SUPPLY CHAIN INSIGHTS

HOW IT STANDARDIZATION SUPERCHARGES CLINICAL LOGISTICS EXECUTION EDGE

Gone are the days when supply chain standardization implied a rigid and inflexible approach. Today, process and IT standardization are the key to unlocking increased speed, scalability, and growth of clinical logistics and specialty pharma operations.

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Deploying and successfully running clinical studies across geographies and accessing diverse population groups requires seamless orchestration that ensures efficiency, compliance and patient centricity.

Robust processes and connected IT systems are essential to achieving the execution edge of complex healthcare logistics networks, and a standardized approach plays a crucial role in this process. Here are four benefits standardized processes and systems can deliver to your global clinical logistics and specialty pharma operations.

Safeguard patient safety across the supply chain

Efficiency, agility, and sustainability are essential growth drivers of successful clinical supply networks, but those would mean nothing without a rigorous approach to quality and regulatory compliance. Clinical logistics are highly regulated, more than the average life sciences and healthcare operation. Therefore, processes and systems must adhere to very stringent requirements. “Standardization plays a crucial role when we deploy systems and processes for our customers,” says Matt Whitman, Global Head of Clinical Operations, DHL Supply Chain. “We follow the required computer system validation (CSV) framework, ensure periodic audits and adherence to quality and regulatory standards, whether it’s the FDA, WHO, European directives, among others.” Integration with quality management systems as part of that standardized ecosystem will ensure consistent product integrity across multiple geographies.

Adding to the complex web of regulatory compliance and patient safety challenges clinical logistics operations have to face is cybersecurity. While 62% of life sciences and healthcare leaders think their organizations are at least minimally cyber resilient[1], data protection and information security are top concerns in clinical logistics. “As a data protection qualified professional, this topic is at the top of my list for every customer implementation,” says Christina Jarvis, IT Manager, Global Clinical Logistics, DHL Supply Chain. “When following a standardized approach that considers industry best practices and guidelines, such as use of GS1 standards[2] for Clinical Studies where possible, we aim to mitigate risks and safeguard patient safety.”

Reduce complexity and improved agility

Process and IT standardization might be the key to reducing complexity and unlocking an unparalleled ability to deploy compliant clinical logistics operations faster and more efficiently. “Standard processes and IT systems open up a wider range of possibilities for our customers who need to be agile when deploying operations across multiple locations,” says Chris Meek, VP IT UKI Healthcare and Specialist Logistics, DHL Supply Chain. “Rather than a rigid, inflexible infrastructure, process, IT standardization takes more of a modular approach with use of enhanced data flows and visibility, meaning it can be adapted to multiple scenarios aligned to our customers’ clinical supply requirements.” IT standardization can not only speed up solution deployment but also reduce manual processes for all the parties involved and improve the overall user experience. “Imagine having warehousing and transport management systems, control tower, inventory and shipment visibility, temperature monitor management, returnable media asset management and more, all within a single integrated network solution,” adds Christina Jarvis. “Standardization makes this possible, enabling lean

[1]https://www.weforum.org/publications/global-cybersecurity-outlook-2024/

[2]https://www.gs1.org/standards/edi-xml/xml-clinical-trials/3-5

operations and an improved customer experience for sponsors, clinicians and other partners in the clinical logistics ecosystem."

The emergence of complex global clinical studies, decentralized trials and direct-to-patient trials, combined with the increasing demand for personalized medicine, have fundamentally altered supply chain dynamics[3], which puts additional pressure on clinical trial sponsors to deliver these efficient, seamless clinical supply networks. Pairing this standardized approach to processes and systems with expert partners can offer more significant insights toward continuous improvement, further enhancing the benefits of standardization.

Increased visibility and enhanced decision-making

From clinicians and patients to supply chain partners and sponsors, running a successful study involves multiple players who work together to deliver the required objectives. The clinical logistics process may be a small fraction of the wider clinical trial process, but it is a vital cog in connecting researchers with the patients they want to benefit. End-to-end visibility and control are essential to ensuring a well-executed clinical logistics operation, including robust inventory management, risk mitigation and even opportunities to boost the sustainability of clinical operations through waste and emissions reductions. For example, standardized connected systems that provide end-to-end visibility and control can enable efficient network design that minimizes road transport and its associated CO_2 emissions. Data flow complexity increases without standardized systems and processes, hindering efficient decision-making.

One report shows that 74% of organizations believe in the high business impact of supply chain control towers and end-to-end performance management, but only 14% cite their ability to address this[4]. "A standardized approach to reporting, communication and control tower capabilities allows us to provide visibility to our customers wherever they operate," says Matt Whitman. "When running their clinical logistics operations, our customers rely on our ability to rapidly implement new depots and ensure the same level of visibility across the entire network."

Future-proof clinical supply networks

Standardized processes and systems are the foundation for future innovation, whether deploying new business models or implementing the latest technological advances. Having a centralized approach with a dedicated team with the right expertise and understanding of changing market trends can boost this ability to roll out these improvements quickly and in a compliant way. Some emerging digital technologies, including AI and IoT, are responding to existing process and system needs to handle increasingly complex data sets, facilitating real-time decision-making and enhancing visibility. "We're exploring a lot of exciting IoT applications for all sorts of shipment tracking, including temperature, humidity, and shocks, particularly of high-value products," explains Christina Jarvis. "These are very niche at the moment, but as the cost of these sensors decreases, they will become the standard."

"Process and IT standardization is also supporting another tier of clinical trial sponsors for whom these capabilities would not be commercially viable," adds Matt Whitman. "We're currently developing a solution that allows some of these start-ups and scale-ups performing cutting-edge research to leverage some of these capabilities, and it's all possible because of that standardized approach, which will allow them to 'plug and play' and scale when needed."

FOR FURTHER INFORMATION

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[3]https://www.pharma-iq.com/events-clinicaltrialsupply/blog/navigating-the-future-key-trends-shaping-the-clinical-trial-supply-industry-in-2024

[4]https://www.capgemini.com/insights/research-library/intelligent-supply-chain/