Pharmaceutical Cold Chain Expertise – the Missing Ingredient in the CMO/CDMO Offering

Pharmaceutical supply chains continue to reach new levels of complexity that challenge even the most seasoned logistics and supply chain professionals. These complexities include:

- Innovative, advanced therapies
- Emerging new temperature requirements for products
- Expanding global supply chain to naïve patient populations
- Additional regulatory scrutiny over good distribution practices throughout the supply chain.

Within this evolving world of biopharma, it is estimated that two-thirds of biopharmaceutical manufacturing is outsourced.[1] Therefore, the supply chain is not only complex, but also largely virtual for pharmaceutical companies bringing their therapies through clinical development and ultimately to market. As a result of the increasing trend of virtual pharma supply chains, pharmaceutical sponsors view relationships with their contract manufacturing partners as not only critical, but vital to the success of their therapies.

Contract manufacturing organisations (CMOs) and contract development and manufacturing organisations (CDMOs) offer expertise in manufacturing and development of therapies, allowing their pharmaceutical company customers the opportunity to focus on their core competencies. These pharma partners can provide transformational value, and effectively help pharma companies bring innovative therapies to market. However, the CMO/CDMO landscape has experienced significant consolidation – which can make it difficult for pharma companies to understand the unique, value-creating differences between competing CMOs and CDMOs.

Challenging Forces for Clinical Trial Sponsors and their Partners

Clinical trials continue to stretch global clinical supply chains as clinical trial sponsors strive to reach naïve patient populations. This is an interesting challenge for clinical supply chain professionals as they are tasked with supporting the distribution of temperature-sensitive clinical supplies to all corners of the world, including many developing countries that potentially lack significant infrastructure to support strict temperature control of these investigational therapies.

Aside from an expanding global supply chain, emerging distribution models like direct to patient clinical trials (where therapies are delivered/administered in the patient's home) and adaptive dose clinical trials, are creating additional supply chain complexities. These added complexities can potentially drive additional cost into the supply chain as typically these situations require white glove transportation services.

In addition to increased supply costs from supply chain distribution complexity, pharmaceutical companies continue to pursue sustainability initiatives. For example, Amgen, a leader in global biotechnology, has published formal sustainability plans since 2008. Amgen is not alone in this effort as many other large pharma companies like Merck, Eli Lilly and others have large-scale sustainability initiatives as well.

As pharmaceutical companies face these challenges of: supply chain complexity, cost pressure, sustainability and temperature control, how can CMOs and CDMOs provide an innovative offering to solve these challenges?

End-to-end Expertise

Aside from manufacturing and processing high-quality active pharmaceutical ingredients, what if CMOs/CDMOs could offer a true end-to-end solution by ensuring strict temperature control of their products in transit? What impact would these solutions have on their current and potential pharma customers?

By leading and guiding biopharma companies to effective temperature-control strategies, CMOs and CDMOs *can* create unique value as they act as an extension of the pharma sponsor's supply chain. After all, even the safest and most effective therapy will have zero impact on patients' lives if it does not arrive at the destination in viable condition.

Reusable Packaging Systems

Exciting advances in thermal packaging technology have resulted in the emergence of robust and reusable packaging systems. These reusable packaging systems provide temperature assurance for a wide range of temperature ranges, and they accommodate both smaller distribution shipments as well as full pallet shipments (for bulk API/drug product/finished drug product).

With space and capacity constraints at CMO/CDMO facilities, temperature-control solutions also require the same innovation and outside-the-box thinking as today's therapies. For this reason, it is important for CMOs and CDMOs to partner with thermal packaging companies who can provide pre-conditioned and ready-to-load temperature-control packaging to their doorstep. Additionally, it's a best practice to seek thermal packaging partners who can support their needs with pre-conditioned, ready-to-load packaging throughout the CMO/CDMO network wherever they are located in the world – due to the global expansiveness of pharma supply chains.

Reducing Costs by $1 Million

With these new options available to CMOs and CDMOs, companies are now able to address the previously mentioned challenges for their pharma sponsor customers. For example, in working with a large pharma customer on supporting their bulk distribution supply chain, the customer has been able to reduce their thermal packaging costs by over $1 million by switching from active systems and single-use boxes to passive, reusable parcel and pallet shippers. This project has also had a profound impact on the customer's sustainability goals. It must be noted that both the financial and environmental impact offer net value because the change in packaging systems has also assured avoidance of temperature excursions.

Deepen Partnerships, Provide Value

In a world where biopharma companies exhaust all of their resources with innovative discovery and development of therapies, these companies are greatly impacted by customer-centric CMOs and CDMOs. The ability to not only manufacture high-quality product, but also ensure temperature control and viability to the destination, provides value that biopharma companies seek from their partners. CMOs and CDMOs already offer tremendous value to pharma customers, and now they have an opportunity to offer a true end-to-end service.

REFERENCES

1. https://isrreports.com/outsourced-pharmaceutical-manufacturing/

James Klingelhoefer

James Klingelhoefer Pelican BioThermal Director of Sales Americas. James Klingelhoefer has over 12 years experience in various leadership, sales and customer support roles having worked closely with pharmaceutical sponsors, CRO's, CMO's, packaging/labeling providers, and other life science organizations to leverage supply chain efficiencies and identify risk mitigation opportunities. As the former North America Sales Director at World Courier he was responsible for sales operations and clinical operations teams.

Email: james.klingelhoefer@pelican.com