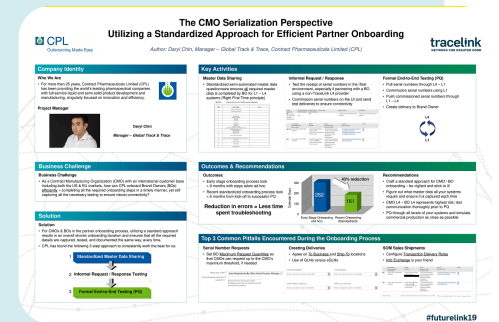


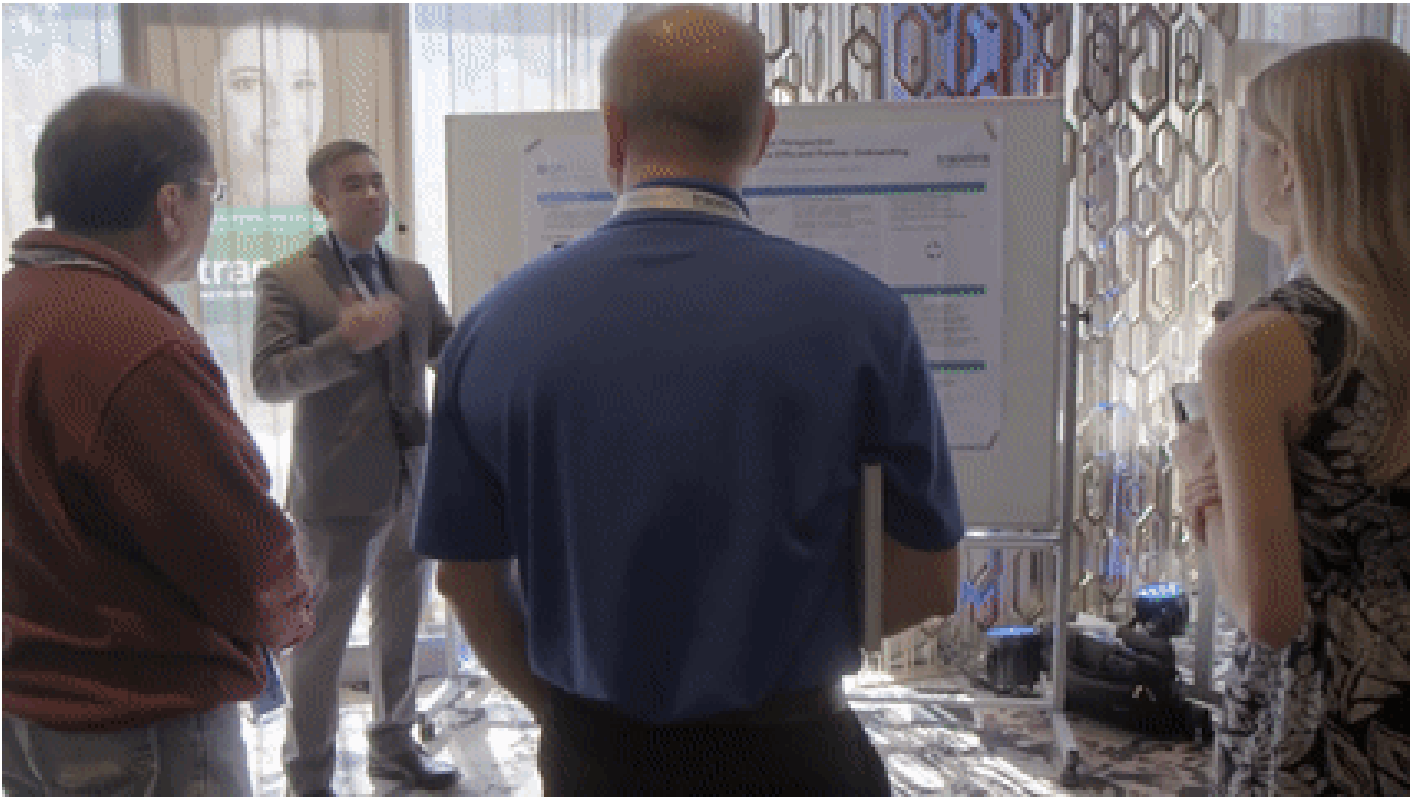
RESOURCES

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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

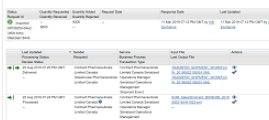
Master Data Sharing

- Standardized semi-automated master data questionnaire ensures all required master data is completed by BO for L1 – L4 systems (Right First Time principle)

Item	Serial Number	SNM
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
10	10	10
11	11	11
12	12	12
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14	14	14
15	15	15
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92	92	92
93	93	93
94	94	94
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96	96	96
97	97	97
98	98	98
99	99	99
100	100	100

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

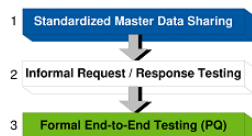
Business Challenge

- 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:

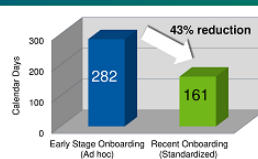


Outcomes & Recommendations

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

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