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

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

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

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

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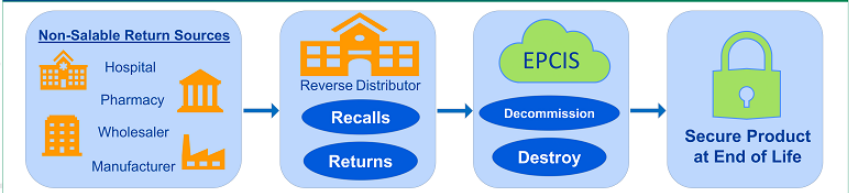
Business Challenge & Solution

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

Non-Salable Return Sources
- Hospital
- Pharmacy
- Wholesaler
- Manufacturer

→ **Reverse Distributor** — Recalls, Returns → **EPCIS** — Decommission, Destroy → **Secure Product at End of Life**

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REVERSE LOGISTICS

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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, Kinßer & Crimmins Associates, & Bradford Rx Solutions. (2018). *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.

#futurelink19

VIEW POSTER SESSION GALLERY

Video Serial Number Manager Global Track & Trace Serialization

United States

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