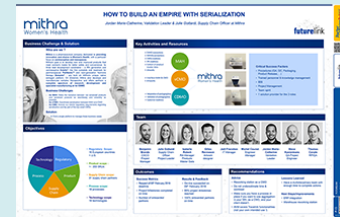




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Case Study: Mithra | Serializing Across Multiple Business Cases



Mithra has a complex supply chain model—as a manufacturer, virtual CMO, and traditional CMO, they operate in 16 different European 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.



HOW TO BUILD AN EMPIRE WITH SERIALIZATION

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



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 (Esterot)**. Mithra also develops and manufactures complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO.

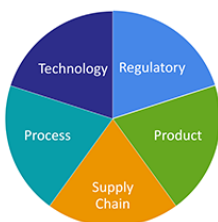
Business Challenges

- 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



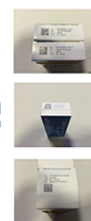
- **Regulatory Scope:** 16 European countries + U.S.
- **Product scope :** ~ 200 SKUs
- **Supply Chain scope:** 31 supply chain partners
- **Process scope:** 18 processes
- **Technology scope:** 18 technologies

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



Outcomes

Success Metrics

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

Results & Feedback

- Go-live succeeded on 09th 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

Poster Session Online

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P-13
FUTURELINK
Julie Gottardi

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 Paul McKenzie Chief Operating Officer CSL Limited	 Michael Wittman Supply Chain Subject Matter Expert
 Moderator Shukru Martin	

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