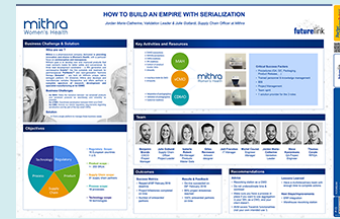


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Case Study: Mithra | Serializing Across Multiple Business Cases



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.

mithra
Women's Health

HOW TO BUILD AN EMPIRE WITH SERIALIZATION

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

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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.

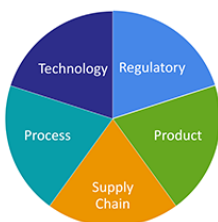
Business Challenges

- 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

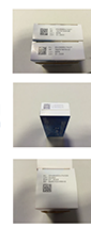
- EMVO connections
- NMVOs connections
- CMOs readiness
- 3PL readiness
- Collect of product master data
- Artworks

- Interface MAH & CMO
- Artworks

- Adaptation of packaging/lines
- Validation of packaging/lines
- Customer readiness



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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
CSO
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

- 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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Julie Gottardi

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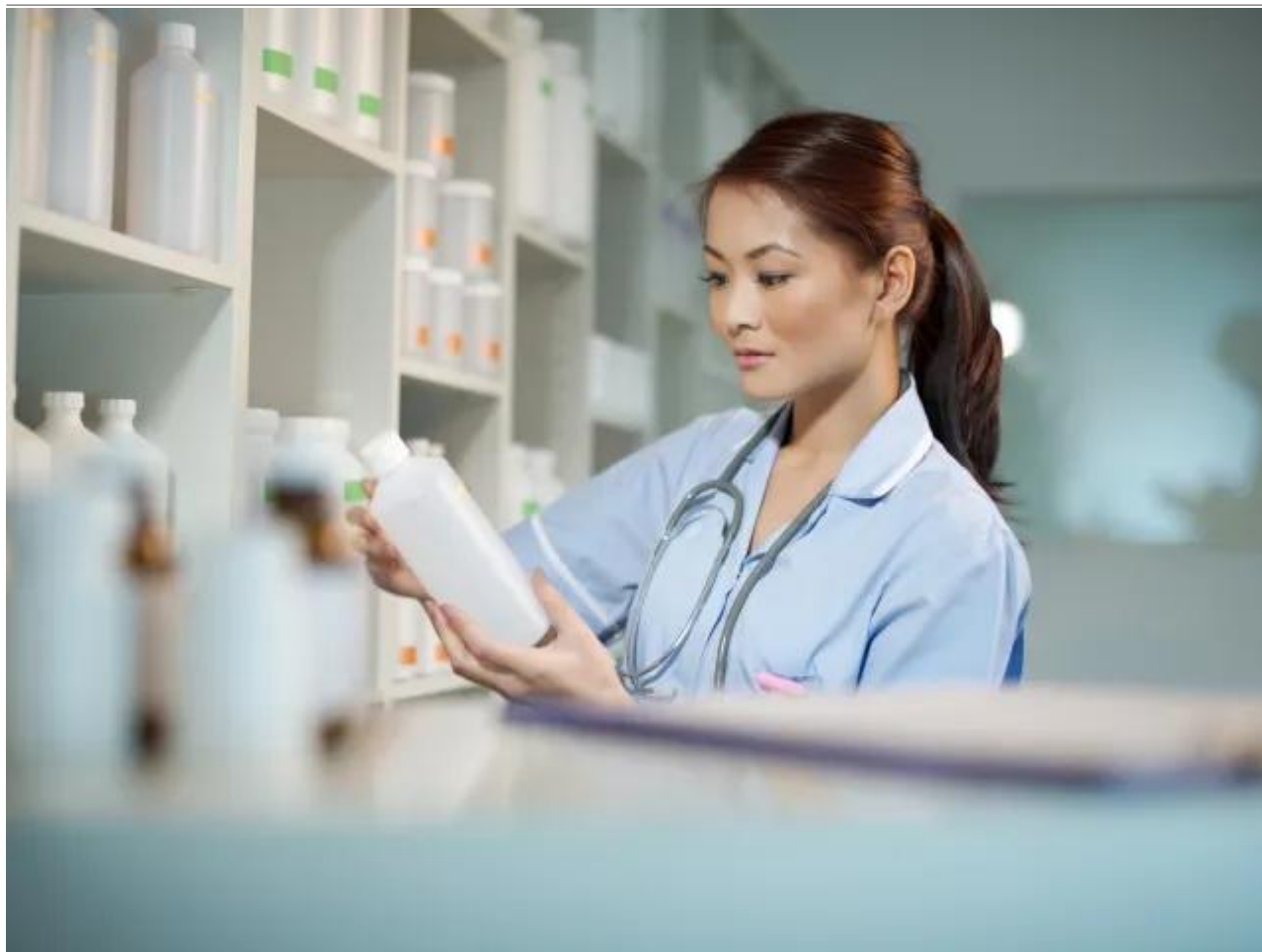
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