CASE STUDY

A Journey to a Single Harmonized Regulatory Content Source Management Solution

»The complexity of the program was quite under-estimated. But now that the system is in place we see an overall good user acceptance. In a survey that was conducted, more than two thirds of the users responded that the new system has improved how they manage submission source content, and for more than 80% it meets the various needs of their business area. This was a great success and a key step on our road to implementing a global regulatory document authoring and submissions management capability to ensure continued regulatory compliance.« (IT Manager for Regulatory Content Management)

Our client is a multi-national pharmaceutical company, developing and producing medicines, vaccines, biologic therapies and animal health products.

Challenge

Strongly growing with global offices, the pharmaceutical client was increasingly challenged with the variety of Regulatory systems, document locations and processes across the different locations involved in the Submission processes, creating a system landscape that was very disjunct, non-scalable and costly to maintain, with several systems nearing their end-of-life. To collaborate globally was problematic and leading to delays, inefficiencies and inconsistencies in the processes creating non-compliances. While working through these challenges, the external pressures for increased compliance kept rising and it was showing that current foundational capabilities were lagging behind industry peers.

Out of these challenges a program was brought in place to implement a Global Regulatory Content Management platform. Goal was to provide a transformative solution to enable collaboration of submissions content across the globe in over 70 countries by making headquarters (HQ) and country documents globally accessible, providing an organized structure that incorporates the required reports and documents needed to globally present a drug application, dossier or inquiry response to a Health Authority for review and/or approval.

Solution

A single harmonized Regulatory Content Source Management solution to serve more than 8,000 users was chosen and implemented, based on one of fme's core partner business application platforms in the R&D space.

The program was organized in mutliple parallel workstreams that had IT, business and technology partner involvement as needed:

- Requirements and Business Processes
- Design, Config, Build
- CRP and UAT Prep
- Data Migration Planning
- Data Migration Execution ~12 Million documents
- Integration
- Change Management and Training
- Project Management and Planning

fme was selected as application implementation and migration partner and was strongly involved in the highlighted workstreams to »Consolidate, Simplify, and Modernize«.

Requirements and Business Processes

The project kicked off with detailed requirements workshops, looking at the out of the box R&D solution and aligning it with business requirements coming out of existing processes and applications, working together with a Business Consulting provider to help analyze and structure the business needs. These sessions were very productive, but looking back, also due to the high volume of requirements being reviewed (1000+), some details slipped through in this process, assumptions were made on all involved sides about the expected system behavior, that did lead to later changes in the application to make sure business needs were met.

Design, Config, Build

As part of the Configuration workstream our global technical team worked in implementation sprints to define the necessary configurations and customizations for a subset of selected requirements as provided by the Business Consulting team. The sprint results were demonstrated to the global key user team in Show&Tell sessions to confirm the correct understanding and collect additional feedback for revisions if needed. Atlassian JIRA was used internally by our team to keep track of tasks, implementation and test status, and to easier communicate across timezones. During this workstream it did show that for certain requirements we did reach the limit of the configurability of the underlying solution platform. In such cases, options were reviewed and discussed with the impacted client teams – and in some cases requirements were adjusted whereas in other cases customizations were agreed on. Due to the vast amount of requirements, the number of configurations ended up being greater than expected but overall almost all requirements could be met and the list of customizations (outside the configuration framework) could be kept low.

At project start it was assumed that the phase 1 of the project could go live after about 15 months. To accomodate additional configuration requirements and updates the timeline ended up extending to 26 months split up over several configuration sprints. Besides longer requirements and configuration phases, another contributing factor was the need to upgrade the underlying business application platform during the project runtime to be able to take advantage of new functionalities provided by the platform with the newer version.

Results

- Robust search functions and modern user interface with multi-faceted filtering and full text search
- More visibility into global content and improved workflow between HQ and affiliates
- Enhanced control of End-to-End content source creation process (e.g., collaborative authoring, version control, approved templates, electronic review and approval workflows)
- A single source of truth due to the centralized, globally accessible repository with role-based, fit-for purpose functionality
- GxP compliance through standardized processes and technologies
- Increased technology support with latest software versions and disaster recovery plans

Outlook

- The current platform is still realized as on-premise installation. Options to bring the solution to the cloud are in plan to be reviewed.
- Mobile client options have only be reviewed on high-level as part of the project but will be looked at closer as well to achieve additional efficiencies for sporadic users.

Further information on www.fme-us.com