NEWSROOM

TraceLink Earns ISO/IEC 42001:2023 Certification for Responsible AI Governance



Certification validates TraceLink's AI governance and oversight as companies scale Agentic Business Processes and agent-enabled supply chain work with security, control, and compliance on the Integrate-Once™ Agentic Business Network.

Summary

The ISO/IEC 42001:2023 certification validates TraceLink's approach to responsible AI governance, giving customers greater assurance in the transparency, accountability, oversight, and trusted execution controls required to support agentic work across regulated life sciences and healthcare supply chains. The certification supports TraceLink's broader vision of enabling Agentic Business Processes where human teams and governed OPUS Agents perform work together using real-time business transactions, operational context, and defined execution controls.

BOSTON, Mass. — June 18, 2026 —TraceLink, the world's largest Agentic Business Network for the life sciences and healthcare supply chain, today announced it has achieved ISO/IEC 42001:2023 certification, the leading international standard for Artificial Intelligence Management Systems (AIMS). The certification validates TraceLink's governance framework for responsible AI and

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governed OPUS Agents. It was awarded following an independent assessment conducted by A-LIGN, which resulted in no nonconformances or opportunities for improvement identified during the audit process.

Achieving certification reflects TraceLink's commitment to disciplined AI governance as life sciences and healthcare companies move from AI experimentation to governed agentic work. By establishing these practices early, TraceLink is helping customers adopt AI innovations with greater confidence, control, and readiness as they move toward an **Agentic Supply Chain Operating Model** where human teams and governed **OPUS Agents** work together across the linked digital twin of their supply network.

> “As one of the early organizations to pursue this standard, TraceLink is taking a proactive approach to establishing the trusted foundation needed to support AI innovation,” said Shabbir Dahod, President and CEO of TraceLink. “The transformation to an Agentic Supply Chain Operating Model depends on AI that can operate within defined business, operational, and compliance guardrails. This audit reinforces the governance, accountability, and trust required for human teams and OPUS Agents to perform operational work together across the supply network.”

A New Era of Governed Agentic Work

Published in 2023, ISO/IEC 42001:2023 is the world's first international standard for Artificial Intelligence Management Systems. The standard provides organizations with a framework for governing AI responsibly, helping ensure appropriate oversight, risk management, and human accountability.

For TraceLink customers, the certification provides additional assurance that responsible AI governance is embedded across the **OPUS Platform** and extends to the development and deployment of OPUS Agents. This disciplined approach is

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designed to support:

- Defined roles, responsibilities, and accountability
- Risk identification and mitigation
- Transparency and auditability
- Human oversight and decision-making authority
- Continuous monitoring and improvement

For customers digitalizing transactions and preparing for agent-enabled supply chain operations, these governance controls provide confidence that OPUS Agents can operate within defined business policies, escalation procedures, approval workflows, and compliance requirements while maintaining human accountability.

> "Achieving ISO/IEC 42001 certification underscores our commitment to building and delivering AI-enabled software and services with responsible governance, security, and transparency at the core," said Dan Nelson, Chief Information Security Officer at TraceLink. "As AI becomes increasingly embedded in business operations, customers and partners need confidence that these systems are governed with strong controls, clear accountability, and a risk-based approach. This certification reinforces our dedication to maintaining trust while enabling safe innovation across our service offerings."

As organizations begin deploying AI agents into operational supply chain processes, governance becomes increasingly important. Unlike traditional enterprise AI applications that operate within a single system, agent-enabled supply chain operations require coordination across companies, trading partners, business transactions, and regulated processes. Organizations need confidence that AI systems can operate within defined permissions, policies, and oversight frameworks while maintaining accountability and auditability. This need is particularly important in life sciences and healthcare supply chains, where product

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quality, compliance, patient safety, and business continuity depend on trusted execution across multiple organizations.

The Agentic Supply Chain Operating Model

As organizations move from AI experimentation to operational deployment, they need assurance that governed OPUS Agents can operate within defined business, operational, and compliance boundaries. TraceLink's ISO/IEC 42001:2023 certification reinforces the disciplined approach the company takes to govern AI practices and OPUS Agent development, with the oversight and control required for regulated life sciences and healthcare supply chains.

Built on the OPUS Platform, OPUS Agents are governed digital teammates that perform specialized work as permissioned users across Agentic Business Processes using real-time business transactions, operational context, and defined roles, permissions, and controls. OPUS Agents help organizations improve productivity, accelerate decision-making, and scale operations across commercial, manufacturing, quality, and logistics processes while maintaining visibility and compliance.

> "Congratulations to TraceLink for earning their ISO/IEC 42001 certification, which is a widely recognized signal of trust and security," said Steve Simmons, COO of A-LIGN. "It's great to work with organizations like TraceLink who understand the value of expertise in driving an efficient audit and the importance of a high-quality final report."

Discover how TraceLink is building the foundation for governed, agentic work across life sciences and healthcare supply chains.

About TraceLink

TraceLink powers the transformation to an Agentic Supply Chain Operating Model

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for life sciences and healthcare by combining human expertise with agentic work across the end-to-end supply network.

Through Agentic Business Processes, Agentic Control Towers, the Integrate-Once™ Agentic Business Network, and governed OPUS Agents, TraceLink helps companies improve productivity, service, inventory, working capital, cost, compliance, quality, resilience, and revenue performance.

Powered by the OPUS Platform and the world's largest Agentic Business Network, which links more than 315,000 authenticated business entities and hundreds of billions of annual supply chain transactions, TraceLink enables companies to digitalize business transactions, create trusted operational context, and perform work across multienterprise supply chain processes with greater speed, intelligence, control, and accountability.

Learn more at www.tracelink.com.

About A-LIGN

A-LIGN is the leading provider of high-quality, efficient cybersecurity compliance programs. Combining experienced auditors and audit management technology, A-LIGN provides the widest breadth and depth of services including SOC 2, ISO 27001, HITRUST, FedRAMP, and PCI. A-LIGN is the number one issuer of SOC 2 and a leading HITRUST and FedRAMP assessor. To learn more, visit a-lign.com.

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TraceLink Wins ISM Supply Chain Trailblazer Award for OPUS, Advancing Real-Time Multienterprise Supply Chain Execution

TraceLink has been named a winner of the Institute for Supply Management Supply Chain Trailblazer Award in the Advanced Technology Digital Impact category for OPUS, the Orchestration Platform for Universal Solutions. OPUS helps life sciences and healthcare companies digitalize supply chain execution across trading partners, processes, and real-time business transactions—reducing manual work, improving responsiveness, and creating the required agentic business network foundation for more intelligent, agent-enabled operations.
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CHEPLAPHARM to Accelerate Global Supply Chain Digitalization with TraceLink MINT

TraceLink today announced that the German-based but globally active CHEPLAPHARM Group, a world leader in the acquisition of original preparations from the research-based pharmaceutical industry, is going live on the TraceLink network with Multienterprise Information Network Tower (MINT), powered by Orchestration Platform for Universal Solutions (OPUS).

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TraceLink Wins 2026 Globee® Cybersecurity Award as OPUS Sets the Standard for Secure, Agentic Supply Chain Operations

TraceLink has been named a winner in the 2026 Globee® Awards for Cybersecurity, recognizing the company's leadership in securing complex, multienterprise supply chain operations. TraceLink's Orchestration Platform for Universal Solutions (OPUS) is a GxP-aligned, industrial-grade foundation for the Agentic Business Network—securing third-party interactions, serialized data, and mission-critical transactions to enable trusted, real-time execution across global supply chains.

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