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↑ pp.20

PACKAGE DESIGN GALLERY: THE PROS & CONS OF TODAY'S OVER-THE-COUNTER PACKAGES

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Annual Design Gallery Reflects 'Natural' and Calm Wishes

We take a look at what's new in OTC design, plus news on the reshoring, traceability, and cannabis fronts.

Perhaps not surprising: healthcare products on shelves continue to reflect desires for stress relief and natural ingredients. This year, our package design gallery (pp. 20) saw more mainstream brands touting what the products are free from, in some cases offering front-panel real estate to what is lacking from the product vs. what it contains. To meet the needs of ever-more-educated consumers, some packages had links to more information—this also saves space on the package to allow for minimalist designs.

Also in package design, we profile High Desert Pure and their range of cannabis-containing wellness products, complete with labels that uphold compliance and withstand potential drips from oil-based products (pp. 28). Cannabis brands have to get creative balancing compliance labels with aesthetics—a challenge not new to life science product veterans.

In other news, Stephanie Neil covers reshoring efforts including diagnostic kits and PPE manufacturing stateside (pp. 14). This is made possible via a combination of advanced technologies: intelligent software and adaptive hardware using computer vision, machine learning, cloud computing, and robotics.

Connectivity plays a key role not just in new automation projects for reshoring, but in supply chain traceability. Experts gathered at HDA's Traceability Webinar series and we cover what's happening (and what's concerning) in regard to data exchange and meeting 2023 traceability requirements (pp. 24).

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TIM HAYES,
CONTRIBUTING EDITOR

1 Pfizer Has A COVID-19 Treatment Pill

Merck & Co. came out with a pill intended to treat coronaviruses. And, according to a recent article from *The Hill*, Pfizer has one now, too. The treatment is a protease inhibitor similar to those used to treat HIV and hepatitis C. It binds to the viral enzyme and prevents it from replicating in the cell. Pfizer has begun preclinical studies, which have demonstrated "potent in vitro anti-viral activity against SARS-CoV-2, as well as activity against other coronaviruses." Mikeal Dolsten, Pfizer's Chief Scientific Officer, said that the oral therapy could be prescribed at the first sign of infection, potentially eliminating the need for hospitalization or critical care.

2 High Schooler Invents Color-Changing, Infection-Detecting Sutures

A recent *Smithsonian Magazine* article discussed an innovative new suture developed by high school student, Dasia Taylor. The 17-year-old set out to solve the problem of Cesarean section infections, an issue that plagues up to 20% of women in some African nations. Thus, she invented sutures that change color to indicate the wound has become infected. Natural skin is slightly acidic with a pH of five, but when an infection occurs, the pH can go up to about nine. Taylor found that beets changed color at the perfect pH point to detect an infection, which is what she made her suture dye of.

3 MIT is Developing Vaccination by Inhalation

A recent *MIT News* article discussed the development of a new type of vaccination that is inhaled directly into the lungs to increase immune responses to respiratory infections or lung cancer. Mucosal surfaces, such as the lining of the respiratory tract, are often the host for viruses. A team of researchers at MIT created a strategy to build up an army of T cells that waits on such surfaces to offer a quick response to viruses. Not only can the concept work for fighting pathogens that attack the lungs, it can also be used to treat cancer metastasizing to the lungs, or even prevent cancer from developing altogether.

4 Labeling Error Leads to Recall

A recent *FDA Safety* article noted Bryant Ranch Prepack's voluntary recall of 47 bottles of Spironolactone tablets at the consumer level due to a labeling issue. Spironolactone is a diuretic used to treat high blood pressure, heart failure, hypokalemia, and edema. Apparently, the packaging was mislabeled, and bottles labeled 50 mg may actually contain 25 mg tablets, and vice versa. If patients inadvertently take a smaller dose, they could experience heightened blood pressure, swelling, and a decrease in potassium that could lead to Hypokalemia. And if patients take twice the intended dose, they could experience a life-threatening increase in potassium.

5 Snoop Dogg and Charles Koch Come Together on Topic of Marijuana

A recent *POLITICO* article discussed the Cannabis Freedom Alliance, a group aimed at drug legalization and criminal justice reform. The initiative is a partnership between right-wing billionaire Charles Koch, rapper Snoop Dogg, and Weldon Angelos, an advocate for criminal justice reform. Having served a 55-year sentence for drug trafficking, Weldon is now the founder of the Cannabis Freedom Alliance. He networked with Koch in an effort to flip "10 to 12 Republican senators" to pass a legalizing marijuana bill at the federal level. The coalition will advocate for removing penalties for marijuana offenses and help usher sellers from the illicit market to a regulated, legal market.

6 This Vibrating Needle Improves Biopsy Yields

When extracting tissue for a biopsy, the amount of tissue collected is crucial. It's estimated that up to a third of fine-needle biopsies fail to get enough tissue for a reliable diagnosis. According to a recent *Medgadget* article though, researchers have developed an ultrasonically actuated needle that can improve the procedure while reducing patient pain and inconvenience. The high-tech needle was created by a team at Aalto University in Finland. It houses a conventional syringe with a fine needle, but it vibrates about 30,000 times a second. This makes the tissue behave more like a liquid so that it can enter the fine needle more easily.

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25,400

THE NUMBER of COVID-19 vaccine shots administered on 5/14/21 in Ohio—two days after the $1 million lottery was announced—making it the highest vaccination day in three weeks.

Source: NBC News

80%

THE PERCENTAGE of companies interviewed that stated they had no idea where in their organization sensitive data was located and had no knowledge as to whether or not it was secure.

Source: PMMI's 2021 Cybersecurity: Assess Your Risk

20%

THE REDUCTION in plastic in GSK's new Advil bottles from a resin change, representing a 500,000 pound reduction in plastic annually.

Source: GSK Consumer Health

3

AT LEAST three organizations have been awarded a Memorandum of Agreement by the DEA that should soon lead to the ability to grow cannabis for scientific research for medical applications.

Source: MJ Biz Daily

IRISH HEALTH SYSTEM CYBER ATTACK ON 5/14:

"National healthcare services are already under strain from the pandemic, which will make this **ransomware attack** even more devastating. That fact will not be lost on the hackers."

-STEVE FORBES, GOVERNMENT SECURITY EXPERT AT NOMINET

"At first, everyone thought virtual FATs were the greatest thing ever. We shipped all the equipment, had great video, glasses. The equipment got on site... six months after, we're seeing the value of sending an employee on-site. Little things were missed, like insulation... and you would have seen that in the field. Maybe those lessons learned will help us for more virtual [FATs] that we're doing now. But we're not as sold on virtual FATs as we were 10 months ago."

-LEN PAUZER, DIRECTOR PROCESS TECHNOLOGY, IPS-INTEGRATED PROJECT SERVICES

"Breaking stereotypes unleashes creativity and drives growth. Degree Inclusive challenges what a deodorant product should be. It's a **breakthrough accessible design** that genuinely serves the needs of people with visual impairment and upper limb motor disabilities."

-ALINE SANTOS FARHAT, EVP OF GLOBAL MARKETING AND CHIEF DIVERSITY AND INCLUSION OFFICER AT UNILEVER

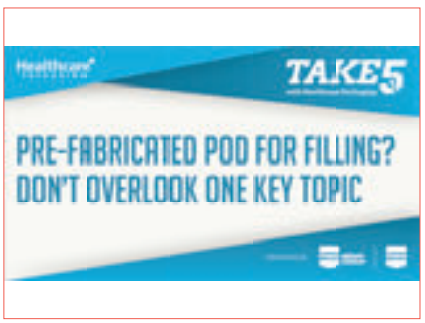
PACK EXPO Las Vegas and Healthcare Packaging EXPO Return

After more than a year without in-person trade shows, attendee registration is now underway for PACK EXPO Las Vegas and Healthcare Packaging EXPO 2021 (Sept. 27-29, Las Vegas Convention Center.) "Our industry's essential role over the past year shed light on new technological needs, and these improvements and advancements in equipment and technology will continue to evolve," says Laura Thompson, VP, Trade Shows of show producer **PMMI**.

With its PACK Ready health and safety program, the show is prepared to welcome the industry back safely, employing thorough and up-to-date protocols for a safe and successful in-person event. Learn more at **packexpolasvegas.com/packready**. Get info and register at **packexpolasvegas.com** and **hcpelasvegas.com**. —*Sean Riley*

Healthcare Packaging Launches Take 5 Video Series

Healthcare Packaging hosts a new video series covering an array of topics facing the industry, all in five minutes. Recent subjects include FDA's medical device program to expedite pre-market review, tips on implementing pre-fabricated PODs in filling, modular manufacturing for injectables, and more. Prefer to listen? Audio is available, too, so you can keep up with packaging and logistics news on the go. Have a topic idea? Send us a note at ksookne@pmmimediagroup.com. We're bringing you new products, regulatory updates, case studies, and more in quick videos that post to our site on Fridays. Check them out here: **healthcarepackaging.com/Take5**. —*Keren Sookne*



NFC-Label for Ypsomed's UnoPen Injector

Ypsomed offers UnoPen™, a disposable pen with variable dose setting for insulin and other multidose therapies. **Schreiner MediPharm** has developed an NFC-Label for UnoPen that serves as a communication interface between the injector and an electronic pen add-on called SmartPilot™ to properly utilize the device and adhere to therapy plans. With the NFC-Label, the drug can automatically be identified, authenticated, and checked in terms of its expiration date. Via the smart device, the injection's time, date, and dosage are tracked and transmitted to the patient's related smartphone app via Bluetooth, and patients are interactively guided through the injection process. Also integrated is a temperature monitoring feature that issues a warning in the event a pen is exposed to critical temperatures in use or storage. —*Keren Sookne*

Also in the News

- **Hoffman Neopac's** Switzerland facilities are now fully powered by renewable electricity via hydroelectric power and an extensive new solar plant. The new plant is one of the largest solar power systems in Switzerland and the extensive green energy initiative will make Hoffmann Neopac fully electrically sustainable at each of its two manufacturing sites in its home country.
- **Thomas Engineering** joined **IMA Active** via acquisition finalized in May 2021.
- GSK Consumer Healthcare committed to make over a billion toothpaste tubes recyclable by 2025, with partners **Albéa Tubes** (Greenleaf laminate) and **EPL Americas** (Platina laminate).
- **Aptar CSP Technologies** earned ISO 13485:2016 certification for its U.S. and France-based plants for Med Device Production.

—*HCP Editors*

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Mechanical Testing for Passive Thermal Shippers: Practical Q&A for Life Sciences

At ISTA's TempPack, experts discussed acceptance criteria guidance, payload selection, actual product versus placebo, testing multiple product configurations, and more.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

During the ISTA TempPack Forum, industry experts held an open discussion on mechanical testing requirements, offering both the end user and supplier perspective. Many of the questions centered around allowable product and shipper damage, as well as payload selection with some real-life examples from panelists.

Will the worst-case scenario always be the maximum payload? How do you go about defining your payload for testing?

The highest weight doesn't always mean the worst-case scenario. Small payloads should also be considered. Carolyn Williamson, President at **Parenteral Supply Chain**, noted that having a heavier box causes people to think they will have more structural damage, which is appropriate from a supplier standpoint. "But once we get into what our specific product is and how that environment is, I think it's critical to be evaluating both min and max," she said.

Bill Mayer, Director of R&D at **Pelican BioThermal**, added, "If you're going to use a minimum payload, one thing to consider then is the use of dunnage material and how you're going to apply that material. Does it cause any interesting or ill effects regarding the thermal performance of the shipper?"

Carmichael Galang, Divisional Cold Chain Compliance Manager, Pharma at Bayer, brought up an example where they were ready to implement a dry ice shipper and had performed testing, but not at the minimum load. They loaded dry ice panels on the side of the container—approximately 200 kilos to ensure temperature stability during the trip—and it collapsed before product was loaded.

The testing had all been performed on the max load, and the design had relied to some degree on product cases stacking up to support the top of the container. "That is something that we learned internally for mechanical testing, using the min loads or less-than-full loads is actually beneficial to understand the overall integrity of the container," Galang explained. Min load doesn't necessarily mean a single product or case, but maybe 20 to 30% of a full load of product stacked on a pallet.

How is mechanical testing for delicate life science products in passive thermal coolers different than mechanical testing for candy bars, lawnmowers, or other consumer goods? What are the considerations specific here that might not otherwise be called out in Test Procedure 3A or other documents?

Mechanical testing is not necessarily different, but the acceptance criteria will be. As Bryan Cardis, Associate Sr. Consultant Engineer at Eli Lilly and Company, explained, "When you're developing your acceptance criteria, you're looking at it from a perspective of a validation or a verification of either system performance, product payload performance, or both together."

You may have criteria that you don't want any minor or critical defects in the structural integrity of your thermal system whether you perform a laboratory-based mechanical study or a field-based

Communicating acceptance criteria with your lab is key in mechanical testing of passive shippers.

shipping study with a physical inspection. "During reasonable, normal, and customary transportation, did you notice any types of defects that would be concerning? From the end user perspective, if you execute your studies you have a focus either on the thermal system, the product, or both, and you meet your acceptance criteria. I'm not sure that it would make any difference if you were doing it for a cooler or a candy bar or a lawnmower," Cardis said.

Galang added, "If you look into the distribution network, your product will ship next to a box of socks or auto parts unless you have a dedicated 2 to 8°C shipment where you have a dedicated truck. With **UPS** or a small parcel distribution network, there's a big mix of product in the same belly of a cargo plane. The mechanical testing from one product to another typically is going to be very similar as far as the amount of shocks, vibration, and compression that is expected to be seen in the environment of distribution."

The difference is product inspection—did vibration or shock change any of the quality aspects of your drug product? If pills start to break apart in bottles, do you need more cotton inserts? Was caking observed or product settling in one area, preventing a homogenous mixture in a syringe? "Those are things to consider, again, not necessarily different mechanical testing, but the inspection or the acceptance criteria would differ," Galang said. Communicating your acceptance criteria is key. Said Williamson, "It's our job as the end user to know the acceptance criteria and let the lab know. The test labs are the experts in executing the test standard but when it comes to whether you passed or not, that judgment is less to the test lab and more to us on what is acceptable." Another key differentiator for life science products is temperature control. Various coolants or mock products may need to be pre-conditioned, and those protocols must be communicated with the lab. "There may be specific orientation requirements that should be considered during the testing that might affect the thermal performance or integrity of the shipper," said Mayer.

Is there a "right configuration" to evaluate through mechanical testing? In the case of a single shipping system being used for multiple products and payload configurations—vials of different sizes, syringes, pens, etc.—does the panel recommend testing each product payload configuration individually, or can a bracketing approach be used?

Knowledge and understanding of your product packaging configuration is going to be critical, said Cardis. Shipping risk or product risk assessments are key in helping you determine what to test. Large volume vials or devices can be quite fragile. As these are exposed to shock and vibration, how is device functionality affected? "A lot of times we do product testing, device functionality testing, or container closure integrity along with quality attribute testing," he said.

Mayer noted that you have to look at risk-based analysis: "If you take a bracketing approach and you look at a technical justification based on risk, and look at a min and maybe a couple of selections in the center and maybe a selection on the high end for the max load, you might consider that acceptable versus the time and expense it might take to actually test 40 configurations." Whatever you choose, ensure to document! When you're in an audit, you want to easily be able to pull up a technical justification for why you picked your test configurations.

On acceptance criteria, is there a general consensus in industry? One customer may feel okay with a cracked shipper as long as vials are intact, while another may not accept damage to the shipper at all.

This is another topic that comes down to the end user's discretion. If tape on the outside of a shipper breaks, one company might say it was just one edge and the box remained completely intact, so it's acceptable. "Another company may determine that from a risk level and for presentation purposes they don't find that acceptable," said Williamson. "That's why I believe that the true acceptance criteria comes out of the user requirements, because I can see where two different places could have different risk-based approaches for totally different kinds of products or the cost of that product."

Galang highlighted new guidance: "There's an amazing document produced by some good folks on this call—the ISTA passive thermal shipper OQ best practice. Appendix Four gives some examples of the acceptance criteria you have from the outer box, shell insulation, assembly panels, refrigerants, and other aspects of the mechanical testing. So it's a good reference point."

Obviously if leaks are discovered, it must be confirmed whether these are due to defective vial stoppers or due to mechanical testing, but in either case, this typically generates a retest to verify the root cause.

From the supplier point of view, Mayer said there are two main points on acceptable damage criteria in thermal packaging.

- For components critical to temperature control, unacceptable damage to functional pieces of the unit includes leaking coolant, leaking PCMs, damage to insulation—whether that's foam insulation or vacuum panels that have come to atmospheric pressure.
- Second, what types of failures would keep the package from arriving safely at its destination? This may be focused on the outer packaging of the shipper, and if any of the interior components can actually cause problems with the exterior of the shipper.

Should dry ice be included in mechanical testing as materials can change or become more brittle with contact?

"I've experienced with dry ice shippers that you can potentially see super cooling, and you can actually see that in your mechanical properties, so I would advocate for dry ice shippers to be tested both

because you want to ensure that you're within your temperature specifications, but also you want to know that you don't see damage," said Williamson.

Mechanical testing should be performed on packages however they are planned to ship, whether with dry ice, 2 to 8°C, or controlled room temperature (CRT). Galang noted that they freeze or refrigerate PCMs and test product so they're getting as close as possible to the actual process. "That's something that I would like to encourage as well when you're doing mechanical testing, do it in a conditioned way. Similar to dry ice, you want to see how the temperature changes any of the characteristics of the material, the packaging, or the devices."

Is it necessary to use the actual product or is simulated product acceptable, especially if primary packaging for the product is kept the same with a simulated liquid used?

Placebo products are often used in testing, particularly where product is still in development. Water-filled syringes can be used, with justification that the weight and viscosity of the water is similar to the actual product. Non-active powder products may be used in place of freeze-dried products. "If there's a variance between the two, documentation is key," said Galang. "One of the tests that we look into is the movement of the vial stoppers. So within the mechanical testing, we want to make sure that the liquids are the same viscosity or weight."

Cardis added, "Some of the product-specific type of questions come down to what is your defined acceptance criteria? Obviously, if you're doing drug product quality container closure integrity, or let's say device functionality testing, you probably want to incorporate the use of actual product to really be able to define and understand things like the viscosity, plunger rod movement, injection times, etc.," If you're doing more of a high level bracketing approach—not necessarily product quality testing, but more visual/functional testing of the primary and secondary packaging or the system itself, the actual product may not be required provided the phase of the placebo product is the same as the actual product when it ships.

Updatable Pharma Kit Packaging Saves Company $200,000 and Counting

Incorporating a kit with a slide cover is providing production flexibility and cost savings—updating the kits only means replacing one component.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

A top global pharmaceutical company has implemented a new packaging system that's saved them over $200,000 in information update costs compared to conventional kits.

The company launched a critical new drug that was a departure from standard medication regimens, and needed an introductory educational kit for certified pharmacies, doctor's offices, clinics, and hospitals.

To fill the need, a new kit was designed by **Contemporary Graphic Solutions** (CGS), a provider of printed components for the pharma, medical device, and consumer industries. CGS was already producing packaging for the drug, as well as various other materials to support the product launch, including pamphlets, brochures, product information sheets, and instructions for use (IFU) items.

The resource kit contains:

- Booklets
- Pamphlets with stands
- Flip charts
- Pocket information guides
- Two sample cartons containing placebos

↑ **The resource kit contains booklets, pamphlets with stands, flip charts, pocket information guides, and two sample cartons containing placebos.**

Slide structure saves costs

CGS reports that it was "the kit's versatility, rather than its comprehensiveness, that made the project stand out" thanks to an easily replaced slide cover that's saved on information update costs compared to conventional kits.

Opting for a large box with a slide-on cover, primary artwork is applied to the cover instead of the inside structure. This means the kits can be produced en masse without becoming instantly outdated if any FDA updates or other critical information changes are necessary. It is estimated that the pharmaceutical company saves $50,000 each time the slide cover requires a revision. The system is also saving time—the comprehensive kit packed with materials has simplified the product education process and cut down on instructional visits by manufacturer's representatives.

Dove's Sleek New Refillable Pack

Launched in January by Unilever, Dove's refillable deodorant comprises a sleek, stainless-steel outer case guaranteed to last a lifetime, paired with refills in recycled-content/recyclable packaging. The innovation is just one of 100 projects Dove is working on across the globe to meet its goal that packaging is plastic-free, is made from 100% post-consumer recycled plastics, or is reusable/refillable. It also represents Unilever's first refill launch on a mass scale.

The system was engineered by Unilever in collaboration with A Plastic Planet—a grassroots organization founded to "turn off the plastic tap"—and Dutch design consultancy **VanBerlo**, which began the project in 2018. The screw mechanism typically used for deodorant packaging was eliminated, as small parts can incur damage over time. Instead, the case is fitted with a recyclable PET insert. Get the full story at: hcpgo.to/DoveRefill

— Anne Marie Mohan

Understanding the Reshoring Effort

Supply chain interruptions related to COVID-19 have prompted manufacturers to consider bringing operations back to the U.S. But success depends on new ideas and new technologies.

STEPHANIE NEIL, EDITOR IN CHIEF, *OEM MAGAZINE*

[*Editor's Note: This is an excerpt from OEM Magazine's Spring cover story of the same name. Get the full article at hcpgo.to/reshoring.*]

In January, President Joe Biden ordered government agencies to take action and require the wearing of masks in airports, on commercial aircraft, ferries, and all public transportation, while encouraging "masking across America." And, if we are going to be buying more face masks, why not purchase products that are also "made in America?"

When the pandemic reached the U.S. early last year, about half of the world's disposable masks were produced overseas in China. And as COVID-19 became a global healthcare crisis, face masks became essential and countries imposed restrictions on exports, which increased the worldwide shortages of masks and raw materials, according to the U.S. National Institute of Health's National Library of Medicine.

"All it took was stopping the supply of disposable masks produced overseas from coming to the U.S. for us to be critically impacted," says Raphael Kryszek, Founder and CEO of Intrepid Protect, a manufacturing start-up focused on producing face coverings that are made at a new state-of-the-art facility in Los Angeles, CA. It was the PPE shortage, dependence on foreign sourcing of goods, and a lack of quality-control standards that prompted Kryszek to make manufacturing in the U.S. a viable option. It is also his small way to create jobs and help bolster the U.S. economy.

And Kryszek is not alone when it comes to setting up shop stateside. According to a recent Thomas Industrial Survey assessing the ongoing impacts of COVID-19 on North American manufacturing, there is heightened interest in reshoring and hiring—mainly as a result of rethinking supply chains.

Of the 746 manufacturing companies surveyed in May and June of 2020, 69% are looking into bringing production back to North America, 38% are actively hiring, and 55% of the participants said they are likely to invest in automation, specifically as it pertains to production performance, process control, and product testing and quality. "With the growing appetite of reshoring and onshoring, respondents shared the top products they are looking to source domestically: metals (15%), machining tools and parts (13%), fabricated materials (13%), and PPE (12%)," the Thomas report states.

"Clearly, the pandemic has been an accelerant to reshoring, as well as nearshoring," notes Paul Wellener, a Vice Chairman at Deloitte LLP, and the leader of the company's U.S. industrial products and construction practice. "Nearshoring is getting into your time zone, like utilizing manufacturing in Central or South

America if you are in the U.S., and reshoring is bringing production back into your country. But as things come back to the U.S., it is not coming back in the same way as it's being done in another part of the world. There is technology being added to help continue to drive the cost targets, quality targets, and safety targets that manufacturers have."

According to Wellener, automation and robotics play a significant role as a way to offset labor costs, but machine learning, artificial intelligence (AI), cloud computing, 3D printing, and supply chain management (SCM) are also aiding in the effort to reshore manufacturing.

Intrepid Protect, for example, uses servo motors and absolute and relative encoders on the assembly line and relies heavily on AI and machine learning to ensure quality control and predictive maintenance to optimize operations and accelerate the delivery of mask inventory at the lowest cost. "There are a lot of moving parts on the assembly line, and they fail due to wear and tear. But we've seen huge improvements due to AI and predictive maintenance cycles, which has increased productivity, efficiency, and reduces pricing due to our ability to minimize waste and minimize faulty products," says Kryszek. "We didn't reinvent the production of three-ply masks, what we did was streamline and automate it by adding technology to improve different parts of the assembly line."

The high price of production

In recent history, the U.S. has had an $800 billion/year trade deficit. The U.S. has been dependent on imports primarily because the cost to manufacture here is just too high. According to Harry Moser, Founder and President of the Reshoring Initiative, his data shows that U.S. manufacturing costs are too often 20% higher than European manufacturing and 40% higher than China and other low labor cost countries, which makes offshore manufacturing more appealing from a cost-competitive standpoint. And the price is too high mainly because the dollar is too high, he said.

In addition, in the U.S. there aren't enough engineers and the country lacks the quantity and quality of skilled manufacturing tradespeople relative to the opportunities, hindering productivity growth that could overcome the impact of the U.S. dollar, Moser says. Plus, the U.S. has too many regulations, high corporate tax rates—which until 2017 were 35% when most of the world was around 22%—and there's no value-added taxes (VAT) here,

whereas other countries apply it. "These are important things that we concentrate on and reversing those over 10-to-20 years would balance the trade deficit and get us out of the problem we're in," Moser says. "We call it leveling the playing field, and if you do that then it is a lot easier to get companies to decide to bring work back."

With that said, Moser agrees that the latest interest in reshoring is driven significantly by COVID-19. "From March 2020 through the end of the year, about 60% of cases of reshoring mentioned COVID-19 as one of the factors causing them to reshore. Some of those cases were COVID-19-related products, like masks, and gowns, and ventilators, and others were related to the company recognizing that whatever it makes, it is too dependent on China or offshore sources, and COVID-19 has educated it to not be so dependent."

In addition, from a longer-term perspective, growth and productivity is the only way to raise the living standards. And the average U.S. manufacturing growth rate for the last ten years is 0.4%, Moser says. So, the lack of applying automation due to concerns that robots will take jobs, for example, has not helped U.S. productivity. In contrast, China's productivity is growing at 6% per year.

"If we don't invest in automation, we don't increase our competitiveness," Moser says. "Some people are afraid of automation because they'll lose their jobs. But throw away that statement, because the U.S. will lose more jobs to Chinese automation if we don't automate than we will to U.S. automation if we do. Since we are competing, you have to automate the best you can just to stay even."

But automation, too, must change to help manufacturers to compete. Moser points to **Bright Machines**, a San Francisco-based manufacturing technology startup that is transforming this space with its modular system for electromechanical product assembly.

↑ Bright Machine's Microfactory at work.

The future is bright

The Bright Machines' Microfactory for assembly, testing, and inspection, is designed to get products to market faster by leveraging intelligent software and adaptive hardware, using computer vision, machine learning, cloud computing, and robotics.

The platform is first focused on hardware standardization and common interfaces that map to a common data model. On top of that, there is a set of algorithms and microservices which are put together via an API gateway for a common set of apps that take the manufacturer through all of the stages of automation, line planning, configuration of robotic cells, deployment, and service and support. Key to this is an AI-powered software layer that configures, monitors, and manages machines and operations.

"We are automating automation," says Bright Machines' Chief Product Officer Abhishek Pani. To that end, Bright Machines will work across a variety of controllers and different components through an abstraction layer that makes it PLC agnostic. "There are a bunch of things happening through different vendors, but it is how we bring it together in one common interface and one common workflow and a common software tool."

To understand how the Bright Machine Microfactory works, and the speed at which this all comes together, one can just take a look at **Argonaut Manufacturing Services**, a U.S.-based contract manufacturer for the biopharmaceutical, diagnostics, and life sciences industries. With a focus on molecular diagnostics and parenteral drug products, the company currently has many active programs in the COVID-19 area, partnering with companies on the manufacturing and supply chain side.

For example, the company produces the kits for COVID-19 testing and collecting of the swabs and the liquid that preserves the sample to be tested to tell if someone has the virus. The company does both filling and packaging of materials, which could be different chemicals in different tubes that make up a kit. "We work with Bright Machines as an enabler to significantly automate the process to increase our scalability in the areas of filling and finalizing these kits," says Eric Blair, Chief Commercial Officer at Argonaut. The benefit is the modularization that fits well into the operational budget. "It enables us to take what tends to be a capital-intensive process and turns it into taking the key parts and building it out for specific needs in shorter periods of time."

This is important for reshoring because there's a need for innovative diagnostic testing and drug discovery here in the U.S., and to do it quickly and at scale while mitigating supply chain risk. To do that, many companies will look to contract manufacturers, like Argonaut. For more, visit **hcpgo.to/reshoring**.

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Modular: The Modern Way of Manufacturing Injectables

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Treatments are moving from hospital to home, requiring user-friendly injectable devices. Oncologics are one sector driving growth.
2. Modular manufacturing allows for a range of products in a single facility with faster changeovers and improved OEE.
3. Modularity may allow companies to fulfill multi-product campaigns requiring different production schedules.

Modular manufacturing is on the rise in the pharmaceutical industry. The last few years have shown an increase of interest in modular solutions for a variety of uses and **Stevanato Group**—a provider of integrated systems for pharma and healthcare—projects that this tendency will only continue, especially in injectables.

This popularity is due to the flexibility offered by modular manufacturing, allowing pharmaceutical processors to produce a range of products in a single facility with faster changeovers and improved overall equipment effectiveness (OEE). Modular manufacturing breaks down a system into discrete component "modules" that perform specific roles and can be integrated into or removed from the overall structure at will.

The following factors are driving this movement in the injectables market:

- Many treatments are moving from hospital to home, reducing costs for healthcare providers and increasing patient comfort. This requires the need for user-friendly injectable devices, which has been further exacerbated by the COVID-19 pandemic.
- The demand for auto-injectors and pen injectors is skyrocketing as lifestyle-related diseases, such as diabetes, become more widespread in both developed and developing countries and as the niche of targeted small batch and personalized medicines, including oncological formulations and certain biologics, grows. This is driving the need for more mobile, less intrusive, and simpler solutions that remain cost-effective, which in turn demands flexibility on the manufacturing side.

These self-administered options allow patients to treat themselves more independently and autonomously than ever in a safe manner. As Editor Aaron Hand says in *Burgeoning Auto-Injector Market Demands Flexible Production Options,* "Auto-injectors help avoid common risks associated with self-administration via syringes, such as incorrect dosages and misuse, serious injuries, and discontinuation of treatment."

The benefits for healthcare providers and patients are clear. As injectables continue to become more customized and self-administered, manufacturers will need to modify the design, engineering,

and production of their assembly line equipment to meet these and future demands. This will in turn benefit manufacturers—contractors and service providers in particular, who will need to prove adaptable—as the industry will continue to evolve with varying shapes, sizes, and materials of injectables as well as in product volumes, demand, and sub-categorical issues like target audience differentiation. Production processes will need to be time-efficient and customizable.

A *Pharmaceutical Networking* article, *Defining ideal modular design for effective pharma packaging*, seconds this perspective and explains that the modular design must be adapted to the existing development process and embedded into ongoing operations during implementation in order to minimize adaptation demands which will surely come.

Automation and pharma 4.0

Stevanato Group outlines characteristics of modular manufacturing that assembly machinery needs in order to keep up with the needs of modern combination products: fast format changeover to reduce costly downtime, flexibility to allow reduced CAPEX investments and achieve shorter time to market, and scalability for additional modules to meet increased volumes.

Another factor Stevanato Group emphasizes is automation. Though lower volumes of product are typically required with auto- and pen-injector production, efficiently switching to wider-scale production efforts can be necessary. Automating processes can also reduce human intervention and further decrease production downtime.

The company explains that automation becomes valuable through its reliability, precision, repeatability, and process optimization. The greatest benefits come from incorporating automation into the very beginning stages of the development process, offering an alternative to the prototyping phase with a benchtop through a semi-automatic pilot line. This offers inherent scale-up advantages, allows early de-bugging, and mitigates future risks as the technologies used from pilot line to large-scale, fully automated line are the same.

Says Stevanato Group, "Involving equipment partners with modularity experience from the early stages offers a distinct advantage, since they've seen for themselves how initial development work is crucial for establishing early proof of principle and validating the assembly process."

Looking at containment systems and automation scale-up early on are key, in part due to injectables' product-specific complexity.

In *Industry 4.0 with a Pharma Focus*, Pat Reynolds covered the efforts of the **Marchesini Group** in the life science space, noting, "...once processes are digitized, it opens the door to other exciting possibilities such as machine learning, condition monitoring, remote-access monitoring, and, ultimately, the smart factory. In the smart factory, operations are carried out with minimal manual intervention, high reliability, and maximum flexibility. The automated workflows, synchronization of assets, and improved tracking and scheduling in the smart factory lead to increased yield and quality along with reduced cost and waste.

"Predictably enough, the pharmaceutical industry is anything but immune to the impact of IoT and Industry 4.0, trends that are transforming pharma manufacturing at a rapid pace."

This is echoed by *Pharmaceutical Networking* which further builds on the potential for Industry 4.0 concepts in modular manufacturing in pharma, such as shared data, artificial intelligence (AI), and increased connectivity enabled through the Internet of Things (IoT).

Systems incorporating these concepts and created by collaborative efforts from **Dividella**—a supplier of cartoners and secondary packaging machines for the pharmaceutical and biotech industry–and **Medipak Systems**—a system provider for the pharmaceutical industry—also use the "Plug & Produce concept of vertical integration that imposes a standardized interface between machines in production and the production control system." This allows modules and production lines to be connected or disconnected through plugging a drive into a computer via a USB interface.

This setup has further allowed Medipak Systems to create advanced systems that include smart packaging, Enterprise Manufacturing Intelligence (EMI), smart devices, and condition monitoring and predictive analytics. These advancements improve end-user experience, user-friendliness for operators, and allow superior decision-making by producers.

Benefits of the modular format

There is a range of benefits that come from modular manufacturing, beyond adapting to market demands, fast changeovers, improved OEE, and up scaling options with automation and plug and play expansions. Modularity can also:

- Deliver standardization—as modules are simplified, produced more economically, and made reusable—and customization by tailoring systems to individual and specialized demands.
- Reduce costs in both implementation and operation.
- Ensure faster production and delivery, and when machine utilization rates are high, offer high return on investment within a short timeframe.
- Allow manufacturers to meet the need to deploy manufacturing regionally, reduce the cost of goods sold (COGS), increase capacity utilization and speed-to-market, and fulfill multi-product campaigns requiring different production schedules.
- Encourage engineering and production teams, through its synergy-centric nature, to collaborate by planning in parallel for near-term and longer-range scaling needs.

Package Design Gallery

This year's gallery featured many calming and minimalist aesthetics, signifying a consumer looking for relief at home and work—outside of the clinical setting.

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

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

Trends on the Shelves

+ While perhaps not pandemic-related (with formulation, package design, and commercialization often taking years), there was a plethora of stress-fighting, anti-anxiety, and calming products, even for children.
+ Blues, greens, and serene imagery were featured more prominently than last year.
+ The minimalist trend continued with whitespace on labels and cartons, and casual copy for a "conservation" with consumers.
+ Larger mainstream brands used nature-inspired images and touted fewer ingredients or "what's absent" from the product.
+ Many had clear disposal instructions and more packages on shelves were recyclable.

Garden of Life Kids Stress Relief

PROS

+ A shrink sleeve makes the most of the real estate, offering founder's story, icons for expected effects, and symbols for gluten-free, recyclability, renewable energy use, and more
+ Calming sea and cloud images; suggested use lets parents know daily dosage
+ Square jar stands out on shelf; wide mouth child-resistant (CR) lid was easy to open

NOTES

- The sleeve was a bit curved on the bottom of two panels, which caused copy to distort slightly but it remained legible
- Customers would presumably need to remove the sleeve before recycling

Olly Goodbye Stress Gummies

PROS

+ Bright standup recloseable pouch features serene blue and turquoise hues
+ Servings per package are clear; touts "Jet Set Friendly" size
+ Matte pouch with spot gloss/foil on front and back gives high-end look; notches for easy opening
+ Usage, warnings, and symbols on back are spaced well

NOTES

- Disposal is not specified

La Mend Inc. The Good Patch

PROS

+ Matte sky blue recloseable pouch with dreamy icons and whitespace (more easily accomplished when Drug Facts are not required)
+ Back panel is well-organized with lines separating ingredients, directions, warnings, a link to a "surprise," and more

Noho Health Inc. care/of Immunity

PROS

+ Matte outer carton in soothing green; matches matte rectangular easy-to-grip bottle
+ This is part of a colorful product family for various needs; enclosed leaflet showcases product combinations
+ Glossy info and imagery are printed on bottle; instructions are small but contrast well against simple background
+ Minimal abstract graphics allow for conversational, explanatory copy without a "busy" feel

NOTES

- Carton says "please recycle me" on bottom, but consumers may not know how to recycle the bottle (#7) depending on local infrastructure.

Procter & Gamble ZzzQuil Pure Zzzs

PROS

+ Flowers and hops make a splash on the carton for an herbal product; bright melatonin-free callout
+ How 2 Recycle symbol leaves no guesswork for blister tray and carton disposal
+ Tablet size and directions are clear on side panel; spot gloss lettering on matte purple band

NOTES

- Consumers may wonder about excess carton depth for one blister sheet, but this was likely needed to ensure the carton stands up

RB Health Mucinex FREEFROM Cold & Flu

PROS

+ Like others this year, the bottle highlights what is absent, including artificial colors and alcohol
+ Stark beige label breaks from traditional cold imagery and keeps the focus on orange accents such as "Free From" copy
+ Back label features two peelable layers to accommodate drug facts—while this required some time in peeling, it prevents the need for a carton or leaflet

NOTES

- One may wonder about peeling two layers of labels to get to the directions, but perhaps this was done to keep the directions on the last (bottle-touching) layer for security

Wyld Cannabis Infused Peach Gummies

PROS

+ Eye-catching hexagonal carton with triangular top; THC symbol and potency are prominent
+ Batch-specific info is printed directly on carton and on jar; bright orange inner carton with warning copy; jar label also features botanical imagery
+ Opaque polypropylene CR pop-top jar features opening instructions on lid; jar opened smoothly and features serving info

NOTES

- It may be difficult to see the tiny recycling symbol on bottom of jar
- Edible-specific instructions are useful and stand out in silver, but could potentially be missed on bottom of carton

SEE MORE PACKAGES AND REVIEW DETAILS AT HCPGO.TO/GALLERY2021, INCLUDING:

↑ Quip Toothpaste: Both the minimalist tube and carton feature clear explanation of tube recycling instructions; bottom of carton notes 100% paper and "please recycle."

↑ Dr. Scholl's Callous Removers' instructions for use are very clear (albeit in small font) in three steps on back panel with images. Cushions themselves feature Step 1 and Step 2 on the backing and top layer for ease of use.

↑ J&J Band-Aid Ourtone Bandages, launched in 2021 after a foray in 2005, add offerings to mutiracial tone bandages on the market.

↑ Hyland Daytime Oral Pain Relief for Baby: Outer carton features an illustration of the inner bottle, fill line, and tablet size so parents know just what to expect.

↑ GSK Consumer Healthcare Robitussin naturals' leaf and honey images highlight ingredients, while label copy notes what is absent.

↑ Bayer AleveX Pain Relieving Lotion features a uniquely shaped bottle—wide and shallow—for easy grip and squeezing.

↑ Pacific Shaving Co. Nick Stick's pithy quote scores points, while right-sized blister shows rollerball against silver backing.

↑ EVERY MAN JACK Hand Sanitizer's slim pocket-ready spray features black woodgrain pattern; forest green foil effects offer an elevated aesthetic.

Pharma Supply Chain: Master Data Exchange in 2021

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

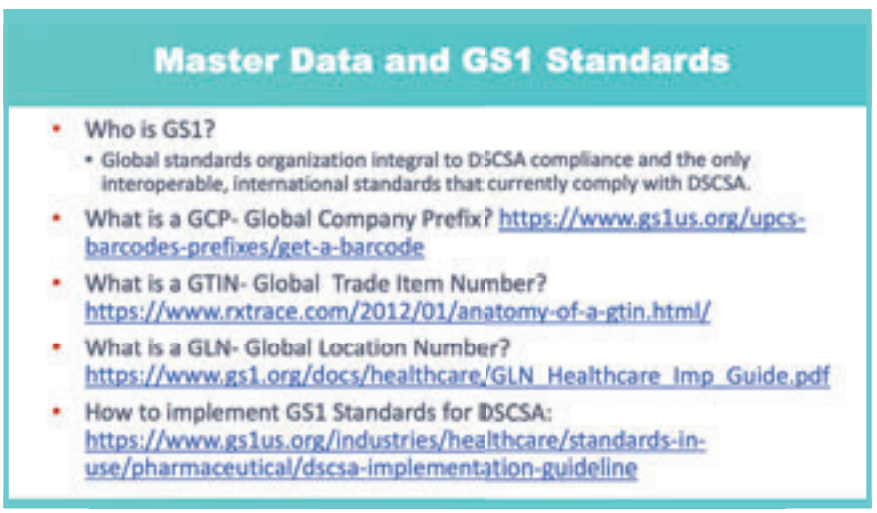
1. The global GS1 standard, EPCIS, offers a common information exchange language.
2. EPCIS onboarding takes time and requires immediate action from pharma manufacturers.
3. To avoid product holdups, it's critical that manufacturers have processes in place for exceptions in data exchange.

In order to arrive at the unit-level traceability sought by the Drug Supply Chain Security Act (DSCSA) by its 2023 deadline, the pharmaceutical industry as a whole must tackle the issue of interoperable systems to share data with trading partners.

The overall goal of DSCSA legislation is to verify product legitimacy, make recalls more efficient, and enhance detection of illegitimate products in the supply chain. A major component of this is the requirement of serialization, the practice of assigning a unique serial number linked to product data—product origin, batch number, and expiration date—to each saleable unit of each prescription drug product.

"But the exchange of master data today is a manual process," explained Allison Sheldon, Senior Manager, Pfizer Digital Serialization, Pfizer Inc. at a recent Healthcare Distribution Alliance (HDA) Traceability Webinar event. Serialization data is manually pulled from internal systems, and spreadsheets are maintained and emailed back and forth to trading partners.

Part of what manufacturers are trying to sort out now is how their trading partners are managing data on their end. "Are they taking HDA's forms and applying changes that are required in their systems? How do we keep that data up to date? We'll see that



↑ Get the links the panelists offered at hcpgo.to/gs1. (Credit: HDA)

Related Stories at HealthcarePackaging.com

+ **Serialization 101** Fraud is a serious issue for drug manufacturing, and pharmaceutical and medical device regulations using serialization have been mandated to defend against counterfeiting. **hcpgo.to/s101**
+ **[Video] MIT PhD on Supply Chain Resiliency in the Face of COVID-19** MIT's Dr. David Simchi-Levi visited with Keren Sookne, *Healthcare Packaging*, to re-examine how life science companies think about their supply chains. **hcpgo.to/resilience**
+ **3 EPCIS Data Exchange Issues in Pharma Traceability** Conformance testing services emerged to cut down on wasted back-and-forth between manufacturers and trading partners to get efficient data exchange up and running. **hcpgo.to/3epcis**
+ **The Logistics of Supply Chain Visibility** Tive and project44 team up to deliver the Open Visibility Network, a way to provide transparency between shippers, logistics service providers, brokers, and customers. **hcpgo.to/visibility**

when there's any type of mismatch, that creates failures when we're exchanging our serialized data. It's certainly not sustainable—we need to come to an automated approach," said Sheldon.

Brad Pine, Vice President, Brand Pharma & Regulatory at Smith Drug Company, Div. J M Smith Corporation, agreed. "Everybody gets HDA spreadsheets and adds the GTIN [Global Trade Identification Number]—it's still not very well-adopted. You're constantly sending them back to manufacturers and saying, 'You didn't have the GTIN on here.' Then loading information from a spreadsheet is painstaking and it's prone to errors because of the formatting. If I don't capture lead zeros correctly, there are issues with that."

EPCIS onboarding

The answer, panelists said, lies in pharma manufacturers using a common framework to exchange data: EPCIS (Electronic Product Code Information Services) files.

EPCIS is a global GS1 standard for creating and sharing visibility event data, both within and across enterprises, to enable users to gain a shared view of physical (or digital) objects. Physical objects include products, logistics units, documents, and more, while digital objects can refer to items such as music downloads, e-books, and e-coupons.

Adoption is off to a rocky start. "Our biggest challenge is finding manufacturers that are willing to send us EPCIS events and get that onboarded," said Pine. In a best-case scenario, Sheldon offered a chart showing that it takes around six weeks to onboard between manufacturer and distributor, covering three main activities:

- Exchanging master data
- Testing
- Moving into production

The six weeks represents a "happy path" where everyone is talking consistently and maintaining momentum. It involves a variety of stakeholders between the trading partner and internal personnel from marketing, IT, logistics, and warehouse operations. "And this could be for just one trade partner. So keep that in mind as we look at the volume of onboarding work that we need to do over the

next year and a half or so," advised Sheldon.

Challenges

Working with wholesale distributor or dispenser partners, pharma manufacturers are running into a number of issues once they are testing or live in production. There are errors in master data files that cause failures, or a trade partner didn't have a particular GTIN—possibly due to scanning an "inner pack."

Following standards is key. There may be timestamp issues in a file, and as Sheldon pointed out, it's one thing to determine the file failed because of a timestamp issue, "but then from the manufacturer side, we need to go back and look at, 'Why was there a timestamp issue?' and then you might uncover other process changes that need to happen to address that going forward. As I'm sure everyone knows, process changes don't happen overnight."

Pine echoed the need to follow standards and start soon. "You find that there's a lot of syntax errors and aspects that are glitchy. When you talk to the bigger manufacturers, they are certainly in test phases with the big three—a few of them are testing with us—but the big three are definitely pushing the issue. It's really important that we start testing and putting together production as soon as possible, because there's a lot to be done before November 2023," he said.

Jeff Falardeau, Manager, Pharmaceutical Information Technology at Cardinal Health, Inc., said that in working with their manufacturing partners, another challenge is readiness. "Communication is another area where time could be compressed. We might get a test file and we'll respond usually within a business day. But we don't know what happens once we send that response out—it may go into some kind of rework and come back. I'm not sure how closely mailboxes are monitored, but there's an awful lot of time lost just in exchanging messages back and forth," Falardeau said. "Proficiency is all over the place. Some companies are very proficient, some are less so. That leads to situations where we might get chronology errors with the EPCIS event times—probably the largest source of errors that we get. We might be missing master data altogether, missing master data elements, or have extra master data inserted where it doesn't belong. Quite a wide variety of things."

Michael Ventura, Vice President, Solutions & Innovations at **LSPediA**, noted that everybody should be working with their solution providers to be up and running on EPCIS version 1.2 and testing with their supply chain partner.

Lower volume manufacturers

EPCIS-formatted messages are usually generated through L4 enterprise systems. But there are options for generating EPCIS messages for low volume or low frequency shipments to avoid the additional costs related to new L4 modules. Falardeau explained that for those who don't have an internal IT group that can extract information and formulate EPCIS files, there are solution providers that will take data in most any form and convert it.

3PL vs. manufacturer responsibilities

Audience members were curious if manufacturers will need to have all their distributors or wholesalers onboarded to their serialization system to track transaction information directly, or whether their 3PL can send that information if they have it. Pine explained, "If you read the law, the law just says that the manufacturer has to

Also in Traceability News

+ HDA, in coordination with the Center for Supply Chain Studies, announced the successful conclusion of an industry-wide pilot of an interoperable "authorized trading partner" credentialing ecosystem to support DSCSA requirements in March 2021. Stakeholders who intend to adopt this model have launched the Open Credentialing Initiative (OCI), a user group that will publish frameworks, address recommendations, work on standardizing artifacts, and explore other use cases.
+ Cardinal Health is one of many distributors working to strengthen collaboration with industry and government to transform the supply chain. For PPE and other critical COVID-19 products, Cardinal began working with freight-tracking software startup **FourKites** in March 2020 to gain better visibility into its delivery network and maximize provider access to much-needed products. They collaborated on a pilot program to track shipments of PPE, and built a customized system to track temperature-sensitive medical products, now used in all Cardinal Health transport modes throughout the U.S. Up next: supply chain solutions for the "last mile" of delivery. More info: **hcpgo.to/covid-supply**
+ Traceability is key to ensuring safe and equitable vaccine distribution. **Antares Vision Group** has designed and installed systems that combine visual inspection and serialization on vial filling lines for several companies. The latest system is equipped with technologies to allow accurate visual inspection for liquids and/or lyophilized products, Container Closure Integrity Testing, and, in integrated mode, the serialization of single doses. This includes in-line printing and control of a data matrix code with visible or UV-visible ink to share information with health authorities, and throughout the supply chain. This is of particular importance with the use of lyophilized products expected to be adopted in the production of COVID-19 vaccines soon.

send the information to us [a distributor]. So that's descriptive in who's going to be sending it to me. But I'm just as happy to get data from the 3PLs as I am from the manufacturer. I think each manufacturer is thinking that through a little bit differently. Some of them want to have control and others are happy with allowing their 3PL to do the work for them."

Just don't forget that while a 3PL facilitates many activities on behalf of the manufacturer, when an FDA auditor comes in and asks for information, the manufacturer is ultimately responsible.

Verification router service

When Pine's company surveyed manufacturers about whether they would be using a verification router service (VRS) system for the DSCSA's saleable returns verification requirement, many mentioned they wanted to use EPCIS files instead. "A lot of them were using 3PLs. I think that they're thinking that they can get around the VRS by using EPCIS, and in a lot of events, that's probably going to be true. But VRS is the only viable thing that we can think of for really verifying products upon return when we don't have the EPCIS events," said Pine.

↗ Data is generated at every level of packaging.

Closing advice

The main point panelists hammered home is (1) to ensure you have processes (resources, tools, and SOPs) for exception management and (2) to get help with data exchange as soon as possible if you need it. "Full and timely adoption for exchange with manufacturers and distributors is key. Risk and impacts are very high and extreme if we can't ship product for which we don't have the data. So when files come in, if they fail, we need to react quickly," said Falardeau. "Cardinal Health looks to invest in automation to help with that, to work with manufacturers, and to reduce that turnaround time. But as I alluded to earlier, there's a wide range of proficiency levels right now. Manufacturers, if they're not already, really need to start pulling themselves in here to get up to speed more quickly or seek help from solution providers. We also highly recommend conformance testing companies that will help you learn EPCIS or help you be able to test rapidly. For now, we're just really concerned about the runway left and the number of manufacturers that still need to jump in the pool and start testing with us before 2023."

Smudge-Proof Cannabis Batch Labels Offer Colorful Compliance

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. High Desert's product line spans about 30 different SKUs.
2. Compliance info is printed on-demand.
3. Labels also include traceability information

Launched in 2015, High Desert Pure is a Bend, OR-based company that produces full-spectrum topicals, tinctures, and bath products, all of which center around health. "Our main focus is providing relief. We sell products containing THC in the Oregon and California marketplaces through those states' recreational marijuana programs. We sell products that contain only CBD online, and these products can be sold direct-to-consumer via mail order," says Jack Robson, Owner of High Desert Pure. Robson started his business after a ruptured disc caused him to seek alternative pain relief, and he found success with cannabis.

As has been the case for many regulated health products, copy and packaging requirements are tough to balance with small real estate or pre-printed packaging. "When we started developing our packaging and labeling requirements, we realized that we had a bit of an unusual requirement in that our labels have a significant amount of batch-specific regulated text and content to facilitate tracking and tracing. So, this precludes a lot of typical approaches such as having a nice screen printing done on your packaging in bulk," explains Robson. "No matter how you slice it, you're going to be at least augmenting the data on your packaging with either a label, heat shrink, or external packaging such as a box, in order to convey this batch-specific detail."

With the added requirement of child-resistance features, High Desert Pure encountered packaging suppliers taking existing child-resistant containers and encouraging use with cannabis and CBD products. Robson notes that what works for an eighth ounce of flower won't work for a lotion closure. "To this day there remains a tremendous dearth of compliant, child-resistant, environmentally friendly packaging solutions for the cannabis industry," he says.

Labeling a wide portfolio

High Desert's product line spans quite a range—about 30 different SKUs with a variety of labels and sizes—including:

- Full Spectrum Tinctures in a 1.7-oz bottle with dosing measurements on dropper, packaged in an outer carton
- Big Balm in a 2-oz recyclable, child-resistant jar with a reclaimed ocean plastic lid
- Full Spectrum CBD Lotion in an airless pump container (3.5 oz)
- Topical Relief Stick in a high potency glide-on application in a 0.52-oz twist up container
- Soak & Fizz Cannabis Bath Salts in a child-resistant 16-oz container with a reclaimed ocean plastic lid

The company needed a way to label products that would allow them to edit the batch details in-house, while generating "an attractive and resilient label, meaning one that would not easily be ruined by water or oil" while in the customer's hands. "Imagine labeling a sunscreen bottle, for example. You will likely get sunscreen on your fingers. If that caused a label to smudge, that would obviously be

↑ The company selected Epson ColorWorks printers for its print-on-demand color label systems.

unacceptable" Robson says.

Because labels require manufacturing dates and testing information depending on the cannabis product and state—such as THC content and pesticide analysis—they are applied post-fill after a batch's results are received. The universal cannabis warning symbol is state-specific and dimensions cannot be altered, adding to the need for customized labeling. Labels are supplied by a number of vendors, with the majority sourced from **Hickman Label**.

How Medical and Adult Use Differ

In Oregon, Robson explains that the difference between the medical and recreational (or "adult use") programs is fairly minimal at this point. "The primary differences being that items sold under the state's medical cannabis program can often have higher potencies and can be bought in larger quantities. The other difference is that it is not taxed, whereas sales of recreational cannabis items are typically taxed at the rate of 20%," he says. The starker difference is between recreational cannabis products and CBD-only products. Robson notes that the latter hemp-derived products are largely unregulated, allowing sales direct to consumers via websites. "Our target audience and demographic is largely the same across these two different product lines," he says.

Resilient labels

Robson was impressed with an **Epson** ColorWorks demo from **Color Label Solutions**—a distributor specializing in print-on-demand color label systems. "We initially used a color laser printer to create labels. While it was fairly straightforward and easy, the quality wasn't what I wanted to represent my company, and it didn't allow us to scale up as business grew," says Robson. "When we saw the ColorWorks, the quality was far superior to anything else we had ever seen. And, with the labels on rolls, it would allow us to automate the application of the labels."

High Desert Pure started with the ColorWorks C7500G on-demand color label printer in Oregon, and after opening offices in Sacramento to help serve the growing California market, invested in the newest ColorWorks CW-C6000A. They use a variety of label media—primarily rolls of matte white polypropylene (BOPP) labels— and both printers use UltraChrome DL pigment ink in four individual CMYK cartridges.

Once labels are printed, they remain on rolls which are transferred to label applicator machines. "We obviously have a variety of different labeling machines to suit our various products having different sizes and shapes. Dare to dream, but hopefully someday we can find a labeling machine that is as dependable as our Epson ColorWorks printers," he says.

Traceability matters

Robson explains that each product is labeled with a unique ID, which allows the product to be tracked and traced through its entire lifespan—from the point of manufacture to distributor to dispensary to the end consumer—and prevent diversion. "To see the test results for a product, a customer can enter the last three or four digits of the batch number on the product label for insight into third party lab test results (terpenes that are in each strain, CBD, or THC percentages) via our website. In addition we often provide barcodes and QR codes on our labels to assist with point of sale scanning and customer support," he notes.

For label data management and barcode generation, High Desert Pure uses in-house proprietary software that they created to track and trace products and lots. "This data feeds into our final labels which are managed, tweaked, and printed using **Adobe** Illustrator," he says. For more product/label images, visit hcpgo.to/desert.

Next steps in sustainability

Their immediate short-term priority is to refocus packaging towards more sustainable options. "The cannabis industry is regulated to provide child-resistant packaging that includes a lot of text, which can result in excessive packaging and a negative impact on our landfills and the environment in general," says Robson. "Where possible, we are simplifying our packaging and moving towards sustainable options. For example, we are swapping out some aluminum and plastic packaging for glass packaging, glass being highly and easily recyclable. And for our caps we are sourcing them from a company—**Sana Packaging** with **Oceanworks**—that makes the caps from reclaimed ocean plastic."

Cannabis Market Update

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Cannabis dispensaries are going digital to adapt to consumer demands. With COVID-19, consumers spend less time in store.
2. Some federal legislators have indicated that they are interested in ending cannabis prohibition, as the industry awaits de-scheduling.
3. Big retailers selling CBD products remain focused on topicals vs. ingestibles for now due to unclear regulations.

It goes without saying that consumer behavior has changed in the wake of COVID-19. As Blake Patterson, MarketHub CEO, explained at the Hemp Industry Daily Conference, cannabis is no exception. Purchasing behavior, which typically takes years to change, changed in mere months after the onset of the pandemic in March 2020.

"People want to get out of the store as fast as possible. The experience is not what it was before COVID-19," Patterson said. People are not necessarily there to browse the glass cases, and he added that masks can create a bit of tunnel vision as well. Now, the consumer generally has a list and knows what they're going for instead of wandering the aisles looking for what's new.

Additionally, some dispensaries have implemented click-and-pick up and delivery options. High quality imagery is key if your only touchpoint with customers is a picture on a dispensary site.

This sudden behavioral change also represents an opportunity for brand owners to talk with retailers and find different ways to engage. Franny Tacy is Chief Creative Officer and Farmer at Franny's Farmacy and Franny's Farm in North Carolina. She noted that they use Facebook messenger, chatboxes, and more. "Everything we're doing now is designed to connect and engage with customers," she explained.

CBD still faces growing pains

In the CBD market, many bigger retailers are only leaning in with topicals. "I would say 90% of our customers, and that includes CVS, Walgreens, and Dollar General, they're all dealing in just topicals right now," said Patterson. "There's very few that are looking at the ingestible market because of the lack of clarification from the FDA."

That also presents an opportunity to brand owners looking to expand—establish yourself with retailers through topical product lines and prove to the retailer that you can meet demand and create value. "When it is time to take on ingestibles, that's who we're going to look to," Patterson advised.

Regulatory update

At the end of 2020, the House had passed the MORE Act which was historic in that it was written to remove cannabis entirely from the Controlled Substance Act (CSA). The bill ended up dying when the Senate adjourned for the year.

In late Jan. 2021, Rep. Greg Steube (R-FL) filed a proposal to move marijuana from Schedule I to Schedule III of the CSA. While this would open up opportunities for scientific research, many advocates prefer that marijuana be removed from the CSA entirely as the MORE Act intended to do.

This spring, Senate Majority Leader Chuck Schumer, Senate Finance Committee Chairman Ron Wyden, and Senator Cory Booker released a joint statement saying that ending cannabis prohibition on a federal level "is necessary to right the wrongs of this failed war [on drugs]." The bill filed in the near future is likely to include components of multiple pieces of legislation from the last Congress.

Says Jack Robson, CEO of High Desert Pure: "When [cannabis is de-scheduled] and we come to our senses from a legislative standpoint, I expect that we should see several benefits ranging from access to banking, to additional research opportunities so that we can learn more about cannabis, to potentially even opening the door to manufacturing, distribution, and sales across state lines. Time will tell how our laws evolve."

Materials Updates

Companies continue to implement recyclable paperboard and glass where possible. Flexible pouches remain popular, and single-stream reclaimed ocean plastics that can be recycled are gaining steam. Some producers have noted that they would like to package cannabis products in hemp-based packaging one day. As a pure material, hemp has a shorter shelf life compared to traditional plastics, but it is strong and biodegradable.

Packaging for the Cannabis Market

Get your FREE download of the 46-page *Packaging for the Cannabis Market* PDF. Also included is **PMMI**'s white paper, *Cannabis Market Update: Unique Packaging Challenges for THC and CBD Products*, with information on cannabis markets, industry outlook, product, packaging, and machinery considerations, and the role of contract packagers. **Get your download at pwgo.to/7025.**

Manufacturing Cybersecurity: Critical Components for Risk Assessment

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

TOP THREE TAKEAWAYS

1. By the second quarter of 2020, cyberattacks targeting manufacturers accounted for 33% of all incidents.
2. Manufacturers have lost hundreds of millions of dollars as a result of cyberattacks.
3. Manufacturers need to implement cybersecurity measures across all networking operations, including machine networks.

According to a new report from **PMMI** Business Intelligence, many manufacturers are still not aware of the tangible risks that result from a lax cybersecurity approach, even despite the growing frequency of cyberattacks directed at manufacturers and the heavy financial burden of costly fixes and expensive downtime. And the speed of industry innovation has often outpaced the digital security infrastructure at manufacturing sites.

Cybersecurity for manufacturers encompasses more than log-in security and email scams. Every sensor connected to a machine, every machine connected to a network, and every network connected to a centralized control system are potential pathways for cybercriminals.

Since every connected device at an operation can potentially be exploited in a cyberattack, manufacturers must be cognizant of the fact that their systems, physical infrastructure, and employees, must all be protected from nefarious outside forces seeking to gain entry into the operation.

There are critical components that need to be assessed to achieve a robust cybersecurity system:

- Perimeter or network detection and firewalls to safeguard vulnerable points, such as: sensors, actuators, and anything with an IP address.
- Implementing cybersecurity best practices and end-point management.
- Cybersecurity budgeting, staff training, and keeping up to date.

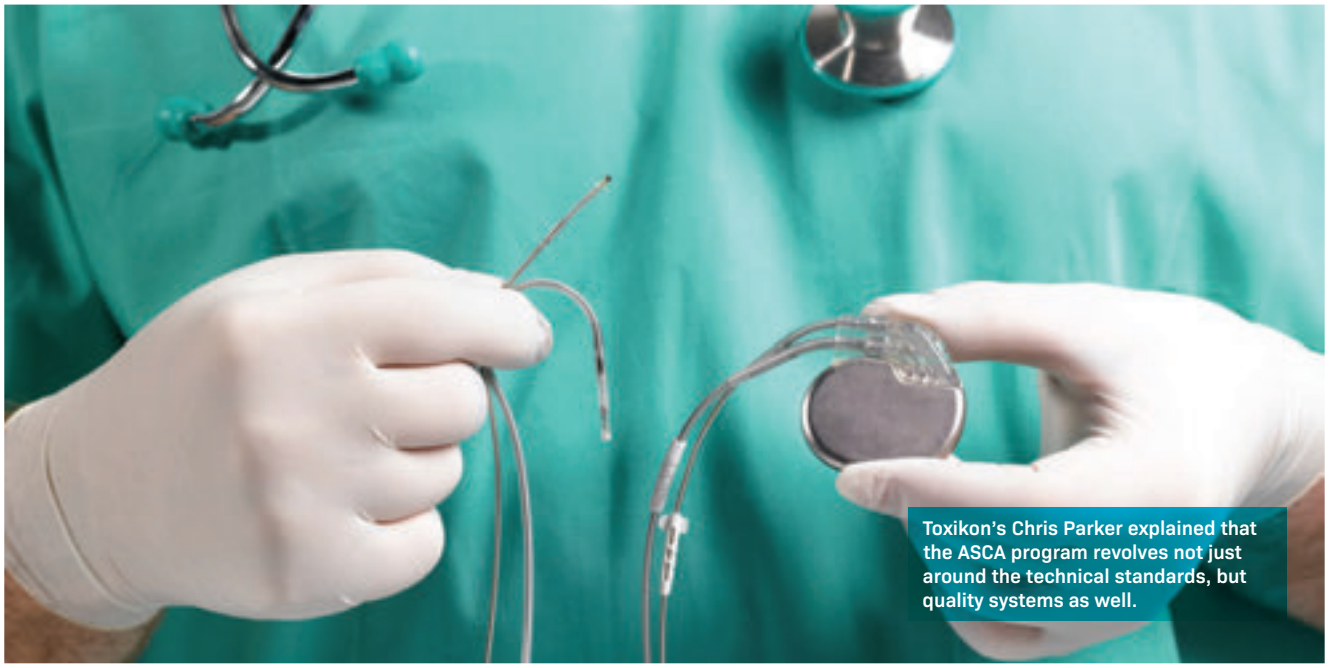
Said one director of a managed services provider, "Best practices for cybersecurity require a holistic approach across the entire company at every vulnerable point of entry." And another managing director at Cyber Partner said, "At this time in our world, it is not if there will be an attack on your company, it is when, and that statement applies to all companies regardless of size."

In the first quarter of 2020, attacks targeting the manufacturing sector accounted for 11% of all cyberattacks that occurred across all industries, and by the second quarter, cyberattacks targeting manufacturers accounted for 33% of all incidents across all industries. In 2020, 28% of all breaches recorded occurred at small businesses.

This increase in attacks is especially alarming given the growing cost to manufacturers that experience a cyberattack. According to the report, in 2020, the average cost of a cyberattack stood at around $3.86 million, and that does not include the impacts of lost opportunity or damaged customer loyalty. It often takes manufacturers a significant amount of time to identify, isolate, and resolve a cyber intrusion—on average 280 days to identify and contain, but to completely resolve an attack and address any damage, affected operations must be shut down for an average of two weeks.

Despite these facts, 34% of manufacturers state that the risks of a cyberattack and the need to implement a cybersecurity defense are not even on their radar for consideration. And in many cases, manufacturers have not kept up with plans to safeguard their technology infrastructure, even if they had them previously.

Download the PMMI Business Intelligence report *2021 Cybersecurity: Assess Your Risk* by visiting: hcpgo.to/cyberreport



Toxikon's Chris Parker explained that the ASCA program revolves not just around the technical standards, but quality systems as well.

Demystifying FDA's ASCA on Biocompatibility for Expedited Review

KEREN SOOKNE, DIRECTOR OF EDITORIAL CONTENT

TOP THREE TAKEAWAYS

1. Device manufacturers can potentially speed review by testing to recognized standards performed at accredited labs.
2. Labs go through rigorous accreditation. The FDA website will show which labs are accredited for which methods.
3. If all testing is performed without issues, manufacturers may submit a summary report instead of a full report to the FDA.

A 2020 FDA guidance may soon help boost consistency in medical device testing and expedite review of submissions for eligible devices.

At MD&M BIOMEDigital, Chris Parker, Head of In-vivo Biocompatibility at **Toxikon**, explained that in Sept. 2020, FDA published final guidance on the Accreditation Scheme for Conformity Assessment (ASCA), launching a program where labs that perform testing for ISO 10993—Biocompatibility and IEC 61010/IEC 60601–Basic Safety and Essential Performance can become accredited by the FDA.

The key ASCA takeaway for manufacturers is that the testing performed to recognized standards at these accredited labs may be submitted with only a summary report instead of a full report (if no unexpected results occur) and they can expect an expedited review during submission.

Parker explained that this effort began as a pilot program, advancing to FDA guidance documents in Sept. 2020:

- **Program guidance:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance*
- **Basic Safety and Essential Performance standards-specific guidance:** *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment — Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*
- **Biocompatibility standards-specific guidance:** *Biocompati-*

bility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Participation is voluntary, and it revolves not just around the technical standards, but quality systems as well.

In early 2021, the first wave of accredited bodies (ABs) was published, and in April the first wave of FDA-approved labs was posted. There were 54 labs on the list of press time.

The FDA website will show (1) which labs are accredited and (2) what they're accredited for as a lab could be accredited for multiple methods, or just cytotoxicity, for example.

- The FDA will audit both ABs and test labs as necessary.
- When a manufacturer performs testing at an accredited test lab, the lab will provide a standard report as well as a summary report.
- Provided testing takes place without unexpected results, the manufacturer can submit to FDA with a Declaration of Conformity (DOC) and summary report for pre-market submission review.

Device eligibility

It's important to note that all devices are eligible except for liquids, creams, gels, hydrogel devices, devices containing nanomaterials, and absorbable and in situ polymerizing devices. "Things that are going to break down, or have an active integration that could polymerize such as a skin glue, because these are more of a dynamic process... the ISO standards are written more for an extraction type of environment and these may have some nuances with irritation. We may need to do some histology to characterize a bit better the reaction that's going on," Parker explained. But devices such as catheters, bone screws, and pacemakers are eligible.

ASCA labs and methods

Parker mentioned that while MEM Elution Cytotocity is included for now, other cytotoxicity methods such as the MTT and NRU may one day be added.

FDA requires training for technicians, study directors, and trainers at labs. Study directors must build up significant education, time, and experience, while trainers must hold extensive experience in each technique. Proficiency evaluations ensure that the "test lab's eyes" see things the same way that accredited bodies' eyes do. "We have to provide an index of all the SOPs that are particular to the ASCA methods we're applying for and provide all of those to the FDA," said Parker. "We also have to supply all of our raw data sheets that we use for collecting data on a study, all of our protocols, and report templates to make sure we're asking for the right data, we're recording the right amount of data, and we're reporting the right amount of data."

Control over sample prep is key—times, temperatures, etc. Any post extraction changes that take place such pH drops or rusting may require manipulation to proceed with testing, "but then you're not performing a standard method anymore as there could be things going on with the device that are unexpected," he said. At that point, the FDA would likely prefer the full report versus the summary version.

Key takeaways

- The brand owner will need to prepare a DOC that includes where and when testing was performed, how test articles compare to predicate, and issues brought up by the lab that needed to be resolved. If anything was questionable, such a result that technically passed but that the lab notes from experience (in seeing thousands of devices) that it may be indicative of a future issue, then discussion of this—as well as any adverse or unusual findings—should be included.
- If all testing is performed without issues, manufacturers receive a lab's "stamp of approval" and then they may see expedited timelines in approval of their submission.
- Parker said he hopes that the entire industry—manufacturers, tests labs, and the FDA—will gain consistency in how they perform testing and report data through ASCA. Additionally, this represents a new open channel between FDA and test labs to get questions answered and innovate together.

FDA-Recognized Consensus Standard	Test method(s)
ISO 10993-4	Complement Activation using a U.S. marketed ELISA kit
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10	Dermal Irritation, Intracutaneous Reactivity Irritation, and Closed Patch Sensitization
ISO 10993-10 and ASTM F720	Guinea Pig Maximization Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediated Pyrogenicity
ISO 10993-12	Sample preparation for all test types

↑ **A list of all the methods that are currently contained within the program as of press time. A lab may be certified for one, some, or all methods.** *(Credit: Toxikon)*

Reducing Aseptic Risk During Filling

MELISSA GRIFFEN, CONTRIBUTING EDITOR

TOP THREE TAKEAWAYS

1. Novo Nordisk eliminated open aseptic connections during the setup of filling lines.
2. They opted to implement clickable pumps that fit into place easily.
3. Much planning went to the pre-assembly of the system in the wash area.

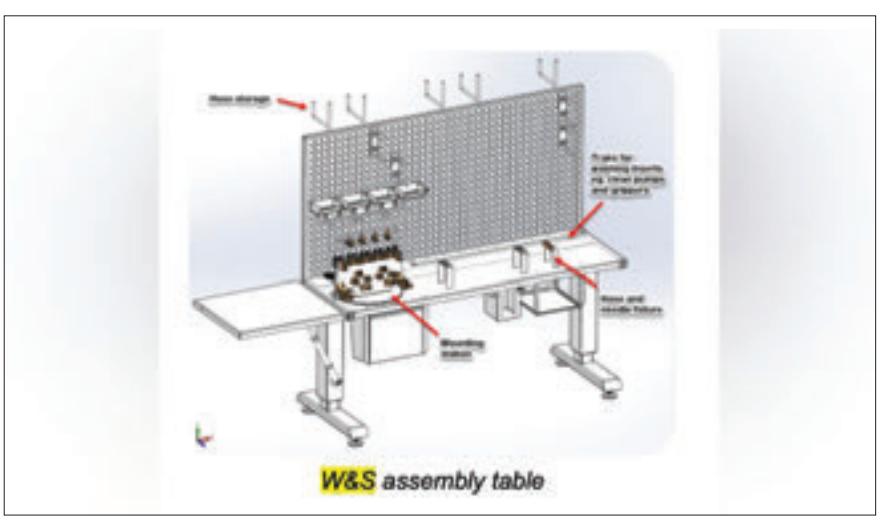
Traditional upgrades to aseptic systems can be difficult to implement in the short term, requiring significant rebuilds and long GMP-regulated manufacturing regulatory approval processes. During the 2021 Parenteral Drug Association (PDA) Annual Meeting, Thomas Busch, Project Director at Novo Nordisk–a pharmaceutical company that discovers, develops, and delivers medicines–spoke on the company's efforts to modernize existing facilities with new technology for the future without shutting down facilities for months or years at a time.

Novo Nordisk places high value on being a technology leader within manufacturing and IT operations. The company aims at continuous, automated, and closed production processes, with products instantly released by real-time quality control and assurance, and digitization of its value chain.

This ambition was showcased in a case study the company presented at the PDA Annual Meeting on aseptic risk reduction during filling. The expectation in the industry is to establish barrier systems on filling lines to reduce the risk of contamination during aseptic filling operations. Novo Nordisk sought to update facilities that still utilized a filling fluid pathway setup by connecting silicone tubing from the manifold to the pump and again from the pump to the filling needle. The company decided to eliminate such open aseptic connections during the setup of filling lines.

Bypassing the traditional approaches–using a different pump principle to close the fluid path, including single use, or by introducing CIP/SIP which would require rebuilds or regulatory approval–Novo Nordisk opted to implement the following:

↑ A prototype based on a single-click pump in collaboration with supplier NeoCeram. (Images Credit: Novo Nordisk)



↑ A special assembly table was developed to facilitate pre-assembly of the pumps.

- Clickable pumps that fit into place easily.
- Pre-assembly of the system—pump, tubing, needle, and manifold—in the wash area.

"To protect this pre-assembly, we needed to put covers on the needles and sterile connectors on the open ends of the manifolds," said Busch, allowing the system to then be autoclaved to ensure complete sterilization before it moves into the fill area to be docked on the filling station.

This cost-effective clickable pump solution reduced batch changeover times by 8% to 18%, while reducing contamination risk and operator risk during setup of filling lines. It also provided a more uniform pump setup, leading to less variation and faster disassembly. Training was key as the critical assembly task was moved from aseptically trained operators to the wash and sterilization (W&S) team. Additionally, a special assembly table was developed by the W&S team to facilitate pre-assembly of the pumps.

Adjustments were made during proof of concept (POC) development, followed by a pilot stage. Busch reports that introduction to the first filling line began 18 or 19 months from overall commencement due to the comprehensive nature of project.

Benefits included minimal regulatory impact and shorter downtime as they eliminated the open aseptic connections they sought to remove from facilities. "We basically had the same pumps, same tubing, and the same filling needles... so the product doesn't see any new surfaces. That was a key design driver—we don't want to change anything that affects product surfaces," Busch explained. Novo Nordisk plans to scale the solution out to 75% of lines at all relevant sites before the end of 2021.

For the latest in life science packaging and processing, make plans to visit Healthcare Packaging EXPO in-person, co-located with PACK EXPO Las Vegas (Sep. 27 to 29, 2021). For safety info and registration, visit **hcpelasvegas.com** or **packexpolasvegas.com**.

1 Lightweight Plastic Tube

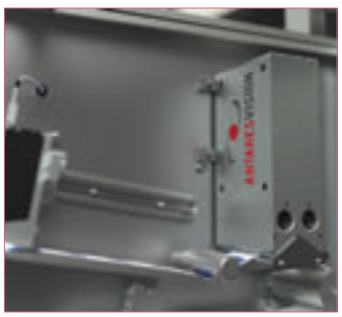
Neopac

+ Lighter plastic tube comprising up to 30% less virgin materials aligns with packaging industry desires to minimize CO2 footprint and material waste
+ The tube—with has reduced wall thickness from 0.5 mm to 0.35 mm without sacrificing exemplary haptics—will eliminate the need for as much as 4.6 tons of HDPE materials per one million tubes produced

2 Ultra-Small Minidose Inlays

Avery Dennison

+ Ultra-small (22x12mm) minidose U8 RAIN RFID inlays for pharma applications are the first products on the market to receive ARC certification (Spec S) from Auburn University's RFID Lab, and to be approved for use by DoseID
+ Performs in the standard UHF RFID frequency band between 860MHz-960MHz; available in dry and wet formats



3 Comprehensive Label & Print Layout Quality Control System

Antares Vision

+ AV Print Inspector offers whole-label inspection at speeds up to 80 m/min
+ Designed to support all major vision system tools for quality control: 1D/2D barcodes; optical character recognition (OCR) and verification (OCV); pattern matching; and color check

4 Recyclable Blister Packaging

Amcor

+ AmSky blister system eliminates PVC from blister packaging–designed to enable healthcare customers to improve the recyclability of packaging
+ The system represents a child-resistant and senior-friendly (CRSF) recyclable package designed to meet the stringent requirements of highly specialized and regulated pharmaceutical packaging

5 Eco-Friendly Line of Cartons

Carton Service

+ Providing an alternative to plastic options, Cartons 4R Earth line offers renewable paper packaging for liquid, semi-solid, or dry products
+ "4R's" represent the mission to help companies incorporate the ideas of "Reducing, Renewing, Recycling, and Refilling" into their consumer packaging

6 Benchtop Syringe Filler for Compounding Pharmacies

TurboFil

+ Offering full control of filling parameters in single or dual operation, TipFil Syringe Filler is designed to provide accurate, consistent fills at a rate of up to 12 pieces/min
+ A piston mechanism draws the needle back via a plunger; fill amount is dictated by the distance the plunger is pulled back

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Dispense Works Inc.	www.dispenseworks.com	5
Greydon	www.Greydon.com	36
Heat and Control, Inc.	www.heatandcontrol.com	35
Lifoam	www.lifoam.com/covid	9
Ossid	www.ossid.com	12
PACKWORLD USA	www.PackworldUSA.com	2
Healthcare Packaging EXPO	www.HCPLasVagas.com	39
Prosys Servo Filling Systems	www.prosysfill.com	25
Stevanato Group	www.stevanatogroup.com	17
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Performance across a wide range of conditions, from room temperature to storage in deep-freeze environments, and all throughout the supply chain is essential. Labels also work with a variety of plastic and glass containers; including tubes and vials, delivering reliable tight mandrel performance.

With demand for these products continuing to grow at a rapid pace during the current COVID-19 pandemic, Weber supports the timely production and shipping of vital labeling solutions.

Our goal is to work together proactively to support you and your business needs during this challenging and rapidly changing time. Weber Sales and Customer Service Teams are available for any questions that you may have for us.

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