The Tale of Two Clinical Supply Chains: The Risks of Fragmented Systems

Signant Health

In the world of clinical trials, where every decision can make or break a pharmaceutical company's future, supply chain management plays a critical role. To illustrate two methods of managing a clinical supply chain, let's follow Crystal, a fictitious Clinical Supplies Manager at BestPharm, as she navigates the complexities of managing pharmaceutical products in a fragmented, manual system versus a centralized inventory management system.

The Fragmented Approach

Crystal is tasked with managing the supply chain for a new oncology drug candidate, CP-4582. Her supply chain spans across the globe, from raw materials in China to finished patient kits in the U.S. But without a centralized inventory management system, Crystal relies on spreadsheets, emails, external inventory systems, and even paper batch records to keep track of everything. Each partner in the chain uses their own tools and processes, meaning data is scattered across multiple platforms, each with different update schedules and levels of detail.

When a genotoxic impurity is discovered in the drug substance, the stakes become even higher. Crystal needs to trace the contamination and recall affected batches, but the fragmented system forces her to contact each supply chain partner individually. She waits hours, sometimes days, for batch records to be collated, scanned, and sent back to her. As she painstakingly pieces together the supply chain information, the clock is ticking, and the risk to patient safety grows with every passing minute. The entire process could take up to 72 hours, jeopardizing BestPharm's license to operate and their commitment to patient safety.

The Centralized Solution

Now, imagine Crystal's scenario with a centralized inventory management system like Signant Health's GxP Inventory. In this version of the story, all supply chain data is stored in one place, easily accessible and up to date. When the contamination is discovered, Crystal doesn't have to scramble to reach out to different partners across time zones. Instead, she logs into the GxP Inventory system and generates a full lot genealogy report with the touch of a button.

The system instantly identifies the affected patient kits and batch numbers, allowing Crystal to direct her partners and clinical sites to quarantine the contaminated material. What once took days now takes less than five minutes. The risk to patient safety is minimized, and BestPharm's commitment to quality and safety is proven, not just to the FDA, but to everyone involved in the trial.

The Value of Centralization

The difference between these two scenarios is clear. Without a centralized inventory management system, the risks, inefficiencies, and uncertainties of a fragmented approach can lead to delays, increased costs, and even endanger patient safety. On the other hand, a centralized system like GxP Inventory saves time, reduces risks, and protects the significant research and development investments tied to clinical investigational products.

Without GxP Inventory	With GxP Inventory
▪ Contact all four drug supply chain partners across four different time zones to request batch tracking info ▪ Wait for partners to triage and process request, including collating and scanning paper batch records where needed ▪ Consolidate and cross-reference each partner's supply chain information to determine which patient kits might have been contaminated ▪ Prepare full lot genealogy report for CP-4582 Program	▪ Crystal logs into her single system of record for Supplies to generate the lot recall with full genealogy report at the touch of a button ▪ The lot recall report instantly returns patient kit IDs and batch numbers for affected drug substance so Crystal can direct partners and sites to quarantine the material and remove contaminated batches from the supply chain
APPROXIMATE TIME TO COMPLETE: **24–72 hours**	**APPROXIMATE TIME TO COMPLETE:** **<5 minutes**
Failure to comply could result in BestPharm's license to operate being revoked, and lack of visibility to contaminated kits increases the risk to patient safety.	**This doesn't just fulfill an FDA requirement, it proves and assures BestPharms commitment to patient safety.**

By centralizing and streamlining supply chain management, pharmaceutical companies can ensure better visibility, traceability, control, and efficiency, ultimately safeguarding their trials and their reputations. In the high-stakes world of clinical trials, where every minute counts, having a centralized solution isn't just a benefit—it's a necessity.

Learn more about how GXP Inventory improves visibility, traceability, efficiency, and compliance.

Interested in reading more blogs from The Signal?

SUBSCRIBE

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

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 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.