
LedgerDomain
DSCSA Exemptions and You!
October 31, 2024

Today's Agenda & Speakers

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- Introduction
- DSCSA Update with Tish Pahl
- FDA Exemptions & You
- ATP Credentialing
- Tracing
- Verification
- ATP Confirmation
- Action Plan + Q&A ☕

What are the blind spots today, and what can you do?

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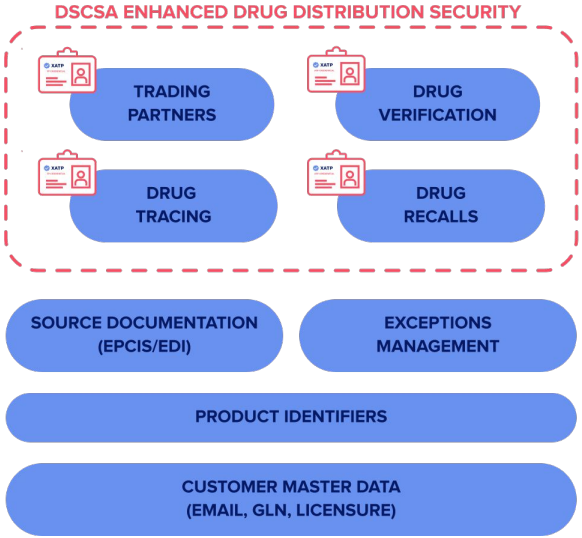
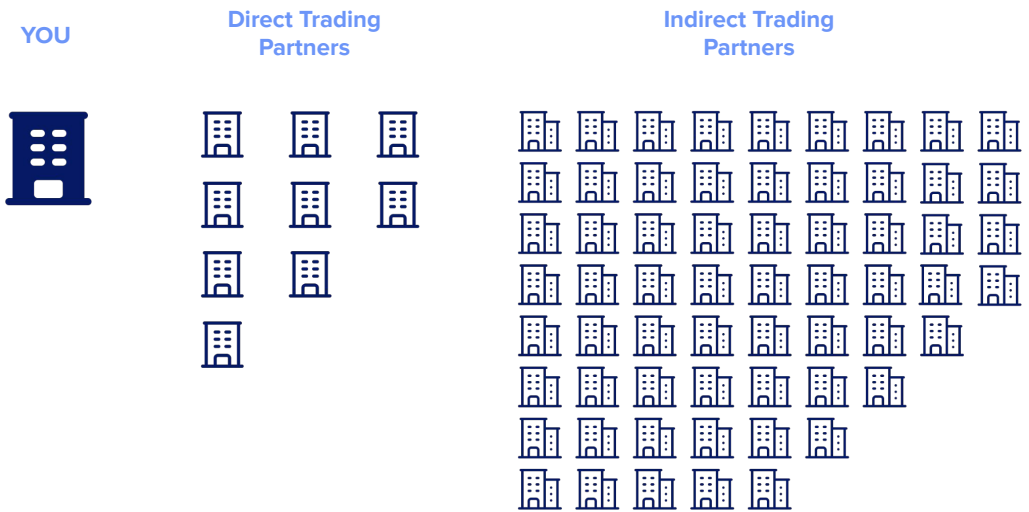
Federal DSCSA Law Calls for Electronic Interoperability

November 27, 2023 deadline, 1-year “stabilization” and now into overtime





DSCSA unique today – requires real-time, indirect partner communication
>200,000 sites, >30,000 entities, no centralized authority

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Enforcement & Inspections Ramping Up

Your written procedure [redacted] *Special Procedures for Drug Supply Chain Security Compliance*, effective date: [redacted], is inadequate because it lacks systems and processes for:

(a) responding to requests for verification of product identifiers from FDA or authorized trading partners;

(b) responding to notifications of illegitimate product from FDA and immediate trading partners; and

(c) identifying suspect product. While the SOP recognizes that returned product may be suspect product, it does not sufficiently detail specific systems and processes for identifying suspect product and it does not acknowledge that suspect product in the firm's possession or control is not limited to returned products.

PHARMA

After Gilead and J&J lawsuits, distributor Safe Chain sees its owners charged in criminal indictment

By Zoey Becker · Jul 1, 2024 5:06pm

Gilead Sciences | Biktarvy | Johnson & Johnson | counterfeit drugs

OBSERVATION 1
Your firm failed to have systems in pla
DSCSA.

Specifically,

(A) Your written procedure, SOP-[redacted] "Notification to the FDA of an illegitimate or suspect illegitimate product," effective [redacted], is inadequate in that it fails to describe systems and processes for (1) identifying suspect product; (2) conducting investigations of suspect product in coordination with trading partners, which must include validating any applicable transaction history and transaction information in your possession; (3) notifying the Food and Drug Administration (FDA) that suspect product is not illegitimate, when applicable; and (4) otherwise investigating to determine whether a product is an illegitimate product.

(B) Your written procedure, [redacted] titled "Receipt of Finished Drug Product," effective [redacted], states in part "Report to the Inbound Import Manager if any questionable, suspicious, misbranded, counterfeited, suspected of being counterfeit, adulterated, or otherwise unfit for human use. QA shall immediately report to the appropriate State Board of Pharmacy and FDA within [redacted]." The Drug Supply Chain Security Act requires that trading partners notify FDA and immediate trading partners within 24 hours after determining a product in a trading partner's possession or control is an illegitimate product. Additionally, the statute requires manufacturers to notify FDA and immediate trading partners within 24 hours after determining a product is at high risk for illegitimacy.

(C) Your written procedure, SOP-[redacted], titled "Notification to the FDA of an illegitimate or suspect illegitimate product," effective [redacted], is inadequate in that it fails to describe systems and processes to notify FDA and immediate trading partners within 24 hours after determining a product is at high risk for illegitimacy, and terminate notifications that are no longer necessary.

(D) Your firm, upon receiving a notification of illegitimate product from FDA or a trading partner, does not have systems and processes in place to identify and investigate illegitimate product subject to the notification that is in your firm's possession or control.

(E) Your firm does not have written systems and processes for responding to requests for verification of the product identifier from FDA or an authorized trading partner in possession or control of a product they believe to be manufactured by your firm.

- On [redacted] your management identified SOP [redacted] as (1) defining your firm's procedures for identification of suspect products, (2) quarantine of suspect products (both physically and electronically), (3) identification of suspect products, (4) investigation of suspect products, (5) notification of trading partners if suspect products are determined not to be illegitimate, (6) quarantine of illegitimate products, (7) terminating notifications of illegitimate product and notifications of product with high risk of illegitimacy, (8) promptly notifying immediate trading partners of a terminated notification, (9) responding to requests for verification of suspect or illegitimate product from FDA or an authorized trading partner within 24 hours, and (10) responding to notifications of illegitimate product from FDA or a trading partner.
- On [redacted] your management identified SOP [redacted] as (1) defining your firm's procedures for identification of suspect products, (2) quarantine of suspect products (both physically and electronically), (3) investigation of suspect products, (4) making notifications of illegitimate product within 24 hours of a determination of illegitimate product or product with high risk of illegitimacy to FDA and immediate trading partners, (5) retaining samples of illegitimate product, (6) disposition of illegitimate product and assisting trading partners in dispositioning illegitimate product, (7) terminating notifications of illegitimate product and notifications of product with high risk of illegitimacy, and (8) promptly notifying immediate trading partners of a terminated notification.
- On [redacted] your management identified SOP [redacted] as defining your firm's procedures for
- On [redacted] your management identified SOP [redacted] defining your firm's procedures for physical quarant
- On [redacted] your management identified SOP [redacted] as defining your firm's procedures for recordkeeping relating to investigation of suspect products and disposition of illegitimate products.

Review of these documents revealed that the procedures within them are insufficient and in certain cases inconsistent with the DSCSA 582(b) verification requirements.

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DSCSA – What and Who

- Drug Supply Chain Security Act enacted November 27, 2013.
  - ***Most requirements are in effect now***.
- The DSCSA applies to:
  - ***Trading partners***.
    - Manufacturers and repackagers.
    - Wholesale distributors and 3PLs.
    - Dispensers (pharmacies, hospitals, clinics, health systems, and individual healthcare practitioners).
  - ***Products***.
  - ***Transactions*** of products between trading partners.

ATPs

- All trading partners must be authorized to engage in transactions of covered products.
  - Manufacturers and repackagers must have a valid FDA registration.
  - Wholesale distributors and 3PLs must have a valid license under State law (or an FDA-issued license once that program begins).
  - Dispensers must have a valid license under State law.
- ***<u>This is a current requirement</u>***.

Products

Covered products

- Finished prescription drugs for human use intended for administration to a patient.

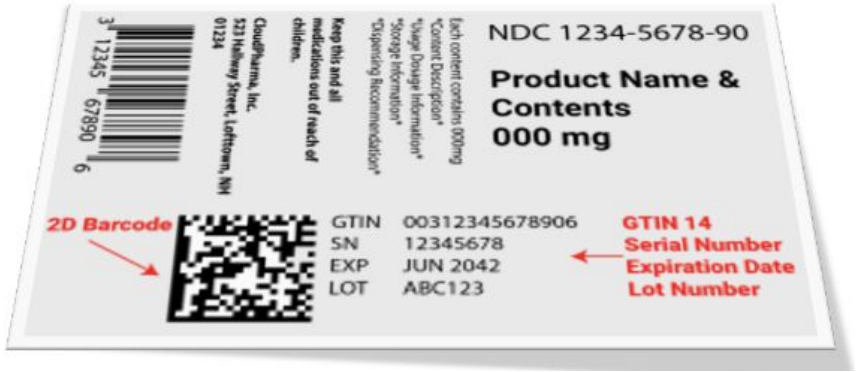
Not covered/exempt

- OTCs, medical devices, API.
- Approved animal drugs.
- Blood and blood components.
- Radioactive drugs/biologics.
- Imaging products, certain IV products, homeopathic drugs.
- Compounded drugs ***IF*** complying with 503A or 503B.

The ***manufacturer*** is responsible for determining if the DSCSA covers its products.

Product Identifiers

- Manufacturer or repackager must affix a unique product identifier on each product package entering commerce after Nov. 27, 2018.
- After Nov. 27, 2019, trading partners may only purchase and sell packages with product identifiers, unless grandfathered.
- ***<u>This is a current requirement.</u>***



Transactions

- A “transaction” means the transfer of a product between persons in which ***a change of ownership (not possession!)*** occurs.
- The following are ***not*** transactions (so DSCSA doesn’t apply):
  - Dispensing to a patient;
  - Intracompany distributions;
  - Mergers and sales;
  - Distributions between hospitals and healthcare entities under common control;
  - And others.
- Any purchase or sale not to a patient, including “borrows and loans,” are probably DSCSA transactions.
- An ATP may only transact covered products with other ATPs.

Product Tracing Data

- ATPs must receive, provide, and maintain ***product tracing data*** with each transaction with another ATP.
- Product tracing data:
  - Transaction Information (TI), Transaction History (TH) (where required), and Transaction Statement (TS) (“TI/TH/TS” or “3Ts”).
  - TH requirement ended on Nov. 27, 2023 – now 2Ts.
  - Maintain data for 6 years.
- ***A current requirement for all trading partners now.***

Exchanging Product Tracing Data

- Before Nov. 27, 2023, ***lot-level*** data exchange:
  - TI includes lot-level product tracing data.
  - 3Ts typically exchanged in an Advanced Ship Notice (ASN) or a portal.
- After Nov. 27, 2023, ***package-level*** data exchange:
  - Product identifiers must be in TI for each package in a transaction.
  - TI/TS typically exchanged in an EPCIS file or posted to a portal.
  - Compliance with ***package-level*** data exchange is delayed. (We'll come back to this).
- Providing, receiving, and maintaining transaction data enables tracing.
  - Regulators and ATPs, under certain circumstances, can request product tracing data.
  - A responding trading partner provides the data it has.

Verification Systems

- ***All*** trading partners (including all dispensers!) must have systems for "verification."
  - Identification, quarantine, and investigation of suspect products.
  - Notify FDA and trading partners of illegitimate products within 24 hours.
  - Disposition of illegitimate products.
- Records must be maintained for 6 years.
- ***A current requirement for all trading partners now.***
- A very high enforcement priority for FDA and State regulators.

Verification of Product Identifiers

"Verify" also means confirming with the manufacturer or repackager that the product identifier on the package is one the manufacturer or repackager assigned.

Current Requirements	Future Requirements
• Manufacturer or repackager must respond within 24 hours/1 business day to a verification request from ATP in possession or control of product. • Manufacturers, repackagers, and wholesalers must verify product identifiers in suspect product investigations. • Regulators can request verification (and are doing so).	• Wholesale distributors must verify product identifiers on returns before resale. • In a suspect product investigation, a dispenser must verify the product identifiers on at least 3 packages or 10% of such suspect product, whichever is greater, or all packages, if fewer than 3. • Originally effective 2019/2020; FDA enforcement repeatedly delayed. (We'll come back to this).

Final “Package-Level” 2023 Requirements

- Effective Nov. 27, 2023.
- The unique product identifier added to DSCSA requirements.
- All trading partners must:
  - Exchange product tracing data securely, electronically, and interoperably.
  - Include product identifiers in TI for each package in a transaction.
  - Be able to verify and trace at the package level, based on the product identifier.
  - To accept a return from a customer, the manufacturer or wholesaler must associate the product and its identifier with outbound TI.
- Current requirements continue.
- In August 2023, FDA issued a “Stabilization Policy”; no enforcement of these package-level requirements until Nov. 27, 2024.

FDA Exemptions

- On July 12, FDA exempted “small business” dispensers from package-level 2023 requirements until Nov. 27, 2026.
- On October 9, FDA issued an exemption for certain trading partners. This exemption applies after Nov. 27, 2024 expiration of the Stabilization Policy.
  - Compliance with final, 2023 package-level requirements rolls out in phases.
    - Manufacturers and Repackagers: May 27, 2025.
    - Wholesale Distributors: Aug. 27, 2025.
    - Dispensers with 26 or more full-time employees: Nov. 27, 2025.
  - Exemption is intended to keep products moving to patients while eligible trading partners work together, in good faith, to resolve package-level data quality problems.

FDA Eligible Trading Partner Exemption – what it covers

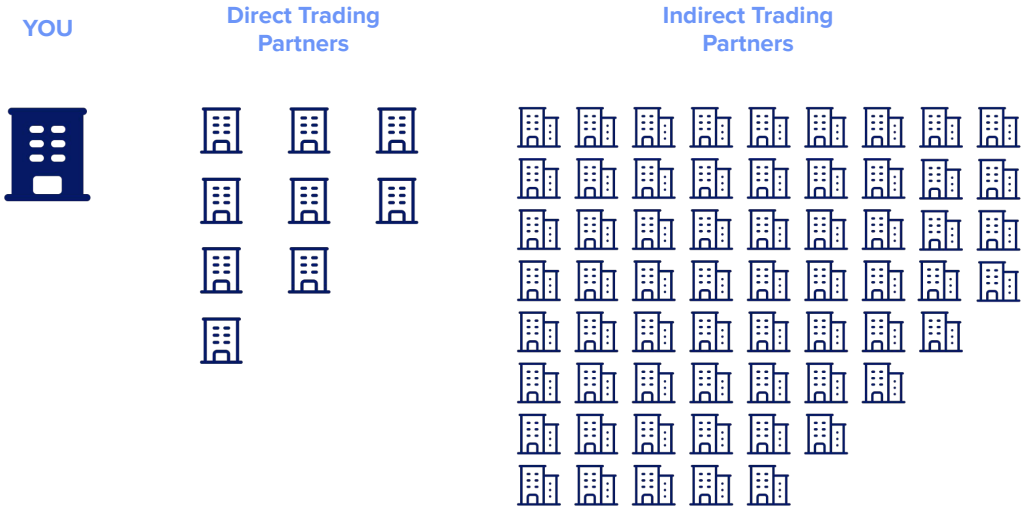
- Eligible trading partners are temporarily exempt from 582(g)(1) enhanced requirements:
  - Don’t have to provide/receive product identifiers in TI (may continue lot-level data) in an electronic, secure, and interoperable manner.
  - Don’t have to be able to trace or verify a product at the package level.
  - Don’t have to associate a saleable return with its outbound TI.
- Delays enhanced verification requirements:
  - Wholesale distributors do not have to verify saleable returns until 8/27/2025.
  - Dispensers (other than small business dispensers) do not have to verify 3 packages/10% of product in suspect product investigations until 11/27/2025.
- Other current requirements continue.
- Likely would preempt contrary State enforcement of package-level requirements.

FDA Eligible Trading Partner Exemption – who it covers

- To be eligible, a trading partner must have:
  - initiated systems and processes for "successfully completing data connections with their immediate trading partners; or,
  - "documented" its efforts to establish connections but not yet fully able to do so.
- If not eligible, after Nov. 27, 2024, a trading partner will need to comply or submit an exemption request to FDA.
- Exemption follows products and trading partners downstream.
- FDA expects eligible trading partners to inform their trading partners if they are relying on the exemption – do not contact or inform FDA.
  - Notification should occur through a "readily accessible resource or communication."
  - Should include a mechanism for trading partners to confirm.

Authorized Trading Partner (ATP) Confirmation

Foundational prerequisite, now underpinning“all electronic” systems



- Mandatory for direct trading partner transactions (including exception resolution)
- Mandatory for tracing & investigations
- Best practice for verification, required by some manufacturers

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

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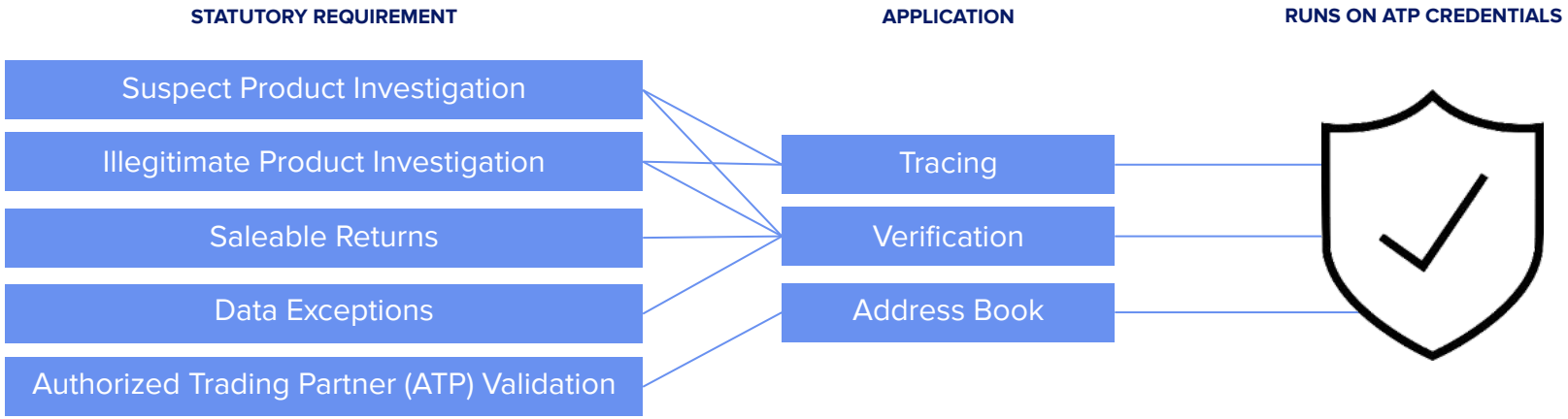
How Credentialing Supports DSCSA Compliance

ATP Credentials are the “digital driver’s license” that unlocks 3 key applications for November 2024 compliance under Federal Food, Drug and Cosmetic Act §582(g)



All non-exempt trading partners need to be able to verify and trace product; Authorized Trading Partner (ATP) validation is a prerequisite

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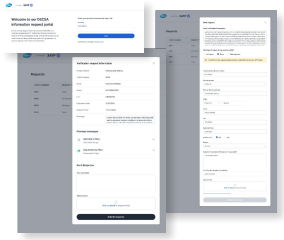
LedgerDomain DSCSA Solution

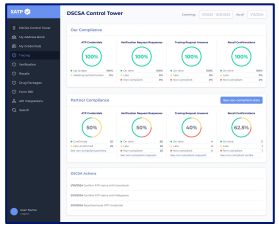
Digital Wallet & Credential

- Address Book
- VRS Integration
- ATP Confirmation



DSCSA Portal

- ATP Login (Magic Link)
- Manual Verification
- Trace
- Data Alignment



Control Tower

- Tracing Manager
- Data Alignment Manager
- ATP Confirmation
- Analytics
- 3911 (2024)

The credential is your "passport" to the enhanced drug distribution security (EDDS) network, while the Control Tower manages DSCSA enhanced workflows

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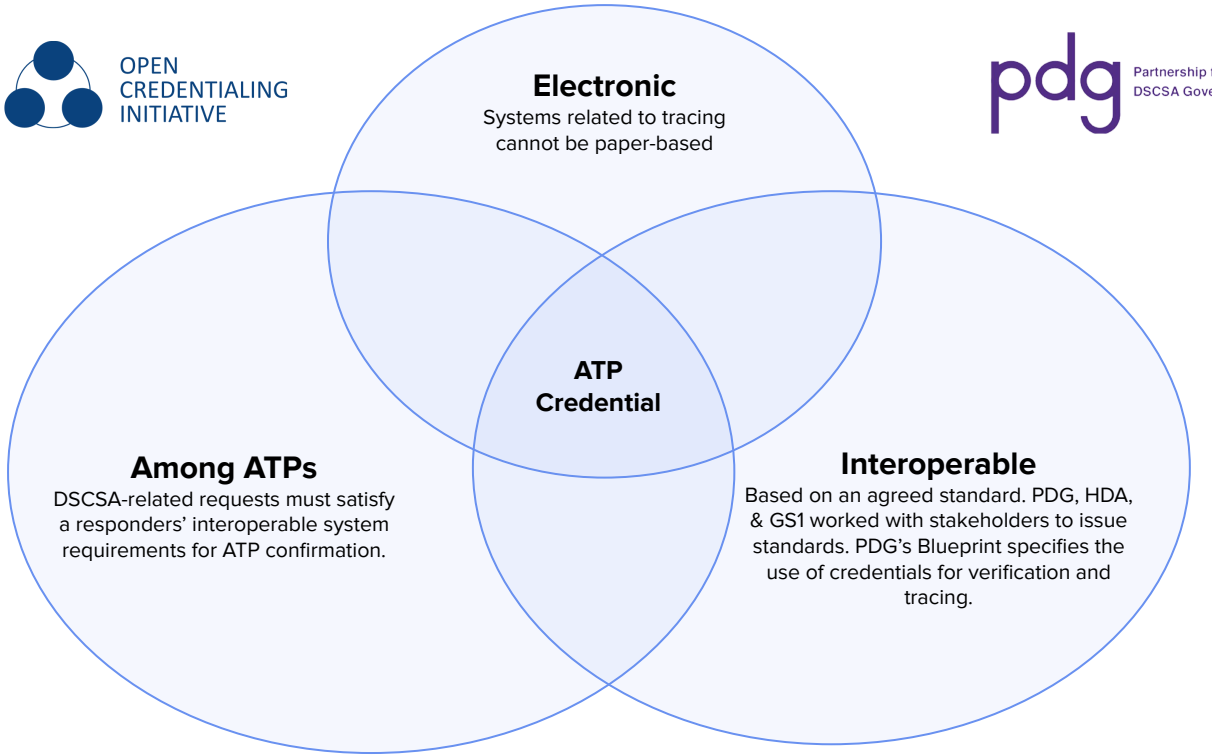
Tracing: DSCSA Enhanced Drug Distribution Security Requires "Interoperable, Electronic Tracing" Among ATPs

OPEN CREDENTIALING INITIATIVE

pdg Partnership for DSCSA Governance



Electronic ATP credentials: the only existing method that meets all three elements of the law

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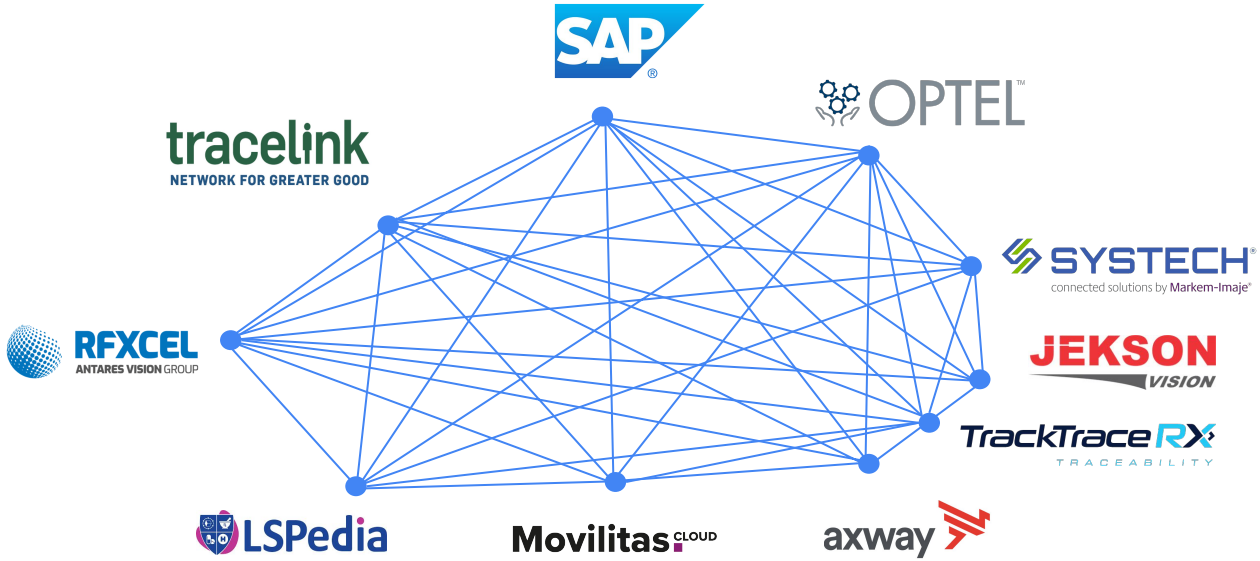
Verification: Authentication on the VRS

Electronic ATP credentials add authentication to the Verification Router Service, so manufacturers can know who is asking



LedgerDomain has its own bridges into the network; standalone service, integrations, and secure fallback available

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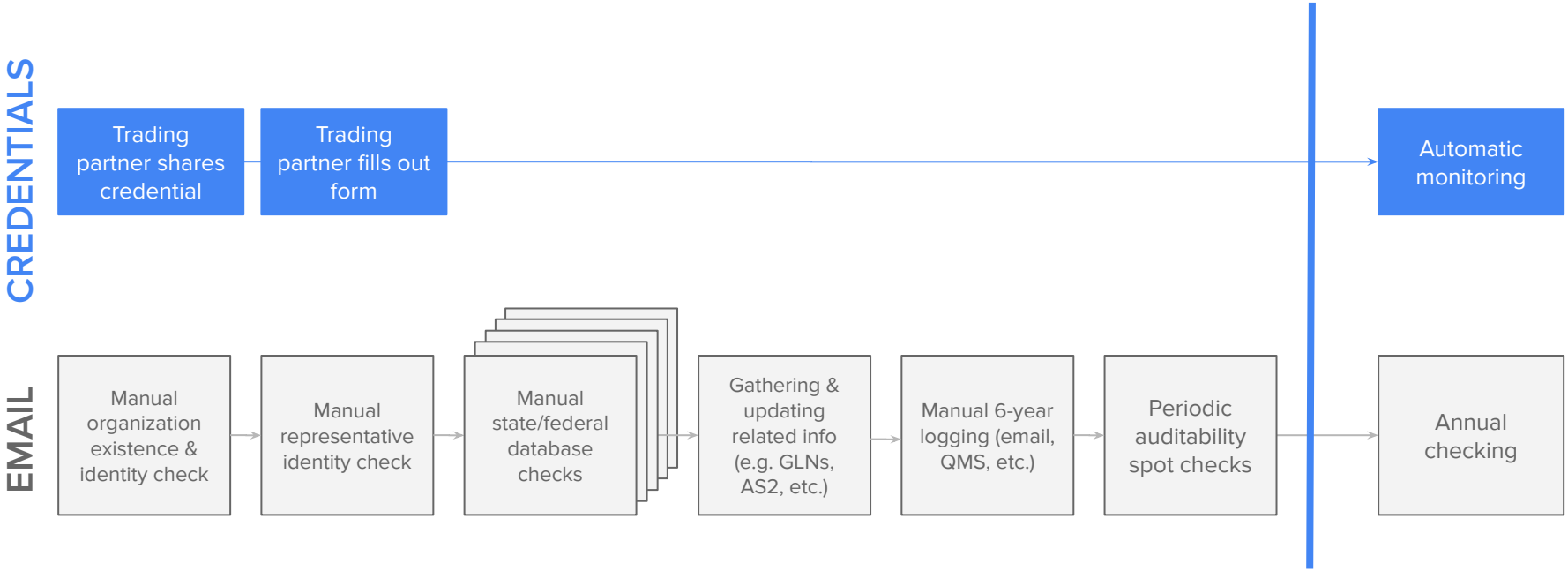
ATP Confirmation: Credentials vs Email



With verifiable credentials, third party does proofing for everyone
With trusted emails, you're burdened to perform your own diligence

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With 27 Days to Go...

- Most key requirements of the DSCSA are already in place
- Compliance means having a complete set of policies and following them faithfully
- **Credentials close the gaps and support your verification, trace, and ATP confirmation policies**
- **Tea time with Tish** ☕

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Thanks for Joining Us Today!

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