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Case Study: PharmaLink | Closing the Gap on Cradle-to- Grave Traceability via Reverse Distribution and EPCIS



Non-saleable pharmaceuticals, including returns, recalls, and other waste products, can leave a gap in supply chain security. But pharmaceutical returns specialist PharmaLink has found a solution this problem. Read PharmaLink's case study poster and watch their FutureLink Nashville video to learn how the company's combination of decommissioning and secure disposal is raising supply chain security levels. The video features PharmaLink's Adam Q. Bottie, who recently took part in TraceLink's Digital Recalls FDA pilot.



Closing the Gap on Cradle-to-Grave Traceability via Reverse Distribution and EPCIS

Author: Adam Q. Bottie, Vice President, Corporate Strategy & Business Development

Business Challenge & Solution

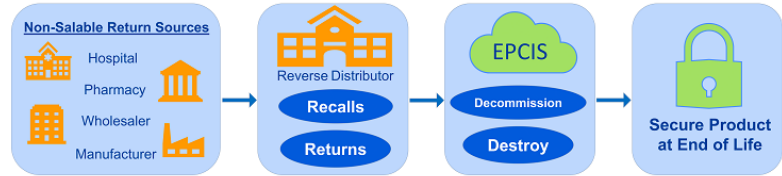
Business Challenge:

- The forward supply of pharmaceuticals has clear track and trace in place for serialized products through dispensing. However, non-salable products, including returns, recalls, and other waste products are untraced and leave a gap in supply chain security.

Solution:

- PharmaLink's process provides a solution for non-salable products to facilitate serial number decommissioning, disposal, and transfer events in EPCIS v1.2 utilizing the TraceLink Serial Operations Manager (SOM)
- Solution available for all Manufacturers, Wholesalers, and Dispensing Outlets.

Solution Process



The PharmaLink Team



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VP, Corporate Strategy & Business Development

Scope of Risk



Outcomes

- Decommission Serial Numbers for ultimate tracking of Non-Salable products.
- Prevent product re-entry to the supply chain.
- Reduce the risk of diversion and the entry of counterfeit products to the supply chain.
- Identify potential illegitimate or suspect products by monitoring the reverse logistics channel.
- Better management of returned goods credits according to Returned Goods Policy.

Objectives

- Enhance Supply Chain Security
- Enhance Enforcement of Returned Goods Policy
- Improve Visibility of Non-Salable Goods including Returns, Recalls, Waste, and other non-salable items.
- Provide a clear solution to agency interoperability requirements of DSCSA ahead of the 2023 deadline.
- Reduce cost by having access to more robust data.

PharmaLink is an active participant in the TraceLink FDA Pilot projects for Trace Histories and Digital Recalls.

Recommendations

Partner

- Partner with PharmaLink to develop a reverse logistics and recall strategy that incorporates EPCIS.

Integrate

- Connect client systems to PharmaLink & TraceLink.
- Identify EPCIS events that should be documented in your reverse distribution process.

Deploy

- Start processing returns while safely & securely removing product from the pharmaceutical supply chain in compliance with FDA and DSCSA guidelines.

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VALUE
DRUG COMPANY

DSCSA Product Investigation, a Compliance Solution

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



tracelink
NETWORK FOR GREATER GOOD

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 longstanding repository issues.

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

TEAM


Julie Malone, Regulatory Affairs Manager
Scott Lushko, Senior Systems Analyst
Robby Shelow, Director of Customer Service (Retired)
Tim Robison, Customer Service Manager
Mike Gonsman, Warehouse General Manager
Tom Donahue, Director - Category Management
Terri 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:


- Isolated suspect and suspected.
- Single point of contact.
- Repeatable for customer service and system support for inventory control and category management.
- Inventory Control and Category Management collaboration and output back to customer service that findings and results if required.
- Disseminated, evidence is contained, history is clear.
- Provided, customer is contacted, the regulatory requirement is updated by email and a checklist is created to document only. Follow-up and report (ongoing, initial).

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 initiated.
- Work is completed by other departments.
- Product investigation is closed.

Resources Required:

- Dedicated team to structure process flow.
- Dedicated hardware, T88 hours over a period of 8 months (project management, training, testing and monitoring reports).
- Updated control technology.

Critical Success Factors:


- Partnership and consistent looking to be able to meet needs.
- Good use efficiency of the system for workflow structure.

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:

- Immediate for response time results on a consistent approach from a staff perspective.
- Although there have been some issues, we are not the only.
- 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.
- Accountant and consistent ability to run a DSCSA product investigation.
- Ability to provide excellent customer service for the individual dealing with customer in a regulated DSCSA issue.
- Ability to track supplier follow-up.

RECOMMENDATIONS

Advice:

- Inclusion and role of Regulatory Affairs in technology solutions.
- Clearly defined roles and solution pathways.
- Ownership in the process built with the tool.

Lessons Learned:

- Building a solution is a process.
- Training is important, including skills and a documented plan.
- Leverage what you have.

Next Steps:


- Launching 2.0 (Additional rollout technology solution).
- Regulation will continue to evolve, so future updates will occur.
- New technology needs and tools are critical only attention to the future.

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

See how Value Drug Company standardized the process for illegitimate and suspect product investigations for DSCSA compliance.


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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 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



INTANGIBLES: Your Brand, Your Reputational, Your Mission, Your Financial, Your Relationship's Network

OPERATIONS: Your Product, Your Staff, Your Mission, Your Financial, Your Growth

OTHER: Your Service Level, Your Marketing Ability, Your Trade Agreements, Your Distributor Network

HOW THE C.O.S.T. MODEL WORKS:

- 1. Intangible resources (Brand, Reputation, Mission, Financial, Relationship's Network) are the foundation of the business.
- 2. Operations (Product, Staff, Mission, Financial, Growth) are the core of the business.
- 3. Other resources (Service Level, Marketing Ability, Trade Agreements, Distributor Network) are the support of the business.

The Greatest Resource is your WORKFORCE

Workforce is the most valuable resource in any organization. It is the only resource that can create, sustain, and improve the business. It is the only resource that can adapt to change and overcome challenges. It is the only resource that can drive innovation and growth.

Outcomes

Example of Cost of Compliance

- Annual Subscriptions: Product Information Manager (PIM), Product Information Manager (PIM) - Master Data Sharing - Product Information Manager - Master Data Sharing - Product Information Manager - Master Data Sharing - Product Information Manager - Master Data Sharing
- Third Party Vendor Services
- Updates to Equipment and Software
- Testing and Education
- Ongoing maintenance of contracts, equipment and training

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

- Partial Compliance with associated costs
- Non-Compliance and the associated fines, liabilities and prosecution

BEFORE YOU GO LIVE!

Review, Assess, Feedback, Adjust, Test, Implement, Done

Recommendations

Achieving a successful buy into full REGULATORY COMPLIANCE

Compliance is not a one-time event and is a continuous process. It is a journey that requires ongoing effort and resources. It is a journey that requires a commitment to excellence and a focus on the customer.

Don't let this be your DSCSA

What's Next?

DSCSA is a complex and evolving regulatory landscape. It requires a deep understanding of the law and a commitment to compliance. It requires a focus on the customer and a commitment to excellence.

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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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.

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