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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

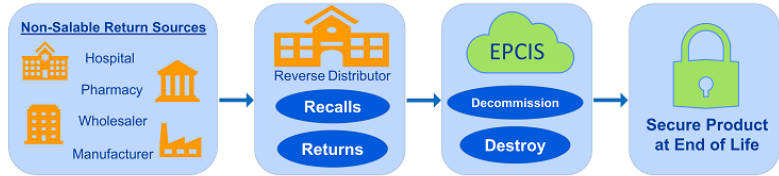
#### Business Challenge:

- 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



Thierry Beckers, MSM  
President & COO

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

### Scope of Risk

Annual  
Non-Salable Returns  
**60-80**  
Million Units

Total Value of Products at Risk  
**1.5 to 2%**  
Industry Sales

Reference: HDA Research Foundation, Kroll & Cramer Associates, & Bullitt & Sullivan, (2016). The Role Of Reverse Distribution. Arlington, VA: HDA Research Foundation.

### 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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# 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 proof if requested by the FDA, other regulatory body, or law enforcement official.

## TEAM


**Julie Malone**, Regulatory Affairs Manager  
**Scott Lushko**, Senior Systems Analyst  
**Abby 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 login for customer profile and system access for inventory control and category management.
- Inventory Control and Category Management collaboration and report 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. Follows and report (signature, 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, TSB hours over a period of 8 months (project management, training, testing and monitoring reports).
- Liberal control technology.


**Critical Success Factors**

- Partnership and consistent looking to be there in event needed.
- Good use efficiency of the system for workflow (status a page).

## 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 investigations should be done, we're not the only.
- The ability to track the response to an investigation and conduct a door review (audit) for corrective action.

### Business Benefits

- Clarity in DSCSA product investigations from a customer reporting perspective.
- Accountant and warehouse ability to run a DSCSA product investigation.
- Ability to provide excellent customer service for the individual (audit) system containing a (suspicious) 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 goals.
- Leverage what you have.

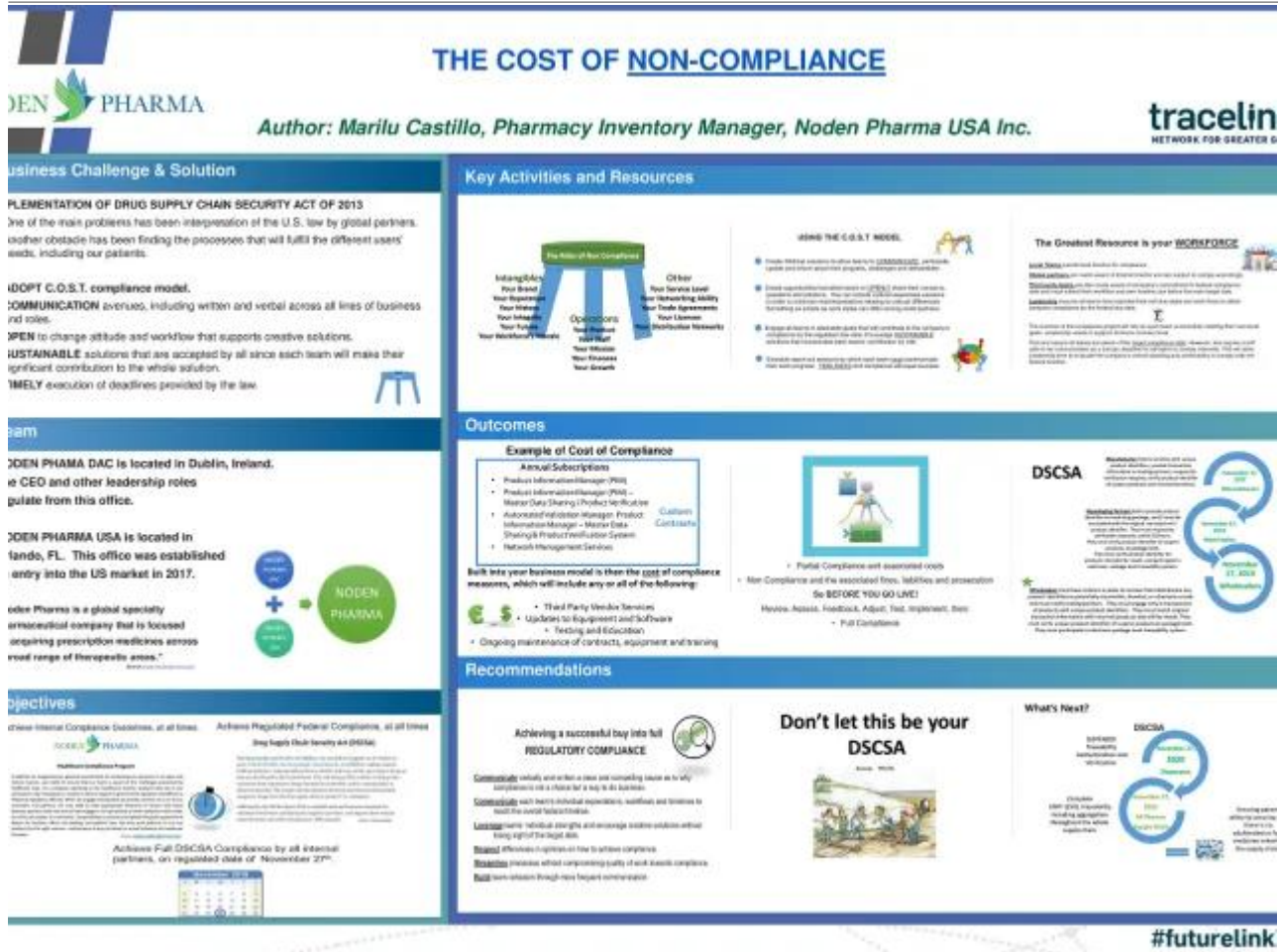
### Next Steps:

- Launching (a) additional (audit) 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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## 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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