

## 2022 Cold Chain Predictions: Creating a new Normal

At this time last year, the world was eagerly anticipating 2021. COVID-19 vaccines delivered hope for normalcy and excitement grew over convenience-related changes to healthcare, work and more. But the pandemic had other plans. New COVID-19 variants emerged, supply chain issues deepened and much of the day-to-day still looks different than pre-pandemic.

The cold chain industry experienced rapid growth in 2020 and continues to experience both growth and change for the foreseeable future. The pandemic's influence remains, which creates opportunities to innovate and better serve pharmaceutical and healthcare customers delivering medicine in new ways. This sets the stage for a few of our predictions this year.

While COVID-19's influence persists, we also see renewed interest in sustainability and the evolving impact of Brexit's export regulations in the United Kingdom (UK). These will also shape how the pharmaceutical and cold chain industries operate. Let's take a look at what all of this means for 2022.

### Outsourcing the Cold Chain

In our predictions last year, we anticipated that more pharmaceutical companies would outsource capabilities to contract manufacturing organisations (CMOs) and contract development and manufacturing organisations (CDMOs). Pharmaceutical companies already engage these organisations in manufacturing and development of therapies, but adding additional services allows pharmaceutical companies to focus valuable time and resources on areas where they have the most expertise.

We did see a shift last year to CMOs and CDMOs adding additional services, like cold chain logistics. We expect to see outsourcing grow again this year. Offering end-to-end expertise will help reduce additional supply chain complexities by standardising more of the supply chain during a time when raw materials are scarce and transportation is unpredictable, necessitating dedicated and seasoned professional resources.

Additionally, we expect companies not yet ready to fully outsource their supply chains to increase their use of services that make cold chain operations easier and eliminate the challenges associated with unforeseen circumstances. These include services like offsite conditioning of coolants or onsite conditioning with coolants inventoried to their unique needs.

### Direct-to-Patient and Direct-from-Patient Growth

Also on our list last year was a new focus on direct-to-patient and direct-from-patient care, including significant growth in home-based clinical trials. In December 2019, 38 percent of pharmaceutical and

contract research organisations expected to engage in a high volume of virtual research trials with 48 percent of those expecting to run a trial with most activity conducted in participants' homes. These numbers increased to 100 percent and 89 percent respectively in December 2020.<sup>1</sup>

Many research organisations initially piloted this new model of clinical trials with smaller Phase I and Phase II trials. In the past year, we saw organisations pilot fully home-based and hybrid clinical trials in Phase III trials.<sup>1</sup> This year we expect to see trials using home-based care grow with continued focus on improving the experience for patients and physicians.

Logistics remain a challenge, especially given the narrow timeframe for deliveries and pick up of biologics or sample materials. All timing must coordinate with homecare visits and ensure temperature-sensitive materials arrive at their final destination still within the required temperature range. Services like phlebotomy, drug administration and sample collection that require refrigeration will require cold chain solutions. We anticipate an ongoing drive toward solutions that require little training and are easy for home healthcare professionals and patients to operate. We should also see even more assessment and evaluation of the cold chain for home-based care in 2022.

### Brexit Runs Smoothly

Brexit, or the UK's exit from the European Union (EU), officially began on January 31, 2020. However, nothing changed until a new trade deal was reached nearly one year later. Implemented in January 2021, the new deal outlined how the UK and EU would live, work and trade together. The most significant concern: new paperwork for export businesses.

As new trade rules began, export businesses did in fact experience significant issues with increased paperwork. As a result, a large number of shipments were delayed, held at customs points or cancelled altogether. The impact of Brexit was further affected by the global shortage of shipping containers and lack of drivers to transport goods.

Over time, exporting companies, shipping agents and logistics companies began to understand the nuances of paperwork required to enable shipments to the EU to take place without issue. This was a learning process for companies that hadn't dealt with the complexities of customs clearance for decades. To enable this, companies recruited for new staff, which further slowed down the processes required.

It is still too early to draw concrete conclusions about the overall impact of Brexit on trade with the EU. The Office of National Statistics (ONS) noted survey data suggesting businesses' trading activities were being held back by Brexit frictions, such as extra paperwork



and higher transportation costs. However, the UK economy showed improvement during the course of the year. Shipments to the EU began to return to pre-Brexit levels as companies became more confident with the complexities of the new rules.

Further growth is expected into 2022, and with the general improvement with trading conditions as COVID-19 restrictions are relaxed, we can expect a surge in UK – EU trade during the course of the next year.

### Sustainability Initiatives Move Forward

Only a few short years ago, pharmaceutical manufacturers viewed supplier sustainability initiatives as a nice-to-have, but not a deciding factor in their decision to do business together. That shifted in 2020 with companies focusing on how they could impact the United Nations' Sustainability Development Goals (SDGs), as well as building plans to execute and measure their efforts.

What began as internal initiatives quickly turned to a focus on how vendor and supplier sustainability initiatives impact a company's sustainability goals. Pharmaceutical companies soon required vendors like Peli BioThermal to demonstrate that temperature-controlled packaging and modes of transportation minimise negative effects on the environment. Additionally, vendors were also asked to provide tools that help pharmaceutical manufacturers measure their actual environmental impact so they can monitor and demonstrate reductions in carbon footprint and waste.

We expect to see this trend continue in 2022. However, we also expect pharmaceutical companies to dig deeper into the supply chain. Vendors and suppliers like Peli BioThermal will be asked to also look at their supply chains and begin monitoring how their

own vendors and suppliers contribute to their environmental impact.

Each year brings hope and anticipation of new challenges. This upcoming year is no different. Though COVID-19 continues to influence supply chains, companies are learning to operate in an unpredictable world. Overall, we anticipate this year will bring more stability and renewed focus on pre-COVID-19 priorities.

### REFERENCES

1. McKinsey, No place like home? Stepping up the decentralization of clinical trials, June 2021

### Adam Tetz



Adam Tetz is the Director of Worldwide Marketing at Peli BioThermal and has more than 25 years of marketing experience. He is responsible for telling the story of Peli BioThermal to our worldwide audiences. His areas of responsibility include brand identity, product launch and communication strategy. Prior to Peli BioThermal, Tetz held positions in product management and marketing communication across a variety of industries, including medical software, financial software, information services and professional consulting services. He holds an MBA in Marketing from the University of Saint Thomas, a BA in Advertising from the University of Minnesota and is a veteran of the United States Coast Guard.

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