SUMMARY:

A Japan-based pharmaceutical and biotechnology company streamlined its clinical supply chain management process by centralizing and digitalizing inventory management functions using Signant SmartSignals GxP Inventory. The electronic platform facilitated the consolidation of supply production, quality assurance, logistics, and distribution activities into a single platform, resulting in reduced risks and improved efficiency across the clinical supply chain.

OVERVIEW:

As a specialized clinical development organization focused on four key therapeutic areas, the company depended on a network of internal business units, external vendors, and partners to produce and deliver medicines for its research and development initiatives.

They selected Signant Health's SmartSignals Supplies GxP Inventory system to enhance visibility and quality oversight of their supply chain. The cloud-based platform centralizes critical functions and enables traceability of clinical supplies from raw material sourcing and production to the delivery of finished kits worldwide.

CHALLENGES:

The company previously relied on numerous, disparate spreadsheets, paper-based batch records, as well as emails and file attachments within emails to track inventory globally across their portfolio of studies. The lack of centralized, real-time visibility into lot status, supply availability, and distribution activities resulted in inefficiencies and risks related to:

- Planning and forecasting material supply needs
- Tracking inventory across vendors and distribution centers
- Generating accurate lot genealogy records
- Overseeing batch releases
- Ensuring proper distribution of materials and preventing unauthorized shipments to certain countries
- Maintaining compliance with regulatory requirements

SOLUTION:

The sponsor selected Signant SmartSignals GxP Inventory to centralize, digitalize, and streamline their clinical supply inventory management process. The system, expertly tailored to the sponsor's needs, combined planning, production, and distribution functions into one application, eliminating the time-consuming process of recording and tracing lot genealogy across disconnected spreadsheets and emails.

Signant Health provided comprehensive implementation services without disrupting existing workstreams. Experienced project managers oversaw a five-point implementation plan, which involved development sponsor-side champions poised to provide on-the-ground support for their user community.

RESULTS:

The implementation of GxP Inventory revolutionized the company's clinical supply chain operations, providing them with an efficient solution that simplifies visibility into how and when material was made, who released it, where it is stored, and whether it is available to be ordered and picked/packed.

The GxP Inventory system proved to be a valuable investment, providing a reliable, compliant audit trail, more efficient inventory management, reduced costs and waste, simplified processes, and optimized supply chain operations to support their current and future inventory management needs.

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Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. For more information, please visit www.signanthealth.com.