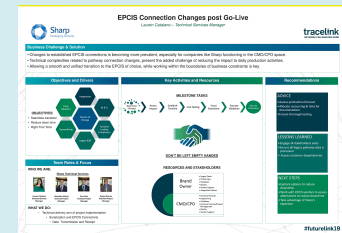




RESOURCES

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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.



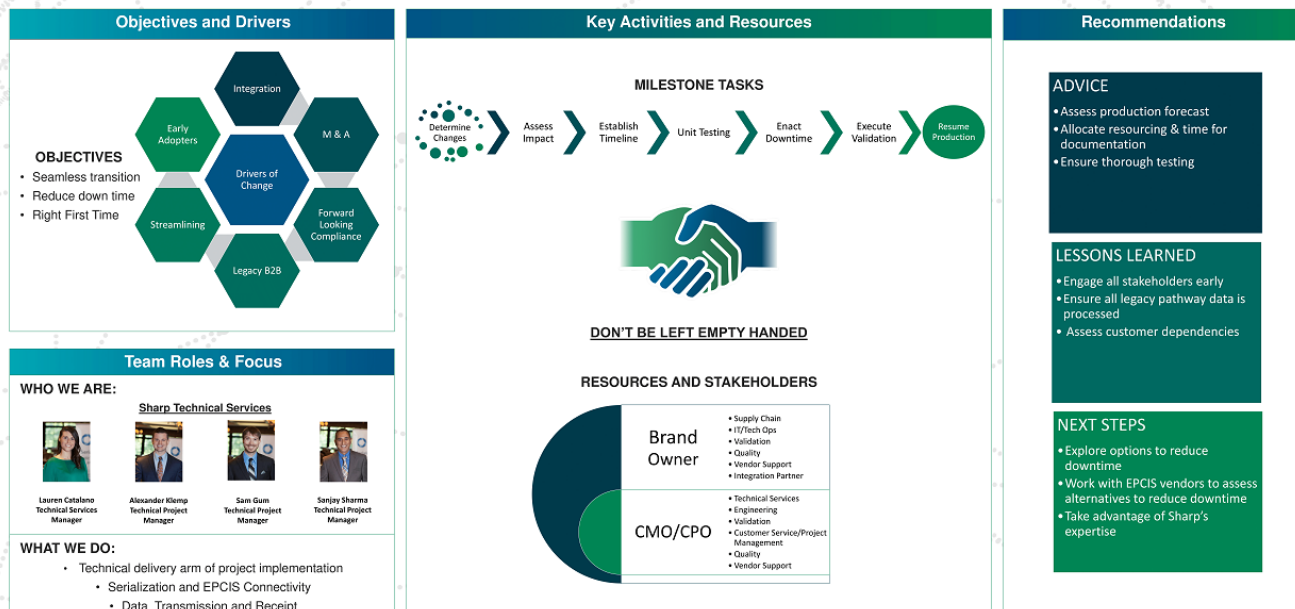
EPCIS Connection Changes post Go-Live

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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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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VALUE
DRUG COMPANY

DSCSA Product Investigation, a Compliance Solution

Authors: Julie Malone, Regulatory Affairs Manager and Scott Lushko, Senior Systems Analyst



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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
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:

- Incident reported and validated.
- Initial call to follow-up.
- Report from the customer arrives and system is open for investigation.
- Inventory Control and Category Management collaborate and report back to customer service that findings and results if required.
- Investigation is completed, results are shared.
- Product is returned to customer, the regulatory requirement is updated by email and a checkbox is added to document entry. Follow-up and report (ongoing, active).

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, TSM 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 there in event of need.
- Good use of 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 is a learning curve, the results are in the end.
- 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.
- Accountant and warehouse 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 a documented plan.
- Leverage what you have.

Next Steps:

- Launching 2.0 (Additional color and technology updates).
- Regulation will continue to evolve, so future updates will come.
- 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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