

Safety and security in the last mile

Softbox Systems is an award-winning temperature-control packaging company that has been designing high-performance solutions for over 20 years. Clive Bryant, senior global business development director at Softbox, talks about how the company's new product innovations now allow clinical trial medicines to be protected in the crucial last leg of their journey.

Most of us follow a well-trodden path when it comes to getting the medicine we need: doctor, prescription, pharmacy, home. On a personal level, we know the drill. But through the eyes of the industry, the continued expansion of biologics – coupled with a health sector that's gradually metamorphosing into a more patient-centric entity – means that this process is under scrutiny as it becomes subjected to new pressures and demands.

The area throwing up some considerable investigation is referred to as 'last mile'. While there is some debate on how to interpret this terminology, in essence it refers to moving products from either the depot or clinical investigator to a person's home. But what is behind the surge in interest around this area of logistics?

The biologics explosion

Nowhere is the issue of last mile transportation more pronounced than in the processes that support clinical trials. Vaccines, drugs and other biologics have revolutionised the treatment of patients suffering from some of the most debilitating and life-threatening diseases on the planet. They are the lifeblood of the industry and a lifeline to people in need.

Biologics is the fastest-growing sector in the pharmaceutical business, with total revenues reaching up to \$240 billion in 2017. And it's showing no signs of letting up; a figure of around \$375 billion is being projected for 2022. In fact, since 1995, the applications for biotech patents have increased by 25% every year. While according to Clinicaltrials.gov, there are nearly 265,000 clinical trial studies currently registered globally, a figure that was just 65,000 only ten years ago.

This rapid growth can be attributed largely to the increased capacity to tackle disease at the cellular level. Jim Datin, president and CEO of BioAgilytix, outlines a shift of investment into "the discovery and development of large molecule therapeutic proteins (as opposed to small, chemically manufactured active-substance molecules)". This, he states, allows companies to tackle conditions that were previously difficult to address, like oncology, neurology, and metabolic and infectious diseases.



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As biological products can be composed of sugars, proteins, nucleic acids, or live entities such as cells and tissues, guaranteeing the integrity of these time and temperature-sensitive products during transportation is a zero-tolerance business. To ensure patient well-being, investigational medicinal products (IMPs) need to be kept in temperature-controlled conditions of either 2–8°C or 15–25°C from the moment they leave the manufacturing site until they reach their final destination.

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The packaging materials revolution

To date, the most forward-thinking temperature-control packaging providers have been keeping pace with change. Packaging materials such as vacuum insulation panels (VIPs) and phase change materials (PCMs) that freeze and thaw within the required temperature ranges for different pharmaceutical products, are combined to great effect in more advanced packaging systems.

Designed for longer transit times, these packages are robust and often guarantee autonomies of 96–120 hours. They are also reusable. This allows pharmaceutical companies to reach their own environmental benchmarks, as well as to meet the increasing demands for zero tolerance with respect to temperature excursions.



Softbox has been relentless in its commitment to technology and innovation, breathing new life – and new products – into temperature control packaging and logistics.

The effectiveness of high-performance shippers that often flirt with acute global climatic variations is well documented. But Softbox is now going the extra mile, leveraging some of this innovation to deliver a solution that is fashioned specifically for last mile transportation.

From depot to doorstep

Plans are already in place for hybrid transportation pods capable for protecting IMPs from depot to doorstep. The pods will comprise of an outer payload container that houses temperature-sensitive products, and if required, a smartbox to provide data to relevant parties in near-real time. IMPs will remain stable during the last uncontrollable critical miles to the patient's home.

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The pods will be easy to condition and completely reusable; at each appointment, patients can simply exchange a used pod with the investigator for a freshly conditioned one. The concept will allow them to take temperature-sensitive clinical trial medicines from the clinical investigator site to the fridge at home, safe in the knowledge that they will remain within their correct temperature range.

The brainchild is also a partial adaptation of the new Softbox Skypod, a thermally insulated packaging system designed to be carried by UAV/LTE-connected drones. It has completed trials successfully and is due to launch in early 2019. A global pharmaceutical company originally identified the need for a solution in the wake

of devastating and life loss from Hurricane Maria in Puerto Rico in 2017.

The Skypod packaging includes a smartbox device powered by the internet of things (IoT) technology. It is geared towards tracking the package and transmitting data that can be viewed on a web and mobile app dashboard. This includes its location, near-real time external and internal box temperatures, as well as light exposure data (determined by the opening and closing of the lid) that signals any tampering during daylight. The dashboard app will flash alerts – whether on breaches of temperature ranges or defined geofencing parameters – to prompt appropriate action.

Skypod is the blueprint for CliniPod, the forthcoming clinical trial last mile shipper.

Breaking new boundaries

Softbox has been relentless in its commitment to technology and innovation, breathing new life – and new products – into temperature-control packaging and logistics.

By leveraging Skypod innovation, this latest clinical trial solution offers significant potential value to the pharmaceutical industry. Its importance cannot be overstated. With the amount of work and investment goes into all facets of the drug development and distribution processes, the idea of it all unravelling in the last mile is unthinkable.

Softbox is launching a superlative, temperature-control packaging system for new and existing temperature-sensitive IMPs. This is a giant step towards making the uncontrollable last mile controllable. ■

Further information

Softbox Systems
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