



Supply Chain Work Management for Compliance Exceptions - Pharmaceutical Manufacturers

**Integrate once, interoperate with all customers to
collaboratively resolve DSCSA exceptions**

With the final phase of U.S. Drug Supply Chain Security Act (DSCSA) regulations going into effect in November 2023, the transition to serialized transaction information exchange will significantly increase exception volume. The Healthcare Distribution Alliance (HDA) has outlined 24 types of exceptions—including product holds, data issues, damaged products, and many more—and pharmaceutical products cannot be sold until exceptions are resolved. Given the expected high volume, exceptions pose compliance and operational risks. Managing this process through portals, phone, and email communication is inefficient, results in slow resolution times, and makes it difficult to pass a compliance audit.

Supply Chain Work Management from TraceLink

TraceLink Supply Chain Work Management for Compliance Exceptions - Pharmaceutical Manufacturers enables pharmaceutical manufacturers to rapidly identify, onboard, and engage supply chain partners in a multienterprise process to intake, triage, and resolve both internal and external issues associated with compliance exceptions. The solution provides a single, centralized location to collaboratively resolve compliance exceptions and capture insights into the current and historical status of exceptions. The multienterprise task capability enables users to create custom cross-functional and cross-company sequences across subject matter experts to quickly resolve exceptions.

Key Capabilities

- Real-time dashboards provide managers and customers with visibility into exception priority, due date, and status, as well as reporting and historical data to ensure prompt resolution.
- Exceptions can be quickly created by manufacturers or their customers through the user interface, API, or email, and exceptions can be classified according to HDA guidelines.
- Configure internal triage processes to meet your unique needs with impact assessments, alerts, and deadlines.
- Multienterprise tasks enable cross-functional and cross-company resolution processes to be sequenced and assigned to subject matter experts based on exception type to ensure rapid response to the customer.
- Collaborate with customers to rapidly resolve exceptions in real-time on a secure, common platform with permissioned views.
- Communicate resolution details back to internal teams and customers so products can be released from quarantine.



WHAT IS SUPPLY CHAIN WORK MANAGEMENT?

TraceLink Supply Chain Work Management is a revolutionary new way to execute supply chain management processes by digitalizing work across multiple levels of supply chain partners. Supply Chain Work Management enables companies to create digital networks with partners to exchange business process information through secure, configurable links, and can connect to enterprise systems to accelerate cross-company sharing of supply chain data and collaboration.

Key Benefits

- **Integrate Once, Interoperate with Everyone™:** TraceLink customers can exchange exception information with all partners without maintaining separate connections to each, and TraceLink will onboard any partners not already on the network at no cost.
- **Scalability:** The TraceLink architecture is designed to scale to handle the large increase in data exchange required by the DSCSA 2023 EPCIS mandate across the pharmaceutical/healthcare supply chain and support collaborative reporting and resolution of exceptions.
- **Continuous Compliance:** TraceLink works with industry and government organizations including the HDA and the FDA to ensure Supply Chain Work Management is updated to reflect the latest standards. Additionally, Supply Chain Work Management can easily be customized to meet the unique exception resolution requirements of supply chain partner relationships.
- **Ensure Supply:** The TraceLink Opus network enables scalable integration of all partners with real-time collaborative capabilities to resolve exceptions quickly and ensure products do not get stuck in quarantine.

About the TraceLink Network

TraceLink Supply Chain Work Management for Compliance Exceptions - Pharmaceutical Manufacturers is built and hosted on TraceLink Opus, the world's largest supply chain network digitalization platform for pharma and life sciences. Opus enables organizations to seamlessly exchange serialization data and compliance information with trade partners across the supply chain. Key network metrics that serve as the foundation for a rapid onboarding and partner engagement experience for customers include:

290K+

authenticated and onboarded network members

7,300+

live CMO connections across more than 1,300 customers

930+

distribution and logistics customers and partners

919M+

regulatory documents processed and exchanged

41.1B+

serial numbers commissioned to date

14,937+

live serialization connections

\$4.7B+

in customer savings by avoiding point-to-point integrations

Contact TraceLink to learn more about resolving DSCSA exceptions with Supply Chain Work Management.