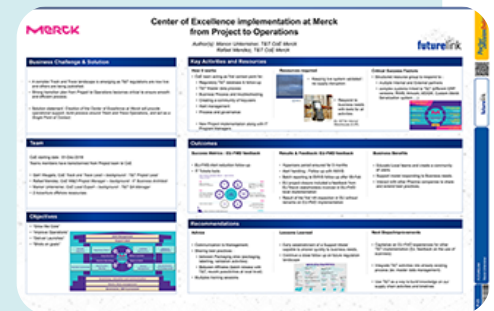


## RESOURCES

Home

# Case Study: Merck | Driving Operational Excellence for EU FMD



See why Merck’s Center of Excellence implementation laid the foundation, from project to operations, for a smooth and efficient rollout of EU FMD compliance. Merck’s poster, “Center of Excellence Implementation at Merck from Project to Operations,” was one of 11 featured during FutureLink Barcelona’s interactive Poster Sessions.





## Business Challenge & Solution

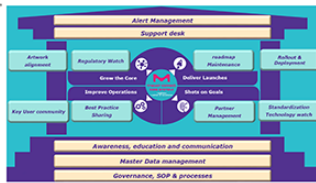
- A complex Track and Trace landscape is emerging as T&T regulations are now live and others are being published.
- Strong transition plan from Project to Operations becomes critical to ensure smooth and efficient process.
- Solution statement: Creation of the Center of Excellence at Merck will provide operational support, build process around Track and Trace Operations, and act as a Single Point of Contact.

## Team

- CoE starting date : 01-Dec-2018  
Teams members have transitioned from Project team to CoE
- Gert Vleugels, CoE Track and Trace Lead – background : T&T Project Lead
  - Rafael Mendez, CoE W&D Project Manager – background : IT Business Architect
  - Manon Unterreiner, CoE Lead Expert – background : T&T QA Manager
  - 2 Accenture offshore resources

## Objectives

- "Grow the Core"
- "Improve Operations"
- "Deliver Launches"
- "Shots on goals"



## Key Activities and Resources

### How it works

- CoE team acting as first contact point for:
  - Regulatory T&T database & follow-up
  - T&T Master data process
  - Business Process and troubleshooting
  - Creating a community of keyusers
  - Alert management
  - Process and governance
- New Project implementation along with IT Program Managers

### Resources required



Ex: SIT for internal Warehouses & SPL

- Keeping live system validated : no supply disruption
- Respond to business needs with tools for all activities

### Critical Success Factors

- Structured resource group to respond to :
  - multiple Internal and External partners
  - complex systems linked to T&T (different ERP versions, RIMS, Artwork, MDGM, Custom Merck Serialization system ...)



## Outcomes

### Success Metrics : EU-FMD feedback

- EU-FMD Alert reduction follow-up
- IT Tickets tools



### Results & Feedback: EU-FMD feedback

- Hypercare period ensured for 3 months
- Alert handling : Follow up with NMVS
- Batch reporting to EMVS follow-up after 09-Feb
- EU project closure included a feedback from EU Merck stakeholders involved in EU-FMD local implementation
- Result of the first HA inspection in EU without remarks on EU-FMD implementation

### Business Benefits

- Educate Local teams and create a community of users.
- Support model responding to Business needs.
- Interact with other Pharma companies to share and extend best practices.

## Recommendations

### Advice

- Communication to Management.
- Sharing best practices :
  - between Packaging sites (packaging, labelling, validation activities)
  - Between Affiliates (batch release with T&T, rework possibilities at local level)
- Multiple training sessions

### Lessons Learned

- Early establishment of a Support Model capable to answer quickly to business needs.
- Continue a close follow up on future regulation landscape



### Next Steps/Improvements

- Capitalize on EU-FMD experiences for other T&T implementation (Ex: feedback on the use of scanners)
- Integrate T&T activities into already existing process (ex: master data management)
- Use T&T as a way to build knowledge on our supply chain activities and timelines

Case Study

European Union Falsified Medicines Directive

Global Track & Trace

Manufacturing

European Union

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