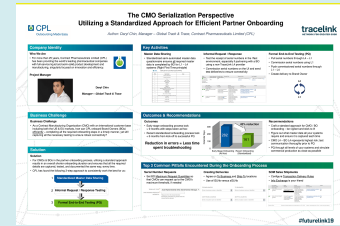




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# Case Study: CPL | The CMO Serialization Perspective—Utilizing a Standardized Approach for Efficient Partner Onboarding



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

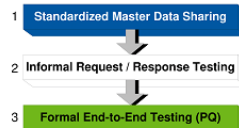
#### Business Challenge

- 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?

### 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:

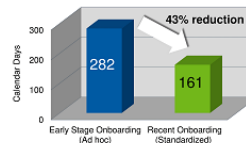


### Outcomes & Recommendations

#### 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

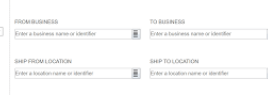
#### Serial Number Requests

- 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



#futurelink19

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## Case StudySerial Number ManagerManufacturingUnited 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. 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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# 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 output if requested by the FDA, other regulatory body, or law enforcement official.

## TEAM


**Julie Malone**, Regulatory Affairs Manager  
**Scott Lushko**, Senior Systems Analyst  
**Abby Shelow**, Director of Customer Service (Retired)  
**Tim Robison**, Customer Service 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:**

- Incident reported and validated.
- Initial call to follow-up.
- Report taken for customer review and system review for inventory control and Category Management update investigations.
- Inventory Control and Category Management collaboration and report back to customer service that findings and resolution if required.
- Investigation, incident is resolved, history are closed.
- Provided, customer is contacted, the regulatory requirement is updated by email and a checklist is created to document only. Follow-up and report (ongoing, initial).

### Screenshot of Initial Form

Customer Service begins the process by filling out the Product Investigation form.




### Screenshot of Email

Users are notified throughout the process using emails with links to our tracking software.

**Summary:**

- Product investigation begins.
- Product investigation is initiated.
- Work is completed by other departments.
- Product investigation is closed.



### Resources Required

- Dedicated team to structure process flow.
- Dedicated hardware, TSM hours over a period of 8 months (project management, training, testing and monitoring reports).
- Updated control technology.


**Critical Success Factors**

- Partnership and consistent looking to be able to meet demand.
- Good use efficiency of the system for workflow (status, a page).

## 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

- Immediate for response time results on a consistent approach from a staff perspective.
- Although there investigations should be done, we're not the only.
- The ability to track the response to an investigation and conduct a post review allows for collective action.

### Business Benefits

- Clarity in DSCSA product investigations from a customer reporting perspective.
- Accountant and consistent ability to run a DSCSA product investigation.
- Ability to provide excellent customer service for the individual dealing with customer in a regulated DSCSA issue.
- Ability to track supplier follow-up.

## RECOMMENDATIONS

### Advice:

- Inclusion and role of Regulatory Affairs in technology solutions.
- Clearly defined roles and solution pathways.
- Ownership in the process built with the tool.

### Lessons Learned

- Building a solution is a process.
- Training is important, including skills and is documented over time.
- Leverage what you have.

### Next Steps:

- Launching 2.0 (Additional rollout technology solution).
- Regulation will continue to evolve, so future updates will occur.
- New technology needs and tools are critical only 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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