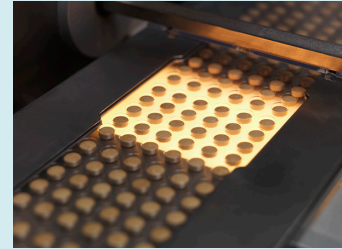




RESOURCES

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Resource Center

3M, Patheon, Reed-Lane, Sharp & Teva Share Serialization Strategies



Original webcast: May 25, 2016

When it comes to implementing serialization, a small number of CMOs are ahead of the curve. Why did they invest early? What lessons have they learned? What advice would they give to other CMOs? And what can brands do to more productively work with these contract partners?

In this on-demand webinar, a top pharma company and four leading CMOs share best practices that will help any company working towards serialization accelerate their progress:

- How pharma companies can best work with their CMOs.
- The CMO business case for serialization.
- The importance of contingency planning.
- LMS vendor experiences.
- The risk of jeopardizing key business relationships if you don't act now.

United States

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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)

traceli
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 questionnaires ensures all required master data is completed by BO for L1 – L4 systems (Right First Time principle).


System	Master Data	Completion Status
L1	Product	Completed
L1	Manufacturer	Completed
L1	Lot	Completed
L1	Batch	Completed
L1	Serial Number	Completed
L2	Product	Completed
L2	Manufacturer	Completed
L2	Lot	Completed
L2	Batch	Completed
L2	Serial Number	Completed
L3	Product	Completed
L3	Manufacturer	Completed
L3	Lot	Completed
L3	Batch	Completed
L3	Serial Number	Completed
L4	Product	Completed
L4	Manufacturer	Completed
L4	Lot	Completed
L4	Batch	Completed
L4	Serial Number	Completed

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

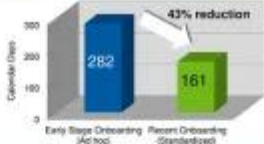
Business Challenge
As a Contract Manufacturing Organization (CMO) with an international customer base including both the US & EU markets, how can CPL onboard Brand Owners (BOs) efficiently – completing all the required onboarding steps in a timely manner, yet still capturing all of the necessary testing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

#futurelink

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

See how contract manufacturer Contract Pharmaceuticals Limited implemented a 3-step process for smooth pharmaceutical partner onboarding.

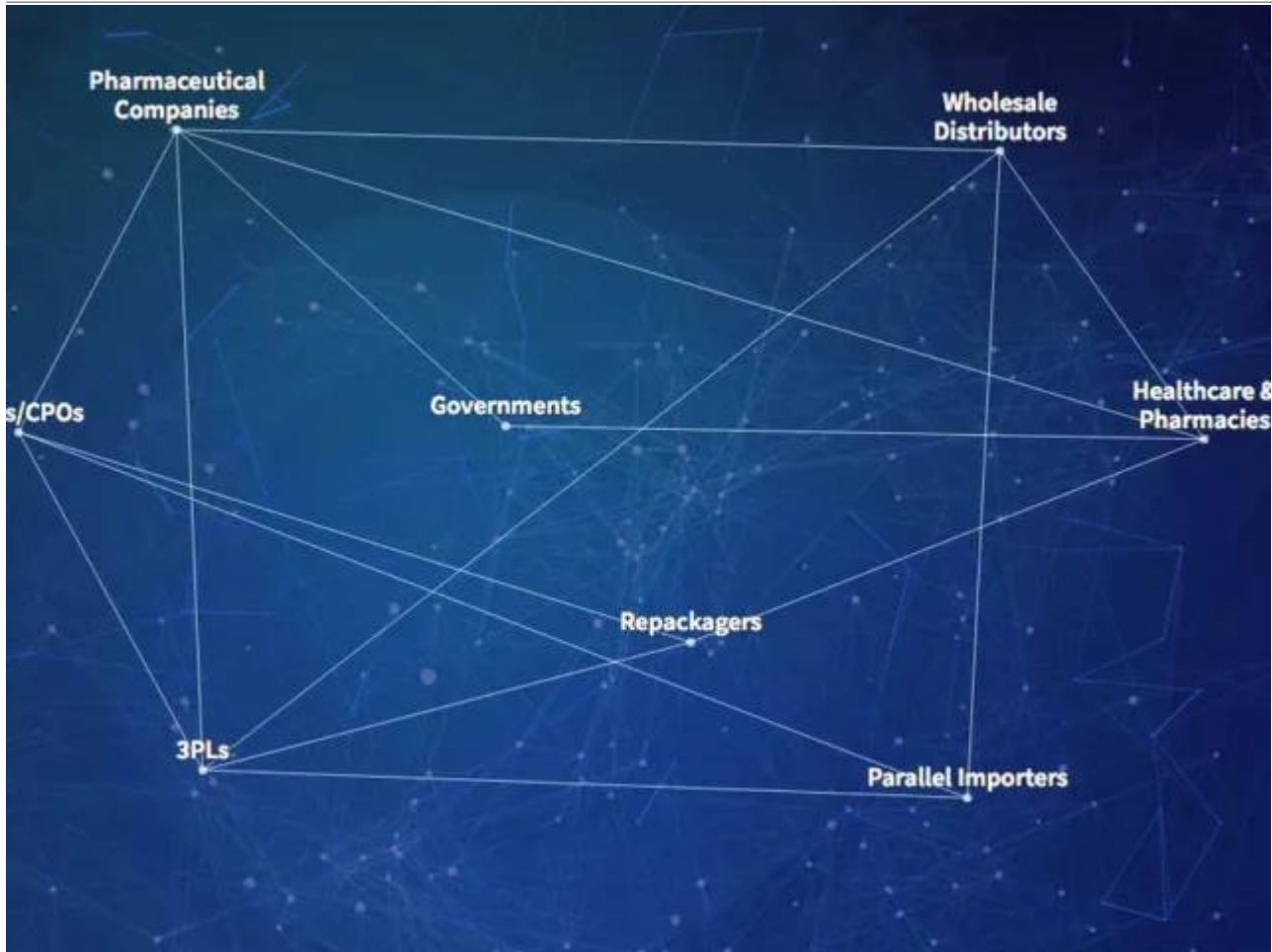
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