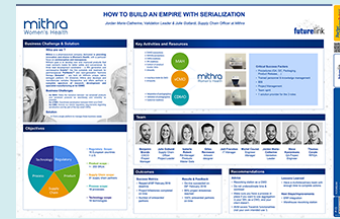




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# Case Study: Mithra | Serializing Across Multiple Business Cases



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

FUTURELINK Julie Gottardi

### 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

### 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

### 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

### 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

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

<b>Advice</b> <ul style="list-style-type: none"> <li>Reworking station as a CMO</li> <li>Do not underestimate time &amp; workload</li> <li>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</li> <li>AVM covers Tracelink functionalities (not your own intended use !)</li> </ul>	<b>Lessons Learned</b> <ul style="list-style-type: none"> <li>Have a multidisciplinary team with enough time to complete actions</li> </ul>
<b>Next Steps/Improvements</b> <ul style="list-style-type: none"> <li>ERP Integration</li> <li>Warehouse reworking station</li> </ul>	

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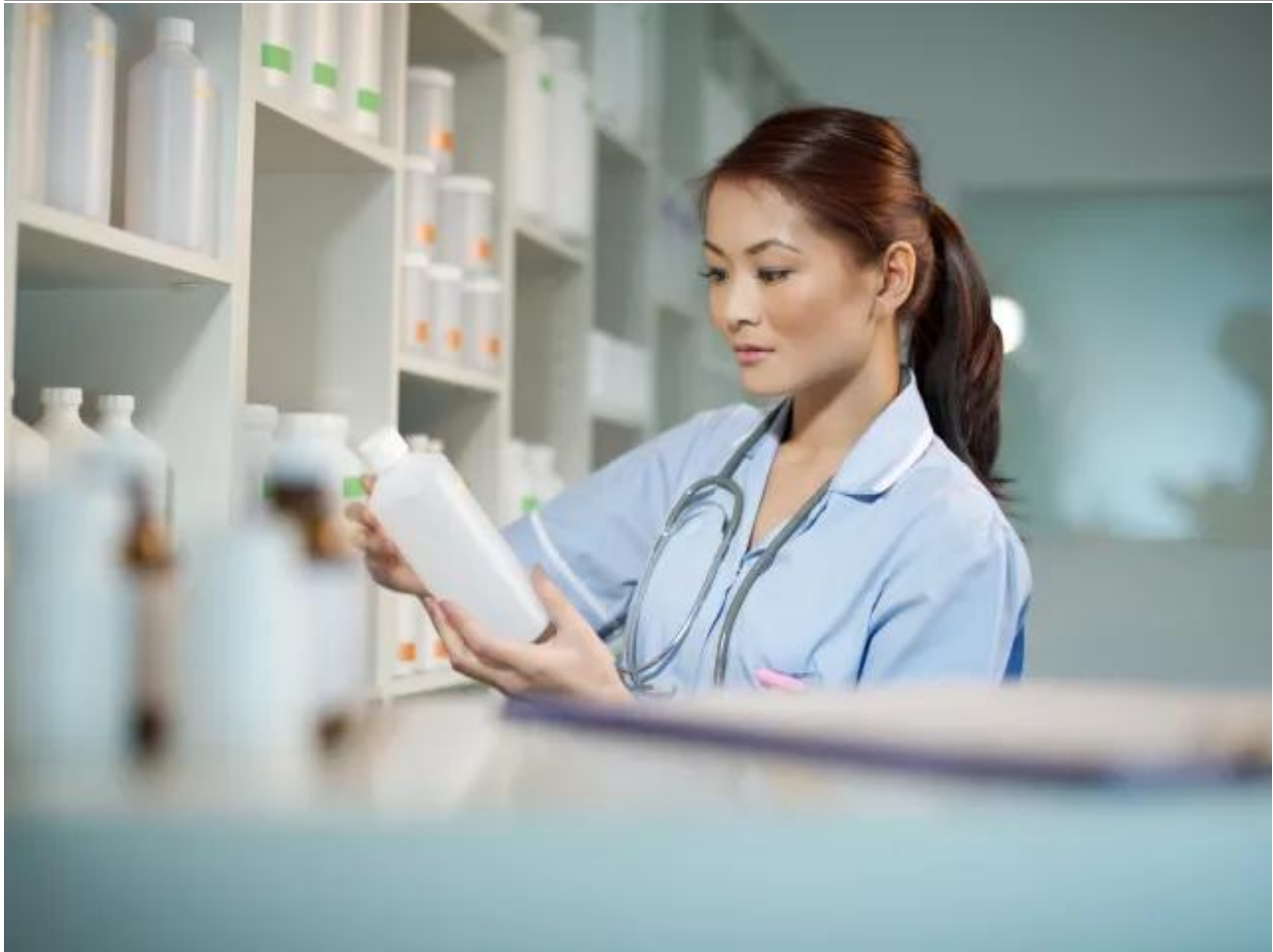
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