

The Center for Supply Chain Studies Launches DSCSA Tracing Pilot to Drive Pharmaceutical Supply Chain Interoperability

The new pilot offers hands-on experience for DSCSA tracing stakeholders to rehearse and deliver interoperability

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/EINPresswire.com/ -- The Center for Supply Chain Studies (C4SCS) is proud

to announce the commencement of its DSCSA Tracing Pilot and Exploration Sandboxes. As part of this initiative, pharmaceutical manufacturers, wholesalers, hospitals, retail pharmacies, and solution providers have new tools to achieve enhanced drug distribution security as mandated by the U.S. Drug Supply Chain Security Act (DSCSA).



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Robert Celeste, founder of C4SCS

Building on the Partnership for DSCSA Governance (PDG) Foundational Blueprint for 2023, the DSCSA Tracing Pilot introduces an architecture and functional design that incorporates data specifications developed and advanced by a range of stakeholders and working groups – including GS1, the Healthcare Distribution Alliance (HDA), PDG, and the Open Credentialing Initiative (OCI).

The pilot will enable stakeholders to gain hands-on experience with DSCSA tracing within a simulated supply

chain, using C4SCS's state-of-the-art tools and data. Participants will have the unique opportunity to optimize their own tracing and verification processes while collaborating with industry peers to foster interoperability.

"As a neutral nonprofit organization, C4SCS has been at the forefront of collaborating with the industry and regulators to advance DSCSA interoperability since 2015," said Robert Celeste, founder of C4SCS. "We are excited to offer industry stakeholders the opportunity to workshop DSCSA tracing at such a critical time for the healthcare supply chain."

The DSCSA Exploration Sandboxes encompass a variety of simulations covering different supply chain configurations, actors, and exceptions. These sandboxes simulate DSCSA contexts and allow participants to interact with product exchanges, data, and various DSCSA-related processes, such as verifying products, tracing products, and filing Form FDA 3911 (Drug Notification) in support of suspect & illegitimate product investigations.

Participants will also be able to simulate credentialed interactions based on OCI's DSCSA Interoperability Specification, which includes credentials for Authorized Trading Partners (ATPs), ATP Equivalents (e.g. Veterans Administration, DoD, etc.), and Authorities (e.g. FDA, state boards of pharmacy, DEA, etc.) as defined in the statute, FDA guidances, and the PDG Blueprint.

Key features of the DSCSA Tracing Pilot and Exploration Sandboxes include:

- Realistic Simulations: Participants can explore datasets representing product exchanges, TI/TS data, current physical inventory, and system alerts that may trigger an investigation.
- Collaboration and Optimization: Stakeholders can collaborate with other participants, optimizing their tracing and verification processes and analyzing the effectiveness of their methods through reports, dashboards, and visualizations.
- Post-2023 Stabilization Period: The sandboxes also support simulations for the post-2023 stabilization period as TI records transition from lot-based to serialized, providing valuable insights into transition inventory supply chain scenarios.
- Private Sandboxes: Organizations have the option to create private versions of the sandboxes for internal team exploration, training, and education.

To participate in the DSCSA Tracing Pilot or explore the DSCSA Exploration Sandboxes, please see <https://www.c4scs.org>.

About the Center for Supply Chain Studies (C4SCS):

The Center for Supply Chain Studies is a neutral nonprofit organization that has been actively collaborating with the Pharmaceutical Supply Chain Industry and Regulators since 2015. Dedicated to fostering interoperable solutions to the DSCSA challenge, C4SCS provides a platform for team exploration and collaboration, sharing insights on compliance issues, emerging technologies, and trends within the healthcare industry.

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