Today’s Pharma Cold Chain: Going Cryogenic

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New leadership, continued vision

Welcome to the first issue of Pharmaceutical Commerce under new ownership. As announced, MJH Life Sciences acquired the multimedia platform in July, after 15 years of careful stewardship by founder Nick Basta. In handing over the keys, Nick mentioned in this space the unique educational role Pharmaceutical Commerce has served—bringing to light useful information on business-impacting practices within an industry that has experienced significant change. You’ve heard that latter part a lot in recent years, but certainly, today, with the influences of a global pandemic, along with sweeping social, cultural, and economic change, it’s not hyperbole. And equally so inside the industry when applied to the not-so-easy task of uncovering what’s truly “needle-moving”—the value from the noise—in a business with so many trigger points in the mix these days, from science and technology, to pricing and policy, to just scratch the surface.

That’s why Pharmaceutical Commerce is not a general studies educator. As we take the helm, much like our predecessor, we will seize on opportunities to educate and enlighten in areas such as pharmaceutical distribution and supply chain management, attempting to fill those knowledge gaps in process and strategy that can cloud the complex path from product packaging...to pharmacy/point of care...to patient. Look no further than our special coverage in this month’s issue on the pharma cold chain. While our cover story (page 20) and contributed features are all closely linked around the evolving demands for safe storage and transport of temperature-sensitive vaccines and drugs, they all examine differing aspects of these journeys and potential solutions to address the many related challenges, which are magnified today amid pursuits for a COVID-19 vaccine and the steady emergence of cell and gene therapy.

We hope you find this issue a valuable resource as you tackle these challenges in your daily work, or, like many, watch in anticipation how perhaps healthcare’s most transformative—COVID-19 vaccine and the steady emergence of cell and gene therapy—will play out. As we continue and grow the vision of Pharmaceutical Commerce into the future, feel free to send me tips or ideas on topics worth exploring or ways we can enhance the coverage you’ve come to expect when opening these pages or visiting our website. Consider it an educational investment.

—Mike Christel
Digital pills, aka ‘ingestible sensors’, are at a crossroads
Proteus Digital Health, a pioneer, is sold, while EtectRx appoints a new CEO

EtectRx, one of a handful of companies pursuing what has variously been called “digital medicine,” “digital pills”, and “ingestible sensors”, has appointed Valerie Sullivan as president and CEO, an executive experienced in patient support functions, and is going forward with its ID-Cap System for monitoring patients taking oral drugs.

Meanwhile, over the summer, a dramatic confrontation has played out among investors in Proteus Digital Health, one of the pioneering firms of this technology. Having reached a market capitalization of $1.5 billion at one point (and absorbing some $420 million of investor funds), a bankruptcy judge approved the sale of the company to Otsuka Pharmaceuticals, one of its investors (and customers), for all of $15 million. Other investors, including Novartis, had contended the price was a fire sale and that the company’s 600-some patents were worth considerably more, but the bankruptcy judge disagreed.

EtectRx’s Sullivan says that in contrast to Proteus and other companies in the digital pill arena, her company’s focus is almost exclusively on patient adherence, in both clinical trials and commercial brands. “This pandemic era we’re in has ramped up interest in telehealth generally,” she says. “The remote patient monitoring that ID-Cap System enables can reduce clinical trial costs, eliminate non-adherence among patients, and allow for real-time intervention with them.” Once the EtectRx capsule is swallowed, a signal of that event is received (via a wearable reader that transmits to a smartphone) by a clinician within six minutes.

EtectRx has four NIH-sponsored trials running or about to start up, involving HIV treatment or prevention and a variety of shorter- and longer-term adherence studies. Otsuka’s interest in Proteus has been based on Abilify-Mycite (aripiprazole tablets with sensor), for various mental-health conditions.

AAM has a new CEO, Dan Leonard
Generics trade association is confronting a new, post-pandemic era

Following the shift of Chester “Chip” Davis from the Assn. of Affordable Medicines (AAM) to the leadership of the Healthcare Distribution Alliance earlier this year, AAM has now elected its new president and CEO: Dan Leonard, most recently president and CEO of the National Pharmaceutical Council. He also has prior executive experience at America’s Health Insurance Plans, the trade association for that part of healthcare.

Leonard joins the organization at a crucial time: as a result of the Covid-19 pandemic, shortcomings in the US’ domestic pharmaceutical supply chain have become more visible—specifically, the dependence of the US pharma industry on non-US suppliers, particularly APIs that are often transformed into finished goods here. (Finished goods coming from abroad are also a concern.) AAM issued a “Blueprint for Enhancing the Security of the Pharmaceutical Supply Chain” in April in which, after getting FDA and other agencies to agree on essential medicines, the federal government should provide:

• Long-term and volume guaranteed contracts, including for resupplying the Strategic National Stockpile (SNS) and for Veterans Administration supply agreements.
• Grants to build or renovate facilities, and/or relocating ones from abroad.
• Tax Incentives of 50% offsetting drug-manufacturing costs, and/or “streamlining” regula-

Addressing the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and have adequate redundancy built into the domestic supply chains. However, other than allowing for a somewhat higher price for domestically supplied essential medicines (versus imported ones), it has no recommendations to fund manufacturing expansion. It also invokes the Defense Production Act as a means to obtain essential medicines—but that’s already existing authority.

Where’s the money?
Which is not to say the Trump administration hasn’t ponied up any funds. There was a $534-million grant (expandable to $814 million) to Phlow Corp. in May for generic API production. That originated with HHS’ Biomedical Advanced Research and Development Authority (Barda) and the Defense Dept. On a separate track, under the direction of Trump’s economic adviser Peter Navarro, a $765-million loan agreement with Eastman Kodak was announced in July. The loan would originate under Defense Production Act authority, and be administered by something called the US International Development Finance Corp. (which, according to press reports, has primarily been involved in smaller-scale funding of humanitarian projects abroad). However, wildly gyrating Kodak stock pricing in the aftermath of the announcement has put the project on hold, pending an investigation by the Securities and Exchange Commission.

Left unsaid, mostly, in all this buzz around the domestic generics supply chain is that any federal action would take years to have an effect on US production of generics. The Phlow announcement did include mention of making some APIs immediately available to the SNS, but that appeared to be based on existing supplies; a new manufacturing plant is not to be built. There is a backdrop to all this: for most of the past decade, the US pharma supply chain has suffered drug shortages, mostly of generics and mostly of sterile injectables within that.

Studies have shown that one of the factors leading to these shortages is the cutthroat competition to fulfill the pricing dictates of group purchasing organizations (hospitals’ suppliers), resulting in shuttered domestic production and more imports. It’s a little ironic, too, that allowing for more-generous pricing of generics would be proposed at the very time that the Trump administration is pushing for lower drug prices overall.

AAM’s Leonard is facing a major challenge, but also a major opportunity.
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When prescription drugs need to be stored, shipped and delivered at a certain temperature, the integrity of that drug depends on reliable temperature stability. What’s more with many of these therapies valued at tens of thousands of dollars, the cost of a temperature excursion can create significant financial risk for manufacturers, sites of care and the parties that handle the product in the supply chain. And most importantly, can compromise efficacy and safety for patients.

The best way to mitigate risk is to work with an experienced partner with deep experience in the pharmaceutical supply chain. Qualified partners will be familiar with the regulations, invested in staying current with changes and be able to offer a range of shipping options designed for pharmaceutical products. In addition to minimized losses due to damage or adulteration, companies will gain peace of mind knowing that their product will reach patients on time and intact.

A new prescription for pack-outs
How cold-chain products travel through the supply chain involves many considerations. Shipper packaging is chief among them. The Pharmaceutical Commerce 2020 Biopharma Cold Chain Source Book reports that of the $17.2 billion to be spent this year on cold chain logistics, approximately $5 billion will be invested in packaging. As new cold chain products come to market, custom packaging is typically designed, created, tested and ordered. However, there are weak links in this chain—speed to market and cost. Custom packaging takes time and money to develop. Long wait times to develop the right solution can set a launch back weeks or even months.

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3PL selection as part of the product launch process

BY JESSICA RANDOLPH, TWO LABS

It might seem that in this world of distancing and delays, working with external partners would be one of the most difficult parts of launching a pharmaceutical product. When it comes to third-party logistics providers (3PLs), however, who are one of the first distribution decisions for manufacturers to make, that doesn't seem to be the case.

Since decisions about 3PL partners heavily impact state licensing strategy, it's important that manufacturers move quickly and think ahead on this step. And because this has always been my preferred approach in working through the supply chain process, I've found that 3PL partners can show a significant amount of flexibility in how they approach RFPs, introductory calls, capability presentations, and audits. Today, adding in the need to make all of this remote, 3PLs have continued to remain engaged and responsive as we work to define timelines in this world of uncertainty.

Benefits of 3PLs

Before discussing best practices for selecting and working with a 3PL, it's important to understand the alternative, and then why many virtual manufacturers choose to work with 3PLs. Instead of using a 3PL partner, another option would be to go direct to wholesale from the CMO. For companies who choose this option, I would argue that they aren't seeing the full picture of what a 3PL can do for them. People often think of them as only helping with picking, packing, and shipping, but if you find the right partner, they are so much more than that. Of course, there are variations in needs depending on what distribution channel the product is intended for—widespread generic to retail pharmacies, specialty to clinics or hospitals, direct delivery to patients, etc.—but across the board, some of the benefits of working with a 3PL are that they:

- Reduce the legwork for state licensing by allowing virtual manufacturers to operate under their licenses.
- Provide leverage and convenience for buying power and rates for freight, packing, and shipping supplies by passing their costs to the manufacturer at a nominal markup.
- Provide full order-to-cash functions, managing accounts receivable, data management and reporting, invoicing, chargebacks, returns, etc. This support is valuable for manufacturers who are often working with lean resources and manpower.
- Provide storage for the large product lots they are producing, avoiding the need to lease extra storage space or sell to the rate and show your ability to provide customized solutions. It's not easy to convey passion and commitment virtually, but this can be the biggest differentiator in a competitive market.

In today's increasingly challenging and uncertain product launch landscape, it is critical for 3PLs to maintain flexibility in service support. Many biopharma companies are performing labors of love to keep their products moving toward launch and require a partner to match their dedication. Ask questions, and show your ability to provide customized solutions. It's not easy to convey passion and commitment virtually, but this can be the biggest differentiator in a competitive market.

In many ways, while operating in a virtual world isn't ideal, this is a great time to vet partners on how they work in a crisis. The industry today is seeing, in real-time, which companies are able to rise to the occasion and optimize their processes to be as flexible for a product launch effort as possible. Many have responded to selection times shortened from the traditional four months to two months. They have also allowed clients to respond to selection times shortened from the traditional four months to two months. They have also allowed clients to begin implementation earlier to ease concerns about current uncertainties. My trust in this space has only increased as I've watched organizations change and evolve to serve customers in this unique and difficult time.

ABOUT THE AUTHOR

Jessica Randolph is Senior Account Director for Commercialization at Two Labs.

ATTENTION TO DETAIL

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Our UPS Healthcare cold chain is holistic, end-to-end, with quality systems installed in storage facilities, manufacturing plants, distribution centers, warehouses, and on planes and delivery vehicles. We oversee temperatures, times of storage, handling procedures and every other facet of distribution.

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• Reduces the handling of your temperature-sensitive products, mitigating possible temperature excursions.
• Allows for complete supply chain optimization for both service and cost.

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Here’s why. Today’s global specialty pharma supply chain handles normal day-to-day shipping volumes … plus, seasonally, millions of doses of flu vaccines.

We can see, however, that accelerated research all around the world will likely soon lead to a COVID-19 vaccine. Then what happens? The global healthcare cold chain must quickly scale to support the packaging, transportation, warehousing and distribution of two billion vaccine doses.

Some believe we’ll need 5.5 billion doses to build herd immunity… spiking to 11 billion doses if a vaccine requires two shots. The surge will come … and we hope it’s soon.

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“For more than 20 years, UPS Healthcare has aggressively invested in infrastructure and expertise to create a cold chain logistics network that’s precise, productive, scalable and smart.”
Fresh perspectives on pandemic response
A conversation with Nicolette Louissaint, president of Healthcare Ready

MICHAEL CHRISTEL

While still a “card-carrying pharmacologist” today, Dr. Nicolette Louissaint points out proudly, the trained chemical engineer, with an accomplished academic background in biological and molecular sciences, has always had a superseding draw to biomedical research in the context of finding solutions for broader populations. A drive Louissaint, currently executive director and president of health preparedness and response nonprofit Healthcare Ready, believes made her transition into the world of emergency response a natural one. “It’s understanding the integration of practical challenges that are faced by communities and patients with how best to create a science- and evidence-based-led response to address those challenges,” says Louissaint, whose initial work in this area focused on HIV and ways to ensure drugs for the disease could maintain thermal stability and be safely distributed.

More crises would come calling. During the height of the Ebola epidemic of 2014, Louissant served as the senior advisor to the US State Department’s special coordinator for Ebola. She joined Healthcare Ready a year later and assumed the leadership role in 2017. The organization supports supply chains through collaboration with public health and private sectors. Last year, Louissaint was appointed to serve on FEMA’s National Advisory Council. Also with experience in areas such as health IP trade issues, and technology transfers, she recently earned an MBA from the University of Baltimore.

Pharmaceutical Commerce caught up with Louissaint to discuss the response to the COVID-19 outbreak.

1. Healthcare Ready has a history of responding to disasters like Hurricane Katrina; how has the COVID-19 pandemic played out differently?

One of the challenges that’s a bit distinct in a pandemic is that while the recovery phase for a catastrophic hurricane like a Katrina or even a Harvey, Irma, or Maria, that tail for recovery is quite long. However, when you’re thinking about a pandemic, the response window, the amount of time when you’re in active response, is extremely long. It’s a very intensive effort that involves a lot of coordination, a lot of deep focus and information sharing. And to sustain that level of engagement in response for months on end is exhausting. It strains partnerships, it strains capacities, but it also strains resources. It’s going to pull from the resources that we would normally use toward hurricane season or wildfire season.

Being able to shift resources from one region that may not have a pressing need to a region that has a greater need is a standard part of many of the emergency response plans that are in place. The complexity, however, is when you’re thinking about a pandemic where the need is global. It’s not quite as straightforward. Especially a few months ago, there were many parts of the world that were dealing with extreme strain at the same time.

2. How involved is Healthcare Ready during events like these in making sure pharmaceuticals and medical supplies get to where they’re supposed to go?

That’s a big part of what we support—the coordination across the entire supply chain. As it relates to patients, first and foremost you’re thinking about who has been impacted by the virus itself, and the medicines that are going to be needed to treat those patients. In the case of COVID-19 infected patients, you’re not dealing with a therapy or a cure, but you are dealing with treatments that may be needed to help them recover.

One very clear example is ventilator usage. Those are painful devices, and when an individual is being ventilated, there are medicines that are typically administered to deal with the pain and with sedation and things of that nature. So you really can’t just have ventilators without having ventilator-associated medicines. Those are the types of things that you think about for those individuals who are actually fighting the disease itself.

3. How frustrating was it, particularly at the height of outbreak, dealing with the reported shortage of pain drugs for these patients?

There were some spots shortages and some challenges, but there were also a number of substitutions and products that were ramped up in production or that were procured from generic partners, including international manufacturers, to be able to assist. What happens in a scenario like that is, while there are an abundance of ventilator medicines for a normal time, it’s difficult to predict that you would need ventilator-assisted medicines prior to the pandemic. It’s not a countermeasure, it’s an assisted therapy.

But then there was also focused effort on making sure both the primary and the secondary preferred medicines that were able to safely ventilate patients were being made available, and that there was continuity in the coordination and information sharing with federal government partners as well as with the manufacturers, the distributors, the GPOs, and the hospitals—so that there was visibility in what hospitals needed and what they were ordering. And, in addition, there was guidance and discussions with the federal partners as it related to being able to allocate and distribute the product that was available based on the number of COVID-infected patients and the actual immediate need. Also important was the coordination with manufacturers to make sure that production was being ramped up and that there was some sense of what would be needed to be able to overcome those shortages.

I don’t know that I would say one [calamity] is necessarily worse than the other. The acute needs that result are acute needs and if you are a patient or a member of a community and you have been severely impacted, it doesn’t matter.
Other key roles for the pharmaceutical supply chain, especially, involve developing medical countermeasures and the process of developing potential vaccines and therapies, and making sure that the manufacturing plans will be able to develop those vaccines and therapies in a way that allows for the necessary surge, but also doesn’t hinder capacity to continue production of products that are needed right now.

In the midst of thinking about individuals who may be infected with COVID or might be infected in the future, we’ve also got to remember that there are a number of chronic care patients that have needs for medicines every day. One of the most important components of what the pharmaceutical supply chain has had to continue to do is ensure that the medicines that these patients need to remain healthy and manage their chronic illness are available to them. That is a major priority — making sure that we’re not so focused on just surging up production of therapies or vaccines related to COVID.

4. Do you think the industry/healthcare systems have done a good job in addressing those patient needs?

I’ve been really proud to see the way in which our partners, both public and private, have come together to do everything, from the messaging, in a manner that allows for the type of information sharing, the type of access to advocates and partners and community organizations that can help ease the navigation for patients. Helping them understand what to do if you’ve lost insurance, for example. Thinking about things like emergency refills and even explaining the difference between [distributors] go into the state or if they cross state lines or with geographical restrictions, requiring, basically, that if [distributors] go into the state or if they cross state lines or are near a hospital, they are required to then self-isolate or quarantine for 14 days. With that, you’re thinking about the challenges for distributors, especially not having enough drivers, they can’t afford for every driver to have to self-isolate after a single delivery or a day of deliveries.

So we had to work on everything from clarifying that type of a mandate or request in order to make sure that either there were exemptions that were in place for drivers or that it was clear how they were going to be able to monitor symptoms or what was truly being expected of them. There were a lot of discussions regarding [personal protective equipment] utilization based on the science of understanding what the appropriate level of PPE would be for a delivery driver if they are making contact with the hospital, if they’re delivering to a secondary site. Also what the appropriate disinfection and sanitation practices would be for a DC or warehouse. We did a lot of work making sure that we were sharing the information that became available from the CDC, but also that our distributor partners had an opportunity to review and ask very specific questions that would have been unique to distribution.

We wanted to make sure that as the response surged, that it was as easy as possible for them to know what was needed. We required to also, from our vantage point, make sure that we were educating our government partners to understand that we need federal, state, and local coordination on these issues related to DCs, specifically distribution, because there are many times where products will be moving across multiple states. One thing that I saw all of our distributor partners do, which was commendable, was working with their customers to make sure that they had ironed out processes for what deliveries would look like, what the cadence of those deliveries would be, where the drivers were approved to make deliveries, etc. The goal was to make sure that they were protecting their drivers but also protecting their customers. By having better control over that handoff and that actual worker protection, they were able to protect their workers and drivers in a way that I think made it much easier for us to sustain ongoing deliveries and distribution throughout the entire response.

6. As discussed, there was an initial reaction to the pandemic of higher demand for pharmaceutical products. How did distributors balance that need with making sure they were protecting their own workers and drivers?

One of the most important things that we’ve all had to remember is how much the situation has evolved. At the beginning of the pandemic, when we were thinking about stay-at-home orders and there were also some states that had geographical restrictions, requiring, basically, that if [distributors] go into the state or if they cross state lines or are near a hospital, they are required to then self-isolate or quarantine for 14 days. With that, you’re thinking about the challenges for distributors, especially not having enough drivers, they can’t afford for every driver to have to self-isolate after a single delivery or a day of deliveries.

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7. Might these experiences and practice adjustments lead to a new business model in pharma distribution?

I don’t know what the future holds. There’s so much uncertainty right now. But I think what has been made clear is the capacity that the entire supply chain has, and the vastness of their resilience plans and the need to be able to have recovery and resilience plans that coordinate across the sectors.

Everything from the way in which AmerisourceBergen worked with the federal government to help move [emergency-use drug] remdesivir at their direction, to the way in which GPOs like Premier were able to make sure they were coordinating and sharing insights they were getting at the hospital level with the federal government. It’s taking that insider capacity from the healthcare side, and using it to improve the way in which we’re taking care of communities and patients in response.

It’s important to remember we saw uprisings and civil unrest across the country in response to the killings of Breonna Taylor, George Floyd, and Ahmaud Arbery. We saw the need to maintain logistics in cities that may not have had an access and reentry point for COVID, but did have a blockade up because of unrest and protests. Things are happening at the same time, and it’s a reminder that you don’t have a plan or create a capability for just one type of hazard. What you do is make sure that that capacity can actually work across multiple hazards.

8. As preparation for the distribution of vaccines and/or therapies for COVID-19 ramps up, is there a preferred approach that Healthcare Ready supports?

What we support are around principles rather than a specific plan. We support making sure that science is guiding the distribution plan and that we are leveraging existing capacities to be able to move the product. We’re also supportive of the work that the National Academies is doing on behalf of the CDC to be able to determine equitable allocation and distribution of vaccines. That is a very complicated set of issues related to coordinating just how you determine across a range of ethical- and equity-based issues, how to allocate a vaccine once it becomes available and what principles should you use as a guide. We’re very supportive of the National Academies as they’re looking to help create some guiding principles and a framework for that.

Science will be the guide. As we learn more about the potential vaccines and we understand which are likely to be approved and then are ultimately approved, there will be a distribution plan that accompanies that. There are a number of partnerships that have been forged, even in assistance ramping up for production, which will certainly change the speed at which product becomes available and needs to be pushed out. We’re watching that all very closely.
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Today’s pharma cold chain is going cryogenic
Both COVID-19 vaccine delivery and the growth of cellular/genetic therapies call for lower storage and shipping temperatures

Suzanne Shelley, Contributing Editor

Providers of temperature-controlled packaging, storage, and shipping capabilities for the biopharmaceutical industry are about to face their potentially finest moment. Though they are used to navigating a uniquely complex supply chain, today’s demands—framed by a worldwide pandemic—are unprecedented, and will require next-level support across critical functions such as logistics planning and data monitoring, analysis, and communications.

"Between the pressure to develop and commercialize a COVID-19 vaccine, the continued global demand for seasonal flu vaccines, and efforts to advance many promising cell and gene therapies (CGTs), it’s clear that companies throughout the pharmaceutical cold chain infrastructure are juggling multiple priorities—all of them critical to lifesaving efforts," says Vivian Berni, director of product management for Sonoco ThermoSafe, also noting existing responsibilities in managing the usual volume of temperature-sensitive therapies and vaccines already on the market.

Rather than relying solely on express deliveries made directly from the manufacturer to the point of care, the pharmaceutical cold chain typically involves multiple players, working in close coordination, to execute a number of handoffs. Pharmaceutical shipments are moved from the manufacturing site, through storage depots, trucks, planes, and ships, to reach the ultimate destination, usually a hospital, clinic, or pharmacy. As pharma companies entrust their cargo to others, there is very little room for error in each of these segmented journeys.

"The COVID-19 pandemic has created new logistical challenges and new country-specific regulations," says Nick Porter, senior vice president of global commercial at World Courier, a part of AmerisourceBergen. "This has reinforced the importance of partnering with a specialty logistics provider that has a global network and a team that can mobilize contingency plans quickly, if needed, to identify an alternative route or to communicate with local officials."

With multiple stakeholders involved in cold-chain shipments—and numerous touch points along the way—no single party has ultimate control over the integrity of the shipment, notes Dharmesh Chauhan, sales director at Softbox, a provider of temperature-control packaging systems and thermal covers for the life sciences industry.

"This raises the stakes for all companies involved," he says. AmerisourceBergen, to better support customers, recently integrated World Courier, a global logistics provider, and Integrated Commercialization Solutions (ICS), a third-party logistics (3PL) company—creating a single specialty logistics partner. According to executives, its cryogenic supply chain includes vapor-charged cryogenic storage systems and temperature-controlled packaging solutions that enable product transport from manufacturer location to its 3PL storage facility and then to each point of care.

Reducing the number of handoffs can help eliminate potential weak points in the cold chain, says Wes Wheeler, president of UPS Healthcare. To that end, he expects to see more stringent standards and regulations—and increasingly optimized supply chain practices—installed to ensure quality management systems are standardized for high-value biopharma products such as CGTs and immunotherapies.

Rising to the challenge
Today, the stakes are higher than ever in the pharma cold chain—at all ends of the spectrum. Large-scale-wise, the cold chain industry is bracing for the arrival of the first of several COVID-19 vaccines resulting from the US’s Operation Warp Speed initiative and parallel efforts elsewhere in the world. Once approved, billions of doses of a new COVID-19 vaccine will need to be delivered to patients across the globe—quite literally on a moment’s notice.

Meanwhile, smaller in scope, the complex cold-chain requirements associated with managing shipments of ultrasmall volumes of temperature-sensitive CGTs are creating new demands, as the pipeline for these advanced therapies continues to grow. Under a typical CGT scenario, a single vial of biological materials (blood or tissue) must be extracted from the patient, and then safeguarded through its journey. That involves transfer from the clinical setting to a...
laboratory, where the sample is manipulated biochemically or genetically, and then sent back to the clinic for infusion. While losses associated with temperature excursions during cold-chain storage and transportation efforts remain a hidden cost of doing business—in terms of spoiled product, excess inventory, and delayed deliveries—today’s cold-chain suppliers are also expanding their arsenal of data-collection tools, and leaning more heavily on the use of telemetry, advanced monitoring systems, and sophisticated data-driven modeling tools, to reduce the frequency and likelihood of preventable delays and temperature excursions.

“There is continued focus on controlling the total cost of cold-chain supply logistics, which, as a rule of thumb, account for roughly 5–10% of the total cost of biologic therapies and vaccines,” says Richard Ettl, CEO of SkyCell AG, noting that if there is a temperature excursion, the product cannot be released to patients—instead, a replacement pallet must be shipped immediately. “This makes a real difference when we’re talking about pallets of vaccines that may be valued at $500,000 each,” he adds.

While today’s new shipping and data-management devices are providing real-time visibility into the status and condition of a shipment, it is critical that these tools are able to be reprogrammed on the fly to better ward off potential obstacles, contends Mark Sawicki, PhD, chief commercial officer, Cryoprot. He says such capabilities are in the process of being established through augmented GPS using Bluetooth, WiFi, Internet of things (IoT) technology, next-generations data loggers, enhanced software management services, geoencoding capabilities, and expanded use of radio-frequency identification. Sawicki adds that the eventual rollout of 5G-enabled sensors should help to open up access to larger amounts of location and temperature data.

David Goldberg, CEO of DHL Global Forwarding in the US, believes industry investment in rapid digitization of supply-chain data analytics has been solid, and sees a concerted effort among shippers to use passive cold-chain packaging to augment active packaging options. “Improved data analytics allow for near-real-time mode optimization, and more effective use of ocean versus air freight,” he says.

Market dynamics

Under the cold-chain umbrella, the “refrigerated” category (2 to 8°C) is by far the largest category by value. However, among today’s newer CGT offerings, other novel biologic therapies, and several of the COVID-19 vaccine candidates currently in clinical trials, there is increasing demand for maintaining product at “deep frozen” temperatures (on the order of -40 to -80°C), and “cryogenic” (requiring liquid nitrogen: -160 to -180°C).

As of early 2020, annual global sales of biologics and vaccines—which require strict temperature control—exceeded $340 billion. Amid the continued growth of these markets, cold-chain logistics account for nearly 18% of all biopharma logistics spending, according to the 2020 Biopharma Cold Chain Sourcebook published by Pharmaceutical Commerce.

On the R&D side, cold-chain providers routinely support thousands of clinical trials, delivering temperature-sensitive drugs to study sites and laboratories around the globe. The 2020 market size for this sector is valued at about $3.8 billion, according to the Sourcebook, and the continued expansion of clinical trials logistics is projected to grow at a rate of about 3% per year, to about $4.2 billion by 2024.

Overall, global pharmaceutical sales are expected reach $1.58 trillion by 2024, according to IQVIA Institute projections released in March. By 2024, experts predict five of the top 10 best-sellers will be drugs requiring 2–8°C cold-chain storage and handling.

In 2019, FDA’s Center for Biologic Evaluation and Research (CBER), which handles the review of vaccines and blood products, approved 12 licenses for new biologic products, 21 of which require cold-chain handling, the Sourcebook reports. (In 2018, 20 such products were approved, 16 requiring cold-chain handling.

“Cost-reduction efforts go beyond just the cost of the packaging and freight but require an assessment of the costs of inventory and labor to complete the pack-out of temperature-controlled products as well,” says Ron Haub, segment director/general manager, Sonoco ThermoSafe. “Working closely with our clients, we try to identify ways to help them open up warehouse space, by holding temperature-controlled inventory and providing it on a just-in-time basis.”

Haub notes that the expanded use of preconditioned shippers can also help to reduce the amount of refrigerator/freezer space required, and that preconditioned shippers are more simple to pack, reducing what he says is usually a 10-plus-step process to just two or three steps, saving time and labor. Tighter process integration can also yield benefits. For example, SkyCell says it was able to create a direct savings of $120 million for one of the world’s top vaccine producers. “Before, the client had almost 30 different solutions in operation to handle its cold-chain distribution and management operations,” says Ettl. “We standardized and streamlined the overall approach to provide near real-time IoT insights that let us pivot to redirect shipments more quickly.”

The elephant in the room

As the world awakes anxiously for the first approved COVID-19 vaccine(s), one perhaps underappreciated element of the overall challenge is whether the existing cold-chain infrastructure will be able to manage the distribution of unprecedented volumes of the vaccine, to every corner of the globe, nearly concurrently.

While specific details related to temperature, shipping, and dosing requirements for those vaccines that will end up in mass distribution are not yet known, billions of the first-approved vaccines will be quickly thrust into the supply chain to meet enormous, pent-up global demand. Stakeholders interviewed for this article described this looming challenge as “historic in scope…utterly unprecedented…a mammoth challenge…truly awe-inspiring…by far, one of the largest challenges we have faced in our lifetime.”

“Many of these investigational COVID-19 vaccines are expected to be in a frozen format, but this is not typical for many of the biologic drug products in the supply chain today (which require refrigerated but not cryogenic temperatures),” says Adam Tetz, director of worldwide marketing for Pelican BioThermal. “Once approved, the new COVID-19 vaccines will be manufactured at a rate of millions of doses per week and will need immediate worldwide distribution, so we are going to see a critical crunch, in terms of the existing cold-chain capacity worldwide.”

Patrick Schafer, CEO of CSafe Global, a provider of cold-chain shipping solutions, notes that COVID is the first pandemic the modern cold chain has had to manage. While global demand will be significant, ongoing demand for other pharmaceuticals will not wane simply because a COVID-19 vaccine is ready to ship, he stresses. “This effort will require coordination on a scale we’ve never seen,” says Schafer. “The market is not currently prepared to handle the way the expected COVID-19 vaccine will need to be distributed, so there is a lot of concurrent activity around building up the basic systems and adding capacity to the system,” adds Sawicki. “One silver lining, though, is that this is also creating a lot of business opportunity for many companies in this space.”

To get a sense of the scale and the capacity gap the industry is facing, consider, in 2020, an estimated 194 million to 198 million doses of the seasonal flu vaccine will be transported (up from 175 million doses in 2019), according to the CDC, notes Angela Kerr, VP of product and program management at SpotSee.

According to Ettl, the industry moves about one million pallets of cold-chain pharmaceutical and life sciences products by air every year. He says if a single-dose COVID-19 vaccine is approved, there could be an additional 160,000
for eight COVID-19 vaccines and/or therapies currently in development for Cryoport, which is supporting logistics of COVID-19 vaccine is creating a very fluid and dynamic situation. Locations far from a major port city.

To prepare for the significant capacity surge, several companies are in the process of building giant freezer farms. For example, UPS Healthcare is currently installing two such units in Louisville, Kentucky and the Netherlands (both near global UPS air hubs) comprised of hundreds of -80°C freezers. “Each of these will be capable of scaling up to 300 freezers and each freezer will be capable of storing 40,000 to 50,000 individual vials of vaccine,” says Wheeler. “We are also moving the same freezers in key clinical trial locations in South America, Germany, and the UK, and we are discussing humanitarian efforts as well.” UPS Healthcare’s clinical subsidiary Marken is working with several biopharma companies and their partners on COVID-19 vaccine and treatment development efforts.

Similarly, in July, DHL opened a $1.6-million, 20,000 square-foot cold-storage facility in Indianapolis, which houses three temperature-controlled chambers with variable temperature options, and FedEx revealed this summer that it would be adding 10 freezer facilities, with more expected to follow, to meet the coming demand.

Last month, the US Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed, tapped McKesson Corporation to manufacture product quickly to meet anticipated demand. Meanwhile, producers of specialized cold-chain packaging are also ramping up production. For example, Tetz says Pelican BioThermal is “pre-buying” supplies and components and has three global manufacturing centers it can use to manufacture product quickly to meet anticipated demand. “We are also actively converting our main products to provide a dry ice capacity and looking at adapting our dry ice parcel shippers, expanding the range of sizes to handle a wide array of payload volumes,” he adds.

Vaccines in development based on mRNA (using RNA-containing vectors) are particularly promising, but pose considerable cold-chain challenges. Chauhan notes that while these vaccines enable rapid development, low-cost manufacturing, and large-scale production, they may require ultra-low-temperature distribution levels (around -80°C) to keep the mRNA proteins viable prior to administration. “The current global supply chain is not fully geared up to handle this,” he says.

Adding to the challenge, Kerr points out, will be the need for any type of vaccine approved for the novel coronavirus to reach many developing nations concurrently, where gaps in existing infrastructures will create additional “last-mile” obstacles. On top of that, Sawicki notes that particularly in remote regions and developing nations, there may not be freezers to maintain adequate storage temperatures at the point of care.

Sonoco ThermoSafe, Haub says, is in the process of examining how its 30-plus manufacturing locations can be optimized, and are adding tooling and potential machine capacity as needed. The company hopes to secure offsite storage locations to build inventories of shippers and refrigerants.

CGT: Small parcels, little risk tolerance

COVID-19 may be grabbing the headlines, but cold-chain and logistics challenges associated with safeguarding CGTs and tissue-engineered products are testing the industry’s capabilities as well. Emerging in recent years, CGTs, also called “cell-to-vein” therapies, are durable, curative-type treatments often targeting life-threatening and debilitating genetic disorders and rare diseases. Typically involving the production of a customized treatment for each patient, the specialized, closed-loop supply chain requirements associated with a CGT create unique challenges. Opportunities for delivery delays and temperature excursions along all the steps in the segmented journey can create potentially damaging financial and clinical risk.

Heinzen, who notes that his company (Cryoport) has supported four marketed CGTs and six more expected to file for regulatory approval by the end of the year, says cold-chain issues are particularly challenging for allogeneic CGT products, as they must be transported to multiple locations, and warehoused or stored until they are infused into one or more patients. On the plus side, according to Schafer, studies have indicated that a single donor set could be used to create therapeutic doses for more than 200 patients. This means multiple doses

as a central distributor for future COVID-19 vaccines and related supplies.

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 Amid the CGT explosion, Srivastava points to the need for logistics providers to run a just-in-time supply chain to facilitate cell transfer operations and deliver raw materials to manufacturers and final product to hospitals. Accenture advocates using the supply chain control tower approach, which can provide greater visibility by generating alerts about expected shortages and/or delays in production at suppliers and contract manufacturers and then sequence the impact these events will have. “The goal is to help logistics providers move from just providing reactive fixes to creating synchronized, event-driven value networks,” says Srivastava.

As the number of CGTs (and their volume in the supply chain) continues to grow, Albert Cooksey, senior vice president, client relations, at ICS, says the company is anticipating heightened demand for cryogenic storage systems, as well as dry shippers that can maintain internal temperatures between -150°C and -180°C for an extended period of time. To grow its cryogenic storage infrastructure and enable clients to scale their specialty products “from many to millions,” Cooksey says ICS has recently “more than doubled its refrigeration storage (2 to 8°C) and added liquid nitrogen cryogenic storage capacity (to enable -180°C).”

Dave Murphy, executive vice president, Quick Specialized Healthcare Logistics, a unit of Kuehne+Nagel and provider of transportation and logistics solutions related to the transport of live cells, says “as more CGTs are approved, their chain-of-custody requirements and volume demands increase substantially, so scalability is key—whether managing deliveries across a country or around the world.”

To that end, Berni believes service providers in the cold-chain space should reassess and redesign their IT infrastructures to “break free from silos and build bridges” in connecting data across logistics and packaging systems to enable synchronized operations.

To support ongoing capacity expansion in the CGT space, six branches of Marken have recently become Cell and Gene Therapy Centers of Excellence, and a central, dedicated CGT control center has been established at Marken headquarters in North Carolina. “These branches are supported by the industry’s largest network of liquid nitrogen (LN2) filling stations, allowing the company to maintain cryogenic supply chains that operate around the world,” says Wheeler. “We are able to support the cryogenic transportation (at -150°C) of CGT products using Marken’s LN2 shipping fleet, which is serviced at 14 geographically distributed locations.”

In August, Cryoport made two strategic acquisitions to expand its footprint in the CGT market—acquiring CypreSFD, a Paris-based provider of containers, packaging, logistics, courier services, and clinical trials support, which operates 22 facilities in 12 countries; and MVE Biological Solutions, the life sciences business of Chart Industries. MVE makes vacuum insulated products and cryogenic freezer systems. It has three manufacturing facilities—two in the US and one in China.

**Data is king**

Perhaps nowhere in the pharma supply chain is real-time data more important than in the realm of cold-chain packaging, transportation, storage, and logistics. The goal is to allow all stakeholders to react quickly, before things go wrong, and enable a data-driven forensic review of events after the fact.

“Smart monitoring” solutions that can track internal temperature, light, pressure, humidity, and tilt—providing real-time visibility and proof of shipment stability—allow teams to mobilize quickly, according to Porter.

For example, a recent shipment using World Courier and ICS’s Cocon packaging tool was able to maintain its internal temperature throughout a two-week delivery from Austria to Iraq, he says, which included 10 days of storage in uncontrolled warehouse temperatures.

Since 2013, SkyCell has amassed more than two billion data points about cold-chain pharma activities, says Ettl, which enables the company to identify specific risks, make the most appropriate adjustments, and improve outcomes. “This allows us to go from ‘just a gut feeling’ to data-driven efforts to optimize the supply chain in a more agile and effective way,” explains Ettl. “It’s not enough to know after the fact that something did not work. It’s far more important to use advanced IoT capabilities to not only react to losses from temperature excursions, but to create opportunities to prevent them from occurring in the first place.”

Experts believe advanced machine learning-based algorithms are already showing great promise, “with the most significant gains being made to inform advanced scheduling systems by finding patterns in track-and-trace data captured using IoT-enabled sensors and using the derived insights to quickly detect patterns and problems,” says Savicki.

“With these capabilities, you can use past performance and variables to continually suggest more efficient routes,” adds Berni.

Richard Wood, technical director at Softbox, says the industry is experiencing a strong shift toward the use of real-time monitoring in combination with new methods for big-data analytics and predicitve simulation software to mitigate risk. “We have seen examples where enhanced visibility has saved millions of pounds of pharmaceutical products from potentially damaging temperature excursions,” he says.

Later this year, according to Schaffer, CSafe Global will be launching a new technology to expand its monitoring and reporting capabilities.

“When you collect the appropriate data and exploit it, you can use the data-driven insights to select the optimum routings, carriers, and packaging solutions to meet the customers’ quality, service, and cost expectations and drive continuous service improvement,” adds Jon Chapman, vice president, pharma healthcare, at Kuehne + Nagel.

COVID-19-sparked challenges present an opportunity for the integration of blockchain technology for temperature monitoring. “Blockchain is expected to fundamentally alter the future of cold supply chain, as that would enable end-to-end traceability of temperature-controlled therapies and vaccines, and the ability to provide an audit trail of environmental condition monitoring,” says Berni. “Importantly, blockchain can help to identify which segments of the journey were in control of the shipment when any temperature excursion or damage occurred.”

In July, SonocoThermoSafe joined forces with IBM to create PharmaPortal, a vendor-neutral blockchain platform for use by pharmaceutical manufacturers and carriers. The tool “intends to record a single version of the truth on all events generated on a package’s journey,” adds Berni.
Like many industries, the life sciences sector is working to reduce its environmental impact by eliminating the use of plastics, reducing waste and shrinking their carbon footprint. In support of these objectives, leading suppliers of temperature-controlled shipping solutions are engineering sustainable packaging that protects temperature sensitive products while simultaneously protecting the planet.

For more than 25 years, Softbox Systems has been helping biotech, clinical research, pharmaceutical, diagnostics, and logistics customers worldwide overcome significant shipping challenges—from variations in temperature to speed in development and delivery. With the introduction of the plastic-free, 100% curbside recyclable Tempcell™ ECO shippers, Softbox Systems is tackling the global issue of plastics challenge head-on.

While plastic-based products have long been the standard for temperature-controlled shipping, and they are technically recyclable, most end up in landfills or waterways. Amidst a global sustainability movement to reduce waste, reuse, recycle and recover, there is growing demand for packaging solutions that are efficient, effective and eco-friendly.

It was precisely this challenge that fueled the creation of Tempcell™ ECO. Using innovative corrugated cardboard insulating technology, Softbox Systems developed Thermaflute®, a “pure paper,” plastic-free corrugate with similar efficiencies to those of traditional expanded polystyrene shippers, while being easily and globally recyclable. Tempcell ECO is designed to prevent temperature excursion when shipping wide-stability temperature-sensitive products and has been qualified for 72 hours of thermal protection. Routinely dispensed prescription products, over the counter medicines and animal health products can now be shipped with complete reliability.

Tempcell ECO’s fit-for-purpose design is light, strong and versatile; an ideal solution for all parcel delivery networks. Available in four off-the-shelf sizes with custom sizes available on request, interiors offer a variable payload space and flexible configurations to keep temperatures constant and payloads secure. And perhaps best of all, the end-user can simply drop it into a recycling bin where the material can be repurposed seven times over into other eco-friendly products.

Additionally, through its partnership with American Forests, Softbox Systems will plant three trees for each one used in production. Through the first half of 2020, Softbox Systems has planted more than 25,000 trees in reforestation projects stretching from Minnesota to Oregon. The company has also earned a Silver Sustainability Rating from EcoVadis, the world’s most trusted business sustainability rating service. And recently, Tempcell ECO was recognized by Fast Company’s 2020 World Changing Ideas Awards honoring companies, products and ideas that are making the world a better place. To learn more about Softbox Systems and its newest eco-friendly solution, Tempcell ECO, visit TempcellEco.com/pc.

Just what the doctor ordered
Innovative packaging systems help pharma address sustainability goals

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Introducing Tempcell™ ECO – 100% recyclable, 100% reliable.

Utilizing Softbox System’s patent-pending Thermaflute® technology, Tempcell™ ECO is qualified against ISTA 7D Summer and Winter profiles. Its innovative “pure paper” design is 100% curbside recyclable while providing excellent thermal and structural protection from pack to unpack. Available in four sizes with flexible interior configurations to meet your specific needs. Tempcell ECO is the product-friendly, planet-friendly solution you’ve been waiting for.
Securing disrupted cold chains with

The role of these tools amid evolving regulatory, geography, and accessibility considerations

BY ANGELA KERR, SPOTSEE

When it comes to the operation and optimization of supply chains, cold chain products have proven to be a temperamental obstacle. Medical and pharmaceutical companies have relied on temperature-controlled supply chains for several decades to preserve and maintain the usability of their temperature-sensitive products. Without total transparency or the ability to monitor temperature at every link in the chain between production and consumption, these complex cold chains are subject to detrimental disruption and irreversible product damage.

While the need for a reliable cold chain is far from new, this demanding logistic segment must now grapple with additional challenges brought about by the global pandemic. Increasing demand at reduced capacity is amplifying the potential for disruption along the chain, while new products and regulations relating to COVID-19 are introducing unprecedented obstacles. Despite these issues, the fight to defeat COVID-19 has made secure transportation of temperature-sensitive pharmaceuticals, test kits, and related medical supplies more critical than ever before. Fortunately, temperature-monitoring devices offer an integral solution for current challenges in securing pharmaceutical cold chains.

Cold chain products

Temperature control is a top issue in cold chain logistics because even the slightest variations can significantly affect the quality and safety of products. Medical supplies, pharmaceutical products, and vaccines need cold temperatures for storage throughout their lifecycle. Blood, transplant organs, medications, tissue samples, and several other medical products have extremely strict temperature control regulations that must be prioritized to ensure their usability. Because the chemical makeup of different pharmaceutical products varies significantly, so do their relative storage requirements. When a medication is exposed to climates outside a specific temperature range, whether it be too high or too low, its chemical stability will likely be impacted. These drugs will degrade and form impurities that could pose potential health threats if administered to patients.

Changes to a drug's physical properties such as variations in color or texture and presence of strong odor are obvious indicators of improper storage. In some cases, however, impurities are not visible to the human eye. If consumed or used, these products could range from being simply ineffective to incredibly dangerous to the consumer's health. In addition to the physical harm it can cause patients, a breach in the cold chain can also cause economic harm to suppliers. The cost of disposing and replacing these pharmaceuticals can amount to tens of billions of dollars annually.

All these issues remain growing threats to cold chain logistics, as the number of cold chain products continues to grow exponentially, and the industry increasingly focuses on product quality and sensitivity. Now that we are in the middle of a pandemic, the dangers of temperature deviations for pharmaceutical products also apply to COVID-19 test kits, related medical supplies, and vaccines. A COVID-19 test involves swabbing a patient’s nose and mouth, and transporting the swab in a kit to a predetermined testing lab. According to the Centers for Disease Control and Prevention’s (CDC) guidelines, these specimens must be refrigerated within a temperature range of 2–8 °C, then processed within 72 hours after collection. Some major commercial labs prefer specimens to be frozen at -20 °C during transportation. Refrigerated samples older than 72 hours and samples exposed to temperatures outside the required range may lead to faulty results and rejections.

Temperature deviations can cause the virus to die in transit, potentially leading to false negative results if not detected and rejected. Patients may then unknowingly continue to spread the virus. Rejected samples require re-tests that take valuable time and may lead to the need for additional testing as a patient with false results infects more people, using valuable lab capacity and costing more money.

Vaccines are one of the most common cold chain products in the medical field. A vaccine’s potency is reduced every time it is exposed to an improper condition, including overexposure to heat, cold, or light at any point between manufacturing and administration. Once lost, potency cannot be restored. Regulations for different vaccines vary in much the same way as medications, but every vaccine is considered a cold chain product. In a world eclipsed by COVID-19, several biopharmaceutical companies across the globe are working tirelessly to pursue a vaccine to stop its spread, each of which are using different methods and technologies for a unique product. As such, there is no current universal temperature requirement for maintaining the vaccines’ stability.

Technology and transport

An unbroken and properly functioning cold chain delivery system keeps temperature-sensitive pharmaceutical and medical products within the required ranges from their manufacturing stage to their point of use.

Medicines, vaccines, test kits, and other pharmaceutical products are made and packaged by the manufacturer before being transported in refrigerated vehicles or insulated containers to their destination, where they are then sold or administered. Depending on demand, capacity, and location, products may also be stored in refrigerated warehouses before or between shipments.

With numerous touchpoints and transportation methods to consider for each medicine, the stakes remain high for...
logistics providers tasked with safely transporting these products across the world.

The COVID-19 pandemic has disrupted the cold chain process for pharmaceuticals and medical products as related shutdowns have limited cold chain capacity while the demand for product delivery only continues to soar.

Additional pressure has been placed on carriers to meet delivery demands of COVID-19 test kits, vaccine trials, protective medical equipment, and prescriptions for at-risk individuals sheltering at home. Prioritizing these products means that other temperature-sensitive medications are subject to unexpected delays and subsequent temperature deviations. New laws and regulations from US and foreign jurisdictions have also impacted the development and transportation of COVID-19-related products.

Test kits and vaccine trials have their own unique set of standards regarding temperature during transportation, and many organizations that rely on these cold chains must now consider foreign regulations, geography, and accessibility in their effort to maintain control over the climate their products experience.

Despite all the complexities, cold chains demand integrity and accountability. Digital technologies like temperature loggers can play a major role in ensuring these demands and securing cold chains in the age of COVID-19 and beyond.

Temperature loggers are available in several different models to address the various needs of users. For most in-transit purposes, temperature recorders have both a sensor and data recorder integrated into a compact and lightweight device. At the end of its journey, data is retrieved from these recorders and downloaded using a USB.

More advanced models allow the use of a wireless network to transmit the measurements. With this method, manufacturers, handlers, shippers, and recipients are alerted when a product is exposed to temperature conditions beyond a specific threshold.

Single-use temperature indicators are another option in the cold chain cycle. These strips are available at several temperature thresholds to alert users of exposure to unacceptable temperature conditions and the time duration during which the products remained outside their ideal range. These types of monitors can be used to ensure COVID-19 test kits remain frozen during shipment as well as storage to avoid false negatives and meet Centers for Disease Control and Prevention (CDC) shipping guidelines.

Altogether, there is a wide range of devices currently available to meet the evolving protection standards for cold chains and solve some of its greatest challenges. Without sensors, there is little-to-no comprehension of climate conditions once pharmaceuticals and medical products leave their labs or manufacturing facilities. Products can unknowingly be damaged by temperature variations and can put patients at risk. Implementing temperature-monitoring devices within the shipping and handling stages of the pharmaceutical and medical cold chain render them more transparent, reliable, and secure.

These cost-effective monitors are a necessary investment for managing the transportation and distribution of medicines, test kits, and vaccine trials during the pandemic, and will likely play a vital role in the discovery and subsequent administration of a COVID-19 vaccine for the global community.

Temperature-monitoring devices

Temperature monitors are portable instruments designed to sense and record temperatures of the indoor and/or outdoor environments of cargo on the cold chain. Consisting of two main parts, the recording system picks up the temperature measured at preset intervals by the sensor and saves the measurements. This provides manufacturers, transporters, and recipients a comprehensive record, complete with time stamps, of the various conditions the products have been exposed to. Not only do these devices certify the safety and usability of the product, but they provide real-time visibility throughout the chain. Logistics operators are then able to pinpoint inconsistencies, proactively respond to disruptions, and reduce the likelihood of product damage.

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ABOUT THE AUTHOR

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These cost-effective monitors are a necessary investment for managing the transportation and distribution of medicines, test kits, and vaccine trials during the pandemic, and will likely play a vital role in the discovery and subsequent administration of a COVID-19 vaccine for the global community.

ABOUT THE AUTHOR

Angela Kerr is vice president of product portfolio and program management at SpotSee.

Temperature loggers are available in several different models to address the various needs of users. For most in-transit purposes, temperature recorders have both a sensor and data recorder integrated into a compact and lightweight device. At the end of its journey, data is retrieved from these recorders and downloaded using a USB.

More advanced models allow the use of a wireless network to transmit the measurements. With this method, manufacturers, handlers, shippers, and recipients are alerted when a product is exposed to temperature conditions beyond a specific threshold.

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How to prepare a cold chain for COVID-19 vaccines

BY MAHESH VEERINA, CLOUDLEAF

A smooth distribution process for approved vaccines for COVID-19 will require successful product storage and packaging, seamless cold chain transit, accurate shipping, and reliable storage solutions at the point of care. A kink in the process, such as cold transport issues or logistics delays, could spell disaster for vaccine distribution.

Two main cold chain challenges need to be solved quickly to enable effective distribution of a COVID-19 vaccine.

1. Temperature excursions. The biologics supply chain is rife with challenges, ranging from preventing temperature excursions to achieving 100% compliance with FDA regulations. As the drive to develop more innovative drugs accelerates, the need for reliable temperature-controlled supply chains has become a critical priority. According to the IQVIA Institute for Human Data Science, the biopharma industry loses $35 billion annually as a result of temperature-control failures across supply chains. These jeopardize drug quality and stability, as well as compliance for products that are shipped globally.

2. Lack of visibility into the cold chain. Companies need specific information about the condition, timing, and location of products, raw materials, and product subcomponents based on real-time data. What’s the real-time location, temperature, and humidity data for perishable products? Have perishable ingredients degraded in a container stuck at a port? Did time- and humidity data for perishable products exist? Have perishable ingredients degraded in a container stuck at a port? If the answer to these questions is yes, it is crucial to improving velocity through points of congestion in the supply chain. Armored with this kind of detailed data and actionable intelligence, pharma companies can focus on prioritizing what is moving out, know when products move through congestion points, and leverage this data to re-route.

Optimizing the cold chain

The foundation of supply chain agility is visibility. Visibility enables knowledge of what is going on to mobilize supply chain members and partners to act accordingly. The company that successfully discovers a COVID-19 vaccine will undoubtedly require visibility, but at this global scale and given the gravity of the situation, simply knowing where a product is will not be enough to effectively deliver it.

Supply chain sensing in a manner that is quick to detect and respond to the slight changes, signals, or influences requires a powerful sensing system. The key to this kind of sensing lies in the ability to use technologies such as Internet of Things (IoT) devices and cloud computing, while leveraging advanced technologies such as sensors, visual machine learning (ML), and integrated systems. By enabling this oversight and insight of the vulnerable points of the cold supply chain, the sensed data can be analyzed, with direct connectivity to planning and execution systems. This way, the value of timely and accurate sensing can help reduce obsolescence or allow a vaccine to be used at the most needed demand points. AI and ML are critical technologies in this process, since they can be used to analyze the tremendous amount of data that will be collected. That data can be reviewed using traditional AI/ML techniques to do predictions with a fair amount of accuracy.

For example, it is highly likely that the lead time to deliver supplies from a third-party logistics (3PL) entity to a factory can be accurately estimated, and an estimated arrival time can be provided to the “receiving” side of the factory so that the appropriate resources can be lined up “just in time.”

The World Health Organization estimates that up to 50% of vaccines are wasted globally every year due to improper temperature management and the inability of logistics to support the end-to-end cold chain. This spoilage rate could mean a billion COVID-19 vaccines could be wasted if not properly handled.

To remain viable, a vaccine needs to be maintained at 2–8 °C throughout the shipping process. It just takes one single transport leg or storage system that isn’t properly temperature-controlled to break the cold chain and spoil an entire shipment of vaccines. As the drive to develop more innovative drugs accelerates, this need for reliable temperature-controlled supply chains has become a top priority. To ensure that temperature-sensitive products don’t spoil or get damaged during transport, pharma companies need accurate, reliable tracking information.

In the past, cold chain storage providers were using a variety of siloed data sources to get supply chain information. This included everything from using manual methods such as handheld bar code scanners to error-prone passive temperature measurements where companies don’t know when or where a temperature excursion occurred. Further, when shipments needed to be located, companies relied on email and phone calls to access needed information.

New packaging technologies and visibility software tools are emerging that can help, including the implementation of track-and-trace technology into Air Cargo container fleets. Supply chain visibility software makes comprehensive real-time tracking and intervention possible, with companies today working on individual dosage-level tracking in response to COVID-19.

One biotech organization was recently able to save $10 million to $15 million every year after deploying supply chain visibility software that enabled them to get real-time location and inventory tracking of their biomedical material containers. The company was also able to easily provide the FDA with a complete record of product movement history.

Before deploying the platform, they had no method for tracking dwell time in each zone so that samples didn’t sit too long before reaching their temperature threshold.

The issue of serialization

Manufacturers also worry about product diversion and counterfeiting. COVID-19 test kits are a good example of this, since many yield inaccurate results due to tampering. Serialization has the potential to greatly reduce counterfeiting. However, serialized tracking is only available at the pallet level and during primary carrier transit. This means that there’s a potential for individual boxes to be removed from the pallet or be exposed to temperature changes and go unnoticed.

Individual dosage-level tracking would drastically increase efficiency and planning accuracy in distribution to emerging markets where delivery routes are less formal and technologically equipped, as it makes remote monitoring possible.

ABOUT THE AUTHOR

Mahesh Veerina is president and CEO of Cloudleaf, Inc.
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Richard Ettl, SkyCell CEO
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**Contact Information**

Pain to practice? Key lessons for supply chain post-pandemic

BY FERDI STEINMANN, OPEN TEXT

The global coronavirus pandemic has triggered fear that the global and extended pharmaceutical supply chain would crumble. In practice, it has proved remarkably resilient with drug shortages kept to a minimum, though the crisis has exposed weaknesses in the supply chain that must be addressed as the world recovers and prepares for what the future holds.

What has traditionally been viewed as a weakness of the pharma supply chain has actually proven to be one of its strengths. Lead times are regularly four to six months or even longer, reports state, ensuring some short-term resilience. However, should disruptions in the manufacturing of raw materials or active pharmaceutical ingredients (APIs) last for more than two or three months, a trickle-down effect could result that may have lasting ramifications globally.

The situation is even more acute for the global supply of medical products. The worldwide shortage of personal protection equipment (PPE) has demonstrated both the difficulty of meeting demand when the supply chain is under-prepared and the challenges in ramping up production and supply when there is pressure to deliver.

Here are a few supply chain lessons that pharma and medical product companies can learn from the COVID-19 pandemic.

Overreliance on few sources of supply. COVID-19 didn’t expose the industry’s overreliance on China and India for raw materials, APIs, and increasingly finished products. Instead, it has brought home that such overreliance can mean when faced with a global health crisis. For example, the US and Europe may be the two largest API manufacturers in the world, but China and India combined have a greater market share than both, and India is the world’s largest manufacturer of generics. Any lasting disruption for these markets will have real impacts further down the supply chain. It is instructive to note that this impact doesn’t always come from direct disruption. For example, India temporarily banned the export of some generic drugs as the government was worried about shortages in its domestic market. COVID-19 has demonstrated just how real these supply chain risks are, and the need for pharma companies to, wherever possible, have multiple sources of supply spread across different geographies so they can quickly switch production from highly impacted to lesser impacted territories.

Security of supply is a matter of national importance. The pandemic woke up regulators and world leaders to the ongoing industry effort in the US and Europe to rebalance the pharmaceutical and medical product supply chains. In truth, this trend has been underway for some time. The US congress and the EU have debated the issues and had tentatively started to legislate to address the imbalance. Both governing bodies spoke openly about the need to safeguard the world’s drug supply from the vulnerabilities inherent in relying on any one region for a significant proportion of essential raw materials and APIs. The security of supply for medicines will be a major political issue and we can expect all governments to continue to develop local capacity and secure local supply.

Supply chain resilience means more complexity. Medical supply chains have only grown more complex as they have integrated many different types of organizations within them. The need to quickly select between suppliers in different markets and regions and expand manufacturing into new territories to satisfy the increasing demand of governments and regulators adds complexity.

Meanwhile, regulations such as the Drug Supply Chain Security Act (DSCSA) placed added stress on how pharma works with partners, distributors, and logistics providers. Although we’ve seen some DSCSA exemptions to deal with the pandemic, resilience is required to meet track and trace, monitoring, and licensing requirements. To achieve this level of resilience, companies need to work harder and smarter to deliver full digitization to every part of their supply chain operations.

ABOUT THE AUTHOR
Ferdi Steinmann is a global industry strategist, life sciences, at OpenText. This article also appeared online at pharmexec.com, an MBI Life Sciences sister brand.
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