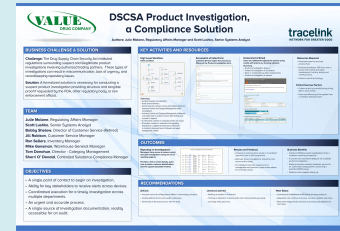




## RESOURCES

**Home**  
**Resources**  
**Resource Center**

# Case Study: Value Drug Company | DSCSA Product Investigation—A Compliance Solution



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

Authors: Julie Malone, Regulatory Affairs Manager and Scott Lushko, Senior Systems Analyst

## 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

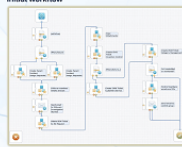
**Julie Malone**, Regulatory Affairs Manager  
**Scott Lushko**, Senior Systems Analyst  
**Bobby Shelow**, Director of Customer Service (Retired)  
**Jill Robison**, Customer Service Manager  
**Ron Sellers**, Inventory Manager  
**Mike Gonsman**, Warehouse General Manager  
**Tom Donahue**, Director - 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 child 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

Customer Service begins the process by filling out the Product Investigation form.

### Screenshot of Email

Users are notified throughout the process using emails with links to our tracking software.

**Summary**

- Product Investigation begins.
- Product Investigation is escalated.
- Work is completed by other departments.
- Product Investigation is closed.

### 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.

Product Investigation Open and Closed Report

Case ID	Case Name	Case Status	Case Type	Case Category	Case Sub-Category	Case Priority	Case Assigned To	Case Created Date	Case Closed Date	Case Last Modified Date
1000000001	Product Investigation	Open	Product Investigation	Product Investigation	Product Investigation	High	Julie Malone	2010-01-01		2010-01-01
1000000002	Product Investigation	Closed	Product Investigation	Product Investigation	Product Investigation	High	Julie Malone	2010-01-01	2010-01-01	2010-01-01
1000000003	Product Investigation	Open	Product Investigation	Product Investigation	Product Investigation	High	Julie Malone	2010-01-01		2010-01-01
1000000004	Product Investigation	Closed	Product Investigation	Product Investigation	Product Investigation	High	Julie Malone	2010-01-01	2010-01-01	2010-01-01
1000000005	Product Investigation	Open	Product Investigation	Product Investigation	Product Investigation	High	Julie Malone	2010-01-01		2010-01-01

### 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

- Clarity 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 StudyDSCSA for ManufacturersRegulatory/ComplianceUnited States

Subscribe to Agile Supply Chain Insights

Subscribe to stay informed with the latest patient-centric agile supply chain thought leadership content.

## More Serialization and Compliance Case Studies

## EPCIS Connection Changes post Go-Live

Lauren Catalano – Technical Services Manager



### Business Challenge & Solution

Changes to established EPCIS connections is becoming more prevalent, especially for companies like Sharp functioning in the CMO/CPO space. Technical complexities related to pathway connection changes, present the added challenge of reducing the impact to daily production activities. Allowing a smooth and unified transition to the EPCIS of choice, while working within the boundaries of business constraints is key.



#futurelink

### Case Study: Sharp Packaging Services | EPCIS Connection Changes Post Go-Live

See how Sharp Packaging Services overcame EPCIS change management challenges in the pharma supply chain with TraceLink's help.

[View More](#)

## The CMO Serialization Perspective Utilizing a Standardized Approach for Efficient Partner Onboarding



Author: Daryl Chin, Manager – Global Track & Trace, Contract Pharmaceuticals Limited (CPL)



### Company Identity

#### Who We Are

For more than 25 years, Contract Pharmaceuticals Limited (CPL) has been providing the world's leading pharmaceutical companies with full-service liquid and semi-solid product development and manufacturing, singularly focused on innovation and efficiency.



#### Project Manager



Daryl Chin

Manager – Global Track & Trace

### Key Activities

#### Master Data Sharing

- Standardized semi-automated master data questionnaire ensures all required master data is completed by BO for L1 – L4 systems (Right First Time principle)

#### Informal Request / Response

- Test the receipt of serial numbers in the iTest environment, especially if partnering with a BO using a non-Traceli L4 provider
- Commission serial numbers on the UI and send test deliveries to ensure connectivity

#### Formal End-to-End Testing (PQ)

- Pull serial numbers through L4 – L1
- Commission serial numbers using L1
- Push commissioned serial numbers through L1 – L4
- Create delivery to Brand Owner



### Business Challenge

#### Business Challenge

As a Contract Manufacturing Organization (CMO) with an international customer base spanning both the US & EU markets, how can CPL onboard Brand Owners (BOs) efficiently – completing all the required onboarding steps in a timely manner, yet still capturing all the necessary testing to ensure robust connectivity?

### Solution

#### Solution

For CMOs & BOs in the partner onboarding process, utilizing a standard approach results in an overall shorter onboarding duration and ensures that all the required tests are captured, tested, and documented the same way, every time.

CPL has found the following 3-step approach to consistently work the best for us:

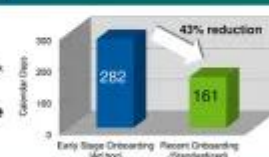


### Outcomes & Recommendations

#### Outcomes

- Early stage onboarding process took > 9 months with steps taken ad hoc
- Recent standardized onboarding process took < 6 months from kick-off to successful PQ

Reduction in errors = Less time spent troubleshooting



#### Recommendations

- Craft a standard approach for CMO / BO onboarding – be vigilant and stick to it!
- Figure out what master data all your systems require and ensure it is captured each time
- CMO L4 – BO L4 represents highest risk; test communication thoroughly prior to PQ
- PQ through all levels of your systems and simulate commercial production as close as possible

### Top 3 Common Pitfalls Encountered During the Onboarding Process

#### Serial Number Requests

- Set BO Maximum Request Quantities so that CMOs can request up to the CMO's maximum threshold, if needed

#### Creating Deliveries

- Agree on To Business and Ship To locations
- Use of GLNs versus sGLNs

#### SOM Sales Shipments

- Configure Transaction Delivery Rules
- Info Exchange is your friend

#futurelink

## Case Study: CPL | The CMO Serialization Perspective—Utilizing a Standardized Approach for Efficient Partner Onboarding

See how contract manufacturer Contract Pharmaceuticals Limited implemented a 3-step process for smooth pharmaceutical partner onboarding.

[View More](#)



**THE COST OF NON-COMPLIANCE**

**Author: Marilu Castillo, Pharmacy Inventory Manager, Noden Pharma USA Inc.**

**business Challenge & Solution**

**IMPLEMENTATION OF DRUG SUPPLY CHAIN SECURITY ACT OF 2013**

One of the main problems has been interpretation of the U.S. law by global partners. Another obstacle has been finding the processes that will fulfill the different users' needs, including our patients.

**IDOPT C.O.S.T. compliance model.**

**COMMUNICATION** avenues, including written and verbal across all lines of business and roles.

**OPEN** to change attitude and workflow that supports creative solutions.

**SUSTAINABLE** solutions that are accepted by all since each team will make their significant contribution to the whole solution.

**TIMELY** execution of deadlines provided by the law.

**Key Activities and Resources**

**THE COST OF NON-COMPLIANCE**

**Other**

**Operations**

**Example of Cost of Compliance**

**Annual Subscriptions**

**Custom Contracts**

**Outcomes**

**Example of Cost of Compliance**

**Annual Subscriptions**

**Custom Contracts**

**Recommendations**

**Don't let this be your DSCSA**

**What's Next?**

**DSCSA**

**What's Next?**

**DSCSA**

## Case Study: Noden Pharma | The Cost of Non-Compliance

See how global pharmaceuticals company Noden Pharma avoided the financial and operational risks of DSCSA noncompliance.

[View More](#)