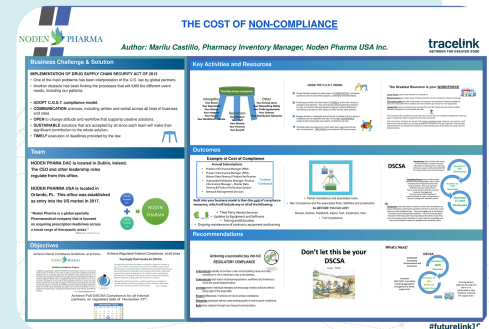# Case Study: Noden Pharma | The Cost of Non-Compliance

Global specialty pharmaceutical company Noden Pharma implemented a COST compliance model—Communication, Open, Sustainable, Timely—to overcome challenges presented by the US Drug Supply Chain Security Act. Read their FutureLink Nashville case study poster—"The COST of Non-Compliance"—and watch this quick video to learn how they avoided the financial and operational risks of non-compliance.

FUTURELINK NASHVILLE 2019

Case Study: The Cost of Non-Compliance

Marilu Castillo, Pharmacy Inventory Manager, Noden Pharma USA

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NETWORK FOR GREATER GOOD

THE COST OF NON-COMPLIANCE

NODEN PHARMA

Author: Marilu Castillo, Pharmacy Inventory Manager, Noden Pharma USA Inc.

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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 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.

Team

NODEN PHAMA DAC is located in Dublin, Ireland.
The CEO and other leadership roles regulate from this office.

NODEN PHARMA USA is located in Orlando, FL. This office was established as entry into the US market in 2017.

"Noden Pharma is a global specialty Pharmaceutical company that is focused on acquiring prescription medicines across a broad range of therapeutic areas."
Source: www.nodenpharma.com

NODEN PHARMA DAC + NODEN PHARMA USA = NODEN PHARMA

Objectives

Achieve Internal Compliance Guidelines, at all times.

NODEN PHARMA
Healthcare Compliance Program

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.

November 2019

Key Activities and Resources

The Risks of Non Compliance

Intangibles
Your Brand
Your Reputation
Your History
Your Integrity
Your Future
Your Workforce's Morale

Operations
Your Product
Your Staff
Your Mission
Your Finances
Your Growth

Other
Your Service Level
Your Networking Ability
Your Trade Agreements
Your Licenses
Your Distribution Networks

USING THE C.O.S.T MODEL
- Create Webinar sessions to allow teams to COMMUNICATE, participate, update and inform about their progress, challenges and deliverables.
- Create opportunities that allow teams to OPENLY share their concerns, questions and solutions. You can include cultural awareness sessions in order to minimize misinterpretations relating to cultural differences. Something as simple as work styles can differ among world partners.
- Engage all teams in attainable goals that will contribute to the company's compliance by the regulated due date. Encourage SUSTAINABLE solutions that incorporates each teams' contribution by role.
- Schedule report out sessions by which each team must communicate their work progress. TIMELINESS and compliance will equal success.

The Greatest Resource is your WORKFORCE

Local Teams submit local timeline for compliance.

Global partners are made aware of federal timeline and are subject to comply accordingly.

Third party teams are also made aware of company's commitment to federal compliance date and must submit their workflow and own timeline due before the main target date.

Leadership ensures all teams have reported their soft due dates and work flows to obtain company compliance by the federal due date.

The success of the compliance project will rely on each team successfully meeting their own local goals. Leadership needs to support all teams at every level.

Post and assure all teams are aware of the target compliance date. However, also require a soft date to be communicated as a primary deadline for all teams to comply internally. This will allow Leadership time to evaluate the company's overall standing and achievability to comply with the federal timeline.

Outcomes

Example of Cost of Compliance

Annual Subscriptions
- Product Information Manager (PIM)
- Product Information Manager (PIM) – Master Data Sharing / Product Verification
- Automated Validation Manager: Product Information Manager – Master Data Sharing & Product Verification System
- Network Management Services

Custom Contracts

Built 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

GO LIVE!

- Partial Compliance and associated costs
- Non Compliance and the associated fines, liabilities and prosecution
So BEFORE YOU GO LIVE!
Review, Assess, Feedback, Adjust, Test, Implement, then:
- Full Compliance

DSCSA

Manufacturers had to serialize with unique product identifiers, provide transaction information to trading partners, respond to verification requests, verify product identifier of suspect products and returned products.

November 27, 2017 Manufacturers

Repackaging Partners had to provide product identifier on each drug package, and it must be associated with the original manufacturer's product identifier. They must respond to verification requests, within 24 hours. They must verify product identifier of suspect products, at package level. They must verify product identifier for products intended for resale, and participate in electronic package level traceability system.

November 27, 2018 Repackaging

Wholesalers must have systems in place to remove from distribution any product identified as potentially counterfeit, diverted, or otherwise unsafe and must notify trading partners. They must engage only in transactions of products with unique product identifiers. They must match original transaction information with returned products that will be resold. They must verify unique product identifier of suspect products at package level. They must participate in electronic package level traceability system.

November 27, 2019 Wholesalers

Recommendations

Achieving a successful buy into full REGULATORY COMPLIANCE

Communicate verbally and written a clear and compelling cause as to why compliance is not a choice but a way to do business.

Communicate each team's individual expectations, workflows and timelines to reach the overall federal timeline.

Leverage teams' individual strengths and encourage creative solutions without losing sight of the target date.

Respect differences in opinions on how to achieve compliance.

Streamline processes without compromising quality of work towards compliance.

Build team cohesion through more frequent communication.

Don't let this be your DSCSA
Team Work

What's Next?

DSCSA

DISPENSER Traceability Authentication and Verification

November 27, 2020 Dispensers

Complete UNIT LEVEL traceability including aggregation throughout the whole supply chain

November 27, 2023 All Pharma Supply Chain

Ensuring patient safety by assuring that there is no adulterated or fake medicines entering the supply chain

#futurelink19

VIEW POSTER SESSION GALLERY

Case Study

Serial Number Manager

DSCSA for Manufacturers

Regulatory/Compliance

United States

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