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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 to 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

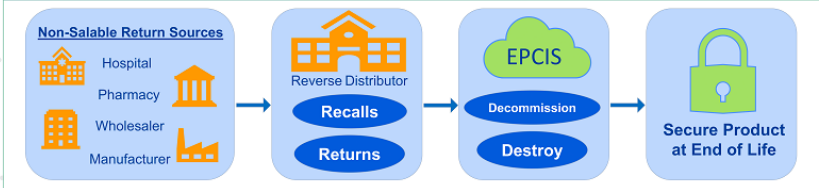
Business Challenge:

- 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



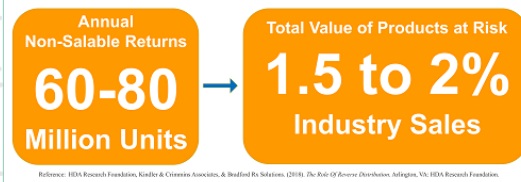
Thierry Beckers, MSM
President & COO

PharmaLinkInc.com
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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.

#futurelink19

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More Serialization and Compliance Case Studies



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**
- Robby Shelow, Director of Customer Service (Retired)**
- Tim Robison, Customer Service Manager**
- John Sellers, Inventory 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**
- Solution required and validated.
 - Single point of contact.
 - Permit team to communicate online and obtain system for Inventory Control and Category Management online investigations.
 - Inventory Control and Category Management collaboration and central task to customer service that triggers and initiates if required.
 - Digitized, customer is contacted, alerts are closed.
 - Provided customer is contacted, the regulator is notified via email and a workflow is created to document and follow up with appropriate entities.

Screenshot of Initial Form



Screenshot of Email



Resources Required

- Dedicated team to structure process flow.
- Dedicated hardware, 150 hours over a period of 8 months including management, training, testing and change efforts.
- External counsel technology.

Critical Success Factors

- Follow-up and consistent follow-up to plan if need arise.
- Good user efficiency of the system for workflow (initially a pilot).

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.

Investigation ID	Customer	Status	Created	Updated	Assigned To
1001	ABC Corp	Open	2023-01-15	2023-01-16	John Doe
1002	DEF Inc	Closed	2023-01-18	2023-01-19	Jane Smith
1003	GHI LLC	Open	2023-01-20	2023-01-21	Mike Johnson
1004	JKL Corp	Closed	2023-01-22	2023-01-23	Emily White
1005	MNO Inc	Open	2023-01-25	2023-01-26	David Brown

Results and Feedback

- Increase in response time results on a consistent approach from a staff perspective.
- Although these investigations should be fast, we are still the reality.
- 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.
- Accurate and consistent ability to run a DSCSA product investigation.
- Ability to provide excellent customer service for all individual trading partners concerning a suspected DSCSA issue.
- Ability to track supplier follow-up.

RECOMMENDATIONS

Advice:

- Involve and test of Regulatory Affairs in technology solutions.
- Clearly defined team and solution pathways.
- Ownership in the process but with the tool.

Lessons Learned

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

Next Steps:

- Launching 2.0 (Additional online technology solutions).
- Regulatory will continue to evolve, so future updates will occur.
- New technology needs and tools are always only a click away from 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 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

- Provide critical information on how to (1) interpret the law, (2) update and create accurate programs, and manage all associated risks.
- Create operational roadmaps and (3) (4) plan and execute compliance activities. This includes (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (40) (41) (42) (43) (44) (45) (46) (47) (48) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67) (68) (69) (70) (71) (72) (73) (74) (75) (76) (77) (78) (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98) (99) (100) (101) (102) (103) (104) (105) (106) (107) (108) (109) (110) (111) (112) (113) (114) (115) (116) (117) (118) (119) (120) (121) (122) (123) (124) (125) (126) (127) (128) (129) (130) (131) (132) (133) (134) (135) (136) (137) (138) (139) (140) (141) (142) (143) (144) (145) (146) (147) (148) (149) (150) (151) (152) (153) (154) (155) (156) (157) (158) (159) (160) (161) (162) (163) (164) (165) (166) (167) (168) (169) (170) (171) (172) (173) (174) (175) (176) (177) (178) (179) (180) (181) (182) (183) (184) (185) 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The Greatest Resource is your WORKFORCE

WORKFORCE is the most valuable resource in any organization. It is the engine that drives the business forward. Investing in your workforce is investing in your future. This includes providing training, development, and support to ensure your team is equipped to handle the challenges of the future.

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 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 to reduce 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

DSCSA

Don't let this be your DSCSA

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

Objectives

Achieve Internal Compliance Deadlines, at all times.

Achieve Regulated Federal Compliance, at all times (Drug Supply Chain Security Act (DSCSA)).

Achieve Full DSCSA Compliance by all internal partners, on regulated date of November 27th.

Recommendations

Achieving a successful buy into full REGULATORY COMPLIANCE

Don't let this be your DSCSA

What's Next?

DSCSA

Implementing DSCSA

#futurelink

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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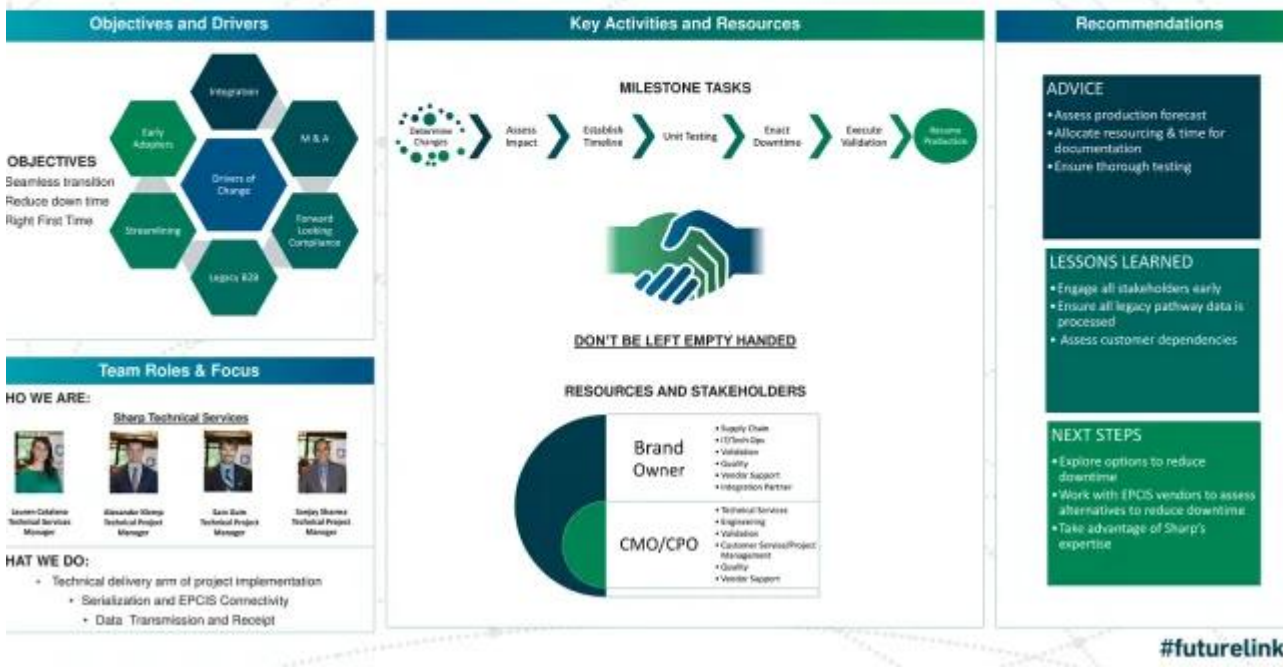
EPCIS Connection Changes post Go-Live

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. 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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