Opening Remarks

MISSION STATEMENT: *The mission of the members of the Louisiana Board of Drug and Device Distributors is to safeguard life and health and to promote public welfare of all citizens by the licensing and regulation of entities engaging in the distribution of legend drugs or legend devices within and into the state of Louisiana.*

DISCLAIMER

COMMENTS

INTRODUCTIONS

Antitrust Caution

During the course of today's webinar, discussions involving pricing, sales terms, territories, production volumes, or other aspects of competitive business practice must be avoided. Should any participant feel that statements or discussion are moving into such areas, they are encouraged to raise the concern immediately so that the conversation may be suspended until appropriate legal guidance confirms that the topics in question do not give rise to antitrust liability.

The Board recognizes the severity of the penalties that may be imposed where conduct is found to violate applicable antitrust law. Should the Board or any of its participants be implicated in a violation of federal or Louisiana state antitrust statutes, exposure may include both civil and criminal penalties – among them imprisonment, substantial fines, and attorney fees.

This policy statement unequivocally affirms the Board's commitment to free and fair competition as contemplated by the antitrust laws, and the Board intends to take all necessary and proper measures to ensure that no such violations occur in connection with its activities.

The Board is committed to interoperability across the drug and device distribution supply chain. However, this commitment does not constitute an endorsement of, or recommendation for, any single technology solution, platform, or service provider. Participants are encouraged to evaluate all available options independently and in consultation with their own legal and compliance counsel.

AI vs Human Eye

The Role of AI in Policy and Procedures

6/25/2026 Victoria Bienvenu, PharmD

Agenda

1. FDA/Purolea Warning Letter - Why does human oversight matter?
2. SOP Essentials and Regulatory Expectations - What makes an SOP inspection ready?
3. AI in Policy Drafting: Challenges and Benefits - Use AI effectively without creating compliance risks.
4. Exercises and Closing

FDA/Purolea Warning Letter: *Why does human oversight matter?*

Purolea Cosmetics Lab Warning Letter: What FDA Signaled

What FDA did (and did not) say

- FDA did not prohibit AI drafting of regulated documents
- FDA stressed the firm remains accountable for CGMP compliance

Compliance failure cited

- AI-generated specifications and procedures were not adequately reviewed
- FDA tied this to Quality Unit oversight responsibilities

Cautionary tale

- The firm missed required process validation and blamed the AI tool
- Regulators expect humans to catch gaps AI will not flag

Practical takeaway for DSCSA documents

- Treat AI output as a draft until a qualified human approves it
- If you cannot defend it to an inspector, do not use it

SOP Essentials and Regulatory Expectations: *What makes an SOP inspection ready?*

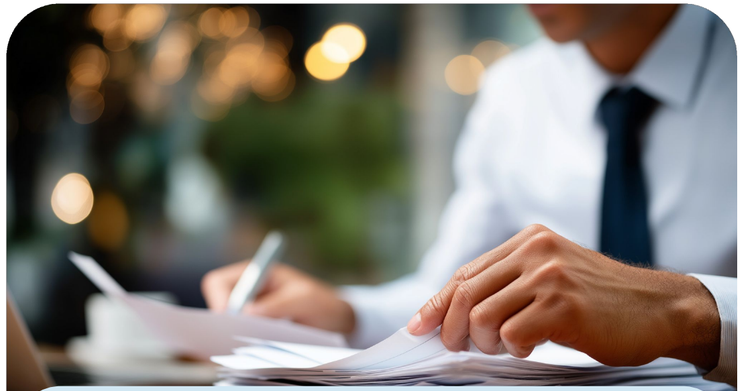
Inspections: Policy vs Working Procedure

The inspection moment

- An inspector asks: “Show me your suspect product handling procedure.”
- You hand over a polished, 12-page SOP that reads well.

Then the inspector asks

- Where is the product quarantined?
- Who verifies the trading partner?
- Where is the transaction data stored?
- Who contacts FDA if the product is illegitimate?
- Has your staff been trained on this procedure?



What’s being tested?

- AI can help create a draft, but the human eye must confirm that the policy is accurate, current, site-specific, and usable.

Five SOP Questions

Who?

- Name the role accountable, plus a backup for absences.
- Specify who escalates issues and who can make final decisions.

What?

- Define the trigger and the exact actions to take.
- List the required records and where they are stored.

When?

- Set clear deadlines and required response times.

How?

- Describe the workflow step-by-step, using your real systems.

How do you prove it?

- Use forms, logs, and training records that show actions occurred.

Inspection Reality Check

**Start with the event trigger

– Define who receives the alert and who must be notified next
– State the first action step and the expected response time

Make quarantine physical and real

– Specify exactly where suspect product is held and how it is labeled
– Clarify who controls access and prevents further distribution

Prove your trading partner checks

– Name who verifies the trading partner and what evidence is retained

Know where the data lives

– Identify where TI/TS is stored and who can retrieve it quickly

Escalate and report correctly

– Assign who contacts FDA or the Board if the product is illegitimate
– Document training so staff can execute the procedure under pressure

Human-eye checklist

Fit and accuracy

- Does this apply to our type of facility (distributor, dispenser, 3PL)?
- Does it correctly cite current law or guidance? Is it the right section of the law for us?
- Are state-specific expectations included where applicable?

Operational reality

- Does it match actual workflow and map the steps from receipt through resolution?
- Does it identify responsibility for each step, including backups?
- Does it include clear timelines?

Proof and readiness

- Does it explain documentation requirements like what records are created, stored, and retained?
- Has management reviewed and approved the SOP?
- Has staff been trained? Can they follow it during a real event?

Louisiana Saw The Gap

What Louisiana measured

– The Board reviewed **273** facilities and **759** policy/procedure documents.

– Submissions totaled about **1.5 million** words across DSCSA topics.

Where coverage looked strongest

– Most facilities addressed suspect/illegitimate product and verification activities.

– Many policies also covered electronic data exchange expectations.

Where gaps remained

– Procedures often under-defined **ATP checks**, exceptions, and waiver-related steps.

– Bottom line: many policies exist, but many are not inspection-ready.

Policy Areas for Distribution/DSCSA

Partners & data intake

- Verify **authorized trading partners** before buying, selling, or receiving product.
- Define how you receive, match, and store TI/TS data.

Serialized product controls

- Specify how product identifiers are captured, checked, and documented.
- Describe how exceptions are handled when data is missing.

Suspect, returns, and recalls

- Explain suspect product identification, quarantine, investigation, and disposition steps.
- Cover returns and saleable returns, recalls, and complaint intake workflows.

Records, training, and readiness

- Set record retention and retrieval expectations, including system outage plans.
- Assign training, contact updates, and inspection readiness responsibilities.

***Required Policy Areas for Distribution/DSCSA

Facilities should have written procedures covering:

- Authorized trading partner verification
- Receiving product and transaction data
- Storage and access to TI/TS data
- Product identifier and serialized data handling
- Suspect product identification
- Quarantine procedures
- Investigation procedures
- Illegitimate product notification
- Returns and saleable returns
- Recalls
- Complaint handling
- Record retention
- Staff training
- Vendor/customer qualification
- System failure or portal access issues
- Contact information updates
- Inspection readiness

Dispenser DSCSA Basics

Know your upstream partners

- Maintain a current list of prescription drug suppliers by location and role.
- Confirm each supplier is an **Authorized Trading Partner** before ordering.

Find and use your tracing records

- Define where transaction data is stored and who can access it.
- Document how staff retrieve tracing information during an inquiry.

Suspect product response basics

- Train staff on what triggers a suspect product concern at receiving.
- Specify the quarantine location, labeling method, and access controls.

Clear roles, timelines, proof

- Name who contacts the supplier, solution provider, FDA, or the Board.
- State record retention duration and where training completion is documented.

Dispenser-Focused Policy Areas

Dispensers should know:

- Who their prescription drug suppliers are
- Whether suppliers are authorized trading partners
- Where transaction data is stored
- How to access tracing information
- What to do if product appears suspect
- How to quarantine product
- Who contacts the supplier, solution provider, FDA, or Board
- How long records must be retained
- How staff are trained

DSCSA: Notify + Quarantine

Your SOP must trigger action

- Write clear decision points for when a product is determined illegitimate.
- Build in the **24-hour clock** for notifying FDA and immediate partners.

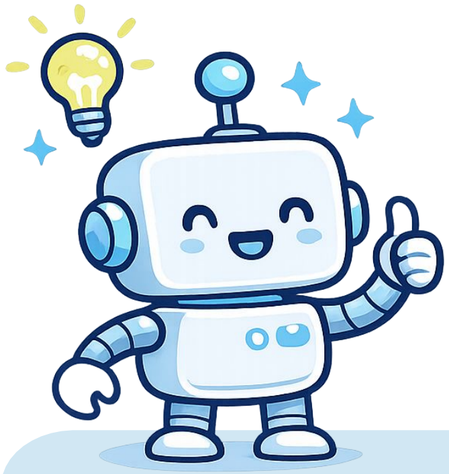
Quarantine and remove from supply

- Define how product is quarantined so it cannot ship or be dispensed.
- Define disposition steps to **remove it from the supply chain**.

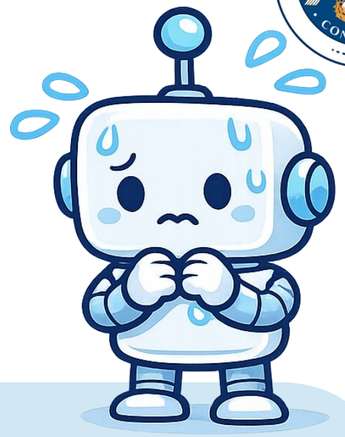
Make it inspection-ready

- Assign who sends notifications (including FDA Form 3911) and who documents.

AI in Policy Drafting Challenges and Benefits: *Use AI effectively without creating compliance risks*



AI 101:
Pros & Cons



AI is good at:

- Turning dense rules into plain-language drafts
- Creating checklists, training aids, and first-pass SOPs
- Finding gaps… *when asked the right questions in the right way*

AI can struggle with:

- Knowing your actual workflow, systems, and staff roles
- Physical reasoning (as a large language model, AI has read a lot but has never stepped into a warehouse)
- Confirming current law, state expectations, or site-specific facts

Frontier models are rapidly improving, but qualified human must make documents accurate, usable, and inspection-ready

Where AI Goes Wrong

Generic, not site-specific

AI drafts “one-size” SOPs that miss your roles, systems, and workflow.

Details get skipped

Key steps disappear: who acts, timelines, forms, and record location.

Confident but incorrect

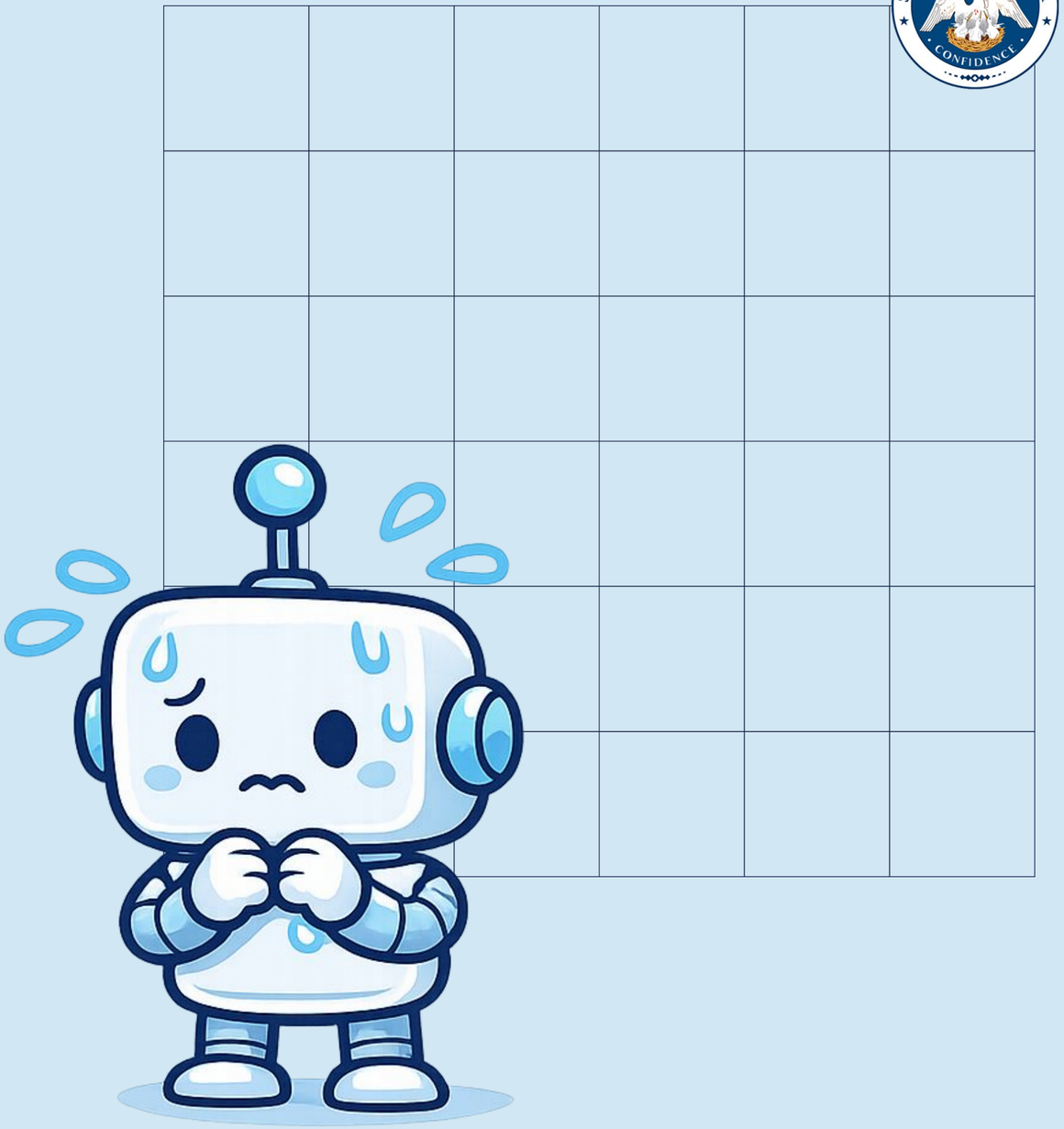
It can invent citations or misread requirements, sounding authoritative.

State blind spots

National templates may miss Louisiana Board expectations and contact needs.

Compliance theater risk

A polished binder fails when staff must execute it during an event.



When AI Misses the Point

Real-world ways AI gets it wrong, and why a human has to stay in the loop.

1

The car wash

Asked whether to walk or drive to a car wash 900 feet away, the assistant gave a lecture on exercise versus driving and did not consider you need your car to wash.

It optimizes for what it thinks you asked.

2

The flowers

An inbox-monitoring bot noticed an employee's relative had passed away and ordered sympathy flowers on the company card.

Give an agent broad reach and it acts in ways no one authorized.

3

The phantom rule

Asked for the governing regulation, AI produced a fluent, confident citation for a rule that does not exist.

It sounds authoritative, so no one checks.

How AI Fails in DSCSA

The same blind spots, pointed straight at your supply chain.

1

stale partner check

AI confirms a trading partner is authorized using a license list that is 60 to 90 days old.

The license lapsed last week.

2

Decommissioned serial

AI says the product identifier looks valid.

The serial number was already decommissioned upstream, long before it reached your dock.

3

Temperature excursion

AI calls a biologic stable after four hours at room temperature.

The manufacturer’s stability data allows ninety minutes.

Context decides. Insulin usable up to 30 days out of the fridge for patients is not the same cold chain storage requirements for pharmacist or distributors.

One Word, Many Meanings

Our terminology is dense and context-dependent. A human who knows the difference has to be in the loop.

The alphabet soup

GxP GMP GDP GLP GCP

GVP **GSP** GAMP **QA** CAPA

COA **LOT** batch release hold

DUR DAW fill count **verify** recall

"Recall" means three different things

Manufacturer: pull a defective batch back from the market.

Distributor: stop shipping and retrieve affected stock.

Pharmacy: find and quarantine product on the shelf or already dispensed.

"Verify": which verification, exactly?

PI verification · **ATP verification** · **verify on receipt**

Same Prompt, Three Different Answers

Prompt: “Draft a temperature-control policy.” Three personas return three different drafts, each equally confident. Only one fits your facility.

1

Manufacturer

Stability and excursion data, validated storage conditions.

Batch-release criteria and a CAPA on every deviation.

2

Distributor

Cold chain in transit and qualified shippers.

Dock checks on receipt; quarantine and ATP rules when an excursion is found.

3

Pharmacy

Fridge and room monitoring on site.

What to do with an excursioned vial at dispensing: the patient-safety call, plus supplier and Board notification.

Where AI Helps

Drafting and simplification

- Use AI to produce a readable first draft from DSCSA requirements.
- Rewrite dense regulatory language into plain steps for small teams.

Checklists and gap reviews

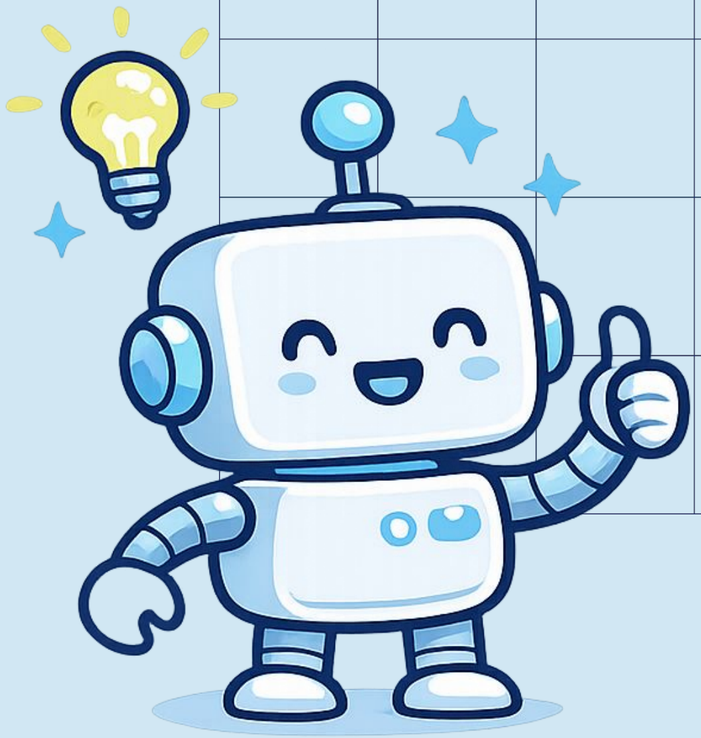
- Generate an inspection-style checklist from your existing SOP sections.
- Compare your SOP against required DSCSA elements to find gaps.

Training and usability

- Turn your SOP into quick training scripts and job aids.
- Use AI to test clarity: can staff follow it during events?

Right mindset

- Treat AI as a drafting assistant, not your compliance decision-maker.



Process First, Paper Second

Policies don’t come first. The way you actually work comes first, and then you write it down.

1

Run your program first

Operate the way you intend, prove it works, then write it down.

The SOP describes reality. It does not invent it.

2

Don’t outsource your judgment

Map the workflow yourself: roles, triggers, records.

AI should not replace your knowledge of your own facility.

3

Then bring in AI

With a clear plan, AI turns your process into cleanly written, easy to execute steps.

Setting AI Up to Succeed

Most frontier tools are similar under the hood. The difference is the knowledge base and the instructions you give.

1 Give it a knowledge base

Point it at the statutes, Board rules, and your own existing policies. Tell it to use those first and stay off the open internet.

2 Set the persona

Instructions define who it is and how careful to be: cite the rule, never guess, give only answers it can back up.

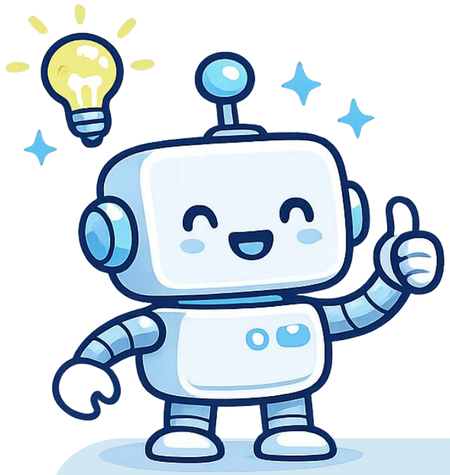
3 Feed it your own work

Drafting from your real policies beats “make something from thin air,” giving a far better first draft that is still human-reviewed.

4 Mind the data

Patient data never goes in**; SOPs are low-risk.** On free tiers, read the privacy policy. Sensitive data should not leave your control.

Live example: ChatGPT June 2026



I produced a solid first draft including role-based responsibilities, workflows, and statutory citations.

6.2 Product Identifier Verification – Saleable Returns

1. **Intake & Quarantine:** Returned product is placed in a physically and logically segregated *Saleable Returns Quarantine* zone.
2. **Data Capture:** Scan the PI (GTIN, serial, lot, expiry) into the warehouse management system (WMS).
3. **Electronic Request:** WMS initiates a **VRS query** to the manufacturer or manufacturer-designated responder.
4. **Disposition:**
   - **Verified = Yes:** Release product to saleable inventory and record disposition code *VRF*.
   - **Verified = No or Timeout > 24 h:** Escalate to Compliance Officer for further investigation; product remains quarantined.
5. **Documentation:** Verification responses are stored in an immutable audit log for ≥ 6 years.

6.3 Product Identifier Verification – Suspect / Illegitimate Product

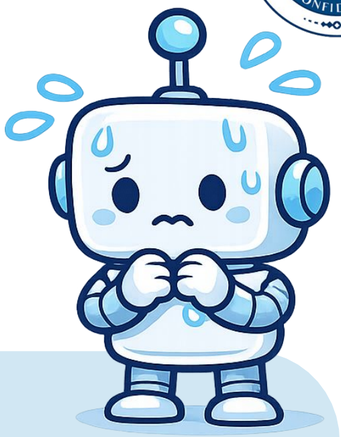
1. **Trigger Events:** Damaged packaging, pricing anomalies, supply-chain alerts, visual inspection failures, or partner notification.
2. **Initial Actions:**
   - Segregate and label product as *Suspect – Do Not Distribute*.
   - Notify Compliance Officer within **1 hour**.
3. **Verification:** Initiate VRS/EPCIS verification request to manufacturer within **24 hours**.
4. **Investigation & Escalation:**
   - If the product is *illegitimate*, file FDA **Form 3911** within **24 hours** and notify all immediate trading partners who received or may have received the product.
   - Maintain quarantine until written release from Compliance Officer.

6.4 Regulatory Requests

- Provide requested Transaction Information/Transaction Statement (TI/TS) or verification documentation to FDA or state regulators within **one business day** of the request.

6.5 System & Data Controls

- **EPCIS 1.2 or higher** is the standard format for serialized data exchange.
- WMS and order-management platforms must enforce user authentication, role-based access, tamper-evident logging, and daily backups.
- All verification records, TI/TS, and system logs are retained **≥ 6 years** in a secure, immutable store.



I don't specify *how* product is segregated and labeled. A lot of my writeup suggests it's still 2025. Confirming ATP status every time an order is placed, but is the sales team the right group to handle that?

Practical Prompts

Prompt 1: Drafting

- Draft a plain-language SOP for a small wholesale distributor handling suspect product under DSCSA.
  - Include assigned responsibilities, quarantine steps, investigation steps, documentation, notification, and record retention.
- Do not invent legal citations. Flag any area that requires human legal or regulatory review.

Prompt 2: Gap review

- Review this SOP for gaps. Identify missing steps, unclear responsibilities, missing timelines, missing documentation, and areas that may not match DSCSA expectations. Do not rewrite yet. Provide a checklist first

Prompt 3: Make it site-specific

- Convert this generic SOP into a site-specific procedure for a small distributor with one compliance manager, one warehouse manager, and one designated representative. Include who does what, when, and where records are kept.

Exercises and Closing

Exercise #1 : Trace Requests

Start with the event

- A DSCSA trace request arrives, and no one responds.
- Ask: Where did the system go wrong?
- Then trace through the SOP: Work backward to find the exact break in the process.

Where the system failed

- The contact list was outdated, or the wrong inbox was used.
- Ownership was unclear, so the request had no accountable person.
- There was no backup role when the primary person was unavailable.
- No monitoring routine existed for portals, email, or after-hours coverage.
- Staff were not trained to recognize and escalate trace requests.

Exercise #2: Build a Better SOP

Start with the weak policy

- Policy: “We investigate suspect product” states intent, not action.
- Example: “We investigate per regulations” is not inspection-ready.

Turn it into a procedure

- Name an owner: Warehouse Manager quarantines in the suspect cage.
- Add a timeline: Notify the compliance manager within one hour.
- Require proof: Document the event on Form DSCSA-01.

Exercise #3: AI vs Facility Reality

Round 1: The AI version

- Read the excerpt and circle what you cannot do tomorrow.
- Mark missing owners, timelines, tools, records, and locations.
- Flag vague phrases like “as required” with no execution steps.

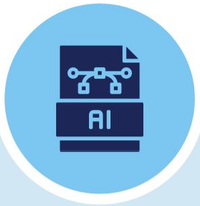
Round 2: The real facility version

- Rewrite using your roles, systems, and where TI/TS is stored.
- Add exact triggers, quarantine method, and investigation workflow.
- Define who escalates and who sends required notifications.

Pass/fail test

- Could a new hire follow it during a suspect product event?

Closing Takeaways



Use AI for speed, not decisions

– AI is a drafting tool; it is not your compliance owner.

– Treat every output as a starting draft, not a final SOP.

Human review makes it real

– Confirm it is accurate, current, and matches your workflow.

– Assign roles, timelines, and records staff can execute.

Inspection-ready means executable

– Your best DSCSA procedure is the one followed under pressure.

– If staff cannot do it, the policy is not compliant.