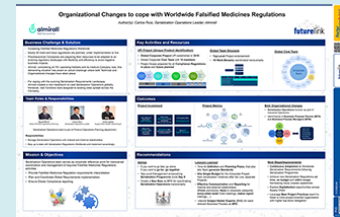


## RESOURCES

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# Case Study: Almirall | Best Practices for Falsified Medicine Compliance



Learn how Almirall made strategic organizational changes to support continuous adaptation to worldwide serialization requirements. Almirall's poster, "Organizational Changes to Cope with Worldwide Falsified Medicines Regulations," was one of 11 featured during FutureLink Barcelona.



## Organizational Changes to cope with Worldwide Falsified Medicines Regulations

Author(s): Carlos Ruiz, Serialization Operations Leader, Almirall



Poster Session Online

futurelink

P-03  
FUTURELINK  
Carlos Ruiz, Manager

### Business Challenge & Solution

- Increasing Falsified Medicines Regulations Worldwide
- Nearly 40 track-and-trace regulations are planned, under implementation or live
- Pharmaceutical Companies are preparing their resources to be adapted to an evolving regulatory landscape with flexibility and efficiency to avoid negative business impacts
- Almirall, considering all 70+ operating Markets and its medium Company size, this demanding situation has posed an actual challenge where both Technical and Organizational changes have taken place.
- For coping with the evolving Serialization Requirements Landscape, Almirall created a new headcount to Lead Serialization Operations globally. Moreover, new functions were assigned to existing roles spread across the Company.

### Team Roles & Responsibilities



Head of Product Operations Planning



Serialization Operations Leader



Supply Chain Master Data Analyst

Serialization Operations team is part of Product Operations Planning department.

#### Responsibilities:

- Manage Serialization Operations with Internal and External stakeholders
- Stay up to date with Serialization Regulations Worldwide and implement accordingly

### Mission & Objectives

Serialization Operations team serves as corporate reference point for transversal coordination and management of required Falsified Medicines Regulations activities.

- Provide Falsified Medicines Regulation requirements interpretation
- Plan and Coordinate Global Requirements implementation
- Ensure Global Compliance reporting



### Key Activities and Resources

#### UPI Project (Unique Product Identification)

- Global Corporate Project UPI established in 2015
- Global Corporate Core Team with 15 members
- Project Scope prepared for all Compliance Regulations in place and future planned



#### Global Team Structure

- Top-Level Project endorsement
- 10 Work-Streams coordinated transversally



#### Global Core Team



### Outcomes

#### Project Investment

- Total Effort of more than 800 man-months
- More than 800 products to be implemented based on 40+ new EU BPs
- 2 Packaging Sites (2 Packaging Lines)
- More than 15,000s with 200 SKUs impacted
- 22 Skatons with 250 SKUs impacted at several Skatons
- Up to 20 Logistic Operations

#### Project Metrics



#### BAU Organizational changes

- Serialization Operations function as part of Industrial Operations
- Identification of Business Process Owners (BPO) and Business Process Managers (BPM)



### Recommendations

#### Advice

- If you want to go fast, go alone. If you want to go far, go together.
- Top-Level Management empowering Serialization Programme since Day 0
- Create a New Role as BPO for coordinating Serialization Operations transversally



#### Lessons Learned

- Time for Definition and Planning Phase, that also lets Team generate Standards
- One Single Budget for the Corporate Project. New serialization initiatives after Go Live, separate Projects.
- Effective Communication and Reporting for internal and external stakeholders (Circle community, News in corporate webportal, every-other-week Core meetings, status report mailings,...)
- Internal Subject Matter Experts (SME) for each relevant Business Process as BPO

#### Next Steps/Improvements

- Continuous Adaptation to Worldwide Serialization Requirements following Serialization Programme
- Achieve new Serialization Regulations on time, on budget and within scope harnessing newly created capabilities
- Explore Digitalization opportunities across Supply Chain
- Leverage Best Project Practices learnt to foster a more project-oriented organization with higher top-down delegation

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### Case StudyEuropean Union Falsified Medicines DirectiveGlobal Track & TraceRegulatory/ComplianceEuropean Union

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#### More Global Compliance Resources



#### Turning Point: From Achieving Compliance to Creating Business Value from Serialization

FutureLink poll results reveal an industry at a turning point. Learn how stakeholders across the supply chain plan to create new business value and make the global drug supply more secure.

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