NEWSROOM



TraceLink Introduces Supply Chain Work Management for Compliance Exceptions to Accelerate Exception Resolution

New capability for Supply Chain Work Management enables seamless resolution of supply chain exceptions and ensures adherence to regulations like DSCSA.

Boston, Massachusetts (August 31, 2023) - TraceLink Inc., the leading digital network platform company enabling end-to-end product orchestration by connecting more than 290,000 healthcare and life sciences entities through its B2N Integrate-OnceTM network, today announced a new capability, Supply Chain Work Management for Compliance Exceptions. This groundbreaking capability addresses the urgent need for compliance with the U.S. Drug Supply Chain Security Act (DSCSA) regulation, which requires the collaborative resolution of exceptions between trading partners before the sale of products to subsequent trading partners.

Supply Chain Work Management for Compliance Exceptions by TraceLink offers an automated and efficient solution to manage, reconcile, and resolve compliance exceptions between trading partners. Drawing on the comprehensive guidance provided by the Healthcare Distribution Alliance (HDA) for DSCSA exception data capture, categorization, and tracking, TraceLink has developed this exception

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management capability to ensure compliance with federal laws, FDA regulations, and industry guidance while accelerating resolution time to keep products flowing through the supply chain. This capability is also available to assist with exception handling in other global markets.

To ensure this new capability launches with broad cross-industry representation, TraceLink has already signed 25+ Supply Chain Work Management for Compliance Exceptions customers now focused on collaborating with an initial target group of more than 700 critical supply partners. By adopting Supply Chain Work Management for Compliance Exceptions, supply chain partners can collaborate seamlessly, resolve issues promptly, and maintain continuity and efficiency in managing supply chain exceptions. With Supply Chain Work Management for Compliance Exceptions, supply chain members gain immediate access to:

- **A market-leading interoperable network** of more than 290,000 authenticated and pre-onboarded trading partners.
- **Standards and processes** to collaboratively identify and resolve exceptions in an agile manner.
- **Continuity and efficiency** for collaborating with trading partners in managing supply chain deviations in a centralized, partner-friendly way.
- **Electronic and automated** abilities for timely issue resolution, minimizing supply chain latency.
- **Integrate existing systems** encountering the exception and automate the creation of a given exception to streamline processes.
- **Continuous compliance** with federal laws, FDA regulations, and industry guidance through maintenance of documents, data requirements, and business practices consistent with regulatory frameworks.

"Compliance exception management represents a key capability within our comprehensive compliance toolkit," said Shabbir Dahod, CEO and President of TraceLink. "We recognize the critical importance of DSCSA compliance and the challenges faced by trading partners in resolving exceptions effectively. Our new

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capability equips supply chain stakeholders with the tools they need to address exceptions collaboratively, ensuring product integrity and patient safety."

TraceLink recognizes how important it is to quickly and reliably resolve exceptions related to DSCSA, a key element at the heart of why the FDA recently called for a 12-month stabilization period for DSCSA compliance. TraceLink has invested heavily into new capabilities to arm trade partners with the tools they need to collaboratively address such exceptions. Key features of the new compliance exception management capability within the TraceLink Supply Chain Work Management solution suite include the ability for application owners and supply chain partners to:

- Create a compliance exception.
- Submit an exception to a supply chain partner or against an internal site.
- Add detailed information about the affected product, including Lot Number, Expiration Date, and a list of impacted Serial Numbers.
- Include a comprehensive list of external transactions associated with the exception.
- Associate entities such as Shipped From, Shipped To, and others with the exception.
- Attach relevant files to the exception for comprehensive documentation.
- Facilitate collaboration among users through comments and communication within the platform.
- Facilitate the update of original compliance documentation based on the results of the exception management process.

With the introduction of Supply Chain Work Management for Compliance Exceptions, TraceLink continues to lead the way in compliance and digital supply chain innovation, empowering life sciences and healthcare companies to navigate complex regulatory landscapes efficiently while ensuring product integrity and patient safety.

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For more information about TraceLink and the Supply Chain Work Management solution, visit **https://www.tracelink.com/products/supply-network-orchestration/supply-chain-work-management.**

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