



January 1, 2026

To: Global Pharmaceutical Industry Stakeholders  
Subject: Position Statement on Rx-360 Joint Audit Program Alignment with the  
U.S. FDA Drug Supply Chain Security Act

Dear Colleagues,

Rx-360 is committed to safeguarding the global pharmaceutical supply chain and protecting patient safety. As part of this commitment, our Joint Audit Program® has been intentionally designed and continuously updated to meet or exceed regulatory expectations, including those mandated by the U.S. Drug Supply Chain Security Act (DSCSA).

#### 1. DSCSA Requirements Embedded in Audit Scope

- The DSCSA mandates that trading partners must:
- Engage only with Authorized Trading Partners (ATPs): Audits require documented verification of valid federal or state licensure and registration status for all trading partners.
- Maintain robust product tracing systems: Audits assess whether distributors capture, store, and share Transaction Information (TI), Transaction History (TH), and Transaction Statement (TS) at each point of sale or transfer.
- Handle suspect or illegitimate products properly: The JAP includes review of Standard Operating Procedures (SOPs) and execution protocols—evaluate the ability to identify, quarantine, investigate, and report suspect or fraudulent drug products in compliance with DSCSA.

#### 2. Consortium-Developed Tools Ensuring Alignment

- Rx-360 employs GDP checklists and audit frameworks created and maintained by our global consortium of industry professionals. These tools are continuously refined to integrate evolving regulatory standards, including DSCSA-specific mandates. Key enhancements address:
- Validated licensure and registration checks for trading partners
- Traceability data verification through physical inspection of records and systems
- Reviews of serialization and data security controls in alignment with electronic TI/TH sharing

#### 3. Audits Identify and Drive Remediation of DSCSA Nonconformance

- Our audit process not only assesses compliance but drives corrective action:
- Detailed audit reports highlight DSCSA-related deficiencies and risks.
- Corrective and Preventive Action (CAPA) management is overseen by Rx-360—ensuring that DSCSA nonconformances are tracked, resolved, and re-verified.
- The program's design ensures that sponsors receive timely updates on CAPA status and are informed of unresolved DSCSA issues.

#### 4. Ongoing Commitment to DSCSA Preparedness

- Rx-360 regularly engages with industry forums, conferences, and regulatory working groups to share best practices, guidance, and tools that support DSCSA interoperability and execution. Our audit scope is continually refreshed to address:
- System integration and validation for data exchange
- Business process adaptations to support DSCSA requirements
- Personnel training and retention of records in accordance with DSCSA timelines

#### Conclusion:

Rx-360 affirms that its Joint Audit Program fully incorporates all DSCSA-mandated elements into its audit framework; effectively identifies any nonconformances from DSCSA requirements through structured audit checklists and evidence-based scrutiny; and drives corrective action using our CAPA process to address nonconformances swiftly and transparently. For more information, email [info@rx-360.org](mailto:info@rx-360.org).

Thank you for trusting in Rx-360,

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