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# How EU FMD Impacts CMOs



This two-minute video will give you a quick introduction to what the EU Falsified Medicines Directive (FMD) means for contract manufacturing organizations (CMOs), and what you need to do by the time it comes into force on the 9th of February 2019.

**VideoEuropean Union Falsified Medicines DirectiveGlobal Track & TraceRegulatory/ComplianceEuropean Union**

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# 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 (Fight 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 spanning 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

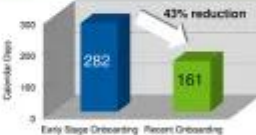
#### Outcomes

- 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

- Create 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



#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.

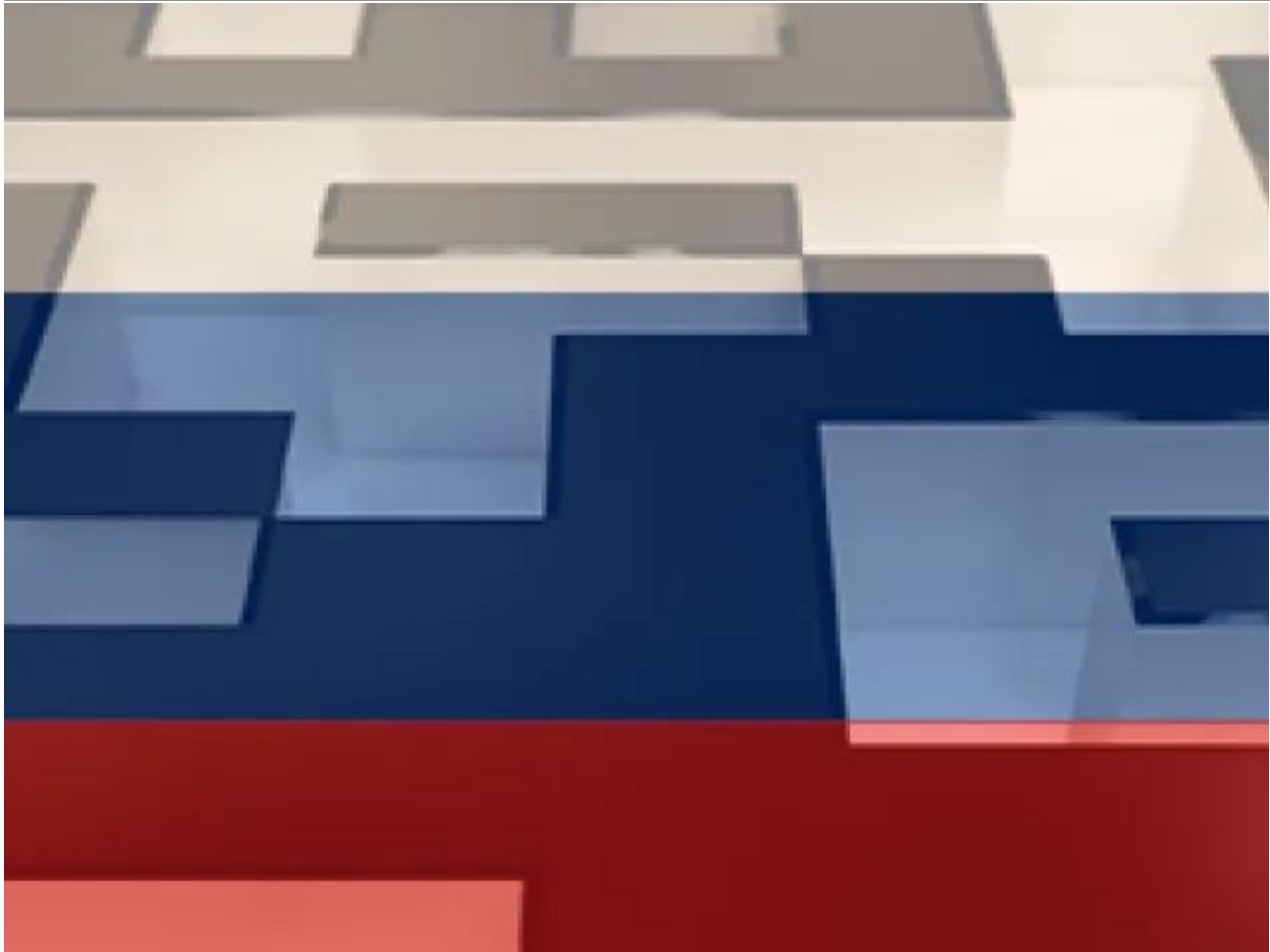
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