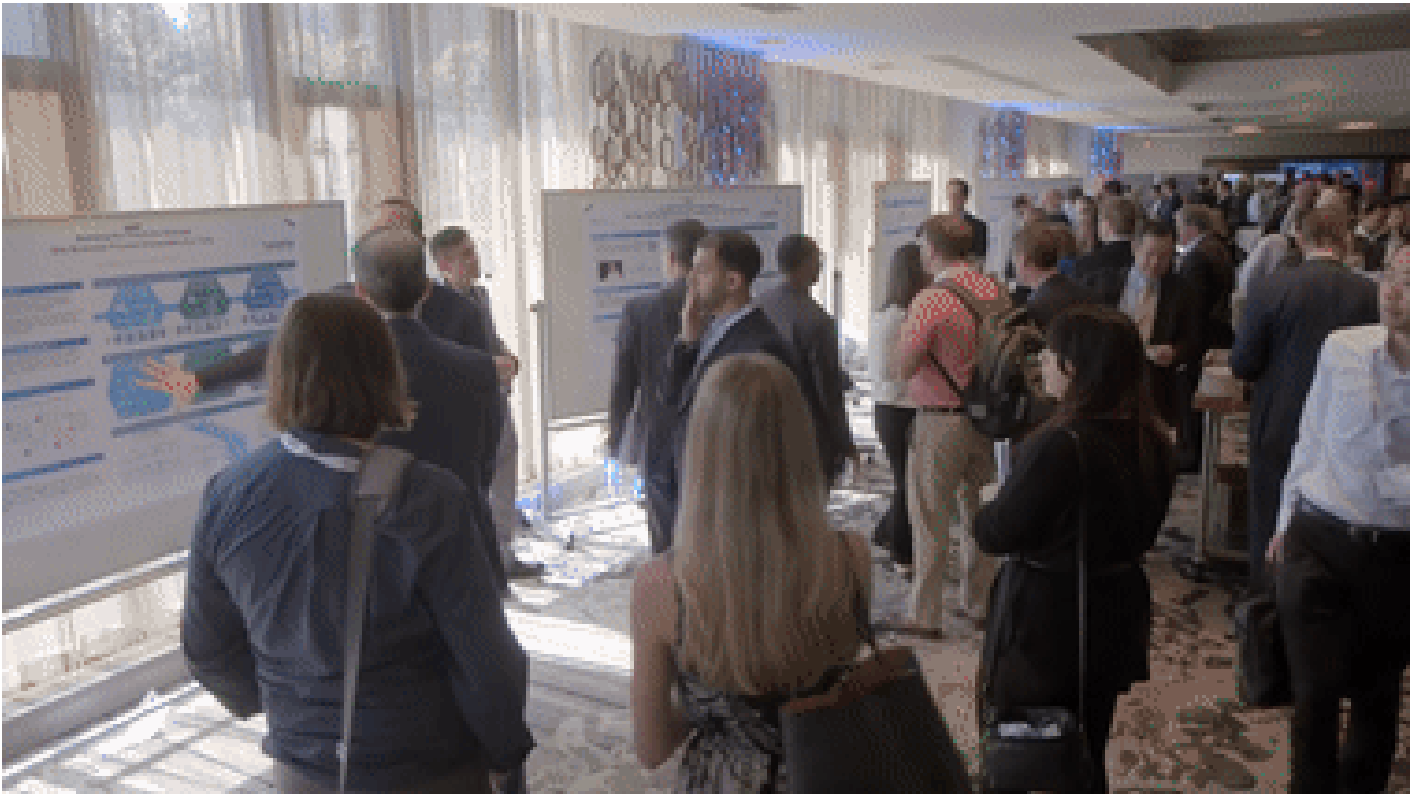


Suspect and illegitimate product investigations can result in miscommunication with trade partners and record keeping problems—but Value Drug Company has the answer. Watch this FutureLink Nashville video and read the case study poster to learn how Value Drug Company is partnering with TraceLink to implement a formalized solution to standardize the process and provide the results of investigations to authorities when requested.



# DSCSA Product Investigation, a Compliance Solution

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## BUSINESS CHALLENGE & SOLUTION

**Challenge:** The Drug Supply Chain Security Act instituted regulations surrounding suspect and illegitimate product investigations involving authorized trading partners. These types of investigations can result in miscommunication, lack of urgency, and recordkeeping repository issues.

**Solution:** A formalized solution is necessary for conducting a suspect product investigation providing structure and tangible proof if requested by the FDA, other regulatory body, or law enforcement official.

## TEAM

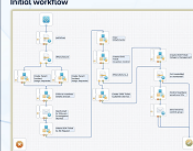
**Julie Malone**, Regulatory Affairs Manager  
**Scott Lushko**, Senior Systems Analyst  
**Bobby Shelow**, Director of Customer Service (Retired)  
**Jill Robison**, Customer Service Manager  
**Ron Sellers**, Inventory Manager  
**Mike Gonsman**, Warehouse General Manager  
**Tom Donahue**, Director - Category Management  
**Sherri O' Donald**, Controlled Substance Compliance Manager

## OBJECTIVES

- A single point of contact to begin an investigation.
- Ability for key stakeholders to receive alerts across devices.
- Coordinated execution for a timely investigation across multiple departments.
- An urgent and accurate process.
- A single source of investigation documentation, readily accessible for an audit.

## KEY ACTIVITIES AND RESOURCES

### High Level Workflow



- Summary**
- Incident reported and submitted.
  - Email sent to followers.
  - Parent ticket for customer service and children tickets for Inventory Control and Category Management under investigation.
  - Inventory Control and Category Management collaborate and report back to customer service their findings and escalate if required.
  - If unfounded, customer is contacted, tickets are closed.
  - If founded, customer is contacted, the regulatory department is updated by email and a child ticket is created to document work. Followers and upper management notified.

### Screenshot of Initial Form

### Screenshot of Email

### Resources Required

- Dedicated team to structure process flow.
- Dedicate timeframe, 136 hours over a period of 8 months (including development, training, testing and meeting hours).
- Utilized current technology.

### Critical Success Factors

- Follow-up and successful testing is key (Not a usual event).
- Ease and efficiency of the system from a workflow standard point.

## OUTCOMES

### Reporting on Investigations

Managers have access to review current and past investigations using one of our reporting engines.

Provides a link to review details, quick view to status, customer identification, and the support specialist involved.

### Results and Feedback

- Increase in response time results in a confident approach from a staff perspective.
- Although these investigations should be rare, we are at the ready.
- The ability to track the response to an investigation and conduct a post review allows for corrective action.

### Business Benefits

- Clarify in DSCSA product investigations from a customer reporting perspective.
- A concise and consistent ability to vet a DSCSA product investigation.
- Ability to provide excellent customer service for an authorized trading partner concerning a potential DSCSA issue.
- Ability to track supplier follow-up.

## RECOMMENDATIONS

### Advice:

- Inclusion and role of Regulatory Affairs in technology solutions.
- Clearly defined terms and solution pathways.
- Ownership in the process (run with the ball).

### Lessons Learned

- Building a solution is a process.
- Training is important, including drills and a documented user guide.
- Leverage what you have.

### Next Steps:

- Launching 2.0 (Additional build out technology solution)
- Regulation will continue to evolve, so future updates will come.
- New technology trends and tools are ahead, pay attention to the future.

Case Study

DSCSA for Manufacturers

Regulatory/Compliance

United States

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