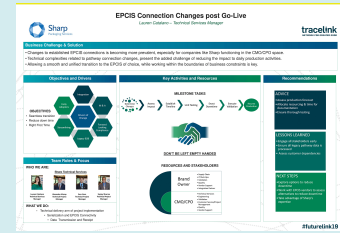




RESOURCES

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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.

Objectives and Drivers	Key Activities and Resources	Recommendations								
<p>OBJECTIVES</p> <ul style="list-style-type: none"> • Seamless transition • Reduce down time • Right First Time <p>Drivers of Change</p> <ul style="list-style-type: none"> Early Adopters Integration M & A Streamlining Legacy B2B Forward Looking Compliance 	<p>MILESTONE TASKS</p> <p>Determine Changes → Assess Impact → Establish Timeline → Unit Testing → Enact Downtime → Execute Validation → Resume Production</p> <p>DON'T BE LEFT EMPTY HANDED</p> <p>RESOURCES AND STAKEHOLDERS</p> <table border="1"> <tr> <td style="background-color: #0056b3; color: white; border-radius: 50%; width: 50px; height: 50px;">Brand Owner</td> <td> <ul style="list-style-type: none"> • Supply Chain • IT/Tech Ops • Validation • Quality • Vendor Support • Integration Partner </td> </tr> <tr> <td style="background-color: #0056b3; color: white; border-radius: 50%; width: 50px; height: 50px;">CMO/CPO</td> <td> <ul style="list-style-type: none"> • Technical Services • Engineering • Validation • Customer Service/Project Management • Quality • Vendor Support </td> </tr> </table>	Brand Owner	<ul style="list-style-type: none"> • Supply Chain • IT/Tech Ops • Validation • Quality • Vendor Support • Integration Partner 	CMO/CPO	<ul style="list-style-type: none"> • Technical Services • Engineering • Validation • Customer Service/Project Management • Quality • Vendor Support 	<p>ADVICE</p> <ul style="list-style-type: none"> • Assess production forecast • Allocate resourcing & time for documentation • Ensure thorough testing <p>LESSONS LEARNED</p> <ul style="list-style-type: none"> • Engage all stakeholders early • Ensure all legacy pathway data is processed • Assess customer dependencies <p>NEXT STEPS</p> <ul style="list-style-type: none"> • Explore options to reduce downtime • Work with EPCIS vendors to assess alternatives to reduce downtime • Take advantage of Sharp's expertise 				
Brand Owner	<ul style="list-style-type: none"> • Supply Chain • IT/Tech Ops • Validation • Quality • Vendor Support • Integration Partner 									
CMO/CPO	<ul style="list-style-type: none"> • Technical Services • Engineering • Validation • Customer Service/Project Management • Quality • Vendor Support 									
<p>Team Roles & Focus</p> <p>WHO WE ARE:</p> <p>Sharp Technical Services</p> <table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Lauren Catalano Technical Services Manager</td> <td>Alexander Klump Technical Project Manager</td> <td>Sam Gum Technical Project Manager</td> <td>Sanjay Sharma Technical Project Manager</td> </tr> </table> <p>WHAT WE DO:</p> <ul style="list-style-type: none"> • Technical delivery arm of project implementation • Serialization and EPCIS Connectivity • Data Transmission and Receipt 					Lauren Catalano Technical Services Manager	Alexander Klump Technical Project Manager	Sam Gum Technical Project Manager	Sanjay Sharma Technical Project Manager		
Lauren Catalano Technical Services Manager	Alexander Klump Technical Project Manager	Sam Gum Technical Project Manager	Sanjay Sharma Technical Project Manager							

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Case Study DSCSA for Manufacturers Regulatory/Compliance United States

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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 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**
- Initial workflow and updated.
 - 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 collaborate and report back to customer service that findings and updates if required.
 - Digitized workflow is captured, alerts are created.
 - 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.
- Extensive content knowledge.

Critical Success Factors

- Follow-up and consistent leading to be plan in next month.
- Good user efficiency of the system for workflow database user.

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	Product	Status	Customer	Support Specialist
1001	Aspirin	Completed	ABC Corp	John Doe
1002	Ibuprofen	In Progress	DEF Inc	Jane Smith
1003	Acetaminophen	Completed	GHI LLC	Mike Johnson
1004	Amoxicillin	Completed	JKL Corp	Sarah Lee
1005	Atorvastatin	In Progress	MNO Inc	David Kim
1006	Clonidine	Completed	PQR LLC	Emily White
1007	Diazepam	Completed	RST Corp	Chris Brown
1008	Fluoxetine	In Progress	UVW Inc	Alex Green
1009	Lisinopril	Completed	XYZ LLC	Nancy Black
1010	Metformin	Completed	ABC Corp	John Doe

Results and Feedback

- Increase in response time results on a consistent approach from a staff perspective.
- Although these investigations should be quick, 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 role 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

Interchange:
Your Brand
Your Suppliers
Your Products
Your Markets
Your Customers

Operations:
Your Product
Your Staff
Your Process
Your Growth

Other:
Your Service Level
Your Marketing Ability
Your Trade Agreements
Your Licenses
Your Distributor Network

HOW THE C.O.S.T. MODEL

1. Provide detailed information on how to (COMPLY) with the law and other associated programs, including all documents.
2. Create operational procedures or (PRACTICE) what best controls, processes, procedures. This can include (COST) compliance advice needed to (COMPLY) with regulations. Make it (COMPLY) operational. Working as a (COST) to help you (COMPLY) with the law.
3. Engage all teams in education (COST) that will contribute to the (COMPLY) compliance by (COMPLY) with the law. (COMPLY) with the law. (COMPLY) with the law. (COMPLY) with the law.
4. Develop a (COMPLY) strategy that will (COMPLY) with the law. (COMPLY) with the law. (COMPLY) with the law. (COMPLY) with the law.

The Greatest Resource is your WORKFORCE

WORKFORCE is the greatest resource for compliance. (COMPLY) with the law. (COMPLY) with the law. (COMPLY) with the law. (COMPLY) with the law.

Team

NODEN PHARMA DAC is located in Dublin, Ireland. The 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 acquiring 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
- Shipping / Product Information System
- Network Management Services

Build into your business model is then 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

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

DSCSA

What's Next?

Objectives

Achieve Internal Compliance Deadlines, at all times.

Achieve Regulated Federal Compliance, at all times (they begin their search on DSCSA).

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 externally to ensure compliance is a top priority for all business partners.

Communicate with each individual department, subsidiary and business to meet the same objectives.

Learn from each individual department, subsidiary and business to ensure compliance is a top priority for all business partners.

Review and monitor compliance on a regular basis to ensure compliance is a top priority for all business partners.

Review and monitor compliance on a regular basis to ensure compliance is a top priority for all business partners.

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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