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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

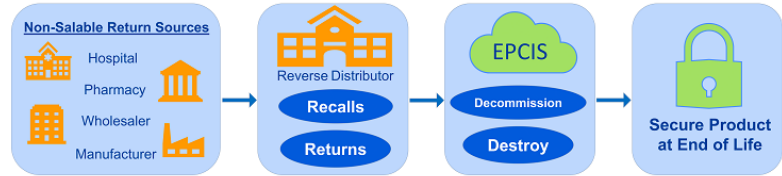
Business Challenge:

- 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



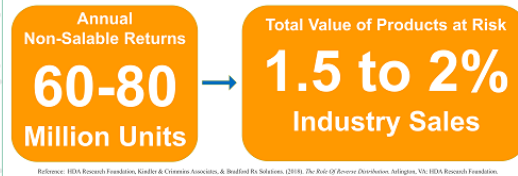
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Adam Bottie, MBA, MSPHarm
VP, Corporate Strategy & Business Development

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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More Serialization and Compliance Case Studies



VALUE
DRUG COMPANY

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 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.
- Repeat back to customer service and system access for inventory control and category management on-site investigations.
- Inventory Control and Category Management collaboration and repeat back to customer service that findings and results if required.
- Disinformed customer to customer, history are closed.
- Provided customer is contacted, the regulatory requirement is updated by email and a checklist is created to document only. Follow-up and repeat investigation, repeat.

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, 150 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 are investigations should be done, we're not the only.
- The ability to track the response to an investigation and conduct a review of the process.

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 is documented over time.
- 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 Integrity, Your Financial, Your Relationship's Network

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

Other: Your Service Level, Your Networking Ability, Your Trade Agreements, Your Distributor Network

ADOPT THE C.O.S.T. MODEL

- Integrate internal resources (human, financial, operational) and external resources (partners, suppliers, regulators) to create a cohesive compliance strategy.
- Develop a comprehensive compliance plan (CPMP) that addresses all regulatory requirements, including data integrity, quality control, and supply chain security.
- Implement a robust data management system that ensures accurate and timely reporting to regulatory agencies.
- Establish a strong relationship with regulatory agencies to ensure timely communication and resolution of issues.

The Greatest Resource is your WORKFORCE

Workforce: Your most valuable asset, including all employees, from executive to frontline staff.


Workforce Development: Invest in training and development to ensure your workforce is equipped with the skills and knowledge needed to comply with the law.

Workforce Engagement: Foster a culture of compliance where every employee understands their role in ensuring regulatory adherence.

Outcomes

Example of Cost of Compliance

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



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!
Full Compliance

DSCSA

Drug Supply Chain Security Act (DSCSA) is a federal law that requires pharmaceutical manufacturers to implement supply chain security measures to ensure the authenticity and integrity of the drug supply chain.

Key Requirements:

- Verify the authenticity of the drug supply chain.
- Implement a robust data management system.
- Establish a strong relationship with regulatory agencies.

Recommendations

Achieving a successful buy into full REGULATORY COMPLIANCE


Commitment: Establish a clear vision and mission statement for regulatory compliance.

Communication: Foster a culture of transparency and open communication.

Collaboration: Work closely with regulatory agencies and industry partners.

Continuous Improvement: Regularly review and update compliance measures.

Don't let this be your DSCSA



What's Next?

DSCSA: Drug Supply Chain Security Act

Key Steps:

- Verify the authenticity of the drug supply chain.
- Implement a robust data management system.
- Establish a strong relationship with regulatory agencies.

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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