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2023

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EMPOWERING EFFICIENCY

Wörwag's Transition to Improved Efficiency in Regulatory Affairs

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Presentation Agenda

01 **Requirements & Implementation**

02 **Transformation & User Acceptance**

03 **EU Specifics**

MRP/DCP Procedures
xEVMPD

04 **System Maintenance**

Cloud Migration
Technical Upgrade 7.1

05 **Outlook**

IDMP Transformation
QualityExpert Projects

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Henrike Miess

After completing her PhD in Pharmaceutical Biology, she started her professional career in 2017 as a Regulatory Affairs Trainee, where she first developed into a CMC Manager. After two years, she decided to further drive the digital transformation and increase efficiency within the RA department, which is why she moved to the Regulatory Operations team. Her focus is to manage and maintain the RIM (and its components) and all kinds of eCTD, NeeS and Non-EU publishing within the RA department.

01

Requirements & Implementation

Selecting an appropriate tool to ensure connectivity and have a single point of truth.

Requirements

Former IT Landscape

- Various manual maintenance processes
- Insufficient data integrity / quality
- Business critical data is not managed in a comprehensive database (Excel, SharePoint, File Explorer)
- eCTD compilation in DocuBridge
- xEVMPD submission via DrugTrack

Future IT Landscape

- Single Point of Truth
- Document Management
- Process Management
- Submission Management & Publishing
- Tracking
- Collaboration
- Reliable Data Integrity

Communication between tools

Implementation

Full implementation of

- R&DExpert™
- RIMExpert™
- ProductExpert™
- SubmissionExpert™

1. Definition of user requirements
2. Data collection and transformation of
   - Master Data
   - xEVMPD
   - Variations
   - Non-EU Dossiers
3. Import of the collected data
4. Quality check / verification of imported data
5. Step by step mapping and import of eCTDs

Benefits

Single point of truth

- All documents and information in one tool
- The full product lifecycle is accessible by selecting the respective Application
    - Variations
    - Submission dossier
    - xEVMPD record
- One document can be used in different product submissions
- Defined lifecycle of documents
- Reduction of duplicate files
- Compliance

Connectivity

- Common master data is used across the solution
- Workspaces present different process views on the same data or content in the system
- Documents can be used throughout the system and linked to any other document as needed
- Change controls can be connected to appropriate activities for clarification
- Connectivity to EMA gateway to support xEVMPD submission from within the system.
- Available drop-down and controlled vocabulary lists reduce typographical errors

02

Transformation & User Acceptance

How to engage end users and achieve system acceptance.

Transformation

How to achieve the change

- Changing processes and revising working instructions and SOPs
- Shifting the mindset to a more digitalized work environment
- Raising awareness on data integrity issues

Benefits:

- More accurate work
- Automated workflows reduce human error
- Increased efficiency and data integrity

Acceptance

How to achieve acceptance

- Qualified key users and respective interactions
- Training sessions
- User manuals and guides
- Regular Q&A sessions
- Lessons learned
- Strong and immediate end user support
- End user community

Benefits**:**

- Trust and reliability
- Contentment

03

EU Specifics

MRP/DCP procedures

Article57 database submissions

MRP / DCP Procedures

Handling of MRP / DCP Procedures

- Automatic creation of all concerned country Authorised Medicinal Products, based on master data
- Creation of the respective country binders during submission compilation
- Submission overview of all countries within the procedure
- Uncomplicated addition and deletion of CMS
- Independent handling of national notifications/variation
- Tracking of national phases possible

Article 57 database submissions – xEVMPD

E2E submission of xEVMPD Dataset

- No need to maintain multiple databases
- Authorised Medicinal Product (AMP) contain approval specifics and the xEVMPD dataset
- Maintenance of the data quite simple
- Secure submission to EudraVigilance (EV) gateway possible through the system
- EMA Response sent to the system, depending on output, system automations are triggered

Requirements

- Trained Staff
- EV gateway connection

04

System Maintenance Projects

AWS Cloud Migration

Technical Upgrade myProcess 7.1

AWS Cloud Migration

Announcement: End of November 2020

- What to be changed:
  - Cloud provider where the environments are hosted
    Destination ALSS Cloud (based on AWS)
- Why it's being changed:
  - Improve quality and efficiency of the service provided
  - Compliance
  - Availability and scalability
  - System performance for the end user
- Impact on Amplexor solution
  - Minimal impact on the end users
  - New URL
  - Additional security for access publishing results

Planned Implementation: Nov/Dec 2020

Actual Go Live: June 2021

AWS Cloud Migration - Implementation

Challenges

- Import of eCTD – new Process
- Elastic search compatibility
- Multi-factor authentication (MFA)
- Refresh of intelligence report

Contentment

- Risk Assessment prepared
- Vendor Qualification
- Support for eCTD import testing

AWS Cloud Migration – Go Live

Benefits

- Linux platform + AWS
- Further increase of performance
- Faster cloning of environments for subprojects
- Faster release cycles
- Faster support from provider site
- Stability of the Environments

Lessons Learned

- A dedicated Project Manager is mandatory
- Open and honest communication throughout the team is important
- Wrong time estimation
- Elastic search was not compatible with AWS and our myProcess version (5.10)

User Acceptance

- New URLs Provided
- Smaller changes were identified through daily business

Technical Upgrade 7.1

Project Start: January 2022

Planned Go Live: September 2022

What to be changed:

- Platform upgrade from 5.10 to 7.0
- Platform upgrade from 7.0 to 7.1

Why it's being changed:

- To stay in support
- Implementation of Analytics workspace
- Self Service Reporting
- Implementation of EAEU functionalities
- Implementation of IDMP platform functionalities
- IE11 out of support

Impact on Amplexor solution

- Medium impact on the end users
- New URL

Planned Implementation: September 2022

Go Live 7.0: September 19th 2022

Go Live 7.1: January 30th 2023

Technical Upgrade 7.1 – Implementation

Challenges

- Hiccups in eCTD import -> again change in Process
- EAEU Module not finally ready
- Solution Consultant was changed close to the end of the project
- Lack of resources on our side

Contentment

- Well prepared Project
- Clear communication throughout the project team
- Clearly defined responsibilities
- Support on both sides when needed
- No severe delays at any time of the project.

Technical Upgrade 7.1 – Go Live

Benefits

- Flexible use of Internet browsers (Chrome, Edge, etc.)
- Disabling of the Internet Explorer (limiting the performance)
- Significant improvement of performance
- New features were available (EAEU, Analytics & Dashboards)
- Better look, handling and feel
- Increased data integrity (immutable objects)
- Self Service Reporting

User Acceptance

- Communication throughout the upgrade process
- Trainings Sessions on what changed from 5.10 to 7.0/7.1
- Updated training Materials
- Training Videos
- Strong and immediate end user support
- Happy with the performance

Outlook

Source: ISO TC 215, Working Group 6 (Pharmacy and Medicines Business), December 2014

ISO IDMP

New Functionalities

IDMP Transformation Project

Project Start: May 2023

Planned Go Live: Q4 2024

What to be changed:

- Platform upgrade to 7.x
- Solution upgrade to 7.x

Why it's being changed:

- IDMP submission readiness
  - Data collection
  - Data transformation
  - Data implementation
- Improved Submission functionalities
  - Faster submission creation
  - Inherited envelope properties
- Implementation of (eCTD) Dossier import profiles for other regions

Impact on Amplexor solution

- high impact on the end users
- New URL
- New functionalities

QualityExpert™ Projects

Change Control – OOB Implementation

Project Start: May 2023

Planned Go Live: September 2023

What to be changed:

- Change Control to OOB

Why it's being changed:

- Change in internal Processes

Impact on Amplexor solution

- Medium impact on the end users
- New functionalities

Transformation Project QualityExpert™

Project Start: Q4-2024 / Q1-2025

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THANK YOU!