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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



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)

Informal Request / Response

- Test the receipt of serial numbers in the iTest environment, especially if partnering with a BO using a non-Traceli 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?

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 tests 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:

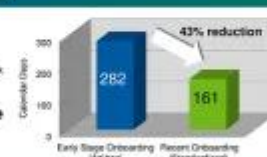


Outcomes & Recommendations

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

#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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