



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

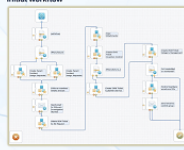
- Julie Malone**, Regulatory Affairs Manager
- Scott Lushko**, Senior Systems Analyst
- Bobby Shelow**, Director of Customer Service (Retired)
- Jill Robison**, Customer Service Manager
- Ron Sellers**, Inventory Manager
- Mike Gonsman**, Warehouse General Manager
- Tom Donahue**, Director - Category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

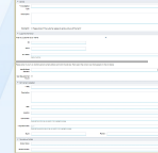


Summary

- Incident reported and submitted.
- Email sent to followers.
- Parent ticket for customer service and 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 unbranded, customer is contacted, tickets are closed.
- If branded, customer is contacted, the regulatory department is updated by email and a child ticket is created to document work. Followers and upper management notified.

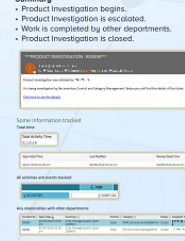
Screenshot of Initial Form

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.



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 standpoint.

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 Close Report																							
2017-01-01	2017-01-31	2017-02-01	2017-02-28	2017-03-01	2017-03-31	2017-04-01	2017-04-30	2017-05-01	2017-05-31	2017-06-01	2017-06-30	2017-07-01	2017-07-31	2017-08-01	2017-08-31	2017-09-01	2017-09-30	2017-10-01	2017-10-31	2017-11-01	2017-11-30	2017-12-01	2017-12-31

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 pathway.
- 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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More Serialization and Compliance Case Studies

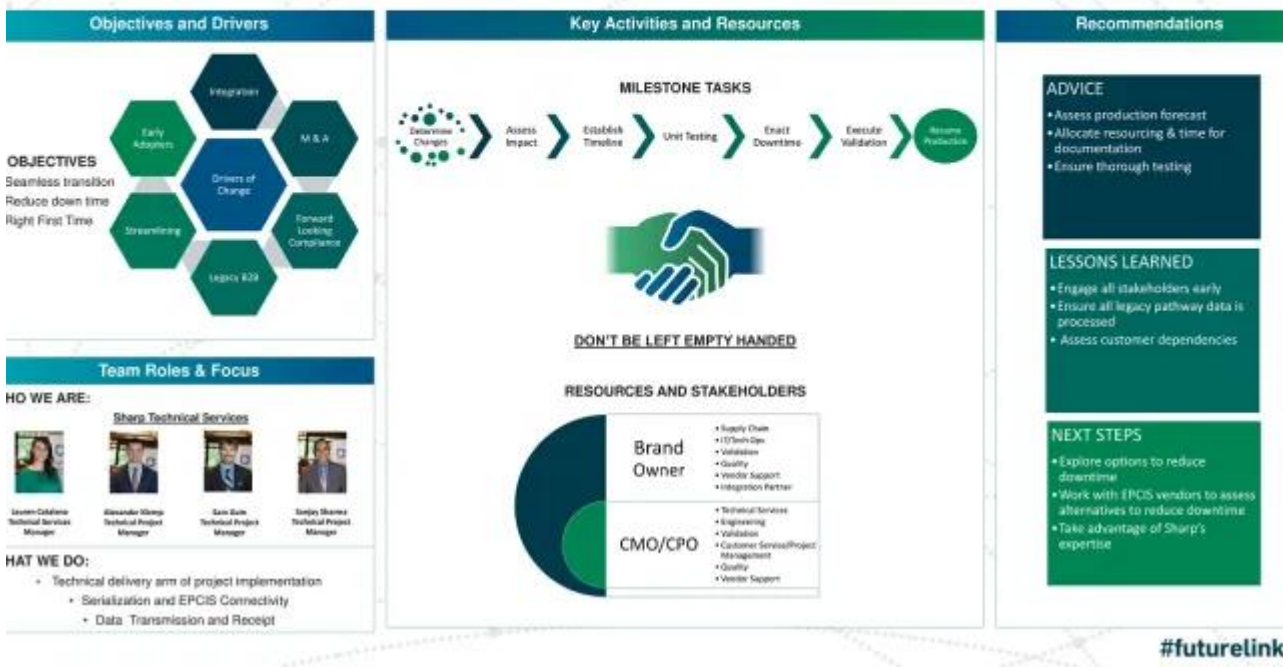
EPCIS Connection Changes post Go-Live

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. Following a smooth and unified transition to the EPCIS of choice, while working within the boundaries of business constraints is key.



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.

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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 (Fight 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-TraceLink 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

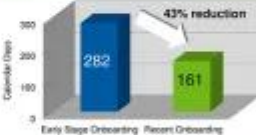
Business Challenge
As a Contract Manufacturing Organization (CMO) with an international customer base spanning both the US & EU markets, how can CPL onboard Brand Owners (BOs) **efficiently** – completing all the required onboarding steps in a timely manner, yet still capturing all the necessary testing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

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



Onboarding Stage	Errors
Early Stage Onboarding (Ad hoc)	282
Recent Onboarding (Standardized)	161

Recommendations

- Create 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

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 details 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:

- 1 Standardized Master Data Sharing
- 2 Informal Request / Response Testing
- 3 Formal End-to-End Testing (PQ)

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



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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.

ADOPT C.O.S.T. compliance model.

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

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



HOW THE C.O.S.T. MODEL

- 1. Provide detailed education on the law to all stakeholders, including regulatory and business partners.
- 2. Create a compliance model that is tailored to the company's specific needs and resources.
- 3. Engage all stakeholders in the process to ensure buy-in and accountability.
- 4. Establish a compliance program that is ongoing and adaptable to change.

The Greatest Resource is your WORKFORCE

Workforce is the greatest resource in any organization. It is the people who make the organization what it is. Investing in your workforce is investing in your future. Training and development are essential for long-term success. Encourage your employees to take ownership of their work and to continuously improve their skills. This will lead to higher productivity and better results for the organization.

Team

NODEN PHARMA DAC is located in Dublin, Ireland. CEO and other leadership roles operate from this office.

NODEN PHARMA USA is located in Orlando, FL. This office was established early into the US market in 2017.



Noden Pharma is a global specialty pharmaceutical company that is focused on providing prescription medicines across a broad range of therapeutic areas.

Outcomes

Example of Cost of Compliance

- Annual Subscriptions
- Product Information Manager (PIM)
- Master Data Sharing / Product Information Manager - Master Data
- Automated Information Manager - Product Information Manager - Master Data
- Sharing Product Information System
- Network Management Services

Build into your business model is more than the cost of compliance measures, which will include any or all of the following:

- Third Party Vendor Services
- Updates to Equipment and Software
- Testing and Education
- Ongoing maintenance of contracts, equipment and training



- Partial Compliance and associated costs
 - Non-Compliance and the associated fines, liabilities and prosecution
- BEFORE YOU GO LIVE!**
- Review, Assess, Feedback, Adjust, Test, implement, Done
- Full Compliance

DSCSA



Recommendations

Achieving a successful buy into full REGULATORY COMPLIANCE

- Communicate** internally and externally to ensure a clear and consistent message to all stakeholders on the importance of regulatory compliance.
- Standardize** processes across all business units to ensure consistency and efficiency in compliance efforts.
- Leverage** technology to streamline compliance processes and reduce manual errors.
- Invest** in training and development to ensure employees are equipped with the necessary skills to maintain compliance.
- Monitor** compliance status regularly to identify and address any gaps or issues promptly.
- Build** strong relationships with regulatory agencies to facilitate communication and problem-solving.

Don't let this be your DSCSA



What's Next?



Objectives

Address Internal Compliance Objectives, at all times. Address Regulated Federal Compliance, at all times. (Buy legally their inventory as (DSCSA))

ACHIEVE FULL DSCSA COMPLIANCE BY ALL INTERNAL PARTNERS, ON A REGULATED DATE OF NOVEMBER 27th

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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.

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