 highlighted that some components may run low in the supply chain, particularly if sourced internationally.

People are still experiencing longer lead times for resin and packaging components. There were concerns over dry ice quantities—mere headlines in the news can cause supply worries. The act of using reusables may help with maintaining inventory so companies are not relying on market fluctuations.

5. Partners up and downstream are watching.

Filed under surprising but true: 52% of biopharma cold chain leaders surveyed by **Peli BioThermal** indicated that they were audited for sustainability by *vendors supplying their organizations*.

Each year, people are more adept at spotting greenwashing claims. It's not enough to make claims, manufacturers have to walk the walk and their partners are looking. A Takeda expert noted that it might become a must soon to be able to do business in certain markets or countries.

This is not easy by any means—brand owners don't want to make sudden reactionary process or material changes with unintended consequences. It often requires a life cycle analysis to determine what "sustainable" means to an organization. Patient safety remains critical.

6. Technologies have come so far.

While per-unit cost may be higher for more sustainable transport packaging, it's easier to pitch to leaders if upgrades can improve performance in shipping lanes and reduce product damage, packaging waste, and their (major) associated costs.

When **Cardinal Health** switched to plant-based reusable PCMs, they found more uniform cooling since water-based PCMs can offer inconsistent cooling after melting. In that same project, reusable shippers improved freight utilization, with the ability to commingle refrigerated and controlled room temperature (CRT) products on the same truck. Ultimately, they reduced product damage and solid waste, saving millions.

The great news is that companies don't have to completely reinvent the wheel. They can lean on suppliers, industry peers, and organization like ISTA and the RPA to evaluate and make changes. There are success stories already out there.

Life Sciences Logistics Playbook

Shipping temperature-controlled products? Get tips on preventing excursions and waste, developing a validation master plan, characterizing shipping lanes, and more. Download the free PDF at **hcpgo.to/logisticsplaybook**

People with Limb, Vision Disabilities Gain Access with Inclusive Deodorant Pack Design

A deodorant pack prototype from Unilever's Degree brand, in beta-testing in certain communities, makes the deodorant application process much more accessible.

MATT REYNOLDS, EDITOR, *PACKAGING WORLD*

Degree Deodorant, a Unilever brand and maker one of the world's best-known antiperspirants, introduces what it calls the world's first inclusive deodorant for people with visual impairment and upper limb motor disabilities: Degree Inclusive.

One in four Americans has a disability, yet products are rarely designed with this community in mind. According to the brand, across the beauty industry, there is currently no deodorant product suitable for people with upper body disabilities to use. Twisting a deodorant cap, turning a stick, or pushing down on a spray with limited arm mobility is a real challenge. In addition to meeting the needs of those with disabilities, Degree Inclusive offers refillable packaging to limit waste impact and a gender-neutral fragrance.

Degree partnered with an inclusive team of design experts from brand agency **Wunderman Thompson**, including occupational therapists, engineers at **SOUR Studio**, consultants, and people living with disabilities across the globe to create a prototype for Degree Inclusive. The pack has been designed with the following features as noted in the brand's product development video (check it out here: **hcpgo.to/degreevideo**):

- A hooked cap design and integral handle on the base for one-handed usage
- Magnetic closures that make it easier to take the cap off and put it back on for users with limited grip and/or vision impairment
- Enhanced grip placement for easier application for users with limited grip or without arms
- A braille label with instructions for users with vision impairment
- A larger roll-on applicator to reach more surface area per swipe

To ensure this original prototype is effective and accessible, Degree is running a beta program to engage and get input from people living with disabilities. In partnership with The Chicago Lighthouse, Open Style Lab, and Muscular Dystrophy Association,

The pack design includes a larger roll-on applicator to reach more surface area per swipe.

Degree has invited 200 people with disabilities in the U.S. to trial the prototype design and share their feedback on the concept, product features, and messaging, to help improve the innovation for its future commercial launch.

"As a brand that's committed to inspiring confidence in everyone to move more, Degree believes no one should be held back from experiencing the transformative benefits of movement," says Kathryn Swallow, Global Degree Brand Vice President. "More than 60 million people in the U.S. live with a disability, yet products and experiences are still not designed with this community in mind. With Degree Inclusive we hope to inspire bold action across the industry to ensure that people with disabilities have an equal playing field."

READ

Read this article on how brands and CPGs are reinventing themselves and their packaging to stay relevant to Gen Z: **hcpgo.to/genz**

As the project rolls out, look for commercials depicting real athletes using the product. Watch two brief commercials at **pwgo.to/7014** and **pwgo.to/7015** to see the application in action.

The brand says that Degree Inclusive marks the beginning of its frontier into accessible design and that they look forward to making further progress on its long-term commitment to create equitable access to movement for all.

"Breaking stereotypes unleashes creativity and drives growth. Degree Inclusive challenges what a deodorant product should be. It's a breakthrough accessible design that genuinely serves the needs of people with visual impairment and upper limb motor disabilities," adds Aline Santos Farhat, EVP of Global Marketing and Chief Diversity and Inclusion Officer at Unilever.

Prototype development

Developing an entirely new pack out of whole cloth for a specific community involved a lot of R&D. Degree sought out prototyping and design consultant SOUR to take this process on.

"In addition to desk research and expert interviews, we collaborated with eight people living with diverse disabilities to explore challenges in deodorant application, co-ideate solutions, and gather feedback on design iterations," says Pinar Guvenc, Partner at SOUR. "The design is inclusive of people with limited mobility or visual impairments, while also bringing ease in application and flexibility in use to a broader audience."

The studio 3D printed various iterations in-house in order to test ergonomics. After several iterations, Guvenc shared the 3D print prototypes with the co-creation panel, including other stakeholders, to gather feedback on the form and ergonomics. This feedback led the company to the final prototype.

"The final prototypes have been scaled for the trial through reaction injection molding, using PU [polyurethane]," Guvenc says. "The pack consists of four components: The hook cap, the thread body (that allows for the pack to be refillable), the base and the roll-on ball. The base is hollow to house deodorant content, and the hook cap is hollow to store the roll-on ball.

Six magnets are used, three on each end of the cap and the base. SOUR had to ensure that the cap did not attach to the base incorrectly, misleading the visually impaired users to assume the cap was closed when it wasn't. So, the magnets are situated in a way that would only allow for the hook to make a 180-deg turn, and make sure it's closed tightly either way.

The magnets also provide auditory confirmation for the visually impaired on closure as well, so SOUR used a number and configuration that delivered an audible "click" sound, and a tactile "click" feel. The separation does not require much force when pulled down, either when hanging by its hook, or when held on the other hand. At the lip of the base, a molded, teal-colored collar "label" includes the product description in print, and in braille for the visually impaired.

Still in beta-testing, neither retail pricing for starter kits, nor pack design or price for refills, are available yet. *Packaging World* will follow this story through commercial launch.

MORE THAN 60 MILLION PEOPLE IN THE U.S. LIVE WITH A DISABILITY, YET PRODUCTS AND EXPERIENCES ARE STILL NOT DESIGNED WITH THIS COMMUNITY IN MIND.

—KATHRYN SWALLOW, GLOBAL DEGREE

Automated Packaging for Insulin Reservoir Syringes

Rapid Development Services and Multivac team up to develop an automated system to package insulin reservoir syringes into a form/fill/seal machine.

CALLAN KEETER, CONTRIBUTING EDITOR

For manufacturers, the continual need to increase production speed and efficiency while reducing labor has spurred a shift toward implementing more automated systems. However, off-the-shelf equipment will not accommodate every application—especially those that are complex with robots and conveyors, or with a host of equipment for manufacturing and assembly in addition to packaging, labeling, and palletizing. These all must be flawlessly coordinated.

"While implementing off-the-shelf solutions can be a starting point for some projects, automating and incorporating robotics frequently requires a custom solution that meets very specific process requirements. For this reason, even large suppliers in this space will often pass on opportunities if they are not easily resolved," says Leon Gurevich, Founder and Chief Technology Officer of **Rapid Development Services** (RDS), an industrial automation equipment builder and integrator.

According to Gurevich, to avoid delays or failure on larger, more complex projects, it is particularly important to work with a supplier that not only has automation expertise but is also nimble and flexible. (Visit **hcpgo.to/sixtrendspharma** for more on automation.)

"When it comes to automating production, equipment can range from very small to complete lines several hundred feet long that can consist of robots, conveyors, vision systems, servo drives, etc.," says Gurevich, who has worked with companies such as Medtronic, Johnson & Johnson, Abbott Labs, and Pfizer. "So, automation suppliers and integrators need a 'tool box' full of solutions including the ability to design and build from scratch in order to fit together all the pieces of the puzzle."

For example, after a major medical device manufacturer received FDA approval of a real-time insulin pump for continuous glucose monitoring, the company needed to automate production with specific attention to packaging.

RDS was called on to develop an automatic system to package insulin reservoir syringes into a **Multivac** form/fill/seal (f/f/s) machine, followed by carton and case packing for ready-to-ship product delivery.

The reservoir syringe was presented to the system in a bulk form. The robotic system utilizes vision inspection to check for the presence of subcomponents before placing reservoir syringes into the formed web cavities on the Multivac machine. The vision inspection identified the presence of the plunger, guard, and overall geometry pattern of syringes by inspecting a set of 10 units/cycle. The system used two six-axis robots, two vibro-feed bowls, and the Multivac web machine to feed, pick, place, and seal reservoir syringes.

↑ **Off-the-shelf equipment will not accommodate every application, particularly those that are complex involving equipment for manufacture, assembly, packaging, labeling, and palletizing that must be flawlessly coordinated. Photo courtesy of RDS.**

↑ **The rising prevalence of chronic diseases and the increasing adoption of automated equipment for diagnosis and therapy are propelling market growth.**

With the robotic system, each of two cells packaged product at a rate of over 120 reservoirs/min, for a total of 240 units/min. The packaging system also had a carton erector, and the sealed packages were robotically inserted into cartons.

RDS initially installed the system in a California plant, which ran the robotic system trouble-free in a clean room for more than five years.

At the company's request, RDS disassembled, moved, reinstalled, and started up the system at a new facility in Puerto Rico, where it has continued to run three shifts per day for another 10 years, according to the company.

In addition, RDS partnered with Multivac to provide engineering and robotic integration services for multiple projects for both medical device and consumer cosmetics applications.

The company has built robotic part handling and unloading systems to load parts into a thermoformed web of the Multivac f/f/s machines, and to unload form, filled, sealed packages and pack parts into cartons and cases after the Multivac machines perform their functions.

LISTEN

Listen to this podcast, *Help Wanted, and Fast!* with Stephanie Neil on the issues causing manufacturers to have a hard time filling well-paying, career-level positions at: **hcpgo.to/helpwanted**

"In RDS's partnership with Multivac, we have utilized proprietary technologies for feeding, staging, and loading an array of parts per each machine cycle with up to 60 parts per pick with a single robot," says Gurevich. "The solution allows one robotic cell with a single six axis robot to place parts into Multivac at rates of up to 800 parts/min."

According to the market research and consulting company Grand View Research, the global medical automation market is expected to reach $79.4 billion by 2024, growing at a compound annual growth rate of 9.9% from 2016 to 2024. The company cites the rising prevalence of chronic diseases and the increasing adoption of automated equipment for diagnosis and therapy as the factors propelling market growth.

So, whether packaging device manufacturers need help automating their production, or need the equipment used in other settings, partnering with an expert in automation can be the surest route to ensuring compliance, reliability, and efficiency.

"Companies sometimes shy away from automation when only focusing on direct labor savings or short-term ROI," concludes RDS President Sunit Mishra. "However, if you factor in increased production speeds and improved quality along with reduced waste, labor management savings, labor hiring and training savings, as well as repetitive motion injury, the investment in automation usually provides an attractive ROI in the short term itself."

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How and Why Pharmaceutical Manufacturers Are Applying Artificial Intelligence

DAVID GREENFIELD, DIRECTOR OF CONTENT, *AUTOMATION WORLD*

TOP THREE TAKEAWAYS

1. The pharmaceutical industry seeks to optimize production with AI but has a long road ahead.
2. Advanced analytics are on the rise for creating opportunities to reduce manufacturing costs.
3. Pharma success stories find that AI applications reduce downtime and prevent production losses.

Advances in the application of artificial intelligence (AI) are starting to have a significant impact on automation technologies used across industry—most notably with machine vision and analytics. And some of the more impactful applications of AI are happening in the pharmaceutical industries.

It shouldn't be too surprising that the pharmaceutical industries are looking to optimize production with AI, considering that single batch values for some drugs can exceed $3 million. Yet, research indicates that this industry lags behind many others when it comes to using analytics to improve production.

According to David Leitham, Senior Vice President and General Manager, Pharmaceuticals, at **Aspen Tech** (a supplier of AI software for industrial manufacturers), while other industries have been applying analytics and predictive capabilities to optimize performance and react rapidly to changes in demand, 87% of pharmaceutical industry executives admit their organizations have a poor digital culture.

The data Leitham references comes from an AspenTech survey of 300 senior pharmaceutical executives in the U.K., U.S., Germany, France, Spain, and Sweden. This same survey also shows that 49% of respondents admit struggling to use data to improve time to market for their products.

"COVID-19 not only triggered a rush to develop a vaccine, it had serious impacts on demand for drugs already in production," said Leitham. "The whole velocity of the market has accelerated—but our research reveals that the pharmaceutical industry has much farther to travel before it gets up to speed."

↑ **Pharma companies are turning to AI for production optimization.**

Asset management, predictive maintenance, and analytics

Two areas of AI application focused on by pharmaceutical companies include asset performance management tools using advanced analytics to create manufacturing efficiencies and predictive maintenance systems to analyze failure patterns and provide anomaly alerts and advance warnings of pending equipment failures.

"Opportunities to reduce manufacturing costs exist across all stages of the product lifecycle. Advanced analytics can reveal those opportunities, allowing pharma companies to take informed action to save money," said Richard Porter, Global Director, Pharmaceuticals, at AspenTech. "Whether using multivariate analytics to identify process degradation and its impact on quality or predicting final product quality to reduce lab testing lag times, these techniques offer pharmaceutical companies a competitive advantage."

Porter also noted that multivariate analytics software can be

applied to existing data sources in pharmaceutical manufacturing facilities to analyze and continually monitor how discrepancies in material properties, variations in procedures, and process anomalies such as sensor drift and changing environmental conditions impact the final product.

"These tools can help identify and troubleshoot process and product quality issues, increase yields, and reduce off-spec product," he added.

WATCH

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

Applying AI in pharma

Highlighting specific types of equipment that predictive maintenance systems have been proven to effectively protect, Porter pointed to primary equipment such as air and centrifugal compressors, boilers, pumps, and water purification systems.

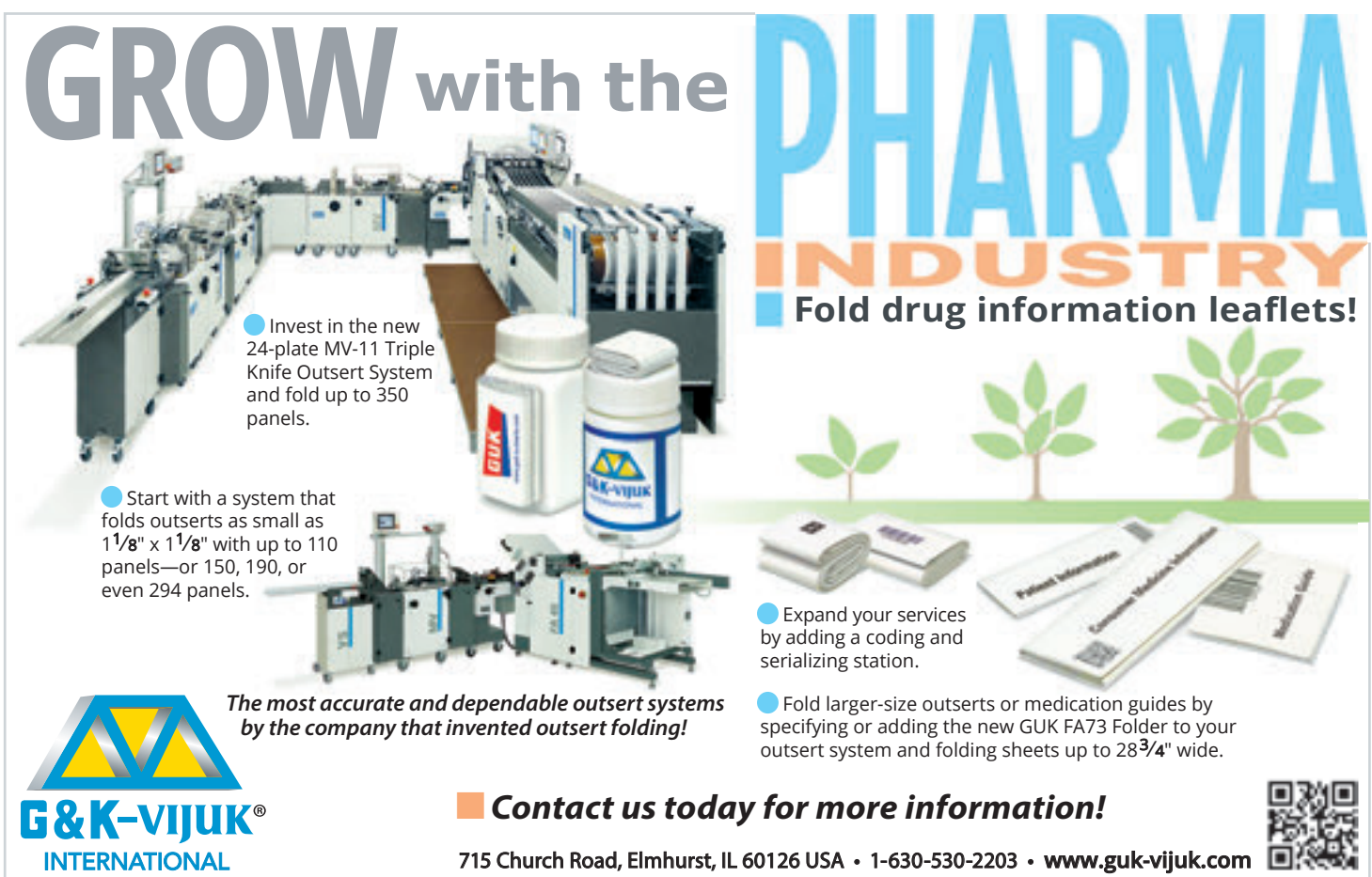
AI can also be applied to secondary production and packaging equipment such as autoclaves, bead mills, centrifuges, chillers, conveyors, granulators, fluid bed and plate dryers, roller and tablet presses, and spray heads.

Porter said one pharmaceutical company AspenTech worked with was replacing the mechanical seal in its bead mill every eight batches to prevent batch loss—at an equipment cost of $25,000 per replacement.

"The company tried to avoid batch losses—with each batch valued between $250,000 to $300,000—as frequent shutdowns to replace the seals limited capacity," said Porter. "As the company needed to ramp up capacity, it purchased two additional mills. Adopting Aspen Mtell, which connects to OPC UA supported devices, for predictive maintenance allowed the company to reduce supply chain disruptions from seal replacements and cut lifecycle maintenance costs by 60%. In addition, the company reduced capital expenditures and associated lifecycle maintenance costs by 50%."

Another pharmaceutical application Porter cited revolved around failures of a purified water system. "These failures shut down entire sections of the plant for as long as a week," he said, "resulting in the production loss of 15 batches."

Using Aspen Mtell to predict pending breakdowns provided the company with 35 days advance warning of a deionizer failure, allowing staff time to schedule maintenance and prevent production losses, according to Porter.



Fresenius Kabi Goes Above and Beyond DSCSA Requirements

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Fresenius Kabi is implementing RFID tracking on the unit-of-use level.
2. RFID tagging is inconspicuous to packaging line operators through the use of antennas.
3. RFID tagging is not a DSCSA replacement but an addition to 2D data matrix barcodes.

The **U.S. Food and Drug Administration** (FDA) put into effect the Drug Supply Chain Security Act (DSCSA), which was enacted by Congress in November of 2013, in order to outline the steps necessary for the industry to build an electronic, interoperable system by 2023 to identify and trace—through the packaging and homogenous cases of products—prescription drugs as they are distributed throughout the U.S.

This legislation is meant to develop and enhance drug supply chain security and includes product tracing requirements which went into effect in 2015 for manufacturers, repackagers, wholesale distributors, and dispensers such as pharmacies.

The DSCSA requires that manufacturers and repackagers affix or imprint to each package and homogenous case of product a product identifier, which includes:

- The product's standardized numerical identifier—composed of the National Drug Code (NDC) and a unique alphanumeric serial number
- The lot number
- The expiration date

This information must be included in a 2-dimensional (2D) data matrix barcode for packages and either a linear barcode or 2D matrix data barcode for homogenous cases which complies with current good manufacturing practice (cGMP).

GS1 US, a not-for-profit information standards organization, provides a system of standards for identifying products, locations, and logistic units, thus enabling manufacturers and repackagers to meet the DSCSA requirements. This allows pharmaceuticals in packages and homogenous cases to be tracked and traced from manufacturers to the receiving docks of healthcare providers at the unit-of-sale level. However, the management of medicines throughout hospitals—from receipt to administration, or at the unit of use level—is not within the scope of DSCSA.

GS1 US member company, Fresenius Kabi—a healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition—was approached three years ago by many of its customers (hospitals and pharmacies) about implementing RFID tracking on medication inventory, which they had been adding manually in a time-consuming and tedious process. Fresenius Kabi's customers had found RFID tracking to be more accurate than barcodes, allowing them to scan many drugs at once, more easily track expiry dates, and better maintain tighter inventory levels. *Healthcare Packaging*'s two part series on RFID (**hcpgo.to/part2rfid**) implementation at Allegheny Health Network goes into further depth on the interest in RFID from a dispenser perspective.

↘ The company began implementation of its +RFID system at its Sweden facility (Photo credit: Fresenius Kabi).

Implementing RFID

So, the company began research into RFID that took up the majority of a year. Considering the lack of mature RFID system vendors available, Fresenius Kabi turned to **eAgile**, a vendor that supplies both RFID-enabled labels and RFID equipment, and spent the next year on the initial equipment design and implementation. In early 2020, the company began implementation of its +RFID system at its Sweden facility, which Jeanne Sirovatka, Senior Director for Packaging Design and Technical Projects at Fresenius Kabi, as well as analytical chemist, explains ran into a few snags when the COVID-19 pandemic hit. Implementation was slowed as countries went into lockdown and the company could no longer send in its U.S. team (that had conducted the research) in person and resorted to using many virtual conferences instead. "Ultimately, we got it done and

it all worked out, but I would have preferred not to do this during a pandemic," Sirovatka says. So, in the fall of 2020, Fresenius Kabi reportedly became the first pharmaceutical manufacturer to embed medication identification data into an RFID tag, relying on GS1 Standards to permit full interoperability and compatibility.

In Fresenius Kabi's research, customers responded that they wanted the NDC, lot number, expiry date, and serial number provided in the RFID tags. The company has been using these tags on specified products, including glass and plastic vials and syringes, which were commonly tagged by its customers in anesthesia and similar fields.

Each RFID tag is embedded into the existing label so it can run on the company's existing packaging lines and this makes the process fairly invisible to the packaging line operators with no physical interaction at the packaging point. The tags are pre-encoded with the Global Trade Item Number (GTIN), and a unique serial number at the eAgile facility. They are encoded with the lot number and expiry date on the Fresenius Kabi packaging line via antennas that interact with the tags through radio frequency. Tags that are unreadable or with incorrect information encoded are rejected from the line.

The RFID antennas, interrogation equipment, and at some facilities the reject equipment (depending on the configuration of the line) were purchased primarily from eAgile. "This gives us a universal solution," says Sirovatka.

Pros and cons

READ Read this story about the benefits of low-cost IoT stickers on pharma and medical device packaging at **hcpgo.to/389**

While testing its RFID system on a syringe plant, Fresenius Kabi learned the hard way that the environment can interfere with the antennas, such as the placement of a metal ladder too close to the antenna, or the presence of water. "Subtleties like that in the environment really had a much greater effect on the equipment than anyone who is new to this technology would have expected," says Sirovatka.

Sirovatka also explains that with vial sizes and RFID reflectivity being unique and dependent on vial material, the RFID tag antenna must have the capability to be customized so that the tags have the signal strength required in the hospital systems.

In addition, with aggregation needs and the cost of the RFID system, this solution is not meant to be a DSCSA replacement but rather an addition to 2D data matrix barcodes. This makes RFID tags an added layer of protection for pharmaceutical integrity for the sake of patients, while saving healthcare providers time and providing precise inventory control throughout hospitals.

Fresenius Kabi's customers have responded positively to +RFID, appreciating these pre-tagged, ready-to-read products that are of high quality and reliability. Gwen Volpe, Director of Medication Technology for Fresenius Kabi and trained pharmacist, says, "Currently, RFID is in its infancy and gaining momentum in the United States. Eleven percent of hospitals are now using this technology and the numbers are growing every day."

Other benefits of using an RFID system include strengthening the DSCSA serialization regulations through the combination of the GTIN, serial number, and tag ID being embedded into the label, which further reduces the threat of counterfeiting.

In the event of a recall, the serialized RFID tags allow items to be identified and pinpointed down to the expiration date and lot number, as well as other related manufacturing details. RFID-tagged medication can also reduce inadvertent entry error changes to a medication's product data at the hospital and other points along the supply chain.

GS1 US involvement

Using GS1 Standards makes the RFID tags readable anywhere, allowing the industry consistency and delivering on interoperability. "The vast majority of the vendors we asked were adamant that we follow GS1 Standards," says Volpe.

According to the company, "GS1 Standards enable any supply chain participant across the globe to read data with the proper RFID equipment, including hospitals and pharmacies that comprise Fresenius Kabi's primary customer base. By tagging each dose of medication, the healthcare provider and patient have an additional serialized measure of unique product identification." This further allows Fresenius Kabi the potential to work with all of their customers' RFID tracking system vendors, thus enabling the customers to choose the system that's right for them.

GS1 US played a supporting role throughout, beyond spreading the word about RFID benefits. They worked closely with Volpe, Sirovatka, and other Fresenius Kabi employees who were involved in creating the company's RFID system, +RFID, to publish a case study and create a white paper at the end of 2020 to help other companies embarking on the RFID path. GS1 US also provided its RFID specialist to guide and collaborate with Fresenius Kabi to confirm the company was taking the correct approach, consistent with GS1 Standards.

"GS1 US approached us about the case study to guide others who are going to be going down this path and we're happy to help. It's not always easy being the first, but you can use the experience to assist others as they join you. Using GS1 Standards ensures customers have a consistent experience with our pharmaceutical products and ensures the most important data attributes are always at our customers' fingertips," says Volpe.

Supply Chain Digitalization is a Source of Differentiation for High Performing Organizations

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

TOP THREE TAKEAWAYS

1. A recent study shows that high performing orgs are 2.5 times more likely to say their supply chain digitalization efforts are differentiators.
2. These organizations are also 2.5 times more likely to be early adopters of various emerging technologies.
3. Leveraging supply chain data by using advanced analytics allows organizations to make proactive rather than reactive decisions.

The University of Tennessee's Dr. Randy Bradley conducted a study with his colleagues seeking to understand the current state of global supply chain digitalization. Bradley and his team received more than 1,400 responses from business industry leaders and professionals in supply chain analytics and IT, representing more than 27 different industries on seven continents. Sixty-four percent of the organizations reported that their annual revenues are over $500 million, and of those, 29% say that their revenues exceed $5 billion.

Speaking at the HDA Distribution Management Conference, Bradley said that high performing organizations were 2.5 times more likely to say that their supply chain digitalization efforts were the source of differentiation for them in the marketplace. He added that these organizations are "no longer just competing on price, or competing on product, or competing on quality of service, what they're saying is the way we're investing and driving digitalization is making a difference in the marketplace for us as an organization."

These organizations are also 2.5 times more likely to be early adopters of various emerging technologies such as advanced robotics, predictive and prescriptive analytics, artificial intelligence, machine learning, or blockchain. Bradley cautioned that digitalization is not all about technology but said that a culture of innovation and experimentation is a different mindset that allows these organizations to determine if a particular technology is going to be of value to them.

These same organizations are also more likely to see the pace of their digital transformation being driven at the enterprise level, or, said Bradley, "the supply chain is not necessarily leading the organization, the organization is leading the supply chain." The study found that leaders of high performing organizations are more likely to adopt emerging technologies sooner in both their personal and corporate life. Supply chain professionals, however, were found to be more risk-averse to the early adoption of emerging technologies. Bradley said that being cognizant of this tendency is the first step, and then "once we're cognizant of it, we have to make sure that when we're making decisions on behalf of our organizations, that we don't allow our own biases or our own apprehensions with respect to emerging technologies to get in the way of the vision and

the mission of the organization that we have espoused to serve."

READ

Read about how supply chain is a key facet of brand sustainability plans: **hcpgo.to/supplychainkey**

↑ **Dr. Randy V. Bradley, Assistant Professor of Information Systems and Supply Chain Management, University of Tennessee.**

Bradley added that a journey to transform both the organization and the supply chain often takes seven to 10 years, and with the rate of change and advancements in technology, what you start with may not be the technology you end with. Therefore, it is important to focus on the "operational backbone" to lay a foundation. "What are your core operational systems?" asked Bradley, "Whether it's your enterprise resource planning system, customer relationship management system, supplier relationship management system, inventory management system, yard management system, distribution systems, or your manufacturing execution systems... whatever is fundamental or foundational or core to your organization, that's where you have to focus, because that's what you're going to continue to build on. All the other solutions are wrappers. You're going to wrap them around [the core] and that's going to enable much of your digital capabilities and your digital competence."

Another finding of the study was that leveraging supply chain data by using advanced analytics allows organizations to make proactive rather than reactive decisions, and 75% of high performing organizations favor predictive and prescriptive analytics as a key aspect of supply chain digitalization.

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From Data to Labor: Manufacturers Are Trying to Make Sense of Traceability Requirements

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. HDA surveys reveal much work is needed to meet 2023 DSCSA requirements.
2. Aggregation, a prerequisite to sending serialized transaction data, has slowed.
3. One company says outbound scanning may require a 12 to 15% increase in their headcount.

Experts continue to sound the alarm on DSCSA compliance progress in the pharmaceutical manufacturing industry, both on implementing GS1 Electronic Product Code Information Services (EPCIS) and trading partner plans for exchanging data. The upcoming November 27, 2023, DSCSA compliance date requires transaction data with product identifiers to be provided with physical product.

As Jeff Falardeau, Manager, Pharmaceutical Information Technology at **Cardinal Health**, said at the Healthcare Distribution Alliance (HDA) 2021 Traceability Webinar Series in April, "...we're just really concerned about the runway left and the number of manufacturers that still need to jump in the pool here and start testing with us before 2023."

WATCH

Watch this video on exchanging master data via EPCIS files: **hcpgo.to/dataexchange**

EPCIS work continues

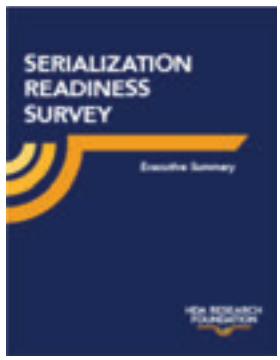
In September, HDA's Research Foundation released its inaugural report, *EPCIS Implementation Benchmarking Survey*, enlightening industry trading partners on the status of successful data connections, defined as "[connections that are] fully integrated and working in a production environment," and highlighting perceived obstacles to implementation.

The 16-page report reflects responses from 70 companies across the pharmaceutical supply chain, including manufacturers, distributors, and 3PLs. The results offered some startling statistics, including the following:

- 59% of manufacturers report they are not currently sending data to distributors—HDA says manufacturers cite "delays due to either past or potential future enforcement discretion" as the top obstacle to implementing EPCIS at 43%.
- More than half (57%) of manufacturers have no successful connections in a production environment today.
- Most distributors are not connected to manufacturers in production today, and no connections in a production environment currently exist with distributors' dispenser customers.
- A typical 3PL currently is working to connect an average of 67 manufacturer clients.

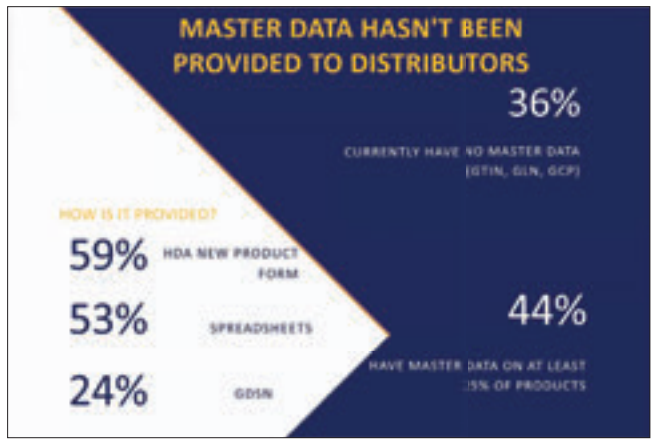
↑ Many companies already face labor shortages. Inbound and outbound scanning will add to distribution employee workloads.

- Respondents cited "readiness of their clients" and "wholesale distributors … not articulating clear deadlines to trading partners for taking necessary steps" as barriers to implementation.



The number of connections that manufacturers or distributors plan to make is concerning. As Allison Sheldon, Senior Manager, Pfizer Digital Serialization, Pfizer Inc. explained in April, it takes around six weeks to onboard a trading partner in a best-case scenario. The survey reports, "Once fully implemented, one-quarter of distributors anticipate having fewer than 10 connections. Half of distributors expect to have somewhere between 70 and 250 connections, and a quarter plan to have between 350 and 650 connections." Resources will be strained in order to onboard numerous stakeholders by the 2023 deadline.

Said Justine Freisleben, VP, Industry Relations, HDA, "FDA's expectations around reaching the 2023 milestone on time are clear. Knowing this, HDA urges trading partners to plan ahead, commit to implementing a solution as soon as possible, and work with their peers to achieve compliance—and for the continued safety and reliability of the U.S. healthcare supply chain."



↑ HDA's Serialization Readiness Survey shows there is much work to be done. (Images this page and next courtesy of HDA.)

↑ Aggregation has slowed—the pressures of the COVID-19 response likely contributed in some part.

Serialization readiness survey

The HDA Research Foundation published its sixth annual *Serialization Readiness Survey* as part of the HDA Traceability Online Seminar in November. The results track with those of the aforementioned EPCIS survey from two months prior, and indicated that "trading partners appear to be deferring their DSCSA-related investments into 2022 or 2023, which could hinder overall supply chain compliance with the federal traceability law."

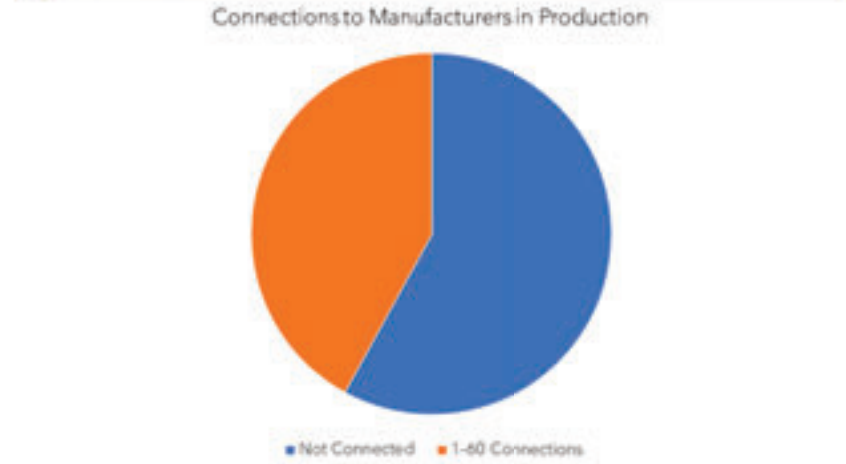
Data reflect survey responses from 40 manufacturers—including 13 of the 2019 top 20 pharmaceutical manufacturers by sales as listed by IQVIA—as well as 25 distributor companies. The findings revealed some additional concerning results:

- Aggregation, a prerequisite for manufacturers to send serialized transaction data, has slowed. While 45% are currently aggregating, 56% planned to aggregate by the end of 2019 in the 2019 and 2020 surveys. Now, nearly 40% will do so by 2023. This number is up from a quarter last year, indicating a shift in timelines.
- 40% of manufacturers are currently sending or plan to send, by the end of 2021, at least some serialized data to their wholesale distributor customers upon shipment. 43% plan to do so by November 2023. Another 16% are still unsure of when they plan to exchange data with wholesale distributors via EPCIS for all products.
- Over the past three years, the number of manufacturers planning to send serialized data with 100% of product has fallen to 12% from 35% (2020) and 21% (2019). Most manufacturers, 65%, anticipate sending 100% of data with shipped product by 2023, when it is legally required.
- Distributors are still preparing for data exchange. Only 60% of distributors can accept serialized data today. However, approximately 48% are receiving serialized data for between 1 and 5% of transactions.
- Two-thirds of manufacturers anticipate using the verification router service (VRS) to support verification requests of non-direct purchasers.

Key challenges for achieving 2023 compliance noted by manufacturers and distributors included "governance of the interoperable system for 2023," "technical challenges," "establishing standards," "collaboration with trading partners" and "differing interpretations" of the law among their top concerns.

"As the Foundation's data show, the healthcare supply chain is entering a critical work period over the next two years," said Perry Fri, Executive VP, Industry Relations, Membership & Education, HDA; and COO, HDA Research Foundation. "The uneven state of readiness among supply chain partners has likely been exacerbated by operating under the pressures of the COVID-19 response; however, our findings also illustrate the range of interpretations and information gaps that must be overcome within the next two years. Educating trading partners, such as the dispenser community, and aligning on requirements will be crucial to getting implementation over the finish line."

Figure 2: Distributor Connections with Manufacturers



Most distributors (58 percent) are not connected to manufacturers in production. Forty-two percent have between 1 and 60 connections in a production environment. Once fully implemented, one-quarter of distributors anticipate having fewer than 10 connections. Half of distributors expect to have somewhere between 70 and 250 connections, and a quarter plan to have between 350 and 650 connections.

Labor requirements

While much of the focus has been on the technological challenges of traceability, Maryann Nelson, Regulatory Manager at Cardinal Health, Inc., discussed a new need developing in the space at the Traceability Online Seminar: labor. This must be considered as soon as possible with many companies either facing or concerned about labor shortages in manufacturing.

Cardinal Health has developed systems and processes to ensure that the EPCIS messages they receive contain all the DSCSA transaction data elements that are required. That data from manufacturers is stored in a serialization repository.

Inbound process: Upon receipt of product on the dock, they will check-in the product by matching the National Drug Code (NDC), the lot, and the quantity of the physical product with the data received. This is followed by scanning a representative sample of barcodes for every purchase order/NDC/lot combination to ensure that those serial numbers are in the serialized data they've received.

"If they match, we intend to infer the remainder of the serial numbers and we'll note which serial numbers have been scanned vs. which have been inferred. That information is going to be helpful for future reconciliation efforts. If data is not available or discrepancies are found, we'll quarantine that product and will be contacting the manufacturer to resolve," Nelson said.

Outbound process: For outbound product, they plan to scan every serial number at picking. Scanning will be performed at case level (if shipping a full case to a customer) or at the individual package level (if sending a less than case quantity). "We do this for two reasons. First, we want to make sure that the serialized data has been received for the item prior to shipment. And this is important because we're going to be using inference on receipt," she said. "Second, it's to capture the elements of that product identifier—the NDC, lot, expiration, and serial number—so we can associate it with the order and with the customer who's going to be receiving it. Just like with receiving, if a scanned serial number cannot be found in our repository, we'll be quarantining that product and reaching out to the manufacturer to resolve the exception.

Nelson noted that Cardinal is not currently scanning 2D bar codes at outbound, though they have built the system functionality to do so. "We have to invest in new 2D scanners for warehouse associates to use, and then we're also budgeting for the additional resources needed to scan the barcodes on every package on outbound," she noted. "That outbound scanning is expected to increase labor by a minimum of 12 to 15% based on recent time studies. As an example, a distribution center with a 50-person night crew will need to hire six additional people just to support the outbound scanning."

Multiplied by the 21 pharmaceutical distribution centers in the Cardinal Health network, that's a significant increase in headcount. This figure only accounts for outbound scanning, she explained, and it doesn't include the resources needed for the future inbound process changes or reconciliation efforts.

HDA Survey Links

Download the complimentary surveys from the HDA Research Foundation.

- *EPCIS Implementation Benchmarking*: hcpgo.to/2021epcis
- *Serialization Readiness*: hcpgo.to/2021serialization

Safety Factors for Ethylene Oxide Sterilization: Patient, Worker, and Environment

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Ethylene oxide sterilization is a commonly used method for sterilizing medical devices, though there are environmental concerns.
2. Certain factors like breatheable packaging and proper airflow can help keep worker exposure below OSHA limits.
3. Facility design is critical to ensuring fugitive emissions are captured through a scrubber or abator system.

Ethylene oxide sterilization is a commonly used method for sterilizing medical devices. It's made headlines for concerns over environmental effects, and while the FDA has encouraged industry to develop new approaches, a singular, comparable alternative sterilization method has not yet emerged.

Watch this video on bold innovations in medical device sterility assurance: **hcpgo.to/bold**

Quick Take: FDA

"The FDA is closely monitoring the supply chain effects of closures and potential closures of certain facilities that use ethylene oxide to sterilize medical devices prior to their use. The Agency is concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care."

—FDA.gov Ethylene Oxide Sterilization Facility Updates

Clark Houghtling, Vice President of Business Development & Technical Affairs for **Cosmed Group, Inc.** spoke at the virtual Medical Packaging Conference about why the method is so versatile, and what practices factor into worker, patient, and environmental safety when using the process.

Ethylene oxide basics

Ethylene oxide (also referred to as "EtO" or "EO") is a simple chemical compound, C_2H_4O. "It was discovered in 1859, so we've known about ethylene oxide for a very long time. In the late 1950s, a gentlemen named McDonald patented a process for processing medical devices with ethylene oxide," explained Houghtling.

It's currently the most widely used method for industrial medical device sterilization covering about 52% of the market, due in no small part to the fact that it can be used for almost all medical devices without deleterious effects. Exceptions include non-vented packaging because EtO is a gas that must be vented, and liquids (as gas will not pass through a liquid).

EtO is highly effective against microbes—bacteria, viruses, yeast, or molds—and diffusive. "It can even go through some plastics that are sealed airtight," he said. "It's compatible with a very wide variety of devices and packaging materials. Another important advantage that can be overlooked is that devices can be re-sterilized with ethylene oxide, which can't be done with some other sterilization methods, such as gamma irradiation, electron beam, x-ray, or high-temperature steam."

EtO has four variables that can be altered to produce a desired result—temperature, humidity, gas concentration, and gas exposure time—which offers more customization than sterilization methods that offer a single variable, the delivered dose.

Worker safety

OSHA sets limits for EtO exposure in the workplace:

- 1 ppm – 8-hr time weighted average (TWA)
- 5 ppm – 15-min excursion limit (EL) for short-term exposure

Houghtling noted some of the factors that can help keep exposure below these limits: device design so that it aerates more quickly inside the chamber and during the aeration process, and breathable packaging and larger packaging surface area so that it is easier for EtO to get into and out of the product. Facility design plays an important role with proper airflow, scrubbers, and abators that minimize workers' exposure.

"Also becoming increasingly more important these days are optimized and sustainable cycles. Where feasible, using an all-in-one process means all the phases of sterilization can be done inside the chamber, which includes the preconditioning or conditioning, the sterilization itself, and most importantly, the aeration," Houghtling said. "It's important to do a very thorough aeration on the product before it comes out into the warehouse to avoid any worker exposure."

Patient safety

It goes without saying that patient safety critical as well, and lethality and residues must be considered. Houghtling said, "These devices must be sterile to a sterility assurance level [SAL] of 10^{-6}, meaning no more than one in one million devices can be non-sterile. If you're in the U.S., there are sometimes sterility assurance levels for topical devices with acceptance of 10^{-3}, which means one out of one thousand devices can be non-sterile. And there are other sterility assurance levels that are being discussed based on their risk-benefit scenarios."

For patient safety, factors to consider to reduce lethality include:

- How easily sterilizable the device materials are
- Whether the design can be accessed easily (such as breathable caps instead of non-breathable caps on a device to help get the

ethylene oxide into the interior of a product)

- If the packaging is high quality and breathable with a large surface area to get the gas both into and out of the product
- Whether the cycle design is efficient
- How the cycle is optimized to ensure EtO can enter and exit

EtO residues must comply with government guidelines before being released to the marketplace. There are two components of EtO—the ethylene oxide itself and a byproduct, ethylene chlorohydrin—and delivered doses of both must meet certain limits.

Design factors important for residues are similar to those listed above for lethality, but Houghtling noted to make sure the residues are reduced to as little as possible, as quickly as possible.

Environmental safety

There is a considerable amount of focus on the environmental safety of EtO and that has led to short supply of contract EtO sterilization capacity. EtO emissions must meet U.S. federal and state limits, while other countries have their own particular limits.

"There are existing limits for EtO emissions, but these emissions are probably going to be severely limited in the future and could be as much as 90% more stringent than they are now. We have to make sure that we're good environmental neighbors because safety is paramount for the environment," he noted.

Factors that are critical for this are the facility design, ensuring all fugitive emissions are captured through a scrubber or abator system to reduce the amount of EtO released to the atmosphere.

Cycles should be optimized, as it's more sustainable to limit the amount of EtO to what is truly necessary and avoid "overkill" processes. "You must capture the primary emissions from the sterilizer chamber, which is a bit easier to do because there are high amounts of EtO in a small volume, but we also have to be very critical about the secondary emissions that can come from spaces like the aeration room, vacuum pump area, gas storage area, post-processing areas, and others, and make sure that those are all thoroughly scrubbed through some type of a maintenance system to make sure we're meeting" or coming in under the limits, Houghtling explained.

ROI on improved safety

Being safety- and resource-conscious is not only the right thing to do. In this case, it boosts business health, as well.

Optimizing EtO cycles to use efficient amounts of gas results in faster processing times with more rapid EtO dissipation, which Houghtling pointed out can be the longest lead time in the process. Becoming more efficient with sterilization can also lead to reduced inventory, improved cashflow, and overall reduction in costs.

Houghtling said he's often asked about the future of ethylene oxide, given all the concerns he discussed at the MPC event and the headlines about EtO release in communities. He posited that because it is the top sterilization method for heat-sensitive products, its use will be continued.

"There is no other low-temperature gas that has the ability to do what ethylene oxide can do, primarily because of three limits of all other low temperature gases: they have trouble in some cases with material compatibility, with penetration, and with scalability," he explained. "Sustainability is key now and will be even more so going forward. We need to use less ethylene oxide and not a gross amount more than is actually needed, which will help minimize the EtO emissions."

Women, E-comm, and Collaborative Tech Shape a New Way of Working

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. An expert panel at the Packaging & Processing Women's Leadership Network discussed women and remote work.
2. Being supportive and empathetic to contract manufacturers proved key to keeping a good working relationship.
3. With limits on learning in person, young people entering the workforce face will face new challenges, but are likely to adapt.

Stephanie Neil: Amid the current skills crisis, a recent study by the Society for Human Resources Management showed that 69% of women who lost their jobs or stopped working due to the pandemic and who identify as primary caregivers to children under 18 don't plan to return to work. How can companies incentivize women to come back to work?

Jan Tharp, Bumble Bee Foods: If you look at pre-COVID and manufacturing, it was all about customization and finding products that were individualistic. Take that thinking and move it over to human resources to become customized in how you go out attracting talent.

You look at it and say, "Okay, this person has children. They may need a different work environment. They may need different work times." You can be flexible with that. I hope that if anything comes out of COVID it is that we realize there is no such thing as one size fits all.

Stephanie Neil: If somebody decides to live and work remotely, are they giving up opportunities at the company?

Jan Tharp: During COVID, we have hired several people at executive levels and most of them are not required to move to San Diego, where we are based. It's actually opened up a whole new world of talent for us. We've been able to attract rockstar talent into our company by being a little more open with respect to where people work. Is that going to prevent them from getting opportunities? No. I think that leads into another discussion of "how are you effective in this new world of work?" If you're not in the boardroom anymore and you're on a computer, it's a different toolbox. This puts a bit more pressure on the team member to say, "If you want to live in Antarctica, and you've got an internet connection, and you can still be as effective, then I'm going to embrace that."

Stephanie Neil: How do you shift as an organization, as a manufacturer, to accommodate for the e-commerce presence?

Jan Tharp: You look at what happened in COVID, and all the channels of distribution increased. But e-commerce increased the most. It went up 58%, compared to mass club general retail. It has slipped down just a little bit, but it's still significantly higher than any other channel of distribution with respect to grocery.

So, it did force us to look into it. Our main product for tuna is a 48-count case. Most people don't want 48 cans of tuna. Your offerings, your assortment online, ends up being a little bit different. And then you've got to think about the cost dynamics of it. A can of tuna retails for about a dollar, then you look at the cost of freight to get that can of tuna to your house, it's an investment we're making. We don't make any money on e-commerce. We lose money. But the idea is to try to get out there and eventually figure out how we can turn that into a profitable business. And lots of CPGs are faced with this challenge.

Yolanda Malone, PepsiCo: Our primary business is chips. And potato chips break when you put them in the bag. So for us, we have to put a lot around packaging, how to ship, if they're going in combi-

nation with cans of tuna, or dish detergent. And really structuring that to Jan's point, profitably.

And adhering to even some of the companies like Amazon that have specific departments to ship our products in, make sure that we do the testing and that our team is set up. And so they're also understanding what testing needs to be done to be qualified. Because we also saw significant growth during COVID, with people ordering online. And our team was challenged to be more efficient, to reduce cost, so that we could get it out faster and supply consumers.

The conversation reflected here is a short excerpt of an in-depth, 40-minute conversation. Watch or listen to the whole panel at: hcpgo.to/PPWLN21

People are buying differently now through e-commerce. Tracey, was your experience over the past year with online buying part of the success of the organization?

Tracey Noonan, Wicked Good Cupcakes: My husband developed a platform called Pronto, which was really to help companies who wanted to do something for their employees—whether it was virtual parties or sending birthday gifts. And to make it easy, all people needed to order was an email address.

And it was brilliant because I don't know about you, but I don't know anyone's street address. I don't know if they're going on a vacation and I don't know if they have food allergies. So in order to send what we call the gift card on steroids, all you needed was their email address. You sent them the gift card. And everyone could go in, pick their delivery date, what flavors they wanted, and put their own home address in. And it had to be easily navigable so people would go in and buy, not just go in and get lost. This really facilitated shopping online for people.

Stephanie Neil: Tracey, in your work with contract manufacturers, is it difficult to manage relationships during the pandemic?

Tracey Noonan: We found that being supportive of our contract manufacturers, and empathetic towards what they were going through, was the key to keeping a good working relationship. We needed to have really good communication, and understand if something was going to be delayed, and if there needed to be an extended time period to receive product.

Stephanie Neil: Sharron, how do you manage collaboration and maintain productivity, especially in a work environment where you have to be hands-on, in spite of the pandemic?

Sharron Gilbert, Septimatech: We had to really rely on different tools and technologies. The adoption of Microsoft Teams really moved us forward into that collaboration—not just internal, among employees, but also with our customers.

When we're having discussions about projects, and design reviews, and then installation reviews, and that whole process there has to be a really good connection with our customers. So, we've been ramping up our online presence, for our people working remotely as well. We're noticing delays with our customers in terms of their projects. It's meant that we have to be really dialed into our customers, to still help them do their product launches, and collaborate with them. We're doing pre-order releases in terms of getting materials in. We're taking a look at our inventories and focusing on those materials we use a lot of and getting rid of some of the other ones.

Stephanie Neil: How do you lead the global team, Yolanda, when you're working remotely?

Yolanda Malone: It's a lot of Zooms. The one thing I do miss is seeing my team face-to-face around the world. But as a leader, understanding where they're at and being available is one of the most important items that I set up for myself. If I'm talking to my team in China, I'm going to be on their time zone. So it might be nine o'clock at night for me, but it's their day.

To know that their leader cares about how they're doing and reaching out and having those one-on-ones—not even necessarily talking about the projects, or the work, but just how the team's doing, and to see everyone, and see all the faces is also important.

Stephanie Neil: Do your leadership skills have to change?

Jan Tharp: I do think there will be a new toolbox as we come out of this and the constituency that I think is going to be maybe a little more challenged are the new people coming into the workforce because they don't get to learn by being with people like I did when I started in CPG 30 years ago. You went to meetings and watched how people address difficult questions. It's a different skill that people will have to learn. I'm confident in our younger generation that they will certainly figure that out.

What we've done inside our company is try to do coffee and conversations for people who are not in the corporate office. We've also been pretty flexible, even in the corporate office where we will go for walks on the beach or sit on the pier and have a meeting. There's a brewery that has all outside seating and we've done a lot of meetings sitting at the bar at the brewery. You have to be creative and think about those types of things.

It's a different toolbox for leaders as well. We need to do a lot more, what I call watching and listening. I am not about setting back-to-work policies. You don't build sidewalks until you see where people are walking. It's too early, in my opinion, to really know where things are going. So if we could just take a step back and watch, listen to our team members, then we will figure out how we move on.

Q&A: Trends Impacting Autoinjector Development

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. The rising adoption of biosimilars is driving development in injection devices.
2. Those entering the biosimilar market may look to use a device that will make their product stand out.
3. Tengroth feels digitization may not have much impact for some time in biosimilars due to costs.

Ahead of Pharmapack Europe, *Healthcare Packaging* spoke with Charbel Tengroth, M.D., of **Tengroth Consulting** regarding his session on current trends in biosimilars and impacts on autoinjector development.

In a year when innovation has pushed ahead, Tengroth offered his perspective on how increasing the number of biosimilar approvals will affect the autoinjector market, what opportunities abound, and his perspective on growth in the near term.

Pharmapack Europe took place in-person at Paris Expo, Porte de Versailles, Paris on Oct. 13 to 14. The event also featured a hybrid format with a four-week long digital platform.

***Healthcare Packaging* (HCP): Can you give a high-level overview of biosimilars?**

Charbel Tengroth: So let's start with the trends in biosimilar use in Europe, where there are more products than in any other market. The market dynamic is different in Europe, you have much stronger tendencies across the health sector to adopt biosimilars in order to reduce the cost of treatment, including the cost for the patient. There must be legislation in place to change the market dynamic I believe; I think a lot of people saw the Affordable Healthcare Act as something that would be promoting the use of biosimilars more in the U.S., but I'm not sure it has played out as expected.

However, what we are also seeing is that the numbers of biologics that are offered with devices is increasing. This is something we must expect and is therefore a positive development for injection devices in biosimilars. If the original product uses a device like an injection pen, then there is high probability that the biosimilar will use a similar mode of delivery.

Devices also offer a huge advantage in terms of convenience including the way the patient can administer the drugs themselves—they don't have to go to a clinic. I envision this will continue to be a big growth area, especially for treating patients with chronic conditions. With respect to the biosimilar developers, this also offers the chance for their product to stand out or be differentiated from their competitors, so I think there's quite a lot to say about biosimilars driving the development in injection devices.

WATCH

Watch this video on expediting med device approval with FDA's new program: **hcpgo.to/expedite**

***HCP*: Does that mean a new device is more likely to have some sort of exclusivity agreement with a company?**

CT: Interesting question, because for a pharma company, negotiating and obtaining exclusivity from a device manufacturer in a single therapy area can be a way of keeping out competitors. The rise of medications that have come to market that help alleviate or treat various chronic conditions has meant that there is also an increase in competition from device manufacturers looking to develop therapy-specific devices. Competition in this case will be very healthy, as there will be many products that are specifically licensed or have exclusivity agreements, making it very hard for device manufacturers to sell the same device to competitors, especially as companies from the pharma side are looking to

enter the biosimilar market and will look to use a device that will make their product stand out.

***HCP*: How are autoinjectors affecting demand for biosimilars?**

CT: The use of autoinjectors is a lot more accepted today than it was 10 years ago, just because of the proliferation of products that use autoinjectors. If you look at the therapy areas, if you look at diabetes or obesity, you have at least one, if not two glucagon pens, and there is a significant number of potential patients within those therapy areas. In the past, autoinjectors were limited to autoimmune diseases or things like MS, those are essentially rare because there are a limited number of people that suffer from them in comparison to heart disease or diabetes. However, autoinjectors are now being used for conditions that are more prevalent.

Another example would be new products like Aimovig which is aimed at patients that suffer from severe migraines. If this is something that is efficient, this will certainly increase the use of injecting—this is a new therapy area where you expose the autoinjectors to new patient groups. Certainly, in the last five years, we are seeing the threshold for acceptance is lowering and that is down to new, efficient therapies and the rise of patient groups. When people start seeing that these treatments are highly efficient, it will have a big impact. New therapy areas will be a driver for the drug delivery devices market, but that's only if the treatments are effective. We saw this firsthand with Cosentyx, which is a treatment against psoriasis. It was a highly effective treatment and the demand for the drug was a lot higher than what was anticipated and a lot more than what they initially could produce. They ended up playing catch-up for a number of months with market demand post-launch!

***HCP*: Does this mean that the patient will become more central in the design process for devices? For instance, in the case of any migraine injector, it's going to have to be fairly portable if you take it when you have one?**

CT: Yes absolutely, it is the same case for these glucagon pens in terms of portability. Essentially it is an emergency-use device for those with diabetes to use when needed rather than following a set dosing regimen. So yes, the designs, the demand...all of these are going to have a huge impact. Real world use is integral to design, all of these things are going to have big impact and also drive innovation and stratification of products in their respective space.

***HCP*: Over the next few years what is your perspective on growth in autoinjectors?**

CT: I would expect to see a very healthy growth and the reason for that is partly down to biosimilars, of course, but also the continued launch of biosimilars will inevitably lead to new market openings for innovative biologics as well.

Biosimilars allow for competition and also allow for production to be moved away from high-cost countries like the U.S. and Europe to other countries to have many different sites for manufacturing for a particular drug. I would expect to see various contract manufacturers pop up in every continent and produce biosimilars and biologics for the local markets.

***HCP*: What about smart devices for biosimilars?**

CT: Digitization is probably not going to have much of an impact for some time in biosimilars, because it completely goes against the principle of affordability and market access. To add on electronics that will require a dedicated infrastructure and, potentially, interoperability between patients, healthcare providers, and pharma companies will add significant costs. Connected devices are very much catered to innovator drugs where there is more incentive for their use, especially where we don't have much data on usage and adherence. However, if you have a biosimilar, you probably have a fairly good idea of what the clinical outcome is, what the treatment is worth in terms of how and when the patients use it. To summarize, it's slightly different priorities.

READ

Read this article about the Pharmapack Europe 2021 award winners: **hcpgo.to/pharmapack**

Care Kits Supplement Telehealth for Medicare Patients and More

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. 57% of Americans with chronic conditions delayed healthcare and experienced a gap in care due to COVID-19, per a recent study.
2. Aetna and other companies are shipping kits with specially curated products to offer self-care or to supplement telehealth visits.
3. Kits involve a high level of supply chain complexity, including secure PHI (Protected Health Information) handling.

Telehealth and e-commerce both experienced major boosts during the pandemic, driven by the desire or need to stay at home and reduce exposure. While swapping a trip to the grocery store for an online order may feel easy, healthcare can require extra tools to accommodate the switch to remote options. Delayed healthcare services during the pandemic can be dangerous for those with chronic or serious conditions.

R.R. Donnelley & Sons Company (RRD) launched Care Kits to help healthcare companies adapt to industry changes and demonstrate their commitment to member and patient wellness. Kits are offered in a wide range of treatment areas including telemedicine prep, COVID-19, diabetes management, asthma, social isolation, and more.

RRD reported that in a recent Wellframe study, 57% of Americans with chronic conditions delayed healthcare services and experienced a gap in care due to the pandemic. Care kits can positively impact a patient's impression of a provider according to the 2021 Medicare Shopping and Switching Study, with 59% of Medicare Advantage members noting that receiving COVID-19 or flu kits improved their opinion of an insurer.

Nicole Williams, Vice President of Go-to-Market Strategy at RRD Healthcare Solutions, explained in a recent release that "healthcare organizations find themselves in completely new territory, looking for new ways to deliver care to members from a distance. Healthcare payers and providers can now supplement in-person healthcare services and keep patients and members healthy by delivering tools and resources to their homes."

Aetna, a CVS Health company, is shipping "Caring For You" kits with specially curated, over-the-counter items to its Medicare Advantage members across the country. The idea is to support members with "simple self-care at home," and kits include a thermometer, hand sanitizer, and two Aetna-branded face masks, among other items.

↑ RRD launched Care Kits for patients and to help healthcare companies adapt to industry changes and demonstrate their commitment to member and patient wellness.

"During this challenging time when many of our most vulnerable members are home, we wanted to provide them with some convenient items to help them stay healthy," said Christopher Ciano, President of Aetna Medicare. "We know that something as basic as an oral thermometer can make a big difference during telehealth visits. Sending these types of important items to our members at no cost was simply the right thing to do."

By the Numbers: According to the latest report from Global Market Insights Inc., the market valuation of telemedicine will cross $186.7 billion by 2027.

Design process

The end-to-end solution encompasses kit ideation, design, item procurement, packaging, fulfillment and communications—both inside and outside of the box.

READ Read this story on one supplement's e-commerce packaging at: **hcpgo.to/supplement**

Because each kit will hold different products depending on the treatment areas, RRD works closely with customers to determine the goal of the kit and design, then they break it down by products. Each customized kit contains products that are carefully sourced and evaluated for quality, meeting the needs of an individual patient or member.

- One kit offered is the "Healthy Mom Kit," which includes prenatal vitamins, nausea treatment, a pregnancy journal, belly butter, antacids, a belly band, and compression socks.
- The "COVID Care Kit" provides patients and members with facemasks, hand sanitizer, antibacterial wipes, facial tissue, a digital thermometer and a COVID-19 home test kit.

"We take into consideration the demographics of those receiving the kits, which helps us decide how elaborate or simple the packaging design needs to be," says Williams. "We've also learned the importance of providing messaging with the care kits. We take advantage of the real estate on the box itself including under the inside lid to provide clear and concise information about the contents of the kits and any instructions for how to use them. In the medical space, for example, the end user is often over the age of 65; by including written instructions on the packaging itself, we ensure the products in the care kits are easily accessible and their intended use is understood."

It is critical that the layout is simple while attractive, and that the kit and contents arrive safely. They ensure branding fits with the product families. Explains Williams, "Everything—from the product itself to after the packaging is disposed of—is taken into consideration during this initial phase."

Materials

Material selection is a collaboration between RRD and the customer. One client might prefer the kit to act as its own shipping container, in which case the material for the kit would be corrugated to withstand shipping. Alternatively, if a client requests a high-end or lower-volume kit, RRD would build a corrugated shipper around a rigid box or folding carton.

LISTEN Listen to this podcast on reusable packaging, refills, and more: **hcpgo.to/reusable**

Logistics: assembly and distribution

RRD reports that development and execution of these kits involves a high level of supply chain complexity, including secure PHI (Protected Health Information) handling, component and commodity shortages, and logistical planning. Taking a kit from design and procurement to assembly and distribution requires the input of multiple teams early on.

"Our facilities are equipped with the systems to handle PHI and FDA-regulated items during the assembly and distribution process, which is important in the healthcare space where sensitive information and proper product handling need to be followed in accordance with HIPAA and cGMP guidelines," notes Williams.

With existing supply chain services, Ken Gammon, Vice President at RRD Healthcare Solutions, explains that they are able "to address healthcare industry challenges, such as compliance, cost, and speed to market, with ease."

Navigating challenges

RRD developed care kits at the end of 2020 that required a very quick process. "Our flexibility and scale allowed us to curate nearly three million care kits on behalf of several clients. In situations where we produced and distributed diagnostic testing kits, we were up against complex elements, such as lab test turnaround. In these situations you have to weigh many factors, ultimately prioritizing timely delivery and turnaround time. We streamlined the process of returning specimens to a lab for testing and ensured we were creating an efficient process for our clients and the end user," says Williams.

Beyond COVID-19

Telehealth has been gaining steam for years as many patients and consumers prefer to treat conditions in the comfort of home, provided they are proficient with smartphones and other devices. As manufacturers and healthcare providers look to improve patient adherence, comfort, and satisfaction, at-home kits offer convenience to supplement telehealth appointments and home care.

Emerging EU Sustainability Regulations for Packaging

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. There are several EU regulations in the pipeline aiming to reduce plastic use and bolster recycling.
2. One part of the European Green Deal focuses on halting natural resource depletion and creating sustainable growth and jobs.
3. Enforcement has not been very strong to date, but may be supported by new green public procurement (GPP) criteria.

We'd be remiss if we didn't begin an article covering packaging sustainability with the reminder that sustainability is more than recycling. However, recycling will clearly have a role to play in advancing a circular economy.

Thierry Wagner, Global Director, Regulatory & Standards – Healthcare at **DuPont**, began his talk at the virtual Medical Packaging Conference with the UN definition of sustainability, meeting the needs of the present without compromising the ability of future generations to meet their own needs. He pointed to the UN's Sustainable Development Goals that encompass social, economic, and environmental targets such as zero hunger, clean water, good health, decent work, and economic growth, all while considering our climate and consuming in a responsible way based on circular economics. "These goals have become the blueprint for many companies to align their development and innovation goals against, including my own company," Wagner said. "Countries around the world have the adopted various actions to move forward on the UN Sustainable Development Goals. The most ambitious plan is probably by the European Union: The European Green Deal, seeking to make Europe the first 'climate neutral' continent by 2050."

Wagner explained that the plan addresses working with nature to protect our planet and health, boosting global climate action, and making transport sustainable for all. It also targets products and the technologies that we use to produce products, energy systems, buildings that we live in, and greener lifestyles. "So, it's really addressing almost everything," he said.

Wagner highlighted a few emerging objectives that will help put these concepts into action.

Circular Economy Action Plan (CEAP): This part of the European Green Deal is mainly focused on halting the depletion of natural resources and creating sustainable growth and jobs. The first CEAP was adopted in 2015, with the latest iteration released in March 2020. A few of the tangible goals include:

- Substantiating green claims made by companies
- Empowering consumers in the green transition, because they are considered as a very important driving force
- Tackling packaging and packaging waste
- Sustainable products policy initiative with eco-design
- Concentration limits on persistent organic pollutants

Watch this video on GSK's 20% plastic reduction on Advil bottles: **hcpgo.to/gsk**

2018 EU Plastics Strategy: Wagner noted that the 2015 demand for plastics in Europe was estimated at 49 million tonnes (54 mm tons) with almost 40% attributed to packaging. In 2018, packaging represented the largest amount of plastic waste generation at 60%.

- In 2019, the EU adopted its single use plastic ban for the most common single-use items found on beaches, such as cutlery, plates, and straws.
- The European **Packaging and packaging waste directive** (PPWD) 94/62/EC (1994) was reinforced with new targets in 2018. By December 21, 2025, at least 65% by weight of all packaging waste must be recycled, with a target of recycling 50% of all plastic. By 2030, the targets increase by 5%. "It was also changed in 2018 to include a new system introducing extended producer responsibility [EPR] schemes by member states by the end of December 2024 so that producers of packaging have to bear financial and organizational responsibility for management of waste. Many countries in Europe have already adopted [EPRs] and the objective is that all countries in Europe will, and it's a concept used by more and more countries around the world," Wagner said. "In Europe, the objective is to minimize the impact of packaging, to encourage reuse and recycling, and to establish effective systems of quality control and traceability of packaging. To make that all possible it's important to have the design for recyclability of packaging."

Read this story on a sustainable procurement guide in healthcare: **hcpgo.to/procurement**

Enforcement must be ramped up as it has not been very strong to date. This may be bolstered by the introduction of green public procurement (GPP) criteria—legislation likely to come out in Q1 2022—directing that public money be spent in a way that supports the objectives. "This is a big target. The European roadmap includes a number of options that are considered and there's going to be an assessment on the impact those options," said Wagner. "It's not enough to be recyclable in theory. You really have to make sure that the packaging is being recycled. And again, the overarching requirements are to make sure that all packaging is recyclable by 2030, and also reusable packaging must be recycled."

Another important consideration in the PPWD legislation: the EU has decided to introduce a new levy to member states at the end of 2020 to finance these activities. Member states will pay a tax of 0.8 €/kg of non-recycled plastic packaging. While the tax's details are controversial, member states will have an incentive to reduce the amount of plastic packaging produced. "Some countries have already come up with a virgin plastic packaging tax, such as Italy, Spain, and Portugal. We've also seen the UK come up with a plastic tax that is going to be applicable next year," said Wagner. "For the moment, the [EU] tax doesn't include medical and pharmaceutical packaging in Europe, but the UK tax includes medical packaging. So that will be an important driving force. The European Union has seen that this change will require a lot of collaboration."

The Circular Plastics Alliance (CPA): The aim is to boost the European market for recycled plastic to 10 million tonnes by 2025 (11 mm tons). Several organizations have signed the plan to contribute.

Wagner noted that the CPA is going to be very strategic for developing an upcoming European Circular Plastic standardization request. "Europe issues standardization requests to its European standards development organization. The objective of that request is also to develop the standards that are necessary to help achieve those recycled plastic objectives. It's going to focus on developing standards for design for recycling, for the quality of sorted plastic waste, for the quality of recyclates, and also to integrate that recycled plastic into different products. The timeline, again, is quite aggressive, so we're expecting to see something by the end of this year, but this may also be delayed to early 2022," he explained.

↑ Thierry Wagner (upper right) discussed the European roadmap to revise the packaging and packaging waste directive, which was launched in 2020, including ensuring that all packaging is reusable or recyclable by 2030. (Image courtesy: Thierry Wagner)

Current limitations for medical packaging

Many of the initiatives he mentioned apply to other types of single use packaging, but often, healthcare plastics are left out of the EPR discussion due to their critical role for patient safety, along with stringent regulatory constraints and long development and validation cycles.

"Some of the materials are 100% recyclable like Tyvek®, but many combinations introduce limitations. Many multilayer films have been developed to add great functionality to packaging, but that may introduce limitations, as well as mixtures of polymers," Wagner explained. "Contaminated waste in hospitals is another problem. That's an inherent limit to recycling because it is mostly incinerated, which is considered the most appropriate way to handle the material. Then introducing recycled content is also problematic because our products have to be designed 'to reduce as far as possible risk posed by substances or particles, including wear debris, degradation products and processing residues.' Also, inconsistent material composition, impurities, adding substances, etc. can have damaging consequences for patients."

Adding to the complexity, using recycled content in healthcare packaging is only possible with tight control and "flawless traceability" as Wagner put it, and that is limited or even impossible in certain cases, leading to conflicts with the EU Medical Device Regulation (MDR) or the In Vitro Diagnostic Regulation (IVDR) requirements.

Closing thoughts

As Wagner concluded, "There's no way around circularity. It will come. The world is moving clearly into the direction of circularity, and medical packaging can be a great contributor by providing high quality recycled materials. Introducing recycled content will need a bit more time. With advanced recycling, more possibilities will come as the technology develops. That is going to be the topic of the next 10 years."

One takeaway is that companies cannot tackle this issue alone. "The way forward—we have to work together and collaborate towards the circular economy. Over time, the industry has worked really well at optimizing packaging operations and sterilization, and at achieving efficient distribution. The supply chain has left treatment of waste to other players in the past, but now it's become the focus area," he said. "Designing packaging for recyclability will be key, and that in turn will impact packaging operations and sterilization. The task is huge—it can only be addressed with collaboration by building partnerships. I'm sharing here from a European perspective. Every region has its own industry networks that are now more important than ever."

1 Vial Labeling Machine

MG America (via Packaging Efficiency Solutions)

+ WL-1-RT wraparound vial labeling machine is suited to high-speed glass vial lines such as those producing COVID-19 vaccines
+ Capable of applying precisely placed labels up to 600 vials/min, the WL-1-RT features positive vial control via a trunnion transportation system; the unit can accommodate both thermal transfer and laser coding printing operations

2 Pharmaceutical Metal Detector

Loma Systems

+ IQ4 LOCK-PH metal detector is capable of inspecting up to 30,000 tablets or capsules/min
+ System offers calibrated detection levels from 0.22mmFE, 0.28mmNFE and 0.37mmSt/St, designed to ensure the smallest fragments of metal are detected and rejected

3 Paper Tray Packaging System

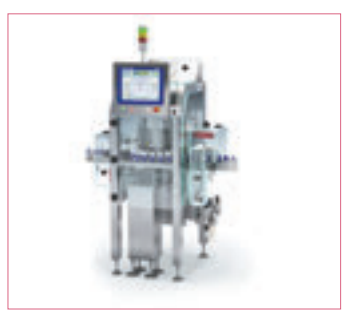
IMA Group

+ IMA Safe has developed a flexible system for packaging a range of parenteral products and medical devices on paper trays inside cartons, creating 100% paper-based packaging
+ At CPhI Milan 2021, the company showcased its IMA NoP (No-Plastic Program); paper secondary packaging is composed of renewable resources, is easy to recycle, and has relatively low energy requirements

4 Mono-Material Barrier Tube

Neopac

+ Recycle-ready in PE rigid streams, MMB tubes can reduce pharma packaging carbon footprints by up to 38% compared with traditional laminated tubes
+ Provided with all pharma grade contact layers, the tubes offer product protection and compatibility with a diverse array of formulations; the tube body is made possible through an adhesive laminated process



5 Checkweigher for Liquid Pharmaceuticals

Mettler-Toledo

+ StarWeigh™ is designed to provide lab accuracy fill levels at production throughputs for small, instable, or lightweight products, incl. glass or plastic bottles, vials, and ampules
+ Up to four load cells can be fitted, including next-generation Mettler-Toledo FlashCell™

6 Robotic Nest Filling Machine

Steriline/ARaymondLife/Stevanato Group

+ The Filling Machine works with the RayDyLyo® all-in-one closure system, which integrates a plastic push-fit cap as an alternative to aluminum caps, and the SG EZ-fill® vials in nest; accomodates Nest&Tub or tray configurations
+ Working with RTU (ready-to-use) containers, the system is particularly suited for small/med volumes in R&D laboratories or pilot lines

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f. Total Distribution *(Sum of 15c and e)* ▶			16,844	17,033
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18. Signature and Title of Editor, Publisher, Business Manager, or Owner: George Shurtleff — Date: 10/1/2021

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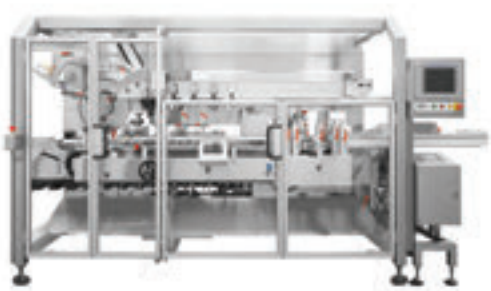

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