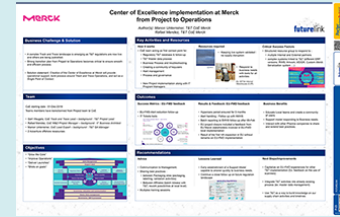




RESOURCES

Home
Resources
Resource Center

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.





Center of Excellence implementation at Merck from Project to Operations

Author(s): Manon Unterreiner, T&T CoE Merck
Rafael Mendez, T&T CoE Merck



Business Challenge & Solution

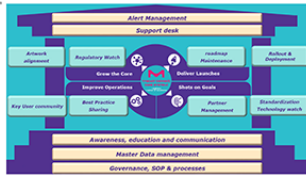
- A complex Track and Trace landscape is emerging as T&T regulations are now live and others are being published.
- Strong transition plan from Project to Operations becomes critical to ensure smooth and efficient process.
- Solution statement: *Creation of the Center of Excellence at Merck will provide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

- Keeping live system validated : no supply disruption
 - Respond to business needs with tools for all activities
- Ex: SIT for internal Warehouses & 3PL

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

Subscribe to Agile Supply Chain Insights

Subscribe to stay informed with the latest patient-centric agile supply chain thought leadership content.

More Serialization and Compliance Resources





Turning Point: From Achieving Compliance to Creating Business Value from Serialization

FutureLink poll results reveal an industry at a turning point. Learn how stakeholders across the supply chain plan to create new business value and make the global drug supply more secure.

[View More](#)



Orient Pharma and TraceLink: Partnering for Success on Serialization and Quality

Learn how TraceLink enables Orient Pharma to deliver serialization at a global scale.

[**View More**](#)