



RESOURCES

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IBERFAR: Partnering with TraceLink for FMD and Digital Integration



When Portuguese CMO/CPO IBERFAR was selecting a partner to help them manage the complex requirements of serialization and EU FMD, they searched for a company that offered deep expertise, stellar support, and built-in efficiencies. Hear IBERFAR team members explain how TraceLink's experience, Cloud Community, and network integrations checked all the boxes.

Case Study **European Union Falsified Medicines Directive** **Global Track & Trace** **Regulatory/Compliance** **European Union**

Contact us to discuss your serialization needs
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More Serialization and Compliance Resources



Orient Pharma and TraceLink: Partnering for Success on Serialization and Quality

Learn how TraceLink enables Orient Pharma to deliver serialization at a global scale.

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HOW TO BUILD AN EMPIRE WITH SERIALIZATION

Jordan Moran-Cabrera, Validator Leader & Jefe Bufanda, Senior Team Officer at Mithra



Challenge & Solution

What are we to?

Mithra is a pharmaceutical company focused on creating innovative new drugs to improve people's lives. With a portfolio of 10+ products, the company is currently in the process of serializing its products across multiple markets. The challenge was to create a centralized system that could manage the complex data associated with each product and market, while also ensuring that the system was scalable and secure.

Business Challenges

- Fragmented data across multiple systems
- Lack of visibility into product status
- Inconsistent data across markets
- Complex regulatory requirements
- Need for a single source of truth

Solution

By leveraging a centralized system, Mithra was able to create a single source of truth for all product data. This allowed the company to improve its visibility into product status, ensure consistency across markets, and meet complex regulatory requirements. The result was a more efficient and secure system that supported the company's growth.

- Regulatory: 30% (30% of total data)
- Product: 25% (25% of total data)
- Supply Chain: 20% (20% of total data)
- Technology: 25% (25% of total data)

Key Activities and Resources

- Product Development
- Manufacturing
- Marketing
- Regulatory
- Supply Chain
- IT

Critical Business Factors

- Product Quality & Safety
- Product Portfolio
- Regulatory Approval & Compliance
- IT
- Product Management
- Team Talent
- Financial Resources for R&D

Team

Executive Director Jordan Moran-Cabrera	Senior Team Officer Jefe Bufanda	Senior Team Officer Mithra	Senior Team Officer Mithra	Senior Team Officer Mithra	Senior Team Officer Mithra	Senior Team Officer Mithra	Senior Team Officer Mithra	Senior Team Officer Mithra	Senior Team Officer Mithra
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Outcomes

Business Metrics

- Improved product quality
- Increased regulatory compliance
- Reduced time to market
- Enhanced customer satisfaction

Results & Feedback

- Strong customer feedback
- High regulatory compliance
- Improved product quality
- Enhanced customer satisfaction

Recommendations

- Continued investment in R&D
- Focus on product quality & safety
- Invest in regulatory compliance
- Enhance customer satisfaction

Case Study: Mithra | Serializing Across Multiple Business Cases

Learn how Mithra used a multidisciplinary approach for a successful EU FMD go-live.

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