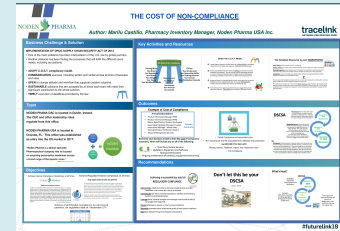




RESOURCES

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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

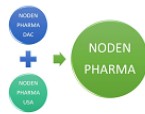
- One of the main problems has been interpretation of the U.S. law by global partners.
- Another obstacle has been finding the processes that will fulfill the different users' needs, including our patients.
- ADOPT C.O.S.T. compliance model.**
- COMMUNICATION** avenues, including written and verbal across 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. We must also 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. We must also 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.

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 ensure that the products are authentic and that they are not counterfeit. The law also 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 ensure that the products are authentic and that they are not counterfeit.

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

November 27, 2019

1	2	3	4	5	6	7	8	9	10	11	12
13	14	15	16	17	18	19	20	21	22	23	24
25	26	27	28	29	30	31					

Key Activities and Resources



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 our partners.
- 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 out sessions by which each team **UPDATE** communicates their work progress. **TRANSITION** and compliance will equal success.



The Greatest Resource is your WORKFORCE

Local Teams are our greatest resource for compliance. **Global partners** are made aware of their contribution and are subject to comply accordingly. **Local partners** are also made aware of their contribution to federal compliance and must report their activities and progress due before the regulated date. **Leadership** ensures all teams have reported their work due date and work flow to obtain complete compliance by the regulated date.

The success of the compliance project will rely on each team successfully meeting their own goals. Leadership needs to support all teams at every level. That is, if a team of teams are aware of their goal (compliance) (DSCSA). However, also require a soft skills to be incorporated as a primary resource for compliance (compliance). This will allow Leadership to ensure the company's overall compliance and accountability to comply with the federal law.



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

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

Custom Contracts

- 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



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



What's Next?



#futurelink19

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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

CPL
Outsourcing Made Easy

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

traceli
NETWORK FOR GREATER GOOD

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:

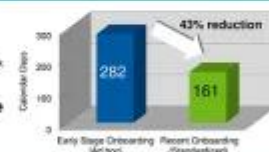


Outcomes & Recommendations

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.



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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.

[View More](#)



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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