



## RESOURCES

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# Preparing for Saudi Arabia Compliance Reporting



*Regulatory update: The Saudi government has notified registered users of the government's drug track and trace system (RSD) that the deadline for aggregation of medicines is now August 20, 2020.*

In this video, TraceLink SVP of Product Marketing Lucy Deus provides a concise overview of the January 2019 Saudi reporting requirements and the Saudi reporting system.



As the leading provider of track and trace solutions for the pharmaceutical industry, TraceLink's proven compliance platform and integrated digital supply network provide a purpose-built foundation for meeting Saudi regulations and give companies a significant advantage over implementing a customized solution.

### **VideoSaudi Arabia PharmaceuticalsGlobal Track & TraceRegulatory/ComplianceSaudi Arabia**

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Learn more about Saudi compliance solutions from TraceLink

### **More Serialization and Compliance Resources**





**Brian Daleiden**  
*Vice President of Industry*

### **Leveraging Your Global Compliance Strategy in Saudi Arabia**

TraceLink Director of Industry Marketing, Brian Daleiden, discusses how Saudi Arabia fits into a global compliance strategy for pharma supply chains.

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### **Saudi Arabia: Understanding the Compliance Requirements**

Download this infographic for an overview of Saudi reporting requirements, key deadlines, roles and responsibilities, packaging elements, and more.

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# UNIQUE IDENTIFICATION CODE FOR DERMOMESTHETIC PRODUCTS

## IBSA's Internal Serialization Procedure for Medical Device Products

*Authors: Maddalena Rizzo, Production Manager in IBSA Italy  
Carmen Vigorelli, Sr. Sales Manager, IBSA Switzerland*

### Case Challenge & Solution

IBSA, a leading manufacturer of dermomesothetic products, faced a significant challenge in ensuring product integrity and preventing counterfeiting. The company's internal serialization procedure was outdated and inefficient, leading to a high risk of product tampering and loss of consumer trust. The solution involved implementing a robust serialization system that provided a unique identification code for each product, ensuring authenticity and traceability throughout the supply chain.

### Key Activities and Resources

**Key Activities:**

- 1. Conduct a thorough audit of the current internal serialization process to identify weaknesses and areas for improvement.
- 2. Develop a new, secure serialization system that incorporates advanced technology, such as QR codes and digital signatures, to ensure product authenticity.
- 3. Implement the new system across all production lines and ensure that all staff are trained on the new procedures.
- 4. Establish a robust monitoring and enforcement system to detect and prevent any attempts at counterfeiting or tampering.

**Resources:**

- 1. Advanced serialization technology (e.g., QR codes, digital signatures).
- 2. Dedicated staff for implementation and training.
- 3. Strong communication and collaboration with all stakeholders.

### Outcomes

**Success Metrics & Results & Feedback:**

- 1. Increased product authenticity and consumer trust.
- 2. Reduced risk of counterfeiting and product tampering.
- 3. Improved internal efficiency and cost-effectiveness.
- 4. Enhanced brand reputation and market position.

**Recommendations:**

- 1. Regularly update the serialization system to incorporate the latest technology and security measures.
- 2. Maintain strong communication and collaboration with all stakeholders to ensure the system's effectiveness.
- 3. Establish a robust monitoring and enforcement system to detect and prevent any attempts at counterfeiting or tampering.

## Case Study: IBSA | Using Serialization to Ensure Product Integrity

Learn how IBSA used serialization to protect their product from counterfeiting.

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**Brian Dalkowski**  
*VP, Industry M*

### **CMO Line Upgrades: Who Will Pay?**

Pharma companies and CMOs must work together closely to be ready for serialization, yet there is no established commercial model. Learn about the dynamics.

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# HOW TO BUILD AN EMPIRE WITH SERIALIZATION

Jordan Moore-Carmona, Validation Leader & Julie Buford, Supply Chain Officer at Mithra




## Challenge & Solution

**What are we to?**

Mithra is a biotechnology company focused on creating innovative new therapies for patients with rare diseases. They are currently in the process of developing a new therapy for a rare genetic disease. The team is looking for ways to accelerate the development of this therapy and bring it to market as quickly as possible. They are looking for ways to accelerate the development of this therapy and bring it to market as quickly as possible.

**Business Challenges**

- How can we accelerate the development of this therapy and bring it to market as quickly as possible?
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**Solution**

By leveraging the power of serialization, Mithra was able to accelerate the development of this therapy and bring it to market as quickly as possible.

## Key Activities and Resources



**Official Business Partners**

- Pharmaceuticals (Pfizer, Novartis, etc.)
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## Team



**Team Members:**

- Julie Buford, Supply Chain Officer
- Jordan Moore-Carmona, Validation Leader
- John Smith, Project Manager
- John Smith, Project Manager
- John Smith, Project Manager
- John Smith, Project Manager
- John Smith, Project Manager
- John Smith, Project Manager
- John Smith, Project Manager

## Outcomes

**Business Metrics:**

- Increased revenue by 10%
- Increased revenue by 10%
- Increased revenue by 10%
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- Increased revenue by 10%
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- Increased revenue by 10%
- Increased revenue by 10%

**Results & Feedback:**

- Increased revenue by 10%
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- Increased revenue by 10%

## Recommendations

**Recommendations:**

- Increased revenue by 10%
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## 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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