



ATP Confirmation and You: Action Plan for Compliance



Today's Agenda & Speakers

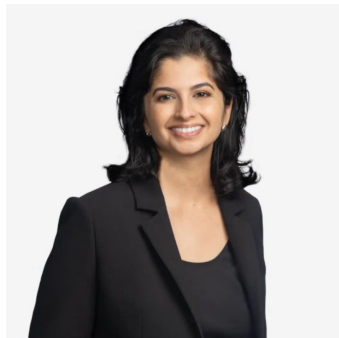


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- DSCSA Requirements
- Dispenser Warning Letter
- Authorized Trading Partners (ATPs)
- DSCSA Credentials & ATP Confirmation
- “Evidence of Review”
- Action Plan + Q&A



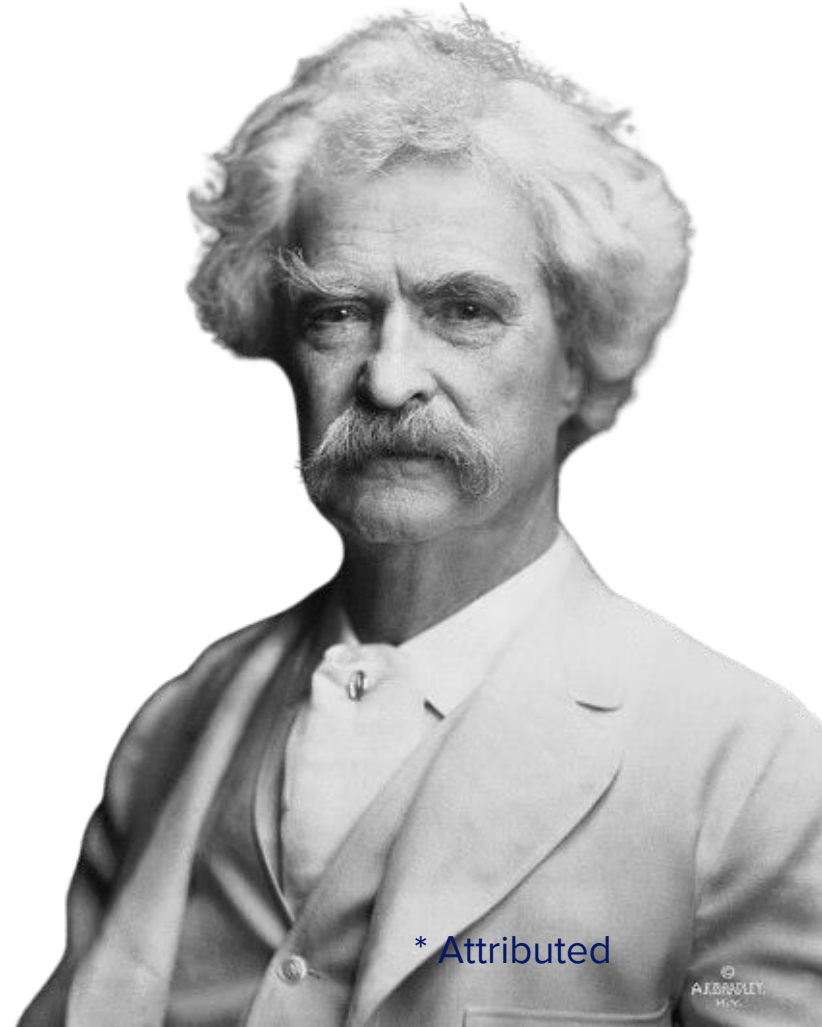
Abha Kundi is an attorney, but she is not your attorney! For advice specific to your organization, please consult your own legal counsel or contact Abha to discuss a formal engagement.



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*“It ain’t what you don’t know
that gets you into trouble.*

***It’s what you know for sure
that just ain’t so.”***



* Attributed

DSCSA Regulatory Requirements

Rolling deadlines for supply chain through Nov. 2026

Domain	Requirements	Statutes
Authorized Trading Partners (ATPs)	Authorized trading partners must hold valid licenses, comply with applicable licensure reporting requirements, and only engage in transactions (and certain interactions) with other authorized entities.	§581(2)(A), §582(a)(3), see also verification and tracing sections
Data Exchange	Securely, electronically, and interoperably exchange transaction information and statements, including unique identifiers for each package.	§582(d)(1)(A), §582(g)(1)
Product Verification	Be able to verify the product identifier in the event of saleable return processing, suspect & illegitimate product investigations, or other circumstances.	§582(b)(4)
Tracing & Investigations	Promptly investigate suspect products, verify their authenticity, notify the FDA and immediate trading partners as applicable, and request traceability information from trading partners as applicable. Be ready to respond to tracing requests from any ATP or federal/state regulator while preserving confidential commercial information and trade secrets.	582(b)(4), §582(g)
Data Retention	Maintain records of transaction information, history, statements, and suspect product investigations for at least six years.	582(d)(1)(A)(iii), 582(d)(4)



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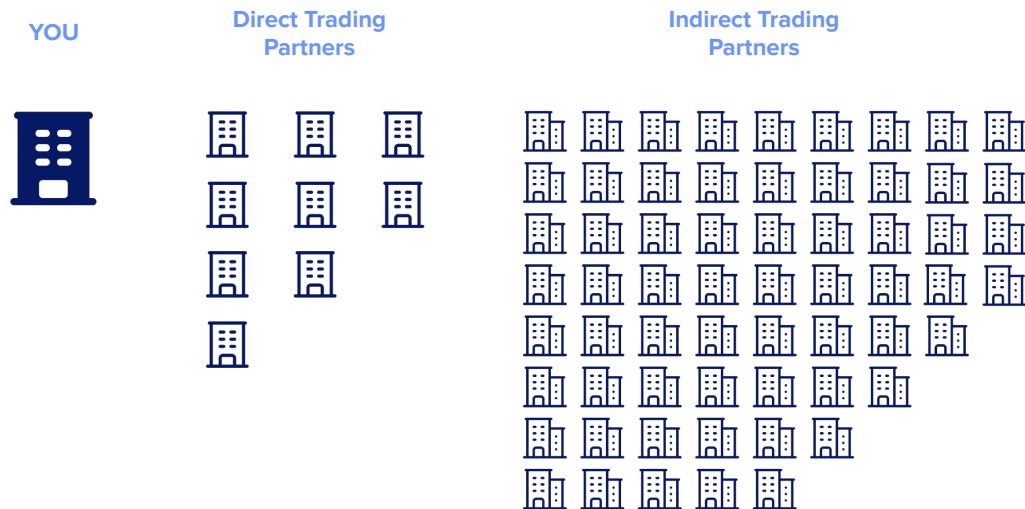


GUIDANCES



Authorized Trading Partner (ATP) Confirmation

Foundational prerequisite, now underpinning “all electronic” systems



- Mandatory for direct trading partner transactions
- Critical for tracing & investigations (“confidentiality”)
- Best practice for verification, required by some manufacturers

OCI-compliant ATP Credentials the only PDG-recognized method to prove ATP status over interoperable networks

Case Study: FDA's First DSCSA 483 for a Dispenser



The screenshot shows a legal article from ArentFox Schiff. The title is "A Wrinkle in the Supply Chain: FDA's First DSCSA 483 for a Dispenser". The article is dated January 10, 2023, and is authored by Aaron Kohn. The article discusses the FDA's inspection of Pure Indulgence Aesthetics, a dispenser of prescription drugs in Southlake, Texas. The FDA issued a Form FDA 483 on December 16, 2022, citing violations of the Drug Supply Chain Security Act (DSCSA). The article highlights the FDA's findings on the dispenser's failure to conduct business only with authorized trading partners, its failure to engage only in transactions involving product with a product identifier, and its failure to maintain accurate records of product purchases, dispensing, and product data. The article also discusses the FDA's enforcement of the DSCSA's interoperable electronic tracing requirements and the importance of the product identifier in ensuring the safety and security of the drug supply chain.

A Wrinkle in the Supply Chain: FDA's First DSCSA 483 for a Dispenser

January 10, 2023 | [AARON KOHN](#) | [Share This Page](#) | [PRINT](#) | [LINKEDIN](#) | [FACEBOOK](#)

The US Food and Drug Administration (FDA) issued an inspectional observation (Form FDA 483) to a Texas med spa, Pure Indulgence Aesthetics, citing Drug Supply Chain Security Act (DSCSA) violations for dispensers.

Listen to this article now
Presented by Timothy Austin
0:00 00:01

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What Happened and Why It Matters

The FDA inspected Pure Indulgence Aesthetics, a dispenser of prescription drugs in Southlake, Texas, on multiple dates between December 1 and December 16, 2022. The product at issue was Botox (onabotulinumtoxinA) manufactured by Allergan and distributed in the United States by its subsidiary, Allergan Aesthetics. The 483 reflects our observations under section 510(d) of the Federal Food, Drug, and Cosmetic Act. First, the FDA concluded the firm failed to conduct business only with authorized trading partners. Second, the FDA concluded the firm failed to engage only in transactions involving product with a product identifier. While a 483 is not a final agency determination, it is a strong signal of the FDA's compliance focus and the evidence it prepared to marshal.

This 483 is significant because it extends the DSCSA's inspectional lens to dispensers in a way concrete ways. DSCSA compliance conversations at the dispenser level have often focused on the "enhance" interoperable electronic tracing requirements. The FDA's observations make clear that baseline obligations – especially the authorized trading partner requirement and ensuring only to product that bears a product identifier – remain fully in force and are far from inspection and enforcement. Stated plainly, dispensers cannot wait for interoperability to be perfect before meeting the foundational DSCSA duties that the FDA has now demonstrated it will check.

It also matters because the evidence shows how the FDA can leverage data sources that are already abundant in clinical and retail settings. In this case, the agency compared manufacturer shipment records with dispenser treatment records, evaluated lot-level documentation, and even corroborated findings through physical evidence and laboratory analysis. That model is scalable and transferable to many dispenser environments, from med spas to clinics and pharmacies.

- FDA cited a Texas med spa for **failing to transact only with ATPs** and for using product (Botox) lacking a required product identifier
- **FDA cross-checked** manufacturer shipments, purchase records, treatment logs, lot documentation, and physical evidence
- **Pharmacies should:**
 - **Tighten supplier controls**
 - **Strengthen product traceability**
 - **Be ready for data-driven enforcement**

Baseline obligations including ATP confirmation are enforceable now; be ready with proof of review!

ATP Confirmation and You

- Checking state and federal licensure should be performed **at least annually**
- **“Owner” HQ vs. “ship-to/from”** both important
- Locations often shift over time
- “Specific patient need” **exempts data but not ATP checks**
- Checks can’t be performed in a vacuum; you need **evidence of review**
- **Is your spreadsheet dusty?**

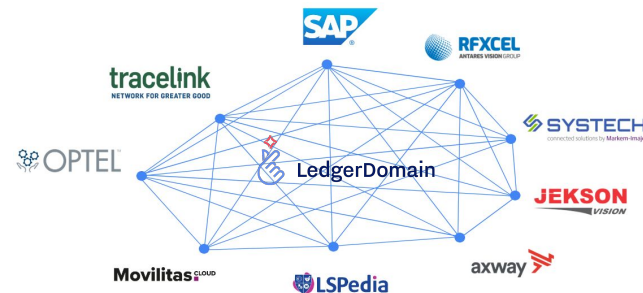


Today's Credentialed Pharma Supply Chain

Digital credentials now support leading drug companies, wholesalers, pharmacy chains, health systems, and regulatory authorities to confidently exchange verifiable data across multiple networks



Indiana University Health



Credential ecosystem now covers top pharma through to 13,000 pharmacies and more every day... supporting authoritative, automatically synced master data



DSCSA Checklist & Gaps



Authorized Trading Partners

ATP Credential for Identity

PDG and OCI-compliant credential for “digital passport”



ATP Confirmation & License Check

Check ATP and licensure status for all your trading partners



Address Book & Audit Log

Track and log licensure and ATP status (including contact information) plus interactions



Serialized Data Exchange

EPCIS Receipt & Storage

Capture shipping events and transactional source data including transaction information & transaction statement



EPCIS Validation & Exceptions

Check the EPCIS file against PO data and flag data discrepancies



Verification

VRS Request/Response

Submit verification requests over the Verification Router Service (VRS), a network that provides instantaneous responses



Verification Beyond VRS

Manage and manually resolve verification tickets that do not get resolved by the VRS



Tracing & Investigations

Trace Request & Response

Send and manage trace requests and responses between and ATPs; track investigation lifecycle



Trace Data Retrieval

Retrieve track & trace data from EPCIS repository



FDA Form 3911 + Investigation

File and track suspect & illegitimate product reports with FDA and trading partners.



How Do We Demonstrate Our Compliance?

The screenshot displays the 'Address Book' interface. On the left is a sidebar with navigation links: My Credentials, Address Book (selected), DSCSA Control Tower, Verify Presentation, VRS Responses, VRS Integrations, Portal Tickets, Trace Tickets, and Account Management. The main header includes a logo, the title 'Address Book', and buttons for '+ Add Entry' and 'Send Message'. Below the header are tabs for 'Contacts', 'Organizations' (selected), 'Locations', and 'Licenses'. A search bar and a 'Filters' button are present. The main content is a table with columns: NAME, TYPE, ADDRESS, and STATUS. The table lists 18 organizations, including Accredo, Akorn Operating Company LLC, Alexion Pharmaceuticals Inc, Alkermes Inc, Allergan USA Inc, Allina Health, Amgen Inc, Amicus Therapeutics Inc, ANDA Inc, ASD Healthcare LLC, Astera Health, Avera Health, and Baxter Healthcare Corporation. The status for each entry is either 'Active' (green shield icon) or 'Not Verified' (red shield icon).

NAME	TYPE	ADDRESS	STATUS
Accredo	Dispenser	1620 Century Center Parkway, Suite 109, Memphis, TN 38134 US	Active
Akorn Operating Company LLC	Manufacturer	1925 W Field Ct, Lake Forest, IL 60045 US	Not Verified
Alexion Pharmaceuticals Inc	Manufacturer	121 Seaport Blvd, Boston, MA 02210 US	Active
Alkermes Inc	Manufacturer	852 Winter St, Waltham, MA 02451 US	Active
Allergan USA Inc	Manufacturer	5 Giralda Farms, Madison, NJ 07940 US	Active
Allina Health	Dispenser	2925 Chicago Avenue, Minneapolis, MN 55407 US	Active
Amgen Inc	Manufacturer	One Amgen Center Dr, Thousand Oaks, CA 91320 US	Active
Amicus Therapeutics Inc	Manufacturer	47 Hullfish St, Princeton, NJ 08542 US	Not Verified
ANDA Inc	Wholesaler	47639 Lakeview Blvd, Fremont, CA 94538 US	Active
ASD Healthcare LLC	Wholesaler	112 N Curry St, Carrollton, TX 75006 US	Active
Astera Health	Dispenser	421 11th St. NW, Wadena, MN 56482 US	Active
Avera Health	Dispenser	3900 West Avera Drive, Sioux Falls, SD 57108 US	Active
Baxter Healthcare Corporation	Manufacturer	1 Baxter Pkwy, Deerfield, IL 60015 US	Active

Log out

How Do We Demonstrate Our Compliance?

Address Book

Contacts Organizations Locations Licenses

+ Add Entry Send Message

My Credentials

Contacts

- First Name
- Last Name
- Email Address
- Secondary Email(s)
- Phone
- Contact Type
- *Custom Fields*

Organizations

- Legal Name
- Organization Address
- Organization Type
 - DBA
 - Entity GLN
 - DUNS Number
 - *Custom Fields*

Locations

- Name
- Address
- Primary GLN
- Additional GLNs
- DEA Number
- WAC vs. 340B
- *Custom Fields*

Licenses

- Licensing Gov't
- License Type
- License / FEI Number
- *Custom Fields*

Organization	Location	Status
1071 Curry St, Danbury, CT 06810 US	Active	
421 10th St, NW, Wadena, MN 56482 US	Active	
3900 West Avera Drive, Sioux Falls, SD 57108 US	Active	
1 Baxter Plaza, Deerfield, IL 60015 US	Active	

Feb-10-2027 (Wed) 11:38:16 am

Darren Nathan

+ Add Contact

+ Add Location

2026 Action Plan & Q&A



- For all but the smallest trading partners, key requirements of the DSCSA are already in place
- Compliance means having a complete set of policies, following them faithfully, and building a documentation trail
- **Credentials close the gaps and the Address Book makes auditable ATP confirmation quick, easy, and sustainable**
- **Getting a credential often takes less than 15 minutes and serves as your passport to the enhanced drug distribution security network**



For more information, look us up at HDA!

