Consolidated Clinical Inventory Management

Manufacturing and managing supplies is one of the most challenging aspects of a clinical trial. Ensuring the right quantity of clinical trial supplies are available for study participants requires careful management of every step of the supply chain process, from drug substance starting materials, to API, to bulk drug product, to primary and secondary packed and labeled product, to global distribution.

GxP Inventory offers complete management of the end-to-end supply chain, providing full visibility of all inventory levels, including genealogy and quality release, within a single system.

Why choose GxP Inventory?

① Implement this cloud-based, SaaS solution cost-effectively without infrastructure investment.

② Eliminate time-consuming, manual processes and fragmented data sources using a single solution.

③ Easily manage rapid and accurate lot recall, when needed.

④ Conduct QA/QP release processes electronically at each inventory level.

⑤ Leverage industry-leading labeling software, fully interoperable with GxP Inventory.

⑥ Comprehensive interactive dashboard reports for complete end to end supply chain visibility

⑦ Meet the needs of any budget, protocol, or program with Essential, Essential+, or Enterprise version options.

Single solution oversight

GxP Inventory provides complete visibility within a single system, eliminating time consuming and error-prone processes associated with disparate data sources and manual tracking.

Transparent compliance

Fully documented quality assurance/qualified person (QA/QP) release processes, and fully 21 CFR Part 11 compliant history of all inventory transactions available in real-time.

Power of integration

GxP Inventory integrates with IRTs/ RTSMs, CMO external inventory systems for outsourced supplies, and reporting systems, enabling reliable processes and up-to-date data.

How is GxP Inventory different?

Unlike generic ERP solutions that try to cover all business processes across industries, GxP Inventory is purpose-built to address the unique complexities of investigational medicinal product management.

SIGNANT VS. COMMERCIAL ERP SYSTEMS

- Rapid implementation (months vs. years) with minimal IT infrastructure requirements
- Native handling of clinical protocol elements like cohorts, blinding, and randomization
- Real-time adjustments for protocol amendments and variable recruitment patterns
- Seamless integration with RTSM/IRT systems capturing patient activity
- Specialized user interface designed for clinical supply managers, not ERP experts

GxP Inventory Models

Flexible implementation models meet all sponsor requirements

ESSENTIAL

Get started right away with a pre-configured version containing the most frequently used elements for inventory production, management, and QA/QP release.

Suitable for use on a single trial, a single program, or more

Implementation timeline
3 months or less

ESSENTIAL+

A pre-configured solution that can integrate with your RTSM, CMO, and reporting systems to serve as a single system of record for manufacturing through distribution.

Suitable for use on multiple programs/trials

Implementation timeline
6 months or less

ENTERPRISE

Meet more individualized requirements such as sponsor-specific terminology/labels and additional workflow or process options with this robust, custom-configured version.

Suitable for use on single and multiple programs

Implementation timeline
10-12 months or less

Use additional modules to extend the utility of GxP Inventory, including:

- **GxP Batch Record** – Digital execution of all manufacturing and packaging batch records
- **Handheld GxP Inventory** – Enhanced warehouse stock management and picking using integrated barcode readers
- **Integration Interfaces** – Real-time data and process integration with RTSMs, CMOs, and other clinical trial systems

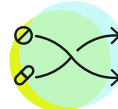# End-to-end clinical supply chain solutions

Unlock the full value of Signant SmartSignals Supplies and RTSM to improve end-to-end clinical supply production, management, and visibility.

Forecasting & Planning

GxP Inventory

RTSM

WHO IS SIGNANT HEALTH?

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**.