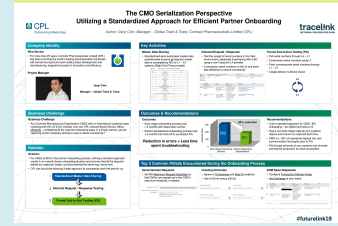




RESOURCES

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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

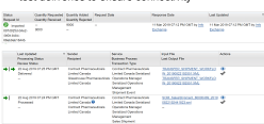
Master Data Sharing

- 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)

- 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

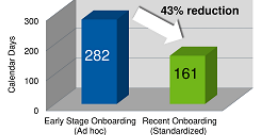
- As a Contract Manufacturing Organization (CMO) with an international customer base including both the US & EU markets, how can CPL onboard Brand Owners (BOs) **efficiently** – completing all the required onboarding steps in a timely manner, yet still capturing all the necessary testing to ensure robust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

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

Top 3 Common Pitfalls Encountered During the Onboarding Process

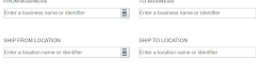
Serial Number Requests

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



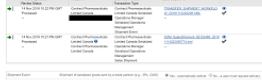
Creating Deliveries

- 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



#futurelink19

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Case Study Serial Number Manager Manufacturing United States, European Union

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More Serialization and Compliance Case Studies

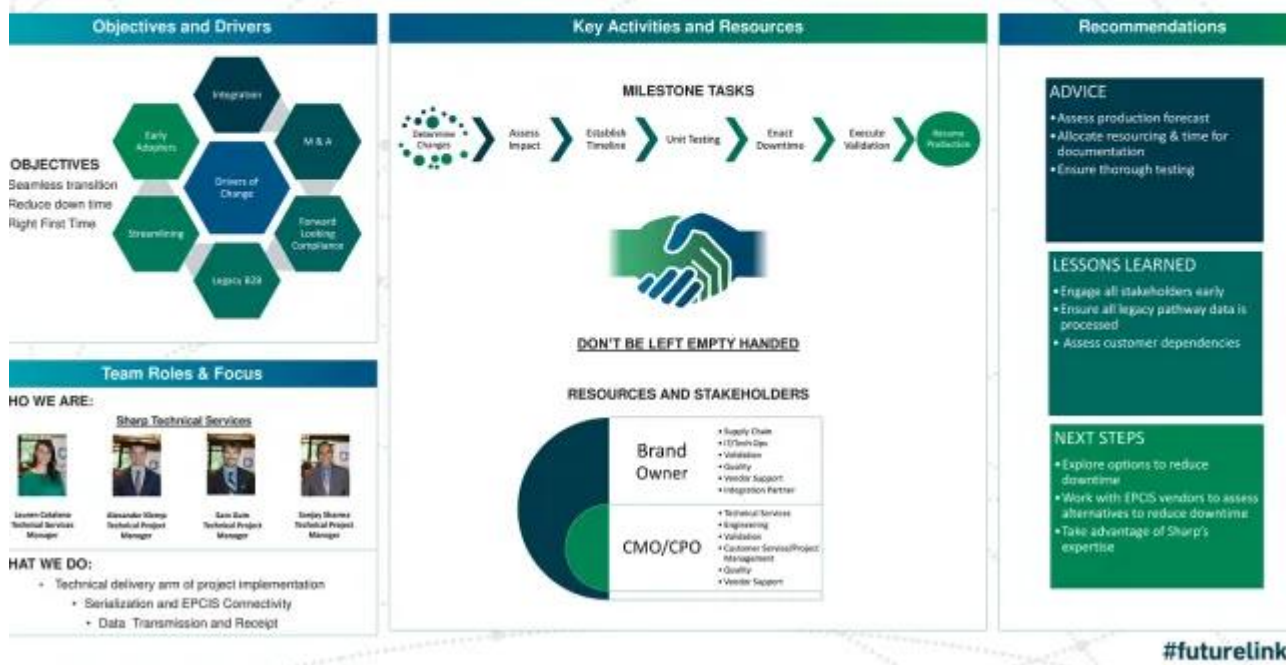
EPCIS Connection Changes post Go-Live

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. Following 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 longstanding 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**
- Robby Shelow, Director of Customer Service (Retired)**
- Tim Robison, Customer Service Manager**
- John Sellers, Inventory Manager**
- Mike Gonsman, Warehouse General Manager**
- Tom Donahue, Director - Category Management**
- Terri 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



- Summary**
- Initial request and approval
 - Single point of follow-up
 - Permit team to communicate online and obtain system for Inventory Control and Category Management online investigations
 - Inventory Control and Category Management collaborator and request back to customer service that findings and updates if required
 - Digitized, customer is contacted, notes are closed
 - Provided customer is contacted, the regulator's response is captured by email and a microblog is created to document any follow-up and other appropriate notes

Screenshot of Initial Form



Screenshot of Email



Resources Required

- Dedicated team to structure process flow
- Dedicated hardware, 150 hours over a period of 8 months including management, training, testing and change efforts
- Extensive control technology

Critical Success Factors

- Follow-up and consistent follow-up to plan if need arise
- Good user efficiency of the system for workflow database user

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.

Investigation ID	Customer	Status	Created	Updated	Assigned To
1001	ABC	Open	10/10/2011	10/10/2011	John
1002	DEF	Closed	10/11/2011	10/11/2011	Jane
1003	GHI	Open	10/12/2011	10/12/2011	John
1004	JKL	Closed	10/13/2011	10/13/2011	Jane
1005	MNO	Open	10/14/2011	10/14/2011	John
1006	PQR	Closed	10/15/2011	10/15/2011	Jane
1007	STU	Open	10/16/2011	10/16/2011	John
1008	VWX	Closed	10/17/2011	10/17/2011	Jane
1009	YZA	Open	10/18/2011	10/18/2011	John
1010	BCD	Closed	10/19/2011	10/19/2011	Jane

Results and Feedback

- Increase in response time results on a consistent approach from a staff perspective
- Although these investigations should be quick, we are not the only
- The ability to track the response to an investigation and conduct a post review allows for corrective action

Business Benefits

- Clarity in DSCSA product investigations from a customer reporting perspective
- Accurate and consistent ability to run a DSCSA product investigation
- Ability to provide excellent customer service for all individual trading partners concerning a suspected DSCSA issue
- Ability to track supplier following

RECOMMENDATIONS

Advice:

- Involve and test of Regulatory Affairs in technology solutions
- Clearly defined team and solution pathways
- Ownership in the process but with the tool

Lessons Learned

- Building a solution is a process
- Training is important, including skills and a documented user guide
- Leverage what you have

Next Steps:

- Launching 2.0 (Additional control technology solutions)
- Regulatory will continue to evolve, so future updates will occur
- New technology needs and tools are always only a click away from 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.

[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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