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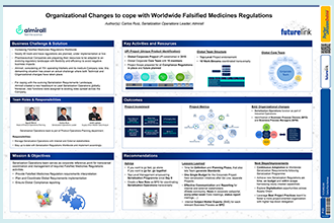
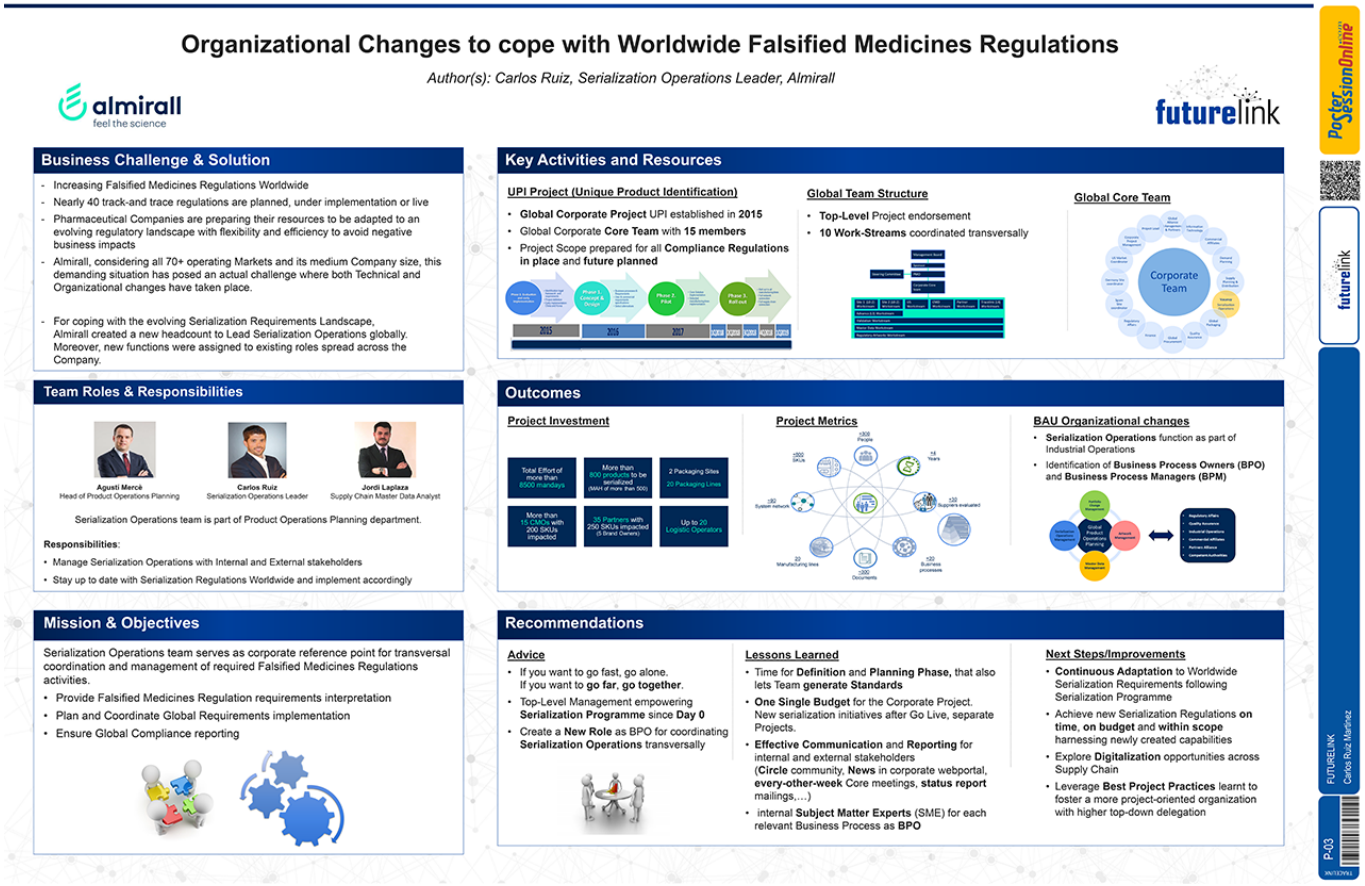
Case Study: Almirall | Best Practices for Falsified Medicine Compliance



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

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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.

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

Team Roles & Responsibilities

Agusti Mercè — Head of Product Operations Planning
Carlos Ruiz — Serialization Operations Leader
Jordi Laplaza — 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

Outcomes

Project Investment

Total Effort of more than 8500 mandays | More than 800 products to be serialized (SMH of more than 500) | 2 Packaging Sites, 20 Packaging Lines | More than 15 CMOs with 200 SKUs impacted | 35 Partners with 250 SKUs impacted (5 Brand Owners) | Up to 20 Logistic Operators

Project Metrics

BAU Organizational changes

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

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

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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