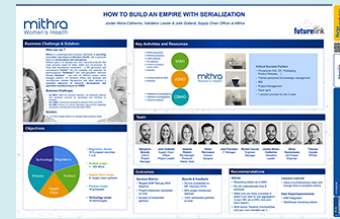




RESOURCES

Home
Resources
Resource Center

Case Study: Mithra | Serializing Across Multiple Business Cases



Mithra has a complex supply chain model—as a manufacturer, virtual CMO, and traditional CMO, they operate in 16 different European countries and the United States with more than 200 SKUs and 31 partners. Learn how they used a multidisciplinary approach to get their serialization solution ready for a successful EU FMD go-live. Mithra’s poster, “How to Build an Empire with Serialization,” was one of 11 featured during FutureLink Barcelona’s interactive Poster Sessions.



HOW TO BUILD AN EMPIRE WITH SERIALIZATION

Jordan Marie-Catherine, Validation Leader & Julie Gottardi, Supply Chain Officer at Mithra



Poster Session Online

futurelink

Business Challenge & Solution

Who are we ?
Mithra is a pharmaceutical company dedicated to providing innovation and choice in Women's Health, with a particular focus on **contraception and menopause**. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive **Estelle®**, the first complete oral treatment for perimenopausal **PenNesta™** and next-generation hormone therapy **Donesta®** - are built on Mithra's unique native estrogen platform, **E4 (Esterol)**. Mithra also develops and manufactures complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO.

Business Challenges

- As MAH: Make the transition between not serialized products and serialized products as seamlessly and smoothly as possible.
- As vCMO: Coordinate serialization between MAH and CMO
- As CMO: Answer our clients' regulatory requirements regarding serialization and be part of the top-rated CDMOs.

Solution
→ Find a single platform to manage these business cases

Key Activities and Resources

- EMVO connections
- NMVOs connections
- CMOs readiness
- 3PL readiness
- Collect of product master data
- Artworks

- Interface MAH & CMO
- Artworks
- Adaptation of packaging/lines
- Validation of packaging/lines
- Customer readiness

Critical Success Factors

- Procedures (QA, QC, Packaging, Product Release,...)
- Trained personnel & knowledge management
- \$\$\$
- Project Management
- Team spirit
- 1 solution provider for the 3 roles

Objectives

- Regulatory Scope:** 16 European countries + U.S.
- Product scope :** +- 200 SKUs
- Supply Chain scope:** 31 supply chain partners
- Process scope:** 18 processes
- Technology scope:** 16 technologies

Team

Benjamin Brands CSCO Project Manager	Julie Gottardi Supply Chain Officer Project Leader	Isabelle Robert RA Manager Products - Master Data	Gilles Renneson Artwork designer	Joël Francken IT Manager	Michel Counet Engineer Manager	Jordan Marie-Catherine Validation Leader	Steve Kustermans QA Project Engineer	Thomas Canale RPI/QA

Outcomes

Success Metrics <ul style="list-style-type: none"> Respect of 09th February 2019 deadline Project Milestones completed on time Number of onboarded partners 	Results & Feedback <ul style="list-style-type: none"> Go-live succeeded on 09th February 2019 99% project milestones reached 100% onboarded partners on time
--	---

Recommendations

Advice <ul style="list-style-type: none"> Reworking station as a CMO Do not underestimate time & workload Make sure you have a process in place if you want to use aggregation in your WH, as a CMO, and your client doesn't AVM covers Tracelink functionalities (not your own intended use !) 	Lessons Learned <ul style="list-style-type: none"> Have a multidisciplinary team with enough time to complete actions Next Steps/Improvements <ul style="list-style-type: none"> ERP Integration Warehouse reworking station
--	---

View Poster Session Gallery

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

Subscribe to Agile Supply Chain Insights

Subscribe to stay informed with the latest patient-centric agile supply chain thought leadership content.

Related Content



94% Recommend Product Track with End-to-End Administration Services

See how pharmacies continue to realize significant time and cost savings with TraceLink service.

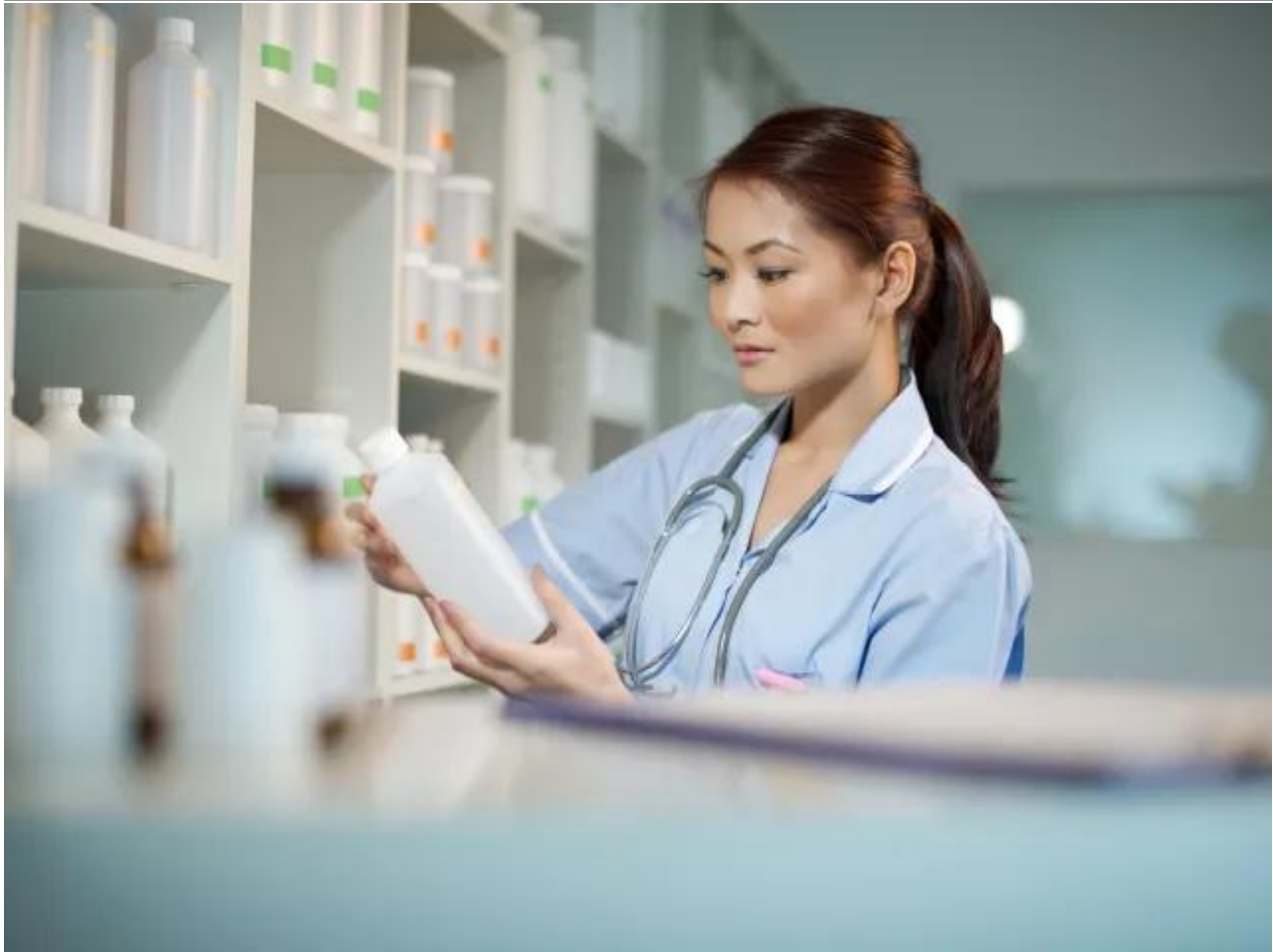
[View More](#)



Why An Open, Standards-Based Approach is Essential for the Pharmaceutical Supply Chain

Learn five critical criteria to determine whether you want a trusted partner or just a vendor.

[View More](#)



Will Serialization Affect Minimum Order Quantity for Rx Products?

Learn key definitions and requirements of how products are identified and sold under DSCSA, and how serialization can make product verification more accurate and efficient.

[View More](#)



Poll: Solution Provider Expertise, Platform Key to Saleable Returns

Learn how companies are trying to balance FDA saleable returns requirements, trading partner needs, and operational efficiency.

[View More](#)



Why Pharmacies and Hospitals Need to Think “Outside the Portal” for Serialization

What pharmacies are required to do to be ready for serialization and why they need to start developing a digital data strategy today.

[View More](#)



Why Serialization Could be a Game-Changer for Health Systems

See why Novant Health's Senior Director of Pharmacy Business Operations is excited about DSCSA.

[View More](#)