

## RESOURCES

Home

# 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 companies 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.



### 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 perimenopause **PenNesta** and next-generation hormone therapy **Donestal** – 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 CMOs.

**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:** 18 technologies

### Key Activities and Resources

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

**MAH**  
**vCMO**  
**CDMO**

**mithra**  
Women's Health

**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

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

**Success Metrics**

- Respect of 09<sup>th</sup> February 2019 deadline
- Project Milestones completed on time
- Number of onboarded partners

**Results & Feedback**

- Go-live succeeded on 09<sup>th</sup> February 2019
- 99% project milestones reached
- 100% onboarded partners on time

### Recommendations

**Advice**

- 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**

- Have a multidisciplinary team with enough time to complete actions

**Next Steps/Improvements**

- ERP Integration
- Warehouse reworking station

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Case Study

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