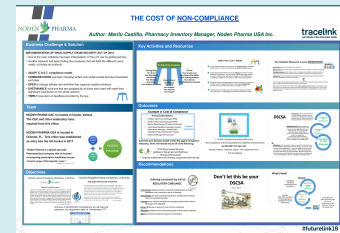




## RESOURCES

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# 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.



## 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 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 PHARMA 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."



### Objectives

**Achieve Internal Compliance Guidelines, at all times.**

**Healthcare Compliance Program**

In addition to supporting our general commitment to conducting our business in an open and honest manner, we intend to ensure that we meet a variety of the challenges presented by healthcare law, which is constantly changing. The healthcare industry presents the most complex and demanding regulatory environment for pharmaceutical companies. We must ensure that our business practices are compliant with all applicable laws and regulations, including those related to the marketing, promotion, distribution, and sale of pharmaceutical products. This includes ensuring that our sales and marketing activities are compliant with the applicable laws and regulations, and that our products are marketed in a safe and effective manner. We will continue to monitor the healthcare industry for changes in laws and regulations, and we will ensure that our business practices are compliant with all applicable laws and regulations at all times.

**Achieve Regulated Federal Compliance, at all times**

**Drug Supply Chain Security Act (DSCSA)**

The Drug Supply Chain Security Act (DSCSA) was enacted by Congress on November 27, 2012. This law requires drug manufacturers to implement a system of product serialization and tracking that will enable them to identify and trace their products throughout the supply chain. This will help to prevent counterfeit drugs from entering the supply chain and will also help to identify and trace the source of any drug-related problems. Manufacturers must implement a system of product serialization and tracking that will enable them to identify and trace their products throughout the supply chain. This will help to prevent counterfeit drugs from entering the supply chain and will also help to identify and trace the source of any drug-related problems. Manufacturers must implement a system of product serialization and tracking that will enable them to identify and trace their products throughout the supply chain. This will help to prevent counterfeit drugs from entering the supply chain and will also help to identify and trace the source of any drug-related problems.

**Achieve Full DSCSA Compliance by all Internal partners, on regulated date of November 27<sup>th</sup>.**

**November 2019**

|    |    |    |    |    |    |    |    |    |    |    |    |
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| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 |    |    |    |    |    |

### Key Activities and Resources

**THE RISKS OF NON-COMPLIANCE**

Intangibles: Your Brand, Your Reputation, Your Integrity, Your Future, Your Workforce's Morale

Other: Your Service Level, Your Networking Ability, Your Trade Agreements, Your Distribution Networks

Operations: Your Product, Your Staff, Your Mission, Your Finance, Your Growth

**USING THE C.O.S.T. MODEL**

- Create theater 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 initiate cultural awareness sessions in order to minimize misinterpretations relating to cultural differences. Something as simple as work styles can often affect workflow.
- Engage all teams in attainable goals that will contribute to the company's compliance by the regulated due date. Encourage **SUSTAINABLE** solutions that incorporate each team's contribution to the goal.
- Individual report on sessions by which each team **UPDATE** communicates their work progress. **TRANSITION** and compliance will equal success.

**The Greatest Resource is your WORKFORCE**

**Local Teams** control local timelines for compliance. **Global networks** are made aware of local timelines and are subject to comply accordingly. **Local networks** are also made aware of company's commitment to federal compliance law and must adjust their workflow and timeline due before the next target date. **Leadership** ensures all teams have reported their work due date and work flow 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. That and a team of experts are what other global participants (GPs) however, also require a soft skills to be incorporated as a primary resource for all teams to comply internally. This will allow Leadership to be successful in the company's overall mission and compliance to comply with the federal timeline.

### Outcomes

**Example of Cost of Compliance**

**Annual Subscriptions**

- Product Information Manager (PIM)
- Product Information Manager - 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

**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** have to verify each unique product identifier, provide transaction information to trading partners, implement a verification system, and provide a digital signature of each product and individual product.

**Wholesalers** have to verify each unique product identifier, provide transaction information to trading partners, implement a verification system, and provide a digital signature of each product and individual product.

**November 27, 2017**  
Manufacturers

**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, workflow 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 as to 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**  
Transparency  
Authentication  
Verification

**November 27, 2020**  
Dispensers

**November 27, 2019**  
All Pharma  
Supply Chain

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

#futurelink19

## View Poster Session Gallery

## Case StudySerial Number ManagerDSCSA for ManufacturersRegulatory/ComplianceUnited States

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## More Serialization and Compliance Case Studies

## The CMO Serialization Perspective Utilizing a Standardized Approach for Efficient Partner Onboarding



Author: Daryl Chin, Manager – Global Track & Trace, Contract Pharmaceuticals Limited (CPL)



### Company Identity

#### Who We Are

For more than 25 years, Contract Pharmaceuticals Limited (CPL) has been providing the world's leading pharmaceutical companies with full-service liquid and semi-solid product development and manufacturing, singularly focused on innovation and efficiency.



#### Project Manager



Daryl Chin

Manager – Global Track & Trace

### Key Activities

#### Master Data Sharing

- Standardized semi-automated master data questionnaire ensures all required master data is completed by BO for L1 – L4 systems (Right First Time principle)

#### Informal Request / Response

- Test the receipt of serial numbers in the iTest environment, especially if partnering with a BO using a non-Tracelink L4 provider
- Commission serial numbers on the UI and send test deliveries to ensure connectivity

#### Formal End-to-End Testing (PQ)

- Pull serial numbers through L4 – L1
- Commission serial numbers using L1
- Push commissioned serial numbers through L1 – L4
- Create delivery to Brand Owner



### Business Challenge

#### Business Challenge

As a Contract Manufacturing Organization (CMO) with an international customer base spanning both the US & EU markets, how can CPL onboard Brand Owners (BOs) efficiently – completing all the required onboarding steps in a timely manner, yet still capturing all the necessary testing to ensure robust connectivity?

### Solution

#### Solution

For CMOs & BOs in the partner onboarding process, utilizing a standard approach results in an overall shorter onboarding duration and ensures that all the required tests are captured, tested, and documented the same way, every time.

CPL has found the following 3-step approach to consistently work the best for us:

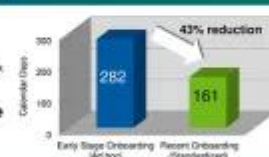


### Outcomes & Recommendations

#### Outcomes

- Early stage onboarding process took > 9 months with steps taken ad hoc
- Recent standardized onboarding process took < 6 months from kick-off to successful PQ

Reduction in errors = Less time spent troubleshooting



#### Recommendations

- Craft a standard approach for CMO / BO onboarding – be vigilant and stick to it!
- Figure out what master data all your systems require and ensure it is captured each time
- CMO L4 – BO L4 represents highest risk; test communication thoroughly prior to PQ
- PQ through all levels of your systems and simulate commercial production as close as possible

### Top 3 Common Pitfalls Encountered During the Onboarding Process

#### Serial Number Requests

- Set BO Maximum Request Quantities so that CMOs can request up to the CMO's maximum threshold, if needed

#### Creating Deliveries

- Agree on To Business and Ship To locations
- Use of GLNs versus sGLNs

#### SOM Sales Shipments

- Configure Transaction Delivery Rules
- Info Exchange is your friend

#futurelink

## Case Study: CPL | The CMO Serialization Perspective—Utilizing a Standardized Approach for Efficient Partner Onboarding

See how contract manufacturer Contract Pharmaceuticals Limited implemented a 3-step process for smooth pharmaceutical partner onboarding.

[View More](#)

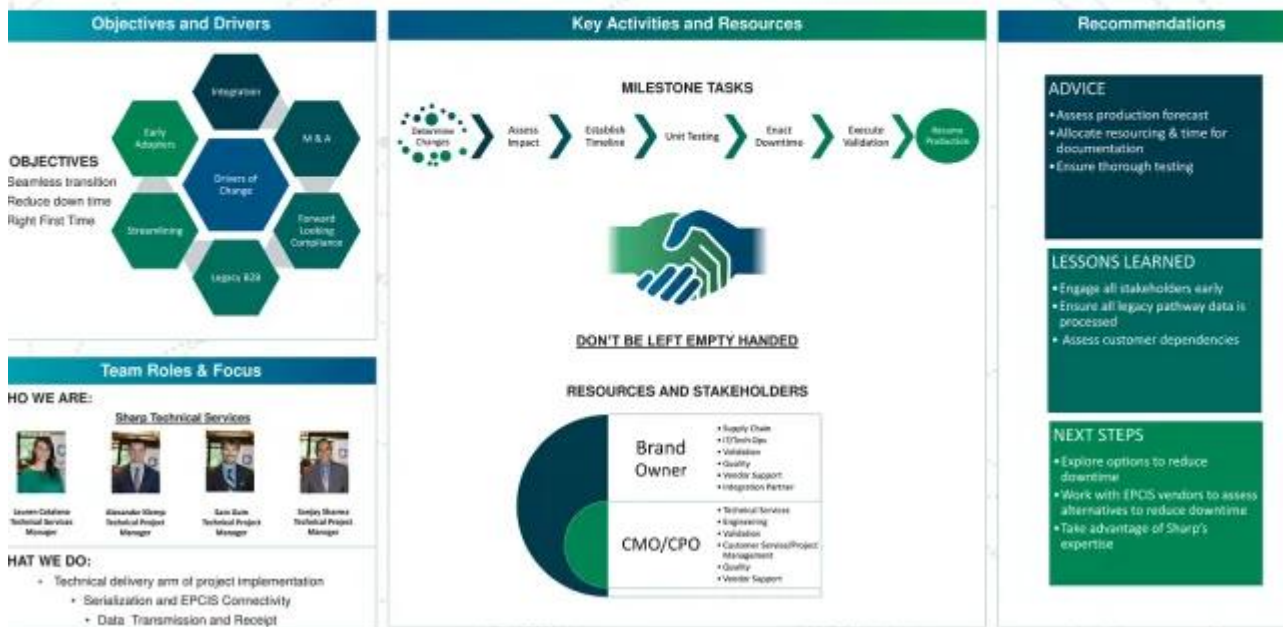
## EPCIS Connection Changes post Go-Live

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.



#futurelink

### 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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**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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