Full Speed Ahead

With the swift rollout of COVID-19 vaccines making the headlines, *PMPS* speaks to Richard Wood from Softbox Systems about some of the latest developments in shipping temperature-sensitive products

***PMPS:* What are the main challenges of distributing vaccines at ultra-low temperatures?**

Richard Wood: Getting shipments expedited quickly is always a priority. Many vaccines require shipping at temperatures below -20°C , and more recently, with one of the mRNA COVID-19 vaccines, within the -60°C to -90°C range, often referred to as ultra-low temperature (ULT). To maintain these states, highly specialised ULT parcel shippers filled with dry ice are utilised. When ULT vaccines have to stay within these parameters for extended periods, a process called re-icing takes place. Surprisingly, perhaps, one of the main challenges is to prevent vaccine temperatures becoming too cold.

The development of ULT shippers for the COVID-19 vaccine presented many new challenges. The final packaging system had to be used for commercial outbound logistics as well as storage at point-of-use sites, all at temperatures far lower than any previous vaccines. This had never been done before. Speed, flexibility, and persistence were crucial.

How well equipped are current temperature-controlled shippers?

Right now, the landscape is continually changing; we are repeatedly being asked to innovate. We have come to expect the unexpected. But it's fair to say that temperature-controlled shippers have the bases covered. There are qualified pallet shippers that maintain ambient temperatures of 0°C to +30°C for widely available treatments. However, where vaccines are concerned, high-performance shippers operate at chilled (+2°C to +8°C), or frozen (-20°C) temperatures. The Oxford-AstraZeneca vaccine, of course, ships chilled. In the wake of COVID-19, requirements changed. Developing ULT shippers to maintain mRNA vaccines in a deep-frozen thermal state, and for long enough to act as a storage device, was new territory. The pattern was 'design it, build it, test it, repeat' until the shipper's performance was perfected.

What will the lasting impact of the cold chain's response to COVID-19 be on the industry?

The speed with which COVID-19 hit has meant we have had to respond in kind. To do that, processes have been operating in parallel with one another. You have to remember this isn't the sort of industry where you can cut corners – there's too much at stake. So, the ability to adhere to development and manufacturing processes, while operating flexibly within them was the only way forward.

With the ULT shipper, design and development went into overdrive. Packaging prototypes were pushed through quickly – with both laboratory and field testing. As soon as the first wave of vaccines was commercialised, we were delivering shippers with stock ready to go. Not many temperature control packaging (TCP) vendors can operate like this, but it mirrored the way the vaccine manufacturers were having to work.

What are the regulatory challenges that must be met for temperature-controlled packaging?

There's a whole raft of qualifications and approvals to which we must adhere. To use a broad brushstroke, products need to remain within their stated temperature range. That may be chilled, ambient, frozen, or deep-frozen.

However, there are challenges where shipping globally is concerned, as regulatory guidelines may vary between continents and countries. The regulatory framework is evolving, however, and Good Manufacturing Practices have been a catalyst for better design.

Interestingly enough, the development of ULT shippers have opened up an area of compliance with the Federal Aviation Administration. There are guideline limits to the amount of dry ice that is permitted to be shipped in aircraft holds, as the substance emits CO_2 and is characterised as a shipper's 'loss rate'. However, after testing in low pressure thermal chambers, the ULT shipper's loss rate was found to be very low compared to traditional shippers. As a result, a 600% increase in dry ice volumes per aircraft is now permitted under the revised guidelines. This is a real shot in the arm for deep-frozen, ULT COVID-19 vaccine shipments.

What are the latest developments in sustainable and reusable packaging for temperature-controlled goods?

The evolution from single use, to reusable, to totally recyclable TCP

solutions is well and truly under way. Reusable shippers combine vacuum insulation panels and phase-change materials to guarantee product integrity. They are supported by a full returns process; we recover, refresh, and refurbish the shippers for reuse. Kerbside-recyclable shippers have now emerged as a result of a demand for low-cost, sustainable packaging. They are plastic-free and can be collected by local municipalities. ULT shippers are the very latest in a long line of innovations. They had to be easy to assemble, reusable, and capable of upholding deep-frozen temperature states for a minimum of 10 days, or 30 days with re-icing. Testing and live trials were thorough, fast, and relentless. To meet high demand in record time, we actually opened two fully operational service centres in Europe and the US.

What new innovations and developments are needed to further improve efficiency and sustainability in the industry?

For us, sustainability means having methods for manufacturing, use, and end-of-life, which doesn't add to the overall waste stream. Pharmaceutical companies are having to tackle inbound and outbound sustainability in their supply chains by utilising either TCP reuse programmes or easily recycled solutions.

Often, the greatest challenge is delivering in the final mile of transit to hospitals or homes, so recycling is preferable to reuse. New, eco-friendly, 100% kerbside-recyclable shippers made from specially engineered, corrugated cardboard are now in market.

What solutions exist or need to be developed to improve the cold chain's impact on emissions?

Our need to reduce plastics and the impact of CO_2, as well as use biodegradable products, are themes that resonate with senior pharma executives. In our recent Sustainability Survey, the 'reuse, recycle, renew' message was a number one priority with more than two-thirds of respondents. New, recyclable packaging solutions need to work alongside reusable or renewable high-performance systems if carbon footprint is to be reduced further. Currently there are cost and disposal implications associated with recycling and upcycling programmes. But the new, kerbside-recyclable TCP systems are effective and affordable. They will protect routinely dispensed prescription products and over-the-counter medicines in transit at 2°C to 25°C, for up to 72 hours.

How are temperature-controlled shippers monitored and what can be done to mitigate against falling temperatures?

The whole Internet of Things (IoT) revolution has been a welcome boost for the integrity of temperature-sensitive shipments. A new generation of surveillance practices has emerged as smart, real-time monitored shipping systems gather and feed back critical data. The ULT shipper, for example, is fitted with a real-time monitoring device.

These IoT devices essentially allow authorised parties to view information relating to temperatures and location on a web and mobile app dashboard. These sense-and-respond feedback mechanisms can be expanded to encompass humidity, air pressure, light, and shocks. They can also be configured to flash alerts that signal any breaches during transportation and prompt appropriate action.

This technology brings enhanced transparency, accuracy, and responsiveness to the delivery cycle, as well as peace of mind.

What impact can smart temperature-controlled packages have on global distribution?

Smart packaging brings another level of visibility, traceability, and security to the cold chain, which is incredibly important where vaccine distribution is concerned. Passive monitoring in data loggers has paved the way for the real-time monitoring we have now, so products can actually be saved through intervention while in the shipping lane.

They also act as an asset tracker. When vaccination centres use shippers for storage, the device remotely monitors temperature and location in real time, identifying the whereabouts of a shipper. The same technology assists with the return of shippers for refurbishment purposes.

Increasingly, predictive analytics, powered by artificial intelligence are helping the supply chain actually become proactive. With the capacity to leverage multiple data assimilations, smart algorithms can detect patterns and make informed, accurate predictions. This technology could have a massive impact on global distribution.

Richard Wood is Executive Director – Technical Solutions at **Softbox Systems** and has over 18 years' experience of designing and engineering innovative temperature control packaging systems.

Having worked in the cold chain industry for almost all his career, Richard has developed high-standard skills in searching for new and innovative ways to help clients overcome their cold-chain distribution challenges by developing market-leading products and services that meet the exacting needs of the life science industry.