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Case Study: Medreich | EU FMD from Project Plan to Post Implementation




Learn how CMO Medreich PLC partnered with TraceLink in their collaborative, five-phase approach to successful EU FMD launch, from project planning all the way to post implementation review. Medreich’s poster, “Medreich’s Successful Implementation of Falsified Medicine Directive,” was one of 11 featured during FutureLink Barcelona’s interactive Poster Sessions.



MEDREICH


Medreich’s Successful Implementation of Falsified Medicines Directive

Jeff Wysocki Project Manager, Amanda Little Production Expert, Alison McCarthy Technical Lead



Business Challenges

- New European Regulation
- New Systems
- Implementation Date (09/02/2019)
- Solution to be workable within our group Medreich PLC and Medreich LTD, over 6 sites and multiple variations of packing lines.
- Training of existing staff, Production, Quality, Regulatory and Warehouse.







Phase 2 Initial Implementation

- Tracelink Training
- Purchasing Equipment for packaging lines
- Setting up Tracelink – collating data, inputting and on-boarding customers and suppliers.
- Setting up designated distributor.
- Connecting to EMVO and NMVO’s (Secur Med)
- Designing Tamper Proof Seal (TPS).
- Artwork reviewing and changes.
- New SOP’s and process documentation.

Phase 3 Implementation

- Installing new equipment for packaging lines
- Validation of the equipment
- Testing line connections with Tracelink
- Moving all the connections with Tracelink from I-Test to Production.
- Training of Production and QA staff

Project Team

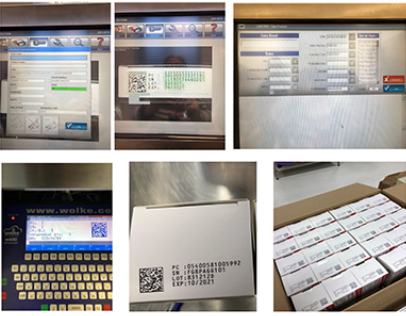





Jeff Wysocki Amanda Little Alison McCarthy Anamika Chaudhary
Project Manager Production Expert Technical Lead QA Expert

FMD General Team, Regulatory, Customer Services, Quality and Warehouse.

Phase 4 Go Live

- Go Live with first batch




Phase 5 Post Implementation Review

- Evaluation of Project and Review
- Go through lessons learned
- Facilitate changes to improve processes
- It is vital especially where both connecting parties are Tracelink to make sure that product master data matches, we found the best way to do this was always share and import using CSV files

Phase 1 Project Planning


- Choosing Production Line Equipment
- Choosing IT solution : in house or third party.
- Formalization meeting with all parties to discuss working together and finding solutions.



Summary

- Due to starting the project in good time, we had to make several changes to Product master data as the requirements were changed multiple times
- As time went on Countries and Customers decided they wanted different printed data, so there were multiple updates required to line equipment; it is vital to carry out tests after every change to make sure nothing else has been effected
- With regards to line efficiency this is a balancing act between running fast enough to be efficient, but not running so fast that you end up with extra rejects.
- It was really good to make use of the Tracelink Cloud Community with the fortnightly calls, this is a great place to air and share issues that are affecting multiple companies

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FUTURELINK
Alison McCarthy

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