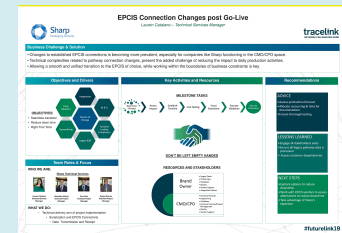




RESOURCES

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Case Study: Sharp Packaging Services | EPCIS Connection Changes Post Go-Live



Sharp Packaging Services provides serialization, packaging, and labeling solutions to pharmaceutical companies around the globe. Sharp's clients often need to change EPCIS connections and packaging requirements after they are in production—and this can result in delays that impact downstream supply chain stakeholders. Read Sharp Packaging Services' FutureLink Nashville case study poster—"EPCIS Connection Changes Post Go-Live"—and watch this video to learn about new processes the company implemented to overcome this change-management challenge.



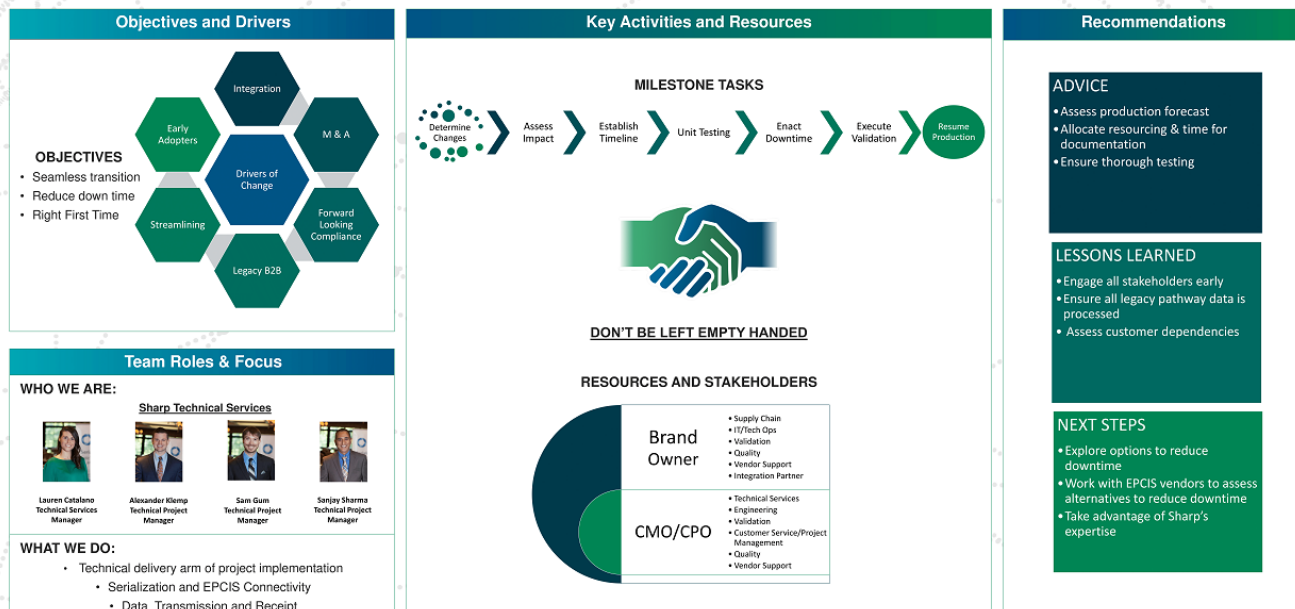
EPCIS Connection Changes post Go-Live

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.



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More DSCSA Compliance Resources



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


Learn how pharma returns specialist PharmaLink increased pharma supply chain security by combining decommissioning and secure product disposal.

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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 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:

- Incident reported and validated.
- Initial call to follow-up.
- Report from the customer arrives and system issues for inventory control and category management to investigate.
- Inventory Control and Category Management collaborate and report back to customer service their findings and resolve if required.
- If unresolved, incident is escalated, notes are added.
- Provided customer is contacted, the regulatory requirement is updated by email and a checkbox is added to document entry. Follow-up and report (ongoing/ended, noted).

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 accepted.
- 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).
- Updated current technology.


Critical Success Factors

- Follow-up and consistent testing to be able to meet demand.
- 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 root review allows for corrective action.

Business Benefits

- Clarity in DSCSA product investigations from a customer reporting perspective.
- Automated and standardized 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:

- Involvement 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.

IDOPT 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

The Pillars of Non Compliance



Using THE C.O.S.T. MODEL

- Trade related activities involve details (COMMODITY), commodity prices and other economic programs, industry trends and forecasts.
- Good opportunities. They provide a lot of information about products and services. They provide a lot of information about products and services. They provide a lot of information about products and services.
- Imported or exported goods that are subject to the various regulations of the government (e.g., import duties, export controls).
- Domestic market and international trade have gone through several changes over time. The world's economy is still recovering from the recession.

Outcomes

Example of Cost of Compliance

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

Culture Change

DSCSA

Partial Compliance with associated costs

- Non Compliance and the associated fines, liabilities and prosecution
- Reprints, Assists, Feedback, Adjust, Test, replacement, loss
- Pull Containment

Objectives

Achieve Internal Compliance Deadlines, at all times.

Achieve Regulated Federal Compliance, at all times.

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

Recommendations

Achieving a successful buy into full REGULATORY COMPLIANCE

Communicate internally and/or external as often and compelling manner as to why compliance is a critical part of a long term business.

Communicate with teams individual expectations, workflows and timelines to meet the overall objectives.


List down every individual step and encourage positive actions without being rigidly legalistic.

Monitor effectiveness regularly on how to achieve compliance.


Rethink measures without compromising quality of work assets compliance.

Build new relations through new frequent communication.

Don't let this be your DSCSA



What's Next?



#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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