



## RESOURCES

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# Almirall and TraceLink: Committed to Quality and Innovation



For Spanish pharmaceutical company Almirall, science, innovation, quality, and security are all of critical importance to the company. Hear the Almirall team discuss how serialization — and a TraceLink partnership — are a natural fit with these values.

### **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-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?

### 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:

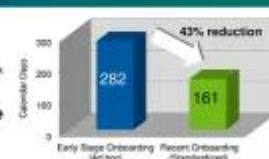


### Outcomes & Recommendations

#### 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

- 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

### 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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## CIT Pharma : the digital transformation from paper to 4.0

Author : Alberto Barrios CIT – Qualified Person & Responsible for the Digital transformation programme

Poster #121

### Key Challenge & Solution

**Challenge:** The need to improve manufacturing quality to comply with regulatory requirements in a highly competitive market. The challenge was to implement a digital transformation program that would improve quality and reduce costs.

**Solution:** The implementation of a digital transformation program that included the use of Industry 4.0 technologies, such as IoT, AI, and Cloud computing, to improve quality and reduce costs.

**Impact:** The implementation of the digital transformation program resulted in a significant improvement in quality and a reduction in costs, leading to a competitive edge in the market.

### Key Activities and Resources

**Key Activities:**

- 1. Assessment of the current state of the business
- 2. Definition of the digital transformation strategy
- 3. Implementation of the digital transformation program
- 4. Monitoring and evaluation of the program

**Resources:**

- 1. Industry 4.0 technologies (IoT, AI, Cloud computing)
- 2. Digital transformation program
- 3. Qualified personnel
- 4. Financial resources

### Outcomes

**Key Outcomes:**

- 1. Improved quality of the product
- 2. Reduced costs of production
- 3. Increased efficiency of the production process
- 4. Improved customer satisfaction

**Key Results:**

- 1. 10% improvement in quality
- 2. 5% reduction in costs
- 3. 15% increase in efficiency
- 4. 10% increase in customer satisfaction

### Recommendations

**Key Recommendations:**

- 1. Continue to invest in digital transformation technologies
- 2. Monitor and evaluate the program regularly
- 3. Implement a digital transformation program that is tailored to the specific needs of the business
- 4. Invest in training and development of personnel

**Key Steps:**

- 1. Define the digital transformation strategy
- 2. Implement the digital transformation program
- 3. Monitor and evaluate the program
- 4. Implement a digital transformation program that is tailored to the specific needs of the business

## Case Study: CIT Pharma | Digital Transformation for CPOs

CIT Pharma looks for a competitive edge with digital transformation.

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