



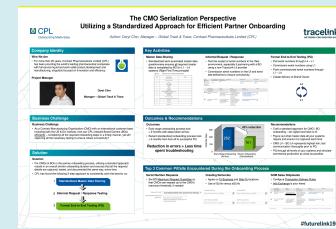
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Case Study: CPL | The CMO Serialization Perspective—Utilizing a Standardized Approach for Efficient Partner Onboarding



As a contract manufacturing organization serving pharmaceutical companies in the US and European Union, Contract Pharmaceuticals Limited (CPL) has found that onboarding brand owners in an efficient and timely manner can be a challenge. Read the company's FutureLink Nashville case study poster and watch this quick video to learn how CPL implemented a three-step process that makes partner onboarding simpler and easier for all stakeholders.



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)

- Push 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

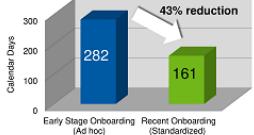
- As a Contract Manufacturing Organization (CMO) with an international customer base including both the US & EU markets, how can CPL onboard Brand Owners (BOs) efficiently – completing all the required onboarding steps in a timely manner, yet still capturing all the necessary testing to ensure robust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

- 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

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



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Case Study Serial Number Manager Manufacturing United States, European Union

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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.



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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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 cardkeeping/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

Sherry Shewell, Director of Customer Service (Retired)

L Robison, Customer Service Manager

in Sellers, Inventory Manager

Ike Gonsman, Warehouse General Manager

Tom Donahue, Director - Category Management

Sherri 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



Schematics

- Incident reported and submitted.
- Email sent to Seller.
- Seller sends the product and evidence to the Inventory Control and Category Management department.
- Inventory Control and Category Management collaborate with Seller to do a further service level analysis and review if required.
- Unpackaged, system is in container, review is done.
- Unpackaged, container is contacted, review is done.
- Unpackaged, container is contacted, review is done.
- Container is sealed and a DSCSA label is created to document audit. Follow-up and audit correspondence is done.

Screenshot of Initial Form



Screenshot of Detailed Form



Resources Required

- Dedicated team to manage process flow
- Dedicated timeframe: 150 hours over 6 days
- Dedicated timeframes: 8 hours for tracking, 10 hours for analysis, 10 hours for reporting, 10 hours for review, 10 hours for audit.
- Utilized current technology

Critical Success Factors

- Provenance and traceability tracking is kept from start to end.
- Good audit efficiency, the system has a workflow interface.

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.



Results and Feedback

- Investigation results are available in a consistent format from a staff perspective.
- Standardized investigation should be used, review of the results.
- The ability to track the response to an investigation and conduct a audit review of the corrective action.

Business Benefits

- Quality in DSCSA product investigations from a compliance reporting perspective.
- A consistent and standardizable review of DSCSA product investigation.
- Ability to provide escalated customer service for an audit and tracking, policies concerning a potential DSCSA issue.
- Ability to track supplier performance.

Recommendations

Advice:

- Inclusion and use of Regulatory Affairs in technology solutions.
- Clearly defined terms and outcome pathways.
- Ownership in the process from top with the board.

Lessons Learned

- Building a culture is a process.
- Training is important, including skills need to be documented over again.
- Leverage what you have.

Next Steps:

- Launching Q3 - Advanced toolset technology solutions.
- Regulators will continue to evolve, be future prepared and remain flexible.
- New technology trends and tools are often pay attention to 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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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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