Cool customers

Ensuring the correct temperature control when distributing pharmaceutical products is crucial to patient safety and satisfaction. *Clinical Trials Insight* talks to Mike Hannay, general manager at Fisher Clinical Services, about the company’s last-mile distribution strategy.

**How have clinical supply chains changed over the years? What complexity has been added?**

*Mike Hannay:* Clinical supplies have been and always will be about getting the right medicine to the right patient at the right time. But it’s becoming more of a challenge as the pharmaceutical industry continues to evolve.

One of the big changes relates to the use of biological drugs. In 2001, there were about 245 of these in clinical programmes. By 2012, that number had risen to 665, and now it’s over 1,000. Depending on what statistics you look at, somewhere between 50–60% of all molecules in development are now biological. That’s important because they are inherently less stable than small molecules and invariably require a much colder supply chain. This means there is even greater emphasis on ensuring the clinical supply chain maintains the right environment, enabling clinical supplies to reach the patient in the right condition.

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Every day is different for us. We continue to transport the more traditional small molecule products under controlled ambient conditions as well as the growing number of biologics that more often than not require controlled conditions of between 2–8°C. We also manage an increasingly large volume of products requiring ultra cold chain conditions including cell and gene therapy products, which require temperatures as low as -190°C. To preserve the integrity of supplies and make sure they are in the right condition for patients to take, we have to make sure we maintain the correct environment the whole way through the supply chain from point of origin to delivery to the patient.

The second big factor that has changed is geography. Traditionally clinical trials were carried out in North America and Europe. In recent years, clinical trials have become more global and the core logistical challenges become more complex.

A decade ago, a typical phase-III programme had about 11 countries involved in the study. Now it’s 34. While the number of countries involved has trebled, the number of patients in a typical study has remained pretty constant.

Today many studies are targeting patient populations in far reaching, often remote locations in Asia Pacific, sub-Saharan Africa, Latin America and, more recently, the Middle East. We’re distributing to so many countries that would have surprised us only a few years ago. Just this week, we started distributing a phase-III study to a large number of investigator centres in Lebanon, for example. We’re now delivering to more than 120 different countries in total, and this will continue to evolve as we address clients’ needs and industry trends.

The different geographies and the changing types of product we’re using also make the supply chains much more complex and challenging. If you are going to some of the more remote, developing countries, with their emerging import and export, tax and duty requirements, it’s really important that you understand these factors and all the different routes that a product needs to take. This needs to be done in a way that maintains the right environment for the drug, which will be exposed to a wide range of climatic conditions across the supply chain.

**What are the main techniques the company deploys to achieve this?**

Firstly, we make sure we have the right shippers and that they retain the temperature specifications the products require while in transit, in motion and at rest.

In the UK, we have a unique system whereby all of the packing, labelling and shipping is done within the appropriate environment. If it needs to be 2–8°C, we do that. If it needs to be -20°C or even -190°C, we can do that as well. This means the product never spends any time out of the environment required for maximum stability when we are handling it. When we ship it, we make sure that it remains in that condition all the way through the distribution process until it gets to the patient.

We’re objective in the choice of courier. We base our decisions on the wealth of data we have collated over the past 25 years on a large number and range of couriers across more than 120 countries. This objective data allows us to select the right courier for the product to ensure we get the material to the patient on time and in the right condition. Because we understand and keep up-to-date with all the regulatory and customs requirements, we mitigate risk by minimising delays through borders. Having local teams strategically located across the globe helps with the smooth transit of supplies.

**What about the high-risk areas? Could you identify those and tell us about the measures you can take to minimise them?**

We’ve been distributing to places where there has been civil unrest, Ukraine for example, and not missed a single
patient dosing schedule. That’s because we work very closely with depots and facilities in these areas to make sure deliveries get to the right places.

More studies are happening in Africa as well. We have our own facilities in South Africa, which is a gateway into the entire continent. By having our own facilities and our own people in place, we’ve set up a robust distribution chain. You can imagine the challenges out there of making sure we’ve got the right conditions all the way through, especially for products requiring ultra cold storage. We have the right vehicles, shippers and refrigeration in the places we need it.

What new technology is the company using to improve the distribution process?
We’re continually evaluating new and evolving technologies in terms of how we can capture data. Standard technology such as data loggers that capture the temperature of the shipment as it goes around the world gives you an added level of reassurance that temperature specifications are being maintained. We’re also reviewing smart mechanisms for how we can provide data to clinicians using QR codes, for example. More recently, we’ve been looking at different sensors and RFID technology so that we can more rapidly provide information to clients on their products. But, it is all very well having data. The question here is - how do you interpret that data so that you provide meaningful insights to the client? Our project management teams do this every day.

We have a global help desk that can track every shipment we send out and provide information to clients on the status of all their shipments. We proactively monitor shipments and deal with any problems or any concerns, ensuring supplies get to the patients on time. In the event of a disaster such as a tsunami or volcanic eruption, we call on contingency plans to proactively manage all shipments. We can get support, information and ultimately reassurance about where materials are and how to overcome any blockages and difficulties that might arise.

How important is it to educate patients and investigators about storage and distribution so they can maintain the quality of their drugs?
We communicate regularly with investigator sites and get their input on how we can make life a little easier for them. We’ve seen a big increase in the size of packs that are received at clinics for patients to take home with them. If they require refrigeration, this can be a serious burden to investigator sites, pharmacies and patients at home. We get input from investigators, pharmacists and patients about how to improve pack design so that it is friendlier for all parties.

We also listen to their various frustrations when it comes to clinical supplies. One very simple proactive approach is to provide them with notice of when shipments are going to be coming in, so that they can prepare and make sure they have the refrigerator space available. This sounds like a really simple thing to do but sometimes, as an industry, we neglect to consider the needs of the investigator sites and patients. For us, communication with all parties to the supply chain is key. Sponsors supply hope to patients with the innovative medicines they develop. We feel privileged to support the supply chain that gets the right supplies to these patients at the right time and in the right condition. Last mile distribution is paramount to the success of the trial.