

# The CMO Serialization Perspective


## Utilizing a Standardized Approach for Efficient Partner Onboarding

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### 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)

Field	Specification	Value
1	Customer Company Name	
2	Customer Street Address	
3	City	
4	State or Region (use ISO 3166 codes)	
5	Postal Code (Zip Code)	
6	Country	
7	Company GLN (GS1)	
8	Product Code Group (automatically calculated - 18 out of Poles 18 and 22)	
9	Electronic Data Interchange (EDI) Partner Code	
10	Item Code Type (Product Code)	
11	Item Code Value (no dashes)	
12	Markets (if a market other than the United States is entered, see next field)	
13	Product Type	
14	Product Origin	
15	Manufactured by	

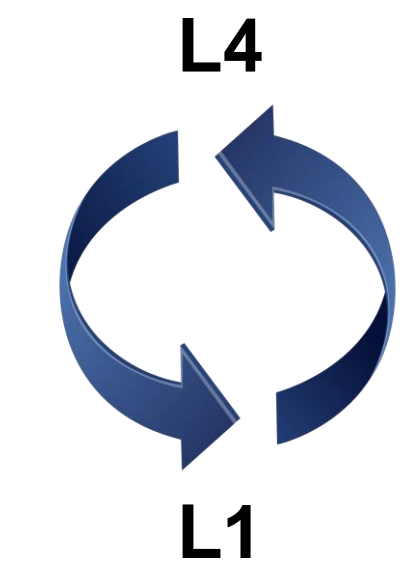
**Informal Request / Response**

- 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

Status	Quantity Requested	Quantity Added	Request Date	Response Date	Last Updated
Imported	9000	9000		11 Mar 2019 07:12 PM GMT by [User]	11 Mar 2019 07:12 PM GMT by [User]
Delivered	9000	9000		Exchanges	Exchanges

**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**

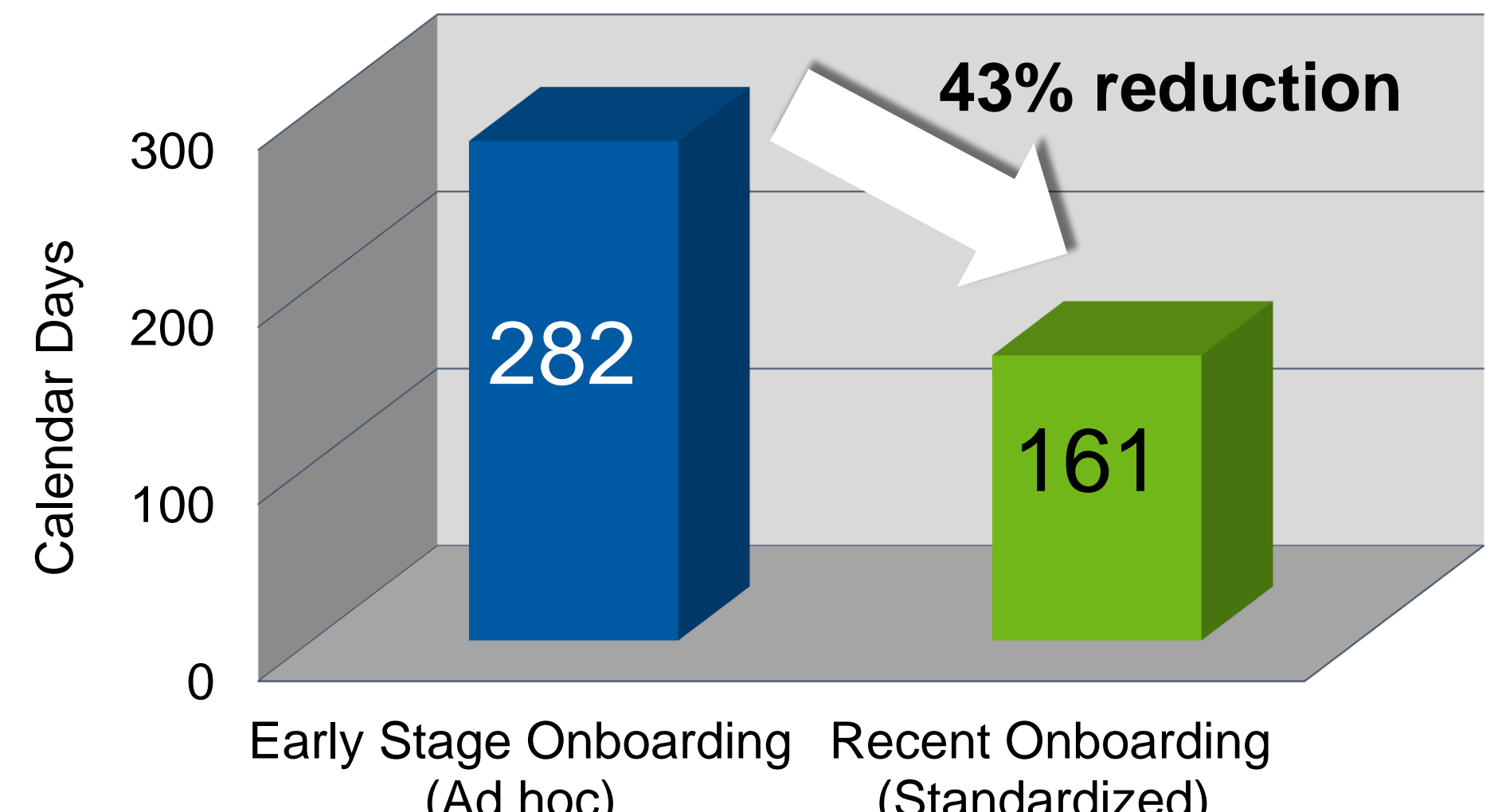
- As a Contract Manufacturing Organization (CMO) with an international customer base including both the US & EU markets, how can CPL onboard Brand Owners (BOs) efficiently – completing all the required onboarding steps in a timely manner, yet still capturing all the necessary testing to ensure robust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

TEMPLATE TYPE: Auto-Replenished By Other Serial Number Manager

SNX MAXIMUM REQUEST QUANTITY: [Input field]

Requests from the Serial Number Exchange subscriber for greater than this amount will be denied

**Creating Deliveries**

- Agree on To Business and Ship-To locations
- Use of GLNs versus sGLNs

FROM BUSINESS: [Input field] TO BUSINESS: [Input field]

SHIP FROM LOCATION: [Input field] SHIP TO LOCATION: [Input field]

**SOM Sales Shipments**

- Configure Transaction Delivery Rules
- Info Exchange is your friend

Last Updated	Processing Status	Review Status	Sender	Service	Business Process	Transaction Type	Input File	Last Output File	Actions
14 Nov 2018 10:22 PM GMT	Processed		Contract Pharmaceuticals Limited Canada	Contract Pharmaceuticals Limited Canada Serialized	Contract Pharmaceuticals Serialized Operations Management	TRANSFER_SHIPMENT_WORKFLOW	IT_2018111522208.XML		
14 Nov 2018 10:21 PM GMT	Processed		Contract Pharmaceuticals Limited Canada	Contract Pharmaceuticals Limited Canada Serialized	Contract Pharmaceuticals Serialized Operations Management	SOM_SalesShipment	8212460_2018	111522059774.xml	

Shipment Event: Shipment of serialized goods sent by a trade partner (e.g., CPL, CMO) Yes - automatically deliver No - a user must request delivery