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Minimizing Risk: Prepping for Serialization with Pharmas & CMOs



As the life sciences industry moves towards serialization under U.S. DSCSA and EU FMD requirements, both pharmaceutical companies and CMOs are negotiating multiple relationships. If companies don't work together, there is big risk for both sides. Watch this two-minute video to learn what to do – and not do – to achieve readiness with your partners.

Video **Serial Number Manager** **Global Track & Trace** **Serialization** **Brazil, China, European Union, Russia, United States**

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Read why delayed development caused a European pharma to re-evaluate their choice of solutions provider for EU FMD compliance.

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CMOs and CPOs: Best Practices for Approaching Serialization

CMOs and CPOs are critical to the life sciences supply chain's ability to meet global serialization requirements. Learn how to prepare.

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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 (Fight 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?

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

- Create 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

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 details 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:

- 1 Standardized Master Data Sharing
- 2 Informal Request / Response Testing
- 3 Formal End-to-End Testing (PQ)

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.

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Serialized Supply Chain

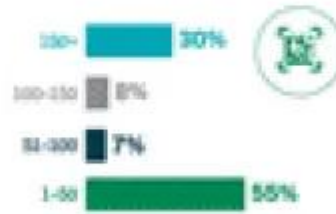
TraceLink's serialization program assessment continues to reveal that pharmaceutical manufacturers of every size want greater visibility into their serialized operations. They want the ability to answer critical business questions using serialization data. They want to replace manual processes with proactive monitoring tools to help them control costs and reduce risk. And they want self-service analytics that let them scale operations as their businesses grow. How do your goals align with these industry benchmarks?

QUICK LOOK: A SNAPSHOT OF SERIALIZED OPERATIONS

Number of Full-Time Employees



Number of SKUs



Number of Markets



SKUs that Require Special Handling



Serialized Operations: Challenges and Opportunities

How do your serialized operations compare with more 100+ pharmaceutical companies? Get the results of TraceLink's serialization program assessment.

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Watch this product demo to see how Serialized Product Intelligence empowers serialized operations teams with self-service troubleshooting capabilities.

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