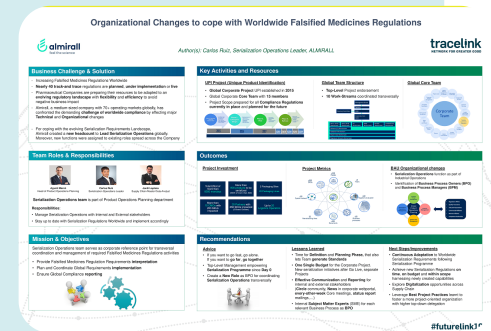


RESOURCES

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Case Study: Almirall | Organizational Changes to Cope with Worldwide Falsified Medicines Regulations



When it comes to complying with the world's many falsified medicines regulations, spot solutions that meet the requirements of just one market will not suffice. Read Almirall's case study poster, which was featured during the interactive poster session at FutureLink Nashville, to learn how TraceLink enables customers to implement compliance strategies that span the globe.

Organizational Changes to cope with Worldwide Falsified Medicines Regulations



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



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 impact
- Almirall, a medium-sized company with 70+ operating markets globally, has confronted the demanding challenge of worldwide compliance by effecting major Technical and Organizational changes
- 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 currently in place and planned for the future



Global Team Structure

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



Global Core Team



Team Roles & Responsibilities



Agustí Mercé
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



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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Case Study

Serialized Operations Manager

Global Track & Trace

Regulatory/Compliance

United States

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