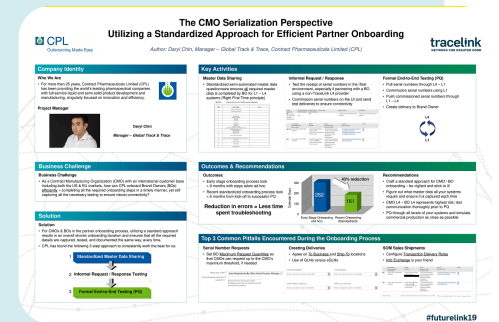# Case Study: CPL | The CMO Serialization Perspective—Utilizing a Standardized Approach for Efficient Partner Onboarding

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

CPL — Outsourcing Made Easy

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

tracelink — 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

L4

L1

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

43% reduction

282 → 161

Calendar Days: Early Stage Onboarding (Ad hoc) / Recent Onboarding (Standardized)

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

Case Study

Serial Number Manager

Manufacturing

United States

,

European Union

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