Healthcare PACKAGING®

Keeping them Safe:

Johnson & Johnson Consumer Health on Unit Dose Packaging

+ Annual OTC Package Design Gallery
+ Aurobindo Pharma USA Automates Warehouse
+ 10 Temperature Monitor Considerations
+ DSCSA and Exception Management

MAY/JUNE 2022

Rodman Media Group | www.HealthcarePackaging.com

It's time to build a traceable supply chain!

Imagine a traceability solution that gives you a **single-pane-of-glass view** of your supply chain data. Gain comprehensive insight for smoother operations, more strategic decision-making and stronger brand protection in the marketplace.

That's intelligence, beyond the mark.

Printer Intelligence. Packaging Intelligence. **Brand Intelligence.**

Download our free white paper,
Traceability: Your catalyst for supply chain excellence
SystechOne.com/UniTrace

SYSTECH®
connected solutions by Markem-Imaje®

↑ pp. 28

Annual OTC Package Design Gallery

COLUMNS AND DEPARTMENTS

Healthcare PACKAGING
www.healthcarepackaging.com

Editorial
DIRECTOR OF EDITORIAL CONTENT Keren Sookne
ksookne@pmmimediagroup.com
CONTRIBUTING EDITOR Melissa Griffen
CONTRIBUTING EDITOR Tim Hayes

Art
ART DIRECTOR Jonathan Fleming
UX/UI DESIGNER Maggie Wilson
CREATIVE DIRECTOR Dave Bacho

Publishing
PUBLISHER Elizabeth Tierney, 815.861.2992
VICE PRESIDENT, CONTENT & BRAND STRATEGY Jim Chrzan
MANAGER, STRATEGY & COMMUNICATIONS Courtney Nichols
AD SERVICES/PRODUCTION MANAGER George Shurtleff

Audience & Digital
SENIOR VICE PRESIDENT, DIGITAL & DATA David Newcorn
SENIOR DIRECTOR, DIGITAL & DATA Elizabeth Kachoris
DIRECTOR, WEBSITES + UX/UI Jen Krepelka

Advertising
VICE PRESIDENT, SALES Wendy Sawtell
wsawtell@pmmimediagroup.com
SENIOR DIRECTOR, CLIENT SUCCESS & MEDIA OPERATIONS Kelly Greeby
DIRECTOR, PRODUCT STRATEGY Alicia Pettigrew

PMMI Media Group
PRESIDENT Joseph Angel
DIRECTOR, MARKETING Sharon Taylor
SENIOR MARKETING MANAGER Amber Miller
FINANCIAL SERVICES MANAGER Janet Fabiano
FOUNDING PARTNER Lloyd Ferguson

PMMI MEDIA GROUP

PMMI Media Group
401 N. Michigan Ave., Suite 300
Chicago, IL 60611
p: 312.222.1010 | f: 312.222.1310
www.pmmimediagroup.com

PMMI The Association for Packaging and Processing Technologies
11911 Freedom Drive, Suite 600, Reston, VA 20190
p: 703.243.8555 | f: 703.243.8556 | www.pmmi.com

Connectiv

PLEASE RECYCLE THIS MAGAZINE
Remove inserts or samples before recycling.

Healthcare Packaging® (ISSN # 21543666) is a registered trademark of PMMI, The Association for Packaging and Processing Technologies. Healthcare Packaging® is published bi-monthly by PMMI with its publishing office, PMMI Media Group, located at 401 N. Michigan Ave, Suite 1700, Chicago, IL 60611; 312.222.1010; Fax: 312.222.1310. Periodicals postage paid at Chicago, IL, and additional mailing offices. Copyright 2022 by PMMI. All rights reserved. Materials in this publication must not be reproduced in any form without written permission of the publisher. Applications for a free subscription may be made online at www.healthcarepackaging.com/subscribe. Paid subscription rates per year are $55 in the U.S., $80 Canada and Mexico by surface mail; $130 Europe, $200 in all other areas. Single copy price in U.S. is $20. Free digital edition available to qualified individuals outside the United States. POSTMASTER; Send address changes to Healthcare Packaging®, 401 N. Michigan Avenue, Suite 1700, Chicago, IL 60611-3789. PRINTED IN USA by Quad. Volume 16, Number 3
The opinions expressed in articles are those of the authors and not necessarily those of PMMI. Comments, questions and letters to the editor are welcome and can be sent to: editors@healthcarepackaging.com. Mailing List: We make a portion of our mailing list available to reputable firms. If you would prefer that we don't include your name, please write us at the Chicago, IL address.

PUBLICATIONS MAIL AGREEMENT NO. 40064408 • USPS #25469

Innovations in Unit Dose and OTC Packaging Abound

The healthcare packaging community has an important role to play in keeping kids safe from accidental unsupervised medication ingestions.

Four busloads of kids. That's the approximate number of children in the U.S. who come into emergency departments every day due to accidental unsupervised medication ingestions. As Dr. Ed Kuffner, Chief Medical Officer at Johnson & Johnson Consumer Health, explains in our Q&A on pp. 18, he's seen firsthand the heartbreak of treating these preventable illnesses in children.

Unit dose packaging has an important role to play in delivering medication safely to adults, while preventing access among children. Dr. Kuffner discusses a new technology: a unique folding blister package design that won their recent QuickFire Challenge.

Next in package design, for a real-world look at what's on shelves today, check out our annual OTC package design gallery (pp. 28). Packages had a bit more "flash" than in previous years, with metallic shrink sleeves, eye-catching foil accents, and an aluminum bottle for antacid tablets touting recyclability.

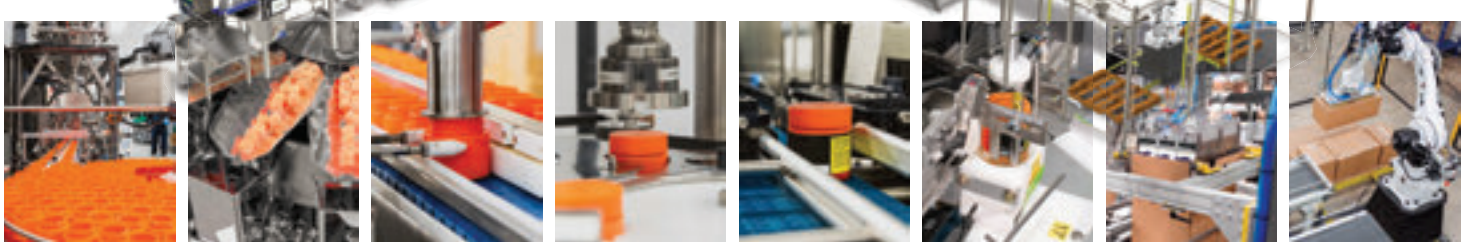
On the logistics side, we cover a warehouse automation case study which allowed Aurobindo Pharma USA to build "up" more than "out" in their New Jersey distribution hub (pp. 22). We also raise some important questions about how quarantined product will be processed under DSCSA traceability mandates (pp. 34).

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

Automation From a Single Source

PAXIOM

Over 30 years' experience delivering automated packaging systems.



CONVEYING | WEIGHING/ COUNTING | FILLING | CAPPING | LABELING | CARTONING | PACKING | PALLETIZING

paxiom.com

1.833.4PAXIOM | info@paxiom.com

PaxiomXperience PaxiomGroup

Visit us in **Las Vegas, Miami, Montreal, Toronto or Milwaukee** to see our solutions in action.

Our team is ready for your next project.

TIM HAYES,
CONTRIBUTING EDITOR

1 DOJ Cracks Down on California Vaccination Card Fraud

A *CNBC* article discussed several cases of doctors, nurses, and medical business executives exploiting the pandemic climate with sales of fake vaccination cards and coronavirus cures, and theft from federally funded pandemic assistance programs. One healthcare fraud, kickback, and laundering scheme brought in over $214 million. Meanwhile, a Colorado resident was accused of using blank vaccination cards to forge and sell hundreds of fake cards in at least a dozen states, including to three Olympians and their coach. A USPS employee is charged with printing fake cards while at work and selling them.

2 Transplanted Immune Cells That Fight Epstein-Barr Reversed MS

A *DailyMail* article said a small trial stopped the progression of multiple sclerosis (MS) by fighting the Epstein-Barr virus—identified as a possible cause of MS. A new T-cell therapy developed by Atara Biotherapeutics was employed to extract ATA188 immune cells from people who have successfully battled Epstein-Barr, and inject them into patients with MS. Twenty of 24 participants' conditions improved or stabilized after a year. After three years, nine patients saw brain scan improvements. The placebo effect can't yet be ruled out, as the virus can remain dormant for periods of time without an immune response.

3 Dyson Announces Air-Purifying Headphones. Wait, What?

The Verge reported on Bluetooth headphones from Dyson, with built-in air purification technology, called the Zone. Designed to combat air pollutants like industrial emissions, car exhausts, bacteria, and allergens, the headphones employ Dyson's existing air filtration technology in miniaturized form. Each earpiece contains a tiny compressor filtering out up to 99% of particle pollution. A visor sits in front of the face and creates a gap of clean air to breathe in. A separate attachment can create a full-contact face mask. These headphones won't release until fall, with specs such as price to come.

4 Packaging Issue Leads to Drug-Coated Catheter Recall

Medtronic has two FDA-approved drug-coated balloon catheters used to treat femoropopliteal disease and fistula stenosis. A *FierceBiotech* article says both the In.Pact Admiral and In.Pact AV were subject to recalls after Medtronic found that a change in its manufacturing lines created risk of damage in roughly 6,000 catheters—the sterilized pouch around the devices could cause the catheters to become unsterile. Now resolved, the company has still asked all customers to immediately return the catheters produced on that line.

5 FDA Says Young Kids Could be Vaccinated for COVID-19 in June

A *New York Times* article says FDA may roll out vaccines for children under 5 in June. The tentative timeline is:

June 7: FDA convenes VRBPAC to discuss an EUA request for a Novavax vaccine to prevent COVID-19 in adults.

June 8, 21, and 22: FDA convenes VRBPAC to discuss updates to Moderna and Pfizer-BioNTech EUAs to include younger populations for vaccination. Scheduling details will come as submissions are completed, reviewed by FDA, and discussed individually by VRBPAC.

June 28: FDA convenes VRBPAC to discuss if the SARS-CoV-2 strain vaccines should be modified, then which strain(s) to select for Fall 2022.

6 Man With Locked-In Syndrome Asks for Beer with BCI

An *arsTECHNICA* article discussed a 36-year-old German man diagnosed with progressive muscle atrophy in 2015—a variation of ALS—who lost the ability to walk and communicate verbally in less than a year, and became dependent on artificial ventilation and a feeding tube. In 2019, he received a brain-computer interface (BCI) implant. It detects neural signals that are sent to a computer and decoded by NeuroKey software, then played back as auditory feedback tones. After much training, the man could select letters to spell words. His first message: "thank you" to his medical team. With practice, he asked for a beer and for his favorite band, Tool, to be played loudly.

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

90%

GARTNER PREDICTS a staggering 90% of public sustainable packaging commitments won't be met by 2025.

$12.5 BILLION

THE VALUE that the ultrasound devices market is expected to surpass by 2026, driven by rising senior populations and relative lower costs and safety for early diagnosis.

Source: Polaris Market Research

67%

THE PERCENTAGE of pharma manufacturers who indicated they're pursuing lightweighting as a sustainability strategy.

Source: PMMI's Pharmaceutical Manufacturing, Trends Shaping the Future

14

AIM North America's Cannabis Work Group released a 14-pg white paper, *Track and Trace for the Cannabis Industry from Cultivation to Consumer*, for all members of the cannabis supply chain—growers, processors, manufacturers, distributors, dispensaries, and even consumers.

ON MED DEVICES IN THE HOSPITAL:

"They're rubber-banded together. They're placed in coat pockets, pants pockets, etc. So, think about that. There's wallets, phones, car keys, etc.—even cash in pockets—next to sterile barriers. Plus, the effect of that handling within the last 100 yards..."

—AUSTIN LIU, JOHNSON & JOHNSON SURGICAL VISION, AT THEPACKOUT

"The End Drug Shortage Alliance #edsa encourages FDA to require greater transparency from manufacturers so that health care providers can be aware of manufacturer supply chain risks.... The current opaque status of finished dosage form, active pharmaceutical ingredient, and key components leaves health care providers with little ability to predict and manage against drug shortages."

—ERIC TICHY, DIVISION CHAIR AT MAYO CLINIC-STRATEGIC CLINICAL LEADER HEALTHCARE EXECUTIVE, VIA LINKEDIN

STATE LAWS AFFECTING MISCARRIAGE TREATMENT:

"Any law that creates a hesitancy for physicians to uphold the standard of care for a patient has a cascade of harmful effects both for the patient but also for everyone else."

—BRYN ESPLIN, BIOETHICIST AND ASST. PROFESSOR OF MEDICAL EDUCATION, UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER, TO NPR

SEC Proposes Rules to Enhance and Standardize Climate-Related Disclosures for Investors

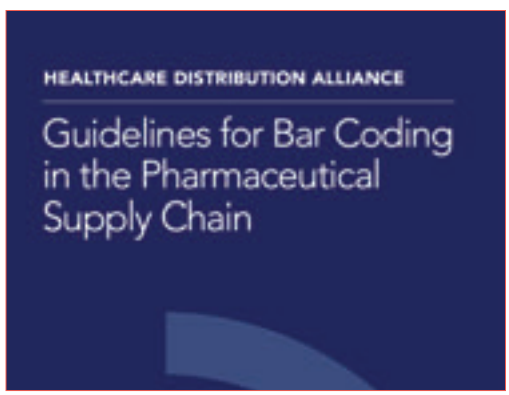
The SEC has proposed rule changes that would require registrants to include certain climate-related disclosures in their registration statements and periodic reports, including information about climate-related risks that are reasonably likely to have a material impact on their business, results of operations, or financial condition, and certain climate-related financial statement metrics in a note to their audited financial statements. The required information about climate-related risks also would include the disclosure of a registrant's greenhouse gas emissions. The proposed rule would include a phase-in period for all registrants, with the compliance date dependent on the registrant's filer status.

—Morgan Smith

HDA Guidelines for Bar Coding in the Pharma Supply Chain Available

The newly updated *HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain* document serves as a resource on the use of GS1 system data structures and symbologies to comply with the Drug Supply Chain Security Act's serialized product and data requirements. The document includes detailed guidance on shipping case bar code label formats, inner packs, the latest FDA and USP recommendations, and industry best practices for marking and placement of bar codes to be used in the U.S. pharmaceutical supply chain. The document is now available as a complimentary download at **HDA.org** under Resources.

—Morgan Smith



Parcel Health Launches Sustainable Medication Packaging Pilot Program

Ten independent pharmacies nationwide are participating in **Parcel Health**'s pilot program involving Phill Box™, a recyclable, compostable, water-resistant, easy-to-use alternative to plastic pill bottles. The Phill Box is made with Forest Stewardship Council-certified sustainably sourced paper and requires 30% less carbon emissions to produce compared to plastic bottles. Every part of the Phill Box has been made and designed with care to the environment, patients, and pharmacies. Pharmacies interested in using the Phill Box can apply to enroll in the next pilot program set for this summer. Inquiries should be sent to: team@parcelhealth.co

—Morgan Smith

Also in the News

- **MedAccred** launched a new contract manufacturer subscriber program, seeking to boost med device quality oversight.
- **J&J Vision** aims to save approximately 10 tons of plastic across Europe annually, placing delivery notes inside orders and removing external plastic pouch packaging for **ACUVUE®** deliveries.
- **The FDA** issued new draft guidance to increase racial and ethnic diversity in clinical trials. For more, visit **hcpgo.to/401**
- **DHL Supply Chain's** AI OptiCarton solution helps to optimize the filling volume of boxes, promoting cost and emissions savings.
- **The FDA** released new draft guidance, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.*

CYBERSECURITY

New Industrial Control System Security Threat

DAVID GREENFIELD, DIRECTOR OF CONTENT, *AUTOMATION WORLD*

TOP THREE TAKEAWAYS

1. A new alert was issued about attacks targeting ICS/SCADA devices.
2. Certain actors have developed custom-made tools for these attacks.
3. The technologies in the alert are used broadly across industry verticals.

If you're reading this, you're most likely a user of industrial control systems (ICS) to control your production operations or, at the very least, these technologies are critical components on the machines you use to produce your goods. That's why you need to heed the latest alert from the Cybersecurity and Infrastructure Agency (CISA) about cybersecurity tools targeting ICS/SCADA devices at **hcpgo.to/cisa1**

According to the alert, "The Department of Energy (DOE), the Cybersecurity and Infrastructure Security Agency (CISA), the National Security Agency (NSA), and the Federal Bureau of Investigation (FBI) have released this joint Cybersecurity Advisory (CSA) to warn that certain advanced persistent threat (APT) actors have exhibited the capability to gain full system access to multiple industrial control system (ICS)/supervisory control and data acquisition (SCADA) devices, including:

- Schneider Electric programmable logic controllers (PLCs),
- Omron Sysmac NEX PLCs, and
- Open Platform Communications Unified Architecture (OPC UA) servers.

The APT actors have developed custom-made tools for targeting ICS/SCADA devices. The tools enable them to scan for, compromise, and control affected devices once they have established initial access to the operational technology (OT) network. Additionally, the actors can compromise Windows-based engineering workstations, which may be present in information technology (IT) or OT environments, using an exploit that compromises an ASRock motherboard driver with known vulnerabilities. By compromising and maintaining full system access to ICS/SCADA devices, APT actors could elevate privileges, move laterally within an OT environment, and disrupt critical devices or functions."

Though this alert is primarily aimed at critical infrastructure organizations (e.g., power generation), the technologies listed in the alert are used broadly across industry verticals. Therefore, companies of all types could be impacted. As we saw with the WannaCry and NotPetya attacks a few years ago, the targeting of specific operations by these attacks does not protect non-targeted companies or verticals from these attacks.

A key aspect of this alert is that it highlights three specific steps users can take to help protect against these latest attacks (see the info in the box at the top right side of the alert at **hcpgo.to/cisa1**).

Eric Byres, CISA ICS Advisor and Chief Technology Officer at ICS software cybersecurity firm aDolus Technology says, "This is a classic case of why we need better supply chain transparency and analytics if we want to secure our critical infrastructure from nation states. Many of the underlying issues aren't in the software Schneider's engineers created, it is in the third-party code supplied by a German company called CoDeSys Group. They provide CoDeSys Runtime, a framework designed for executing industrial control system software. According to information that used to be [on the] CoDeSys website in 2019 (now removed), the CoDeSys Runtime product has been used in more than 350 devices from dozens of different OT vendors, and is widely used in the energy sector, industrial manufacturing, and Internet of Things systems."

This could lead industrial users to believe that, if they use Schneider software, they should then look for the vulnerabilities assigned to Schneider products in the National Vulnerability Database. But Byres says companies that do this "won't find a thing [because] the vulnerabilities are all listed as CoDeSys issues. For example, CVE-2022-22519 doesn't mention a single product that is affected."

Byres adds that this CISA Alert hints that this alert is "just the tip of the iceberg" in its statement that: This capability may work against other CoDeSys-based devices depending on individual design and function, and this report will be updated as more information becomes available.

"There are thousands of industrial facilities across the nation who believe they have dodged the bullet because they don't use Schneider or Omron products. They haven't dodged anything—they are just sitting ducks to these nation-state attackers," he says.

Eric Byres, CISA ICS Advisor and Chief Technology Officer, at aDolus Technology.

READ

Read this story for basics on ISTA's Standards 20 and 7E and potential updates.

10 Temperature Monitor Qualification Considerations

From the 2022 ISTA Forum TempPack: Panelists discussed the latest on temperature recording device (TRD) qualification, including dry ice and LCD screens, probes that disconnect, and what to consider before selecting a shipper integrated with a TRD.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

↑ Speakers from left at TempPack: **Mark Maurice, Sensitech; Eric Silberstein, eBiotech Consulting, LLC; Bryan Cardis, Eli Lilly and Company; Arif Rahman, MaxQ Research LLC.**

A panel gathered at the TempPack conference at the 2022 ISTA Forum in San Diego to talk about real-world challenges and best practices for monitor qualification in thermal packaging. Key takeaways included the following:

1. Dry ice packouts: Mark Maurice, Solutions Consultant, **Sensitech**, noted that some in the industry aren't aware that LCD screens don't necessarily operate at ultra low temperatures, making it appear that the sensor has stopped functioning. Testing your sensors will offer confidence that the sensor is still monitoring correctly even if the screen is not, or help you discover that the temperature recording device (TRD) truly did stop mid-shipment. The sensor should continue working if it is designed for those conditions.

Moderator Bryan Cardis, Sr. Advisor, Eli Lilly and Company, noted he has heard of scenarios where technicians discarded the TRD

because the screen was bleeding, so it's important to define how to handle failure modes properly. Some data is likely recoverable as long as the TRD is receivable.

2. Startup delay: There is often a duration of time that the data logger takes to get down to or up to the desired temperature. Because of how TRDs are designed, be aware of the response rate of that unit and ensure there is a startup delay for logging. (Document how long it takes for the whole system—panels, gel packs, PCMs—to equilibrate and come to within your temperature range.) Additionally, make sure your SOP defines startup and when the shipment is considered "ended" to keep quality from chasing down false alarms.

3. A note on scanning: Arif Rahman, Director of Technology, **MaxQ Research LLC**, explained that packaging for hospital blood products may be tagged with a chemical indicator. An issue can arise when the employee sets the package on the table to scan it before placing it in a secondary container: if the chemical indicator makes contact with the table as it's set down, it can warm up and change color leading to a false alarm.

4. Disconnecting probes: If a probe can easily be disconnected from its electronics, ensure you align with your metrology group to confirm whether that's acceptable, said Eric Silberstein, Principal, **eBiotech Consulting, LLC**.

From the audience, **Network Partners'** Karen Greene explained that standalone temperature data loggers are calibrated as a system, meaning as either a single channel or multi-channel device, any swap out of the temperature probe will invalidate the calibration status. The probe or probes must remain with the logger to maintain appropriate calibration status. As a best practices note, it is highly recommended that frequent quality/temperature performance checks are executed on the temperature data logger to ensure temperature performance within the calibration tolerances. As a typical calibration period is a 12-month interval, it could be problematic to discover that the logger was found "out of tolerance" at the 12-month calibration interval as it can call your data into question during that interval. When did the logger fall out of tolerance? What impact does the "out of tolerance" condition have on your data?

5. Multi-use TRD recovery: Silberstein also cautioned about cases where a multi-use TRD (in essence a reusable device) cannot be located for its 1-year recalibration. People may stick a TRD in a desk drawer for six months, or it may not return from its original destination. Brian Wallin noted that this can lead to costly and frequent deviations for devices not found. Silberstein recalled an example where quality asked him to find a device, but it was likely located in Puerto Rico, far from the California facility it originated from.

6. TRD ownership: If you're implementing multi-use TRDs, you need to consider the full lifecycle of the devices: reverse logistics, upkeep, and purchasing. Silberstein noted that for many companies, it may be best to put ownership of TRDs on the transportation service provider. Because a third party has a wide network, it might be ok for them to let a device sit in another country for a while and wait to send several back after they've accumulated, but he doesn't see the value for many biotech companies to handle the work of TRD upkeep and logistics.

7. Integrated TRDs: Some packaging suppliers integrate TRDs into their shippers, and there are pros and cons to be aware of. They offer convenience to end users as all-in-one systems, and they eliminate concerns over qualifying probe locations.

But before implementing, consider protocols for battery replacement, data access for the end user, and if additional (supplier-specific) software will be necessary to read the data. If the vendor owns the process and data, will there be an extra step for issue resolution, where you as the end user have to work with their customer service department instead of your own quality group? Address gaps in inter-company communication.

Carolyn Williamson highlighted that if the TRD battery dies, you'll have to remove it. A battery has so much shelf life, and you'll need safety stock to deal with supply chain disruptions, which will require space at your facility.

8. Light sensors: Questions remained regarding qualification of light sensors designed to alert end users if a shipper is opened. Williamson said she determined in at least one case that the sensor needed a certain level of light to register, so she wasn't confident that that feature could prove lack of opening to a health authority.

9. PDF data transfer: Maurice said not all PDFs are the same—there are higher and lower levels of encryption. Some monitoring systems embed their data in PDFs that are fully open source which can be modified with Word.

He recalled an investigation into a freight forwarder that falsified a document because of the high value of the shipments, but he also stressed that the vast majority of companies are trustworthy. "It goes to 21 CFR part 11. If you can modify a document with Word, then you have to do a risk assessment," he said. Photo editing software may be able to make changes, so it's important to ask yourself how you're managing the process to stay compliant with 21 CFR part 11. He also cautioned that even email is being scrutinized as a non-validated process for data transfer.

10. Predictive models: More and more focus is being placed on the power of predictive models to try and intervene when an excursion appears likely. An audience member asked, "How do quality groups look at prediction? How do you validate a predictive model?"

The panelists said this will take time. Over time, you're collecting

↑ Sensitech recently launched its TempTale® Ultra BLE, the newest wireless addition to its line of digital temperature monitoring solutions.

data, feeding it back in. You keep tweaking the process and analysis so that the model becomes more accurate and confidence levels increase, explained Maurice.

Silberstein said bringing in a neutral third party may help for testing the 100 or 200 test cases that this effort will need over the course of a year, along with issuing papers on the topic and ensuring it's being computer validated. Rahman agreed, "It's a process. First, we have to come up with a lot of test cases. We want to do performance verification, continuous monitoring to know that it's still matching the prediction."

Parting words: While various features beyond temperature can be measured (e.g. light, humidity, and shock), ask yourself if those sensors are necessary to your process. If they're not useful to you, then consider whether you need to go through the work of qualifying them.

Filling and Capping Solutions

Made in the USA

Streamline your Production with a Complete Solution for Automated Assembly

Ring Dex 2

Automated Filling & Capping Machines...

From compact benchtop designs to full scale production machines. We have the equipment to fit your needs!

Multiple Industries...

Dispense Works provides global application expertise in Pharmaceutical • Food Healthcare • Chemical Industrial and other Packaging Industries

RF-2415

Hopper / Feeders

Filling & Capping

Screw Caps

Servo Torque

Packaging

Dispense Works Inc

(815) 363-3524 | dispenseworks.com | info@dispenseworks.com

Linear Servo Track System Allows Production-on-Demand for Liquid Filling

With the help of a track system from B&R, this Polish OEM is building machines that make it practical for liquid product CPGs, like pharma or cosmetics companies, to plan for short and specialized product runs.

MATT REYNOLDS, EDITOR, *PACKAGING WORLD*

For CPGs hoping to launch new liquid products into industries like pharmaceuticals, cosmetics, and household chemicals and cleaners, highly customized or short runs have always been severely limited by cost and implementation times. Traditional customization methods made it unprofitable to release small batches.

Consider this scenario: The production department at a large cosmetics company at a manufacturing plant in the suburbs of a European capital takes a call. Someone from the marketing department is asking to order a small batch of shampoo for a promotional campaign. How big is the order? It's quite small at only 5,000 units. That's a problem in and of itself, but this marketing person is requesting a couple of changes, too, asking that the shampoo color be different, and filled into some custom bottles instead of the usual ones. Oh, and they'd also like to change the caps and the labels. And the deadline happens to be early next week.

These expectations wouldn't sound acceptable to most CPGs. Unless the product is already waiting on the shelf at the warehouse, it's simply unprofitable to apply so many changes to a well-oiled machine of a production line. At least, that used to be the case.

Today, Polish packaging machine builder **Unilogo Robotics** is trying to make these scenarios not only doable for liquid product CPGs, but downright practical. Its Cleanline system, a new, fully automated packaging line based on **B&R's** ACOPOStrak transport system, makes short runs with high variability possible—in fact they can be deployed extremely rapidly and provide unprecedented optimization performance with just a few clicks.

↑ Unilogo Robotics' Cleanline packaging system targets liquid product CPGs in industries like cosmetics, pharmaceuticals, and household cleaners and chemicals. Cleanline as a whole complies entirely with Industry 4.0 and Internet of Things principles in that the machine is coupled with a smart network. The entire process is very simple to control and monitor, and it can all be done in real time, according to the company.

Pioneer and visionary in the packaging technology market

Unilogo Robotics is a medium-sized Polish OEM that designs and manufactures solutions for the cosmetics, chemical, and pharmaceutical industries, specializing in liquid product customization. According to its supplier B&R, the company's machines and production lines are the embodiment of innovation in its complete form, and of true engineering panache.

"Initially, we provided services to large corporations moving their

manufacturing plants to Poland," says Tomasz Nowacki, Founder of Unilogo Robotics. "After some time, large retail chains appeared, too, and began to roll out private labels. This changed the playing field: the market started to demand machines adapted to diverse bottle shapes, caps, and labels. At that time, we set ourselves the goal to create the highest-performing productive production line."

The company also set itself specific objectives and targets for its lines' productivity. Production batches are getting shorter and require constant machine changeovers, so Unilogo assumed that its line would always produce 12,000 to 15,000 units per shift, regardless of how complex the customer's components (bottles, corks, labels) are and if changeover would be required one, two, three, or four times.

E-commerce standards in B2B

An approach that has become a standard now at the consumer level is one we've all become familiar with in e-commerce: speed and flexibility of service are universally required qualities. Is this approach also penetrating the B2B market? Most companies still have a traditional supply and production chain in place, built for an outdated sales model based on holding expensive product in inventory. According to B&R and Unilogo Robtoics, though, today's world demands immediate response and flexibility, a product-on-demand concept. Unilogo is preparing for such a revolution and is already gaining competitive edge by using adaptive manufacturing in its design process.

Thanks to Unilogo's Cleanline, cosmetic, chemical, and pharma CPGs are able to implement production-on-demand, and the company says it will bring new dynamics into production and let their customers realize meaningful savings in warehouse and product storage. Cleanline is an integrated system of robotic modules in the form of a compact production line, designed and developed in accordance with the Industry 4.0 concept. It includes a fully automated robotic production line for lotions, personal care products, perfumes, household chemicals, and similar liquid products, with changeover and start-up times of only a few minutes. Parts are 3D-printed to allow the line to work with any type of packaging and closure, and additionally make it possible to launch new packaging to the market within only a few days.

The biggest advantage of Cleanline is its flexibility, which is an extension of its modular design. The whole line is based on building blocks that can be easily combined and adapted to the needs of the individual business, as well as expanded with new modules. Cleanline includes a module responsible for sorting and capping, a dosing module, labeling module, and a module responsible for packing the units into corrugated shippers and placing them on pallets. Part of the modules connect with the ACOPOStrak intelligent transport system.

ACOPOStrak intelligent transport system

According to Nowacki, the innovation that makes Cleanline so versatile is the specially developed intelligent transport system. It is based on magnetic trolleys [also called movers in other linear servo contexts] that move along a magnetic track. The trolley shape makes it possible to handle and transport any pack type without having to perform a changeover. The core of the system is B&R's ACOPOStrak technology. It shortens the entire line considerably while making it extremely flexible and sustainable; particularly important for the calculation of capital expenditures.

The entire process takes place in an end-to-end system, without involving human operators or manual labor. What also makes Cleanline stand out is the fully robotic unpacking/packing module. A set of several robots autonomously unpack the pallets with the packaging units, as well as perform their blowing, laser marking, and feeding. Robots are also used at the final stage of packing of the finished products, and human labor is only required to transport the empty pallets and collect the loaded ones.

Capping module using 3D printing

After seven years of experiments, Unilogo Robotics successfully developed a capping module that the company is really happy with. It is fully automated and uses 3D-printed format parts, allowing Cleanline to remain a 100% versatile machine, the company says. The whole system is efficient and optimized in terms of dimensions, occupying only 2.1 m of line length.

↑ **The core of the system is B&R's ACOPOStrak technology. It makes the entire line considerably smaller than it would otherwise be, and provides a high degree of flexibility, which is particularly important for the calculation of capital expenditures.**

Cleanline as a whole complies entirely with the Industry 4.0 and Internet of Things (IoT) principles. This means, among other things, that the machine is coupled with a smart network. The entire process is very simple to control and monitor, and it can all be done in real time.

Control panel, OPC UA, and Pack ML to save more resources

Cleanline is controlled using a universal HTML5-based panel. This solution makes sure that all process parameters can be changed from a single place. On top of that, the panel can be expanded by adding features required in the customer's process, as well as personalized and adapted to the individual expectations, the standards adopted in the relevant manufacturing plant, or simply to the operators' habits. Another advantage is the use of the OPC UA (Open Platform Communication United Architecture) technology. It makes it possible to monitor data, also in real time, and to access detailed reports, or even videos recording key process stages or emergencies. Data is stored in the cloud, maximizing working convenience and making it possible to control the whole process from any place. This solution also significantly facilitates repair and maintenance of the line as well as shortens the response time of Unilogo tech support in emergency situations.

A particular advantage of the line for businesses with more than one production device is its compatibility with the PACK ML system, providing time savings, working comfort, and software standardization. Unilogo Robotics' initial goal was to provide a production line that would be able to unpack a pallet of empty packaging units, fill them, cap them, apply labels, and pack them into boxes ready to be shipped to the customer, all done efficiently and involving as few people as possible.

"We believe that robotic Cleanline solutions will soon replace overly complicated and inefficient product customization and packaging systems," Nowacki says. "The market's future lies in flexible solutions enabling customization and series production in small batches. We look for companies that think like us and see this as their opportunity for success."

Smaller Cannabis Vape Pod Carton Brings Big Sustainability Benefits

Cannabis brand STIIIZY redesigns its vape pod packaging with 25% less material, resulting in sustainability and efficiency gains, as well as reduced costs.

ANNE MARIE MOHAN, SENIOR EDITOR,
PACKAGING WORLD

"With great power comes great responsibility," so the saying goes. That's why when cannabis provider STIIIZY's cannabis pod was recognized as the best-selling brand in California and the third best-selling brand in the U.S., the company felt compelled to provide its consumers with more eco-conscious packaging.

STIIIZY, a brand of Los Angeles-based cannabis holding company Shryne Group, was "born out of authentic Los Angeles culture and a desire to provide the highest-quality cannabis products at affordable prices." That's according to Jackie Kim, STIIIZY's Director of Integrated Marketing, who adds that the brand name itself is inspired by the term "steez," style and ease. "The three 'I's represent 'innovate,' 'inspire,' and 'influence,'" she adds.

STIIIZY's pod is part of a proprietary vape system that includes the custom-made pod filled with high-grade cannabis oil and a sleek, proprietary handheld battery into which the pods are inserted for vaping. In late 2019, the company began working on a redesign of the paperboard packaging for the pod that would use less material in order to gain cost and resource efficiencies.

The new packaging was created in-house by STIIIZY'S large team of in-house designers. Shares Kim, when recreational cannabis took off, the company had a difficult time working with third-party designers and companies, which were not yet familiar with cannabis laws, culture, and compliance. "So we built our own team, and never looked back," she says.

To set the stage, the existing packaging comprised an outer paperboard carton, with an inner tray, die-cut to hold the pod. The tray took up two-thirds of the package, on the right side of the carton, with the left side empty. Each carton was customized, with the variety name included with the logo lockup. An anti-counterfeit authentication sticker appeared on the front of the carton, but only for those products sold in California. The child-resistant (CR) mechanism was positioned on the left side of the box.

In creating the new package design, the guiding principle was to

↗ **The STIIIZY vape pod package BEFORE.**

↗ The STIIIZY vape pod package AFTER.

use less material. One of the biggest material savings came from right-sizing the carton so that its dimensions are the same as the tray, getting rid of the empty space on the left side of the carton. Another was eliminating a paper-insert user manual—measuring from 2.5 to 3.5 in.—and replacing it with a QR code printed on the left side of the inner tray through which consumers can easily access, by way of a smartphone, user instructions, information on product features, and disclaimers.

"We realized things like this were a total waste of money, material, and production time," says Kim. "By getting rid of this insert and decreasing the size of our package, we easily reduced our material use by more than 25%."

Another modification made to the package that helped make a smaller carton possible was a change in placement of the CR feature and some of the graphics. As Kim explains, the CR mechanism comprises a round die-cut in the carton that exposes the inner tray. The "button" acts as a latch. To get to the product, consumers hold down the button, while pulling a tab at the top of the package, which allows the tray to slide out.

For the new design, the CR feature was moved from the side panel to the back of the carton. In its place, STIIIZY positioned the tamper-evident label, which now also carries batch information. Says Kim, "Before the redesign, our packages featured both a batch and a tamper-evident function. Moving forward, our tamper-evident stickers will pull double duty. Aside from keeping the contents inside each carton safe and secure, the labels will also feature batch information, which is required by state. By combining these two, we really maximized our use of space."

To enhance its anti-counterfeit measures and ensure consumers they are getting authentic product, STIIIZY also changed its use of the holographic sticker. Instead of being added only to those products sold in California, the sticker will be used on all packaging.

While to the casual observer, the changes in STIIIZY's packaging may not be that noticeable, given that the graphics remain largely the same, the redesign has had a significant effect all across the STIIIZY supply chain. "In the very early days, we produced packaging in the tens of thousands of units. Today we produce millions of units," Kim says. "Reducing the amount of packaging we use, whether an insert or a reduction in the overall size of the package, has a tremendous impact on our operations and bottom line. Our products are available in multiple states, and the total savings in aggregate across all of these state lines really adds up. It also takes less time for our teams to package our pods, we're saving a ton of paper, and we've reduced our overall waste impact."

Johnson & Johnson Chief Medical Officer Highlights Unit Dose Packaging's Role in Preventing Accidental Ingestion

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. About four busloads of kids come into emergency departments each day in the U.S. because of accidental unsupervised ingestions.
2. Dr. Ed Kuffner discusses how packaging innovations, including unit dose packages, can reduce these risks.
3. A recent QuickFire Challenge winner, Packlock, offers a new take on blisters with a two-step mechanism to access the dose.

Healthcare Packaging talked with Dr. Ed Kuffner, Chief Medical Officer at Johnson & Johnson Consumer Health, where he leads a global team of medical and safety professionals. Throughout his career, Ed has been passionate about patient safety and has worked with a broad range of internal and external stakeholders to tackle complex public health issues, such as preventing medication errors, accidental unsupervised ingestions, misuse, abuse, and overdose. [*Editor's note: Answers have been edited for brevity.*]

Healthcare Packaging (HCP): How did your experience lead to your involvement in the unit dose packaging community?

Dr. Ed Kuffner (EK): I'm an emergency physician and a medical toxicologist. I've worked in different emergency departments over my career and at a poison center. Both in the ER and at the poison center, I've unfortunately cared for many children whose illnesses and injuries may have been prevented. I've treated young kids who've gotten sick after getting into medicines when they were not kept appropriately out of their reach or kids who suffered medication errors when given an incorrect dose by a caregiver. When you're in that setting and a kid needs to be admitted to the hospital, or even the ICU, it's heartbreaking for all parties involved. It's hard for me as a clinician, it's hard for the staff, and it's

certainly tough on the kids and their families. So, for me today as the Chief Medical Officer for Johnson & Johnson's (J&J) Consumer Health business, we have doctors, nurses, and pharmacists working together to keep all the users of our products safe, especially young kids.

↑ Dr. Ed Kuffner, Chief Medical Officer at Johnson & Johnson Consumer Health.

HCP: What led to J&J choosing a unit dose technology focus for its recent Packaging Design QuickFire Challenge?

EK: Last year, we worked with a variety of people within the company—R&D, our safety team, and Johnson & Johnson Innovation—and launched a QuickFire Challenge which sought to crowdsource potentially groundbreaking ideas to improve unit dose packaging.

Some may ask, "Why would you launch a challenge like this?" Unit dose packaging really has the ability to help prevent accidental unsupervised ingestions, which is when kids get into medicine when it's not appropriately kept out of their reach. Having worked in the ER and at the poison center, I think some people may be surprised: every day in the U.S., about 150 children—about four busloads of kids—come into emergency departments because of accidental unsupervised ingestions (source: **hcpgo.to/safekids**), and many more will have parents or caregivers call the poison centers.

Packaging innovations, like unit dose packaging, can reduce these risks. You have adults who are trying to use medicines appropriately—many who may have limited dexterity with their hands, people who may have arthritis and may have difficulty or struggle when they're just trying to use medicines appropriately. If they can't get into the packages easily, that may compromise their health if they consequently decide not to take the medicine. If people feel it's too difficult to access, they may take their medicines out of a child-resistant package and put it in another type of container which isn't as safe. That's where kids can get into trouble. On top of that, all of us—as individuals, as companies—we want to become more environmentally friendly. I think we all have a job to do in protecting the planet.

At the end of the day, if we can make the packaging a little bit easier for people, we can hopefully enhance adherence and help people to take medicines more appropriately. Thinking about all these different aspects, we wanted to stimulate innovation and hopefully make packages that are child-resistant, senior-friendly, environmentally friendly, and that potentially increase medication adherence. One way of doing that was through the QuickFire Challenge, where we try to inspire innovators. We offered $100,000 in grant funding, and our awardee, **IDEEWISS AG**, is a Swiss company with a unique packaging design called Packlock.

HCP: What stood out to you about IDEEWEISS AG's Packlock in terms of protective features beyond a traditional blister card?

EK: Different blister cards have different backings which help control the amount of force that's needed to push a tablet through the backing.

If you have a backing that's easy to push the pill through, even young children can access that medicine relatively easily.

If you have backings that are stronger or you use other technolo-

WATCH

Watch this brief video, where Dr. Kuffner offers actionable tips for those within and outside the packaging community to prevent unsupervised medication ingestions in kids.

↑ IDEEWISS AG, a Swiss company with a unique packaging design called Packlock, won the Johnson & Johnson QuickFire Challenge in unit dosing.

gies like a bend-and-peel technology, it gets more difficult for young children to self-access, but it also gets more difficult for the older patients, those with arthritis and other people trying to use the products appropriately.

Packlock's design offers a two-step mechanism in order to access the pill via the blister card. We know that two-step mechanisms really can help prevent accidental unsupervised ingestions because they're a little more cognitively difficult for kids to figure out. What Packlock created is a blister card, which when you put some pressure on the card, creates a rectangular prism. Applying pressure and creating the rectangular prism is required to open up a space between the backing of the card.

This allows the user to push a pill into the space and have the pill drop down. We think this design will both help protect kids and hopefully make it easier for adults to appropriately access medicines. Another positive about Packlock's innovation is that it uses a relatively traditional type of blister card design. We think that the cards could be produced on packaging lines used to produce blisters today, with only minor modifications, making it easier to implement.

HCP: What do you feel is the intersection of child-resistant, user-friendly, non-recloseable designs with sustainability? For so long, these concepts seemed at odds with each other, at least at face value.

EK: There are many different considerations. We've talked about some of them: it's all in striking the right balance between preventing accidental unsupervised ingestions, encouraging adherence, and not overburdening adult users of these products. In addition, we want to try to prevent medication errors, protect the environment, and also be able to manufacture these at a reasonable cost. At the end of the day, if you don't produce a package that really delights patients and consumers, people aren't going to use it and you really defeated the purpose of the innovation.

It's not easy to strike that right balance. This is where I try to use my position as the Chief Medical Officer within J&J's Consumer Health business to advocate for the safety and wellbeing of patients and consumers, and try to prevent those curious young kids, which we all love, from becoming patients. I try to encourage and motivate the R&D teams to innovate and make sure we're striking that right balance. It's a constant balancing act, but with innovations like Packlock, new designs, and new technologies, I think we're really moving in the right direction.

HCP: Parent, caregiver, and clinician burnout have made numerous headlines lately, and people are on their phones a lot. We're all fairly distracted compared to 10 or 20 years

↑ Applying pressure to the Packlock blister card and creating the rectangular prism is required to open up a space between the backing of the card, allowing the user to push a pill into the space and have the pill drop down.

ago. Is that causing issues that designers should be factoring in? On the positive side of that, patients are more educated, connected, and knowledgeable.

EK: You highlight a lot of the considerations when I look at preventing medication errors or accidental unsupervised ingestions. I look at it like a continuous journey that we're all on together: patients, healthcare professionals, industry, healthcare systems, regulators, and consumer advocacy groups.

For me, it's always about digging deep into the root causes of medication errors and accidental unsupervised ingestions. The more we understand the root causes, the more we can innovate, design technologies, and implement new packaging and techniques to try to address them.

When new products come onto the market, let's understand what's going on with those products. When we start expanding into new categories, it's an opportunity to take a step back and dig deep again and ask if we really understand what's happening with the product and packaging.

I'll give a couple of examples:

- The legalization of THC-based products. When companies started to formulate and market them in appealing food-based forms, that created risks, not just for the users, but for kids when it relates to accidental unsupervised ingestions.
- We're seeing expansion in natural products and supplements. I think there's an opportunity for all of us. How do we further refine how these supplements are dosed? Can we put additional measures in place to protect children like adding dosing devices and child-resistant packaging as we have on more traditional over-the-counter or prescription medicines?

I think digital tools have the ability to help make dosing much more accurate to prevent medication errors. How do we better educate patients, consumers, and caregivers about these things?

With all these new advances, I'm optimistic that new technologies and digital solutions could help us reduce medication errors and accidental unsupervised ingestions.

HCP: Do you have any tips for packaging engineers who are designing or updating unit dose packaging and drug delivery devices?

EK: I know I've said it, and I'll say it again: it's all about striking the right balance in making it easier for the users so they can access medicines, safer for the kids so that they don't get into them, and being environmentally friendly.

I would encourage packaging engineers to always think beyond the brief. When you get that brief from R&D which is primarily focused on sustainability, I would say, how in the same redesign process could we delight users and further enhance the safety by preventing accidental unsupervised ingestions or medication errors and find that win-win.

If a packaging brief says to focus on decreasing costs—which is certainly something people are interested in—as a packaging engineer, can you also find a way to funnel some of those savings back into upgrading the packaging in other ways like adding or upgrading the child-resistant feature? Sometimes that means pushing your business partners to look at ways to simplify across the portfolio. For me, it's really about these win-win type of situations.

One other aspect is how do we find more ways to co-create with patients, consumers, and healthcare professionals and put prototypes in their hands? Even skilled and experienced packaging designers and safety experts who've worked in this area for many years have things to learn—when you co-create and put products and prototypes in the hands of patients and consumers, it helps you dig deeper into their experiences. Oftentimes, I'm even surprised. I think working together with patients and consumers, you can really unlock some of the insights that may be overlooked if we don't partner in that way.

Innovations in Drug Delivery that Boost Patient Adherence

Kuffner says: We've seen a lot of new innovations recently, and we'll continue to see more. It's an exciting time. When I think of some of the innovations that excite me personally, it's technologies that allow us to deliver more sustained release or a longer duration option. A number of years ago, sustained release meant 24 hours, or over a couple of days. Now we actually have the ability to deliver sustained release medicines that are released over months and are starting to get to years. It makes it much more convenient for patients. When they don't have to dose as frequently, we know that this improves adherence and that improves outcomes.

Certain technologies like microneedle technologies have the potential to deliver medicines in new settings with less pain. I think that's really going to help patients and consumers.

As we start to get more data on genomics and personalized drug regimens, I think that will also spark innovation in how we work to deliver medicines not just to the broad population, but in ways that help individuals.

And even today, coming out of the pandemic, we've seen a big rise in telemedicine. We've seen people using technologies more that allow healthcare providers in health systems to monitor remotely. I think these types of technologies will continue to push the boundaries and create new opportunities for different drug delivery options. There's a lot coming in the future.

Aurobindo Pharma USA Increases Distribution Throughput and Performance With New Automated Warehouse System

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. While expanding its U.S. footprint, the generic pharmaceutical giant wanted to automate its U.S. nerve center in NJ.
2. They sought an automated storage and retrieval system (ASRS) that boosted storage capacity by 450%.
3. An operating system manages the location of every pallet for optimal traffic, and pallets can be stacked high to make the most of space.

India-based Aurobindo Pharma manufactures and distributes millions of generic pharmaceuticals to more than 150 countries, overseeing a complex, global operation where safety, security, and speed are paramount.

Seeking to manage its expanding U.S. footprint, the company broke ground in 2016 on a new state-of-the-art 567,000-sq-ft distribution center in East Windsor, NJ. Located about 50 miles outside of New York City, the facility is FDA-approved, Current Good Manufacturing Practices-compliant (cGMP), and powered by 39,000 rooftop solar panels.

It serves as the exclusive hub for Aurobindo Pharma USA, the company's vertically integrated U.S. distribution entity. The facility currently ships more than 200 million units annually across 200 product categories to hospitals, doctors' offices, commercial pharmacies, and retail outlets nationwide. With annual growth routinely surpassing double digits per year, even this advanced operation required further automation investments to meet current and future demands.

One of the company's manufacturing sites in India had already enjoyed great success with StorFast ASRS, a system engineered by **Signode**, a global provider of packaging automation. The company decided to invest in the system for its New Jersey operation in late 2017, with further build-out in 2020. "We were able to work collaboratively with the global team at Signode to develop and implement a strategy that had the ability to address our ambitious growth objectives," said James Downey, Senior Director of Distribution, Aurobindo Pharma USA.

The investment paid off. Aurobindo Pharma's U.S. nerve center has dramatically amped up its warehouse storage capacity, from 7,000 pallets to 34,000 pallets, a remarkable 450% increase. "Optimal outcomes start with listening to the customer, learning about their needs, then meeting them with the right scalable solutions that ensure their current and future demands are met and accounted for," said Byron J. Paul, Group President, Automation & Packaging Technologies, Signode. "Our partnership with Aurobindo is a perfect example of this in action."

ASRS: Path to efficiency

The StorFast ASRS (automated storage and retrieval system) provides high-density, 24/7-access to all products in the warehouse. The shuttle & cart system allows multiple orders to be processed simultaneously and can flex between high-volume input and peak shipping schedules to optimize utilization and efficiency at all times.

While the StorFast ASRS has been gaining popularity in both

↑ The StorFast system knows which pallet to pull from—so if there is a pre-picked partial pallet that meets the need, the system pulls from there instead of retrieving a full pallet.

↑ The modular system can easily be added to and combined with future automation enhancements.

↑ In this application, the system spans seven floors. The pallets can be stacked as high as is needed.

↑ Large orders are proactively planned; the system allows for order sequencing so that larger orders can be picked and packed during slower processing times.

existing and new facilities across industries, Aurobindo Pharma USA is the first U.S.-based pharmaceutical warehouse and distribution center to deploy an ASRS. "This sophisticated system seamlessly manages the inbound and outbound storage and retrieval of up to 80 pallets per hour simultaneously," said Scott Pruner, Distribution Manager, Aurobindo Pharma USA. "In one month, that equates to approximately 18 million units, which is a high benchmark we couldn't reach without the StorFast system."

The pallets can also be stacked as high as is needed, making use of untapped vertical warehouse space. In dense urban environments where land is at a premium, like the New York City metropolitan area, the ability to "build up instead of out" allows the company to maximize its automation investment through smart, vertical scalability. In this application, the system spans seven floors.

Simplifying complex system integrations

Advanced automated warehouse systems are coordinated, maintained, and operated by interwoven and complex technology, operations, and human interactions. Signode designed a complete operating system, with StorFast ASRS at its core, that manages the location of every pallet for optimal pallet traffic. It is seamlessly integrated with Aurobindo Pharma USA's existing Enterprise Resource Planning (ERP) and Warehouse Management System (WMS) to ensure protection and security throughout the product journey.

Order management software indicates what products are required to fulfill a specific customer request. The WMS determines which pallets should be pulled from the warehouse for fulfillment, and the ASRS control system determines the sequence of processing and guides carts, shuttles, and lifts to optimize the throughput and ensure product is presented for shipping to meet time requirements.

"It's a very intelligent system that can do wonders," said Khantesh Pandya, Distribution Manager, Aurobindo Pharma USA. "There are no issues with its ability to smoothly interface with our current systems—with accurate data transfer throughout the process."

Data transfer starts with product arrival at the facility, where U.S. regulatory agencies stand at the ready to verify the overseas shipments, including U.S. Customs and Border Protection (CBP), the FDA, the Department of Agriculture, and the Drug Enforcement Administration.

"ASRS is the best thing we've ever invested in," said Lorie Johnson Lawson, Distribution Manager, Inbound Import Receiving, Aurobindo Pharma USA. "From where we are now, we can move more product faster and with greater accuracy to our customers."

Arrivals are tracked and traced in the system. Pallets are sorted and placed in the most appropriate location—based on volume, product type, expiration date, and other factors—and then store-

General Flow of Goods

Entry: Products typically arrive in cartons inside of containers from the production facility by truck. Currently, cartons are unloaded and palletized manually. This is an area identified for the next phase of the automation project.

Wrapping: Pallets go to an automatic wrapper before being loaded into the ASRS warehouse.

Retrieval: Pallets are retrieved automatically from the ASRS and sent either as a complete pallet directly to the loading area or to a pick-and-pack area where mixed pallets are created for shipment to individual customer locations. Partial pallets are automatically returned to the ASRS warehouse.

Loading: Pallets are loaded onto trucks for delivery via forklift.

↑ **The facility currently ships more than 200 million units annually across 200 product categories to hospitals, doctors' offices, commercial pharmacies, and retail outlets nationwide.**

duntil ready for retrieval-based order fulfillment needs. For instance, high-volume items are stored on lower levels and closer to picking stations in order to maximize throughput. In addition, high-volume items are placed in dedicated rows in the warehouse to minimize pallet movement. These rules are defined by the user and can be adjusted based on changing order patterns, seasonality, product portfolio changes, etc. Reports and dashboards assist in the adjustment of pallet positioning.

For products near expiry, the WMS defines Date Code rules, and the Signode ASRS software complies by delivering the oldest pallets first for picking and fulfillment. Pallets can be requested by the WMS software for retrieval if required based on Date Code requirements.

Scalable compliance

"Increased control yields required compliance and are among the system's best benefits," said Downey. "We can easily fill both large and small orders, everything from full pallets to cases for wholesalers and retailers to individual cartons delivered to your local doctor's office or neighborhood pharmacy."

Because some shipments contain more than one type of medication, they must be assembled by pulling products from various pallets. The StorFast system knows which pallet to pull from—so if there is a pre-picked partial pallet that meets the need, the system pulls from there instead of retrieving a full pallet.

Large orders are proactively planned; the system allows for order sequencing so that larger orders can be picked and packed during slower processing times, optimizing the number of

READ
Read this story on 30 warehouse improvement tips.

orders that can be fulfilled during peak delivery times. When Aurobindo Pharma USA has to prepare time-sensitive shipments, it can avoid time crunches, versus suddenly having to shift gears and work at double the speed to meet important deadlines.

For added efficiency—and because customers with high-volume orders tend to procure full pallets—orders can be delivered directly from the ASRS warehouse to the shipping area, automatically bypassing the mixed pallet picking area.

Scalability and customization are built into the system that was designed through the collaboration of the two global organizations. Moving from manual to automated wasn't without its challenges during the three-month installation and testing period. "Signode's support at every step of the process made a huge difference," said Pandya. "We had highly skilled and qualified Signode technicians who were on-site every day, supporting us through the transition, and we never had issues with pallet traceability or orders unfilled."

Future-proofing for growth

The StorFast system is designed to grow as quickly as Aurobindo Pharma USA, which is still in the midst of rapid expansion. The company notes that an additional 20 to 50 of its products are in the FDA-approval pipeline, with continuing double-digit growth projected year-over-year. The modular system can easily be added to and combined with future automation enhancements.

In fact, Aurobindo originally was looking for a 20,000-pallet location system but worked with Signode mid-planning to increase it to the current 34,000. Future expansions are already being planned, and the facility has the capacity to hold more than 40,000 pallets.

"This only comes together with the commitment of senior management to provide the resources, systems, and capital needed for us to deliver the volume and precision our customers expect," said Downey.

Added Pruner: "Without Signode and StorFast ASRS, we wouldn't be where we are today."

Annual Package Design Gallery

Each year, *Healthcare Packaging* evaluates an array of over-the-counter product packaging designs, assessing the pros and cons from a user perspective.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

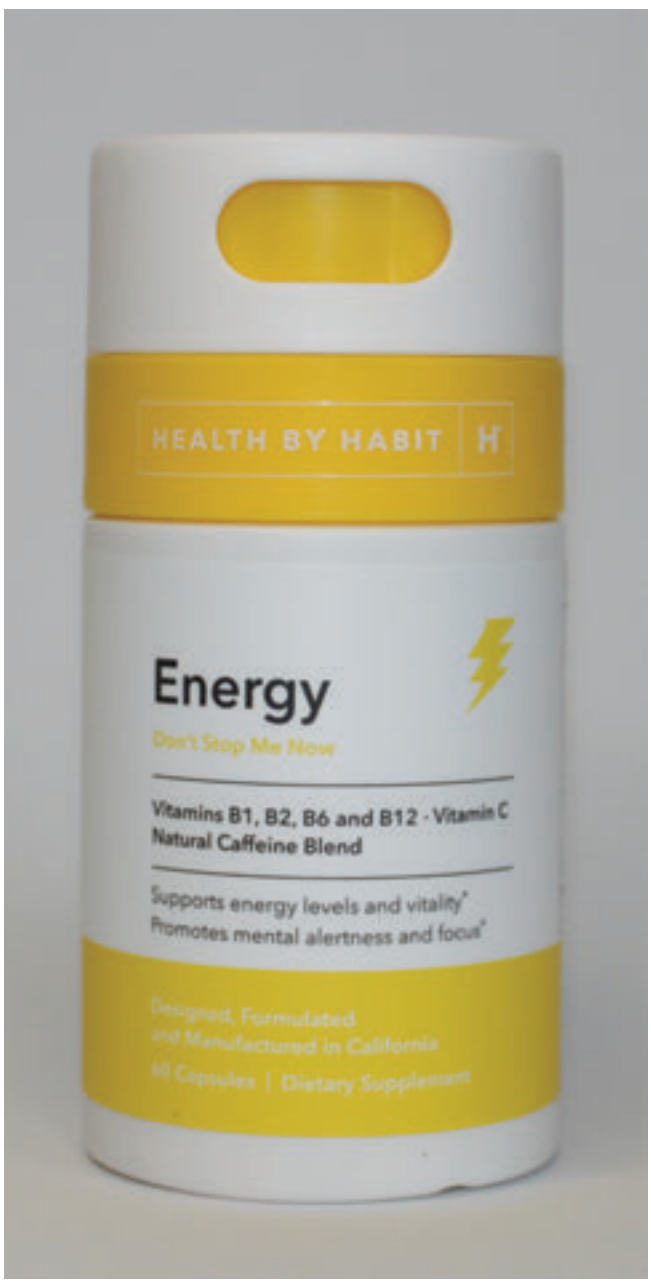
Health By Habit Energy Supplement

PROS

+ In matte white and yellow, the lightweight HDPE container features a unique, sturdy two-tone cap that twists to reveal an opening for capsules
+ With minimal graphics, the front of the label notes active ingredients in clear black type, with quippy copy
+ Black font on the back is clear, along with suggested serving size and social handles

NOTES

- Cap is removable by unscrewing the traditional way and offers a wide mouth for easy access to capsules
- Without cues, some consumers may miss that the cap overlay twists to reveal an opening (where the yellow oval is in the image); while fast, several capsules came out at once when using the cap opening
- The clean, minimalist aesthetic is nice, though it could be difficult for some users to read the white font on yellow background for the Energy blend in particular (other styles are different colors and easier to see)
- The bottle stands out and doesn't feature a carton, but it does have 2-in. headspace



McNeil Consumer Pharmaceuticals Co. Mylanta® One Antacid + Anti-gas EcoCare™ Tablets

PROS

+ Sleek, opaque silver EcoCare bottle stands out on shelf
+ Label notes EcoCare is composed of "infinitely recyclable aluminum"
+ Packaging with recloseable cap can be repurposed by consumer
+ For tamper evidence, label notes not to use if cap is broken from ring

NOTES

- With years of consumer perception that "aluminum containers mean liquid," the user may need to take a close look at the label to understand this is not a liquid format—particularly with the opaque bottle—though the cap and label feature tablet copy and imagery

Crayola™ Crayon Shaped Antibacterial Bandages

PROS

+ The lightweight paperboard carton looks like the charming and familiar crayon carton kids know
+ Front and side panels show bandage designs; primary packaging clearly notes "not made with natural rubber latex"
+ Instructions are clean, albeit small, allowing the crayon carton graphics on both sides

NOTES

- Presumably the carton is recyclable in paper streams, but there is no disposal symbol on the carton

Maty's® Organic Coco Mint Cough Syrup

PROS

+ Bottle gives a natural vibe with a tan, matte shrink sleeve (that remains on the bottle after peeling the tamper-evidence portion) and leaf and chocolate images on the HDPE bottle
+ Silver cap features instructions to "Shake Well Honey"
+ Label makes use of every panel with copy—ingredient images, Instagram handle, a warning about not giving honey to infants, made in America, and a callout that a portion of sales are donated to Vitamin Angels—and explains the need for headspace to shake the syrup

NOTES

- Could the honey warning be bigger or placed in a text box? Perhaps, but honey is listed as the first ingredient in one panel and the front says "For ages 1+"
- Presumably the consumer needs to remove the sleeve before recycling in the #2 stream

Nature's Bounty® Gold Series Multi Jelly Beans

PROS

+ While many have moved to shorter and more square-shaped bottles, the PETE bottle is tall with a wide-mouth, easy-open, child-resistant cap
+ Gold on the shrink sleeve and cap is striking, while the clear bottom of the shrink wrap lets consumers see the jelly beans inside
+ Label features strawberry and lemon graphics without looking cluttered

NOTES/CONS

- Directions are easy to understand but a bit hard to see in small white type on teal; the sleeve was a bit curved on the back, which caused copy to distort ever so slightly, but it remained legible
- The taller bottle stands out, but consumers may wonder about the need for approximately 2 inches of headspace

FR!SKA™ Men's Daily Enzyme + Probiotic Support Capsules

PROS

+ Attractive, clean matte navy paperboard tube features metallic foil brand name and accents
+ Symbols on the back and top of tube accompany easy-to-read product features
+ Clear sticker for tamper-evidence allows copy to show through
+ The bottle inside—in a well-fitting insert—offers a high-end, cohesive look in clear blue glass with matte label

NOTES/CONS

- The tube is large, which offers a lot of real estate for supplement facts, but some consumers may be concerned about excess packaging with a larger tube housing a smaller bottle

The Mentholatum Company Rohto® Cooling Eye Drops in Optic Glow™

PROS

+ White carton conveys "cooling" with eye-catching foil elements in iridescent silver, blue, and purple, and a bottle image showing what's inside
+ Top panel features a QR code to "Scan for Reviews," enticing the consumer to check reviews in-store
+ Back panel has an outline of the actual bottle size under the drug facts
+ Inside, the child-resistant bottle features an iridescent label and is wrapped in a clear inner pouch; inner pouch and bottle feature opening instructions to push down cap and twist

NOTES

- The directions printed on the inner pouch are in white ink on a clear pouch, but the bottle label itself features clearer directions with more contrast
- The QR code takes the user to a general reviews page for various eyedrops in the product family, and not Optic Glow drops specifically

Buoy Easy Squeezy Electrolyte Drops from Better Tmrw LLC

PROS

+ Portable compared to pre-mixed electrolyte drinks, the 2-oz. HDPE bottle features a shrink sleeve with vintage wave-themed stripes and a pelican on a buoy
+ Easy-to-squeeze bottle and pouring membrane offer a mess-free and convenient way for those with or without chronic illness to add hydration on-the-go or at home
+ While small, the front panel clearly notes the number of servings, along with zero calories and sugar
+ QR code on the top links to usage instructions, ingredients, and more

NOTES

- The bottle is surprisingly squeezable with minimal hand pressure per the directions, however a consumer may be curious if the drink needs to be a certain number of ounces for dilution

GSK Sensodyne Pronamel Toothbrush (2-Pack)

PROS

+ Front panel touts 100% plastic-free packaging; sturdy paperboard tray and lid are entirely recyclable in the paper stream
+ Window offers clarity to see brushes, while maintaining recycle-readiness
+ Clean front panel design features symbol to convey brush motion; can be stacked on shelves or hung on racks

CONS

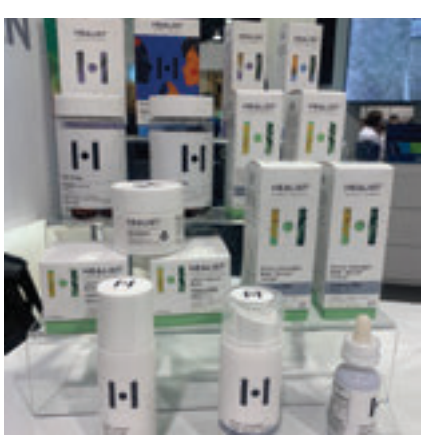
- The tray and lid width are slightly wider than some traditional, less recycle-ready 2-pack blisters

PACKAGING HIGHLIGHTS FROM NATURAL PRODUCTS EXPO WEST 2022

Paper tubes, minimalist aesthetics, and CBD products were all on display at the show in Anaheim, CA, in March. See the slideshow video at: hcpgo.to/expowest22

↑ Packages offer high-contrast and minimal graphics—Sports Research Marine Collagen Peptides, Bulldog Skincare for Men, and Oars and Alps personal care offer a new look in gender-neutral or traditionally masculine color schemes.

↑ Paper tubes for skin/suncare and deodorant from Attitude and Honestly pHresh make a splash in square, round, and twist-up configurations.



↑ CBD products were everywhere, with offerings for people and pets, like these from Healist Naturals, CBD Living, and Rescue Remedy®.

DSCSA and the Importance of Exception Management

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Processes are still emerging for data issues, organizing quarantine, and more under DSCSA.
2. Various exception scenarios include "product/no data" at the trading partner site.
3. For a high volume of quarantined product, space and organization will be critical.

Efficient resolution of EPCIS data exceptions will be key to ensuring pharmaceutical products move through supply chains and reach patients in a timely manner under the Drug Supply Chain Security Act (DSCSA) mandates coming into force in 2023.

When physical products arrive at a distributor and the accompanying data doesn't match, how will the industry resolve those issues? At HDA's Traceability Online Seminar, experts held a roundtable discussion for trading partners—manufacturers, suppliers, and distributors—to discuss exception management concerns. HDA's exception handling workgroup has identified approximately 19 different scenarios deemed to be exceptions.

Libby Dewey, Sr. Consultant, Operations Technology at **Cardinal Health, Inc.**, and Mike Mazur, Director, Trade Operations at Pfizer Inc., co-facilitated the discussion. Pfizer had "been live" with Cardinal on EPCIS data exchange for eight months when the seminar took place (along with other trading partners), which yielded preliminary feedback and learnings on how to deal with exceptions in the data exchange files Pfizer is sending.

Not familiar with the Drug Supply Chain Security Act? Start here: **hcpgo.to/serialization101**

Product without data

Of the many different scenarios deemed exceptions, one major example is overages. In this "product/no data" case, the downstream trading partner may have 16 cases show up, but only receives data for 15 of those. How does the manufacturer get notified of the issue so it can begin its investigation? How does the manufacturer correct that transaction information so that the case can be removed from quarantine in a timely fashion? (It should be noted that "timely" is a relative term at this point.)

The workgroup is looking at developing standards for how a distributor would notify a manufacturer and what information and formatting that notification would entail, such as the product identifier and the delivery/PO the extra case was on. "That's really where the industry needs to be in the next two years, to put processes in place to be able to handle an instance of product/no data if we have one," said Mazur. "There is ongoing work within HDA in these workgroup sessions to help standardize the messaging between the distributor and the manufacturer."

It may not be so simple to identify which case is the extra one. From the distributor perspective, Dewey noted, "We're working on the way that we're going to pick out the excess product, how we're

going to identify it, and how we're going to communicate that. We see this currently as an extension of how we're handling returns verification exceptions—which we're doing right now—as well as an extension of how we're handling ASN [advance ship notice] overages and things of that nature. We're planning to sample on inbound and utilize a type of interim status to identify a product that has been received inbound, but not picked yet for outbound and verified."

Of course, manufacturers will then need to investigate the issue on their end to determine the cause. "We need to understand why we don't have a ship event against that product if it was shipped. Was something sent that shouldn't have been sent? Or what's missing to close that loop? Is there an overage and an under-data scenario that we need to research?" said one attendee who is part of the workgroup. "And with data integrity issues, it's not as easy to generate something that's missing. We've taken that back to our internal team to walk through all the steps that are needed, but it's just that added complexity that's not as easy to fix, while we also try to build in proactive measures as much as we can to not run into that."

Other exceptions

Manufacturers have to start looking at exception scenarios and how they'll resolve each one. Issues may be site-specific or broader in nature. A few other examples came up in discussion including:

↑ To meet DSCSA requirements, processes must be put into place to handle supply chain data exchange exceptions.

- Flags, such as whether a batch is serialized and aggregated to a case or pallet, drive other processes in the system. If an aggregation flag is not set, the system is not going to look for the parent-child relationship and infer the contents. The manufacturer then ships out good product, but only with a case-level serial number and not the contents of that case, because the flag was not checked properly.
- Data issues include GCPs incorrectly formatted, causing the whole file to fail; the syntax GLN is incorrect; or GTINs are missing.
- If a case is the unit of sale, but the contents of the case are also serialized, the differing case GTIN and content GTIN can cause the file to fail.
- An exception discovered later can also add to the complexity, as not all issues will be discovered in receiving. A product/no data situation may not be found until the product is actually picked (deeper into the process), at which point it would go to quarantine. "A worst-case scenario is ultimately product that's found in a fulfillment area of a distributor where it's been disassociated from that shipper-case… you don't know what delivery that came in on or its shipper-case," said Mazur.

Throughout the seminar, attendees made mention of seeking clarity around processes for decommissioned product.

Data/no product

The opposite problem of product/no data can occur where a distributor receives more data and less product, if perhaps product is shipped to an incorrect customer while data is sent to the correct customer. In this case, distributors may not have a process developed to do anything with extra data. It's likely the manufacturer would discover such an issue first as distributors routinely receive data followed by the physical shipment a day or two later. This makes it difficult for the distributor to determine what is extra data vs. what product simply hasn't been received yet. "We don't know that the product is not still on its way to us. We're certainly open to coming up with a process to give feedback, should the industry decide there's some mechanism that makes sense for that," said Dewey.

Staffing

An attendee asked if a certain department handles the back-and-forth at the manufacturer site. In Pfizer's case, they have a dedicated group handling overages and missing files with regard to lot traceability, but for the EPCIS data exchange, which is not yet a regulatory transaction, they are still onboarding and in test mode. "We're still learning, we're still identifying what tools we'll need to build in order to fix discrepancies. Some discrepancies will be fixed at the site, some of them can be fixed in the market. Some of them have to

be fixed by a quality individual," said Mazur. "Ultimately, we'll build the processes to fix them. Right now, we have the luxury of learning."

Organization and product location

Items with data issues will be moved into a quarantine section, to be held until the exception is resolved. "A big challenge that we've found is just making sure that we have a good organization system to be able to facilitate finding that product—especially if we have high volume—when we get the information back from the manufacturer," Dewey said.

In a related roundtable, speakers discussed what systems distributors may use to locate product once an exception is resolved with the manufacturer. Ian Cannell warned attendees of potential space constraints, particularly for worst-case scenarios where an entire pallet or more must be quarantined.

Matt Sample is VP, Manufacturer Operations at **AmerisourceBergen Corporation**. As he explained, "We're leveraging software called Investigator from **LSPedia** for exceptions today. We were using them for saleable returns, and we'll most likely be using that going forward for exceptions so that we can log them.... All exceptions would be managed centrally. I have 26 DCs [distribution centers], so when we clear an exception, we will communicate to the DC that it's okay to release said quarantined inventory."

Sample reiterated Dewey's point that volume matters. One box can be moved back to distribution quickly, but for a high volume of product, it may be challenging to find or create bin locations for every exception. Without data to determine how many exceptions there will be, methods of organizing remain "to be determined."

Could RFID or IoT (internet of things) stickers play a role in locating product in quarantine? It is certainly a possibility. However, distributors commented that solutions would need to be implemented at the manufacturer level, and it would require many manufacturers adopting the technology on case packs in order for it to make sense. (For clarity, this would not replace 2D barcodes.) Distributors would also need to factor in time spent scanning if any IoT solutions are added.

Co-facilitator Omid Ghobadi, Sr. Director, Dinance & Technology at HyGen Pharmaceuticals, Inc., noted that Walmart may have had a similar experience with its serialization in the past. He added, "That could work to scan a high volume of product as soon as the pallet hits the dock, but like Matt mentioned, it should come from the manufacturers. And, you cannot have that only for two manufacturers—it only works if the majority sign up for this technology."

Closing thoughts

The conversation at the seminar touched on the more philosophical and ethical issues around serialization requirements and drugs critical to patient care. In 2023, companies will be faced with handling exceptions and fixing data issues while some patients wait for life-saving treatments. And further to that point, can a company be sure it's merely a data issue? Or could the product be suspect?

This should be a strategic conversation between compliance and legal groups at an organization. If product can't be received per the intent of the law, will trading partners have the SOPs and bandwidth in the schedule to quarantine it and follow exception management procedures?

As is the case with any DSCSA-related news, experts advise to start working as soon as possible to put processes in place for exceptions, to minimize issues that could hold up patient care.

EPCIS Adoption Progress

Updated survey data released by the HDA Research Foundation in March indicate that healthcare supply chain partners remain in the formative stages of establishing the interoperable transaction data connections required to comply with the DSCSA by November 27, 2023. However, some progress has been made since a survey conducted last spring. Among the updates from the last survey:

- Approximately 69% of manufacturers now plan to use a third party to connect—a seven-percentage-point increase from the previous survey. Respondents cite a range of challenges, including a "lack of guidance," delays due to FDA's past enforcement discretion and the perception by some that the agency will postpone the deadline, less than adequate employee resources and availability, and the ability to dedicate an IT team to test and implement EPCIS. (The FDA has stated publicly that it does not plan to extend enforcement discretion to beyond the 2023 milestone.)
- More distributors are connected to manufacturers in production environments. Just 38% have yet to connect (down from 58% in the previous survey) while more than two-thirds are in the process of connecting. "Lack of trading partner commitment" is noted to be the top hurdle to implementation.
- A typical 3PL is working to connect 81 manufacturers. With an average of four successful connections currently, 3PLs plan to have connections with 104 distributors once fully implemented. 3PLs cited client readiness, lack of resources or knowledge, and upgrading warehouse management systems among their greatest challenges.
- One carryover from the previous survey is that no connections exist between distributors and dispensers today. Respondents noted that this lack of direct connections may be because many dispenser customers are planning to access a portal provided and maintained by the distributor. As indicated at HDA's recent Distribution Management Conference, dispensers likely will not connect until Q1 2023.

Paper Tube Differentiates a Unique Brand of Cannabis

ANNE MARIE MOHAN, SENIOR EDITOR, *PACKAGING WORLD*

TOP THREE TAKEAWAYS

1. Live-rosin cannabis maker äkta selects a paper tube package for its vape cartridges and concentrates.
2. They sought a Scandinavian pop-art feel to align with the brand's name, which means authentic, genuine, real, and true.
3. The resulting design uses a rainbow of colors offering flexibility as they expand the brand into the future.

Colorado cannabis brand äkta is committed to authenticity and sustainability, both in its production methods and its product packaging. The company's solventless cannabis products, which include live rosin batter, vape cartridges, and gummies, are made from whole, fresh-frozen flower, grown by parent company Hava Gardens.

Differentiating the brand is the fact that it is one of only two companies in the cannabis space that is single-source; all its products are made from plants grown by Hava. Also a differentiator, its supplier (Hava) employs a soil-focused growing technique, whereby all of its cannabis is planted in Living Soil, which contains a robust and complex collection of microbes. Äkta also stands out for its extraction method, which is based on the traditional artisanal hash-making process of using ice, water, heat, and pressure versus extraction with solvents, such as butane, ethanol, and carbon dioxide.

↑ For the tube graphics, was looking for a Scandinavian pop-art feel for the packaging to align with the brand's name, which in Swedish means authentic, genuine, real, and true.

According to äkta CEO Blair Kralick, while its use of this extraction method is not unique—it's currently the fastest growing segment in the industry—the brand is trying to create unique ways of using the process and new systems with newer technology and equipment that will allow it to continually innovate within the process.

Given the brand's emphasis on clean and sustainable cultivation and extraction, when it came time to design packaging for its products, äkta was determined to follow suit. "We felt like the cannabis industry as a whole is extremely wasteful—a lot of plastic, a lot of things that get thrown away due to regulatory requirements within the market," says Kralick. "So, we really wanted to be creative and look at packaging options that would meet these compliance requirements without being wasteful. We didn't want to put a bunch of trash out there, a bunch of plastic filling landfills, just to sell products."

Kralick adds that the brand also wanted to bring a touch of professionalism into the CPG world of cannabis. "I've worked with a lot of brands in the past, and we've always followed the norm of what the industry was doing," he says. "We really wanted to raise the bar and bring something new to the market."

The solution came from a Google search. It was there that Kralick came upon **The Paper Tube Co.**, a supplier of eco-friendly paper-based packaging. Wanting to avoid plastic as much as possible and looking for a format that would align with the brand's soft, approachable aesthetics, äkta selected a paper tube format. "When I came across the tube, I liked that it was made of paper and had rounded edges—it was everything I was looking for," Kralick says.

Äkta is using two different tube designs. One is for its Live Rosin Vape Cartridges in three varieties. The tube measures approximately 3.5 in. tall x 1.5 in. wide and holds a cartridge with 500 mg of full-spectrum, strain-specific, solventless live rosin hash oil. The consumer accesses the cartridge by pushing up on a paper insert on the bottom of the tube, which features a round hole to hold the product upright. Says Kralick, the insert "slides up and down like a push-pop," propelling the product out of the tube.

To meet regulatory compliance, the tube is topped with a plastic, child-resistant closure with a lineup feature that only allows the consumer to open the lid when it's lined up on the ring of the tube.

The second tube, measuring 1.25 in. tall x 1.5 in. wide, is used for its Live Rosin Concentrates and is made from paper only. The concentrates are packaged in a CR jar, with the tube acting as a marketing vehicle.

For the tube graphics, äkta worked with a Brooklyn-based graphic artist, who designed the brand logo and the aesthetics for the entire line. Says Kralick, äkta was looking for a Scandinavian pop-art feel for the packaging to align with the brand's name, which in Swedish means authentic, genuine, real, and true, as well as the inspiration for the brand, which the company says is "the untouched elements of the Scandinavian alpine."

Approachability was also at the top of the design brief. Says Kralick, "In the solventless world, we see a lot of dark colors, a lot of edginess, kind of almost a cool factor, per se, but very masculine. We wanted to lighten that up and give it more of a feminine feel with more colors and more brightness, so even if you didn't know what product was inside, it wouldn't be intimidating."

The resulting design uses a rainbow of colors—up to seven, according to Kralick. "It allowed us a lot of flexibility on which color we wanted to lean on for which variety, so there wasn't necessarily a primary color," he explains. "This also gives us a lot of flexibility as we expand the brand into the future." Designs include stylized illustrations of marijuana leaves, water, and the sun, conveying nature and a breath of fresh air.

The design of the packaging took eight months, but it was time well-spent, says Kralick. "I'm glad we took our time and went in that direction because it really sets us apart," he shares. "Especially when you're looking at a lot of packaging in some of these stores, you can really see the difference in the work that went into it."

Äkta launched its first vape cartridge SKU in October 2020, followed by two more in spring 2021. Its products are available in 120 retail cannabis locations in Colorado, primarily in the Boulder and Denver areas.

Produced by:

PMMI

PACK EXPO® INTERNATIONAL

SEE IT. EXPLORE IT. EXPERIENCE IT.

The industry's defining event is back in Chicago and is THE place to explore life sciences packaging innovations.

The Healthcare Packaging Pavilion

Your one-stop shop for solutions targeted to pharmaceuticals, biologics, nutraceuticals, medical devices and more. Discover new innovations to scale up production, ramp up e-commerce, streamline operations and increase usability in the Healthcare Packaging Pavilion.

2000+ LEADING SUPPLIERS ■ **FULL-SCALE MACHINERY** ■ **100+ FREE SESSIONS** ■ **SUSTAINABILITY SOLUTIONS**

LEARN MORE & REGISTER NOW FOR ONLY $30

October 23–26, 2022 ■ Chicago, IL USA ■ McCormick Place ■ PACKEXPOINTERNATIONAL.COM

Pharma Manufacturers Seek Visibility into Processes to Drive Efficiency

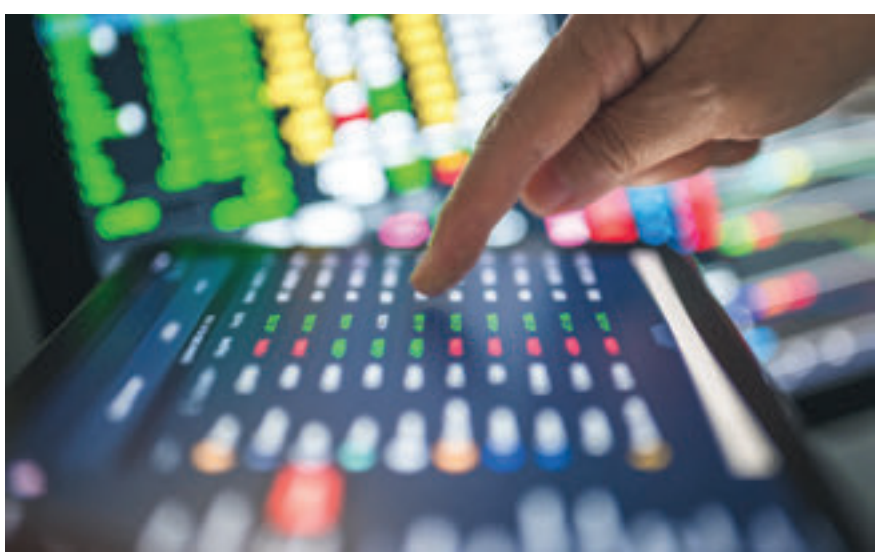
KIM OVERSTREET, DIRECTOR, EMERGING BRANDS COMMUNITY

TOP THREE TAKEAWAYS

1. Shorter, customized pharma runs strain production capacity at many plants.
2. The expansion of data collection and analysis often requires significant operational changes.
3. Product tracking with blockchain allows a variety of stakeholders to access data.

According to a new white paper from **PMMI** Business Intelligence, 2022 *Pharmaceutical Manufacturing, Trends Shaping The Industry*, sought-after visibility is achieved by expanding the amount of digitized data being collected on machines and finding meaningful ways to analyze and utilize that data to drive operational efficiency.

This is easier said than done, however: the expansion of data collection and analysis often requires significant operational changes that are both costly and time consuming. To assist manufacturers on their digitization journey, suppliers can frame the process as a gradual, stepped approach that is more palatable to pharmaceutical companies.



↑ Manufacturers are seeking to improve efficiency by increasing visibility into their operations.

The first steps in this process involve expanding data collection through the addition of smart sensors on machines, which can be gradually integrated to increase the level of data gathered. These improvements can yield tools such as real-time views of OEE, downtimes, and production levels.

As integration increases and data expands, suppliers can guide manufacturers in how to interpret and utilize accumulated data. Analyzing this "big data" can have significant benefits for manufacturers, increasing efficiency and decreasing waste in processes across operations.

Blockchain: the future is now

One cutting edge technology expanding access to digitized data is blockchain, a form of distributed ledger technology. A secure, immutable ledger, blockchain technology can enable pharmaceutical manufacturers to address a number of challenges faced in the utilization and security of their proprietary data.

For instance, blockchain is an extremely powerful tool for serialization, enabling products to be accurately tracked through production, storage, and distribution to protect against counterfeit, tampering, expiry dates, environmental damage, and recall requirements. Only 27% of companies interviewed are currently using blockchain, all of whom are utilizing distributed ledger technology for product tracking and inventory management applications.

The majority of pharmaceutical companies interviewed are either not using blockchain or remain unfamiliar with how blockchain

works, signaling future opportunities for both education and deployment of this technology.

"We are using blockchain now for incoming product supply data, but not for any production data at this time," said one production engineer at a large OTC manufacturer.

Product tracking with blockchain can be taken one step further by allowing stakeholders across the pharmaceutical industry access to production and distribution data, all without compromising data integrity or divulging proprietary processes—in fact, the data itself never leaves the control of the company managing it. An example of the power of this system can be seen in the UK National Health Services (NHS) rollout of the COVID-19 vaccine, in which two hospitals in the UK utilized distributed ledger technology to track the movement of COVID-19 vaccines in the supply chain.

Because of the nature of the ledger itself, this enabled the data to be tracked by a wide variety of stakeholders—from hospitals and pharmacies to pop-up vaccination sites—without compromising its integrity, accuracy, or security. Most notably, this data repository tracked not just barcode verification to combat counterfeiting, but also thermal sensors, allowing organizations administering the vaccine to verify their shipments were never compromised by temperature fluctuations.

As blockchain usage grows, it is likely that entirely new applications and uses will be found, with the potential to greatly increase cooperation amongst all stakeholders in the pharmaceutical industry, according to the new white paper.

READ

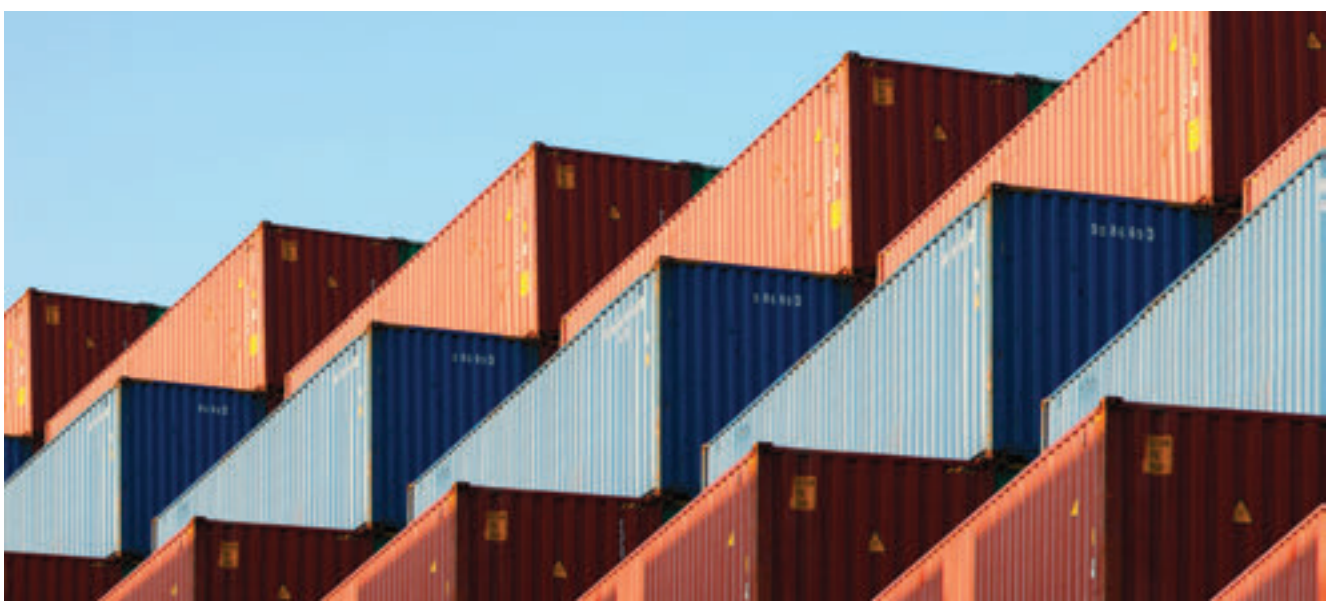
Download the complimentary report, 2022 Pharmaceutical Manufacturing, Trends Shaping The Industry.

Tips for Exporting Goods in 2022

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Brand owners/exporters should always know their buyers and ensure that customers are not on the U.S. denied party list.
2. Exporters need to apply for a license to export to a country with active sanctions, and contact the Office of Foreign Assets Control.
3. Consider cargo insurance—the right insurance can protect you from certain claims in the case of damage to *other* containers on the ship.



↑ When exporting goods from the U.S., brand owners/exporters should ensure buyers are not on the denied party list.

If you're exporting goods from the U.S., knowing risks and obligations is key to a smooth operation—or as smooth an operation as is possible.

Allan Christian, Senior International Trade Specialist at the U.S. Commercial Service in Portland, OR, discussed best practices for exports at Natural Products Expo West in Anaheim, CA.

Denied parties

He cautioned that brand owners/exporters should always know their buyers and ensure they're not on the denied party list, which is a list of companies that U.S. entities cannot engage in trade or financial transactions with legally. Not limited to foreign companies, the list can also include U.S. companies that have violated regulations.

While you can search for denied parties at the consolidated screening list, Christian noted that there are a few companies that offer denied party screening software. In his opinion, the automated screening tools are money well spent.

If you ship your goods to a distributor in another country and they then resell to a company located where the U.S. has an embargo, you can be held liable. Even if it's technically the distributor reselling the goods, the resale must be in accordance with the law.

Per the presentation, you can protect yourself in the eyes of U.S. Customs and Border Protection by placing a Destination Control Statement (DCS) on your commercial invoice that reads:

"These items are controlled by the U.S. Government and authorized for export only to the country of ultimate destination for use by the ultimate

consignee or end-user(s) herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations."

Food, medical products, and sanctions

Some of Christian's advice was especially pertinent given new sanctions imposed on Russia amid the ongoing invasion of Ukraine. Food and medical products can be exempted from economic sanctions—this includes medical devices and supplements. You may need to apply for a license to export these goods to a country with active sanctions, and Christian advised that companies in this situation contact the Office of Foreign Assets Control (OFAC).

Related takeaways

- Christian highlighted that there are resources for proper documentation, best practices, and even video tutorials at: **trade.gov/navigate-shipping-and-logistics**
- Marine cargo shipments are approximately five times more expensive as they were just before COVID-19. Shipping containers are currently manufactured in China and shipped to the U.S., but he noted that one company may be poised to change that. A new manufacturing site in Memphis has been proposed to build the containers, offering a shorter trip (read: less freight cost) to domestic ports than that from China.
- Consider cargo insurance—transport problems happen, particularly on the open ocean. He explained that General Average is a concept in which sea cargo stakeholders share any damage or losses that occur. If the ship hits rough water, and some containers go overboard but not all, everyone shares in the damage estimate. This remains true even if your particular items arrived safely. "You still have to pay your percentage value of what was on the ship," he explained. The right insurance can protect you from paying General Average claims.

Other Suggested Resources

+ **NASBITE International**, an authority and industry standard for global business education, trade credentialing, training, and practice
+ **The Global Entrepreneur**, a primer by by James F. Foley

9 Sustainability Initiatives in Life Sciences

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. There are numerous circularity initiatives across industries, including the Ellen MacArthur Foundation and LOOP.
2. Here, we highlight the rise in partnerships targeting sustainability specifically in life sciences and healthcare.
3. Goals range from cutting carbon emissions to bolstering reusables, cutting waste, and improving access to medication.

Earth Day should be every day—planetary health is critical. While there are numerous important cross-industry initiatives, this year, we took "official Earth Day 2022" to focus on the rise in partnerships targeting sustainability specifically in life sciences and healthcare, from material sourcing to cutting carbon emissions in production and supply chains.

1. **Alliance to Zero** is a non-profit partnership dedicated to enhancing sustainability throughout the pharmaceutical supply chain. It aims to facilitate the transition of the pharma sector to compliance with net zero emissions in line with the goal of the Paris Climate Agreement.

2. **Kilmer Innovations in Packaging** (**KiiP**) is an industry initiative "solving wicked problems in healthcare packaging." With one of their four focus areas dedicated to sustainability, they're gathering passionate volunteer team members to tackle nebulous topics in medical device packaging, ultimately improving patient safety.

3. **Global Self-Care Federation** (**GSCF**) is a collaborative effort in the self-care industry, and they recently launched the Charter for Environmentally Sustainable Self-Care, which is "the first industry-wide climate action resolution issued by the consumer health sector." It seeks to minimize environmental impacts without compromising healthcare outcomes and safety, and counts Johnson & Johnson, Bayer, GSK, and Sanofi among its members.

4. **Sustainable Medicines Partnership**, is a not-for-profit, private-public collaboration aimed at reducing the amount of effective medicines going to waste, cutting CO_2 emissions, making medicine and knowledge more accessible, and more. They recently announced a partnership with the **WPO** (World Packaging Organisation).

5. Founded in 2010, the **HPRC** (Healthcare Plastics Recycling Council) is a private, technical consortium of industry peers across the healthcare, recycling, and waste management industries seeking to improve the recyclability of plastic products and packaging within healthcare. Comprised of globally recognized members, the HPRC engages in pioneering projects designed to help boost plastics recycling efforts in the clinical settings of hospitals. They recently released findings from their advanced recycling pilot.

6. **Practice Greenhealth**, working closely with **Health Care Without Harm**, is a membership and networking organization for sustainable healthcare that delivers environmental solutions to more than 1,100 U.S. hospitals and health systems.

7. **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.

8. **Glass Futures**, is a UK-based yet globally reaching non-profit researching the production of more sustainable glass.

9. **Alliance to Modernize Prescribing Information** (AMPI) is an effort to reduce prescribing label waste to healthcare providers. Members include AbbVie, AmerisourceBergen, Johnson & Johnson, Merck, Bristol Myers Squibb, Viatris, Pfizer, Teva, and Fresenius Kabi.

Looking for more? Check out decarb:Healthcare and Kalundborg Symbiosis.

If you have an initiative you'd like to share, reach out to Keren Sookne on LinkedIn.

1 Freeze-Drying Equipment

NJM

+ Dara Pharma Group's Coolvacuum freeze-drying equipment includes a range of lyophilization solutions from small, standalone freeze dryers to large, fully integrated systems.
+ Designed to meet FDA, GMP, and GAMP5 regulations, and available with SCADA software for FDA 21 CFR part 11 compliance, the equipment helps pharmaceutical and biotech manufacturers and contract packers achieve the highest product quality standards.

2 Case Sealer

SIGNODE

+ With belt speeds up to 155 fpm, the LDX-RTB 4.0 semi-automatic random case sealer features patented technology that enables the processing of void-filled and over-stuffed cases with a pneumatic top cartridge.
+ The design features case-hardened rollers and non-mechanical side rail actuation for long performance and durability in the most demanding applications, and easy-to-access motors, electrical components, and belts.

3 Track and Trace Software

PELI BIOTHERMAL

+ Crēdo ProEnvision™ 2.0 software allows Crēdo™ on Demand customers to order and track rental orders directly in the program, giving them full visibility to reusable shipper inventory and data to help improve cold chain operations.
+ An audit trail captures past orders, including location, while the newly designed interface creates an intuitive look and feel for an overall better user experience.

4 Continuous Inkjet Printer

MARKEM-IMAJE

+ The 9750 continuous inkjet printer features traceability coding, including text messages up to five lines, logos, and high-resolution 1D and 2D codes for a variety of packaging applications.
+ Its Intelli'Inks system ensures optimal performance and flexibility when coding different package materials, while Jet Speed Control technology automatically adjusts ink and printer variables to ensure drop placement, quality, and code consistence.

5 Paper-in-Paper Technology

CRYOPAK

+ The EcoPak reusable, pre-qualified temperature assurance shipping solution is ISTA 7E/AFNOR S99-700 validated to maintain temperatures for 48 hr or more.
+ Fully customizable, the 100% curbside recyclable solution is made of a recycled fiber blend wrapped in a craft paper to absorb moisture, and can be made in any almost size, with multiple thickness options for customizable performance.

Cooler, natural wonder, or both?

Made from **100% bio-based**, renewable resources, the **Envirocooler™** with **Bioffex™** technology provides the durability and performance of traditional EPS while positively impacting the **sustainability** efforts of your cold chain shipping operations.

Learn more at **bioffex.com**

brought to you by

LIFOAM™

a division of

Jadex

We help people make a material difference every day.

ALLTRISTA LIFOAM LifeMade SHAKESPEARE ARTAZN

www.jadexinc.com

POWDER²
BOOST YOUR ASEPTIC

[NEW] SMART 300 POWDER AUGER

IMA Life presents the new SMART 300 POWDER AUGER, an innovative powder processing concept. Output of the 3 augers reaches 300 pcs/min, also enabling multiple dosing of two pharmaceutical powder types inside the same vial. Aseptic processing speeds have never been so safe.

PERFORMANCE ENHANCED THROUGH INNOVATION

- MULTIPLE DOSING
- CIP/SIP OF THE AUGER SYSTEM
- INTEGRATED STOPPERING
- SUPERIOR PERFORMANCE UP TO 300 PCS/MIN.

www.ima.it/pharma

IMA LIFE
Aseptic Processing & Freeze Drying Solutions