WHITEPAPER

The Move from Legacy Systems to Veeva's Regulatory Information Management Cloud Platform

Managing Migration Complexities

Life sciences companies are focused on bringing effective drugs to global markets, retaining a healthy product pipeline of innovative products, and being profitable while delivering therapies to patients in need. To do this, they must manage changes to their submissions across multiple markets, meet the regulatory demands of different health authorities, ensure clear oversight of the life cycle of the drug, and track their submissions globally for regulatory and commercial purposes.

To improve regulatory efficiency and leverage data across functions, systems, and markets, companies have increasingly turned to integrated regulatory information management (RIM) systems that provided clear oversight of a product from discovery to commercialization. This is not possible with legacy solutions, which typically don't enable information to be easily shared between different stakeholders, making it difficult to get an authoritative source of the regulatory content and product registration data.

While life sciences companies have been slower to adopt cloud or off-premise RIM solutions, that is changing. According to a 2018 Gens and Associates survey, 39% of participants reported that they plan to move to cloud within two years. Adoption will be further accelerated by the move to end-to-end (E2E) RIM platforms, with the Gens survey finding that, of those investigating E2E solutions, 67% are more focused on a cloud-based model.

Among the reasons that life sciences companies had been reluctant to move to cloud were fears over security and data access. But those concerns are starting to break down as a growing number of companies recognize that leading cloud vendors provide more robust security than most in-house solutions. Furthermore, disaster recovery is better supported by cloud vendors, which operate highly secure data centers.

Life sciences companies are looking to cloud for improved data integration across multiple systems and applications, improved collaboration between functions, faster implementation of business services and applications, reduced costs, and the ability for employees to access the information they need from any location using any device, allowing data to be made available to whoever needs it and speeding up regulatory and other processes.

Companies are also looking to tap into digitization to further improve efficiencies and insights. Progressive cloud-based RIM platforms allow companies to take advantage of digital technologies, such as automation and artificial intelligence, blockchain, and advanced analytics capabilities.

Veeva a Leader in the RIM Charge

In recent years, Veeva has emerged as a leader in the RIM space, with a rapidly growing number of life sciences companies adopting applications in Veeva Vault RIM. Veeva is highly regarded in the Gens & Associates satisfaction ratings and innovation index and is respected for its commitment to making product enhancements based on client feedback.

As a certified Veeva Services partner, fme helps companies that plan to move from legacy systems to the Veeva Vault so they can more seamlessly manage their data migration. Clients benefit from fme's certification in the following ways:

- Access to Veeva Product Support Portal, best practices and methodologies and client searchable database
- Early access to newly released education sessions, including preview webinars.
- The ability to tap into fme's expert team that is not only familiar with the Veeva RIM system but can introduce processes and train teams in order to drive user adoption.

The fme 5-Step Approach to Migrations

The transition from legacy on-premise solutions to Veeva Vault undoubtedly will benefit life sciences organizations; however, they must first deal with the complex issue of data migration. When moving large volumes of documents from many different sources – clinical, medical, safety, regulatory, marketing, and so on – problems such as data complexity, data corruption, and data validation can weigh down a migration project and derail projects if not properly planned for and managed.

5 Steps to Migration Success:

1. **Analyze and extract**: Assess the source data and the target system's structure, rules, and logic – all carried out in close collaboration with the client. At this stage, a sample of the source documents are scanned using migration-center to allow the migration team to perform additional metadata and content analysis.

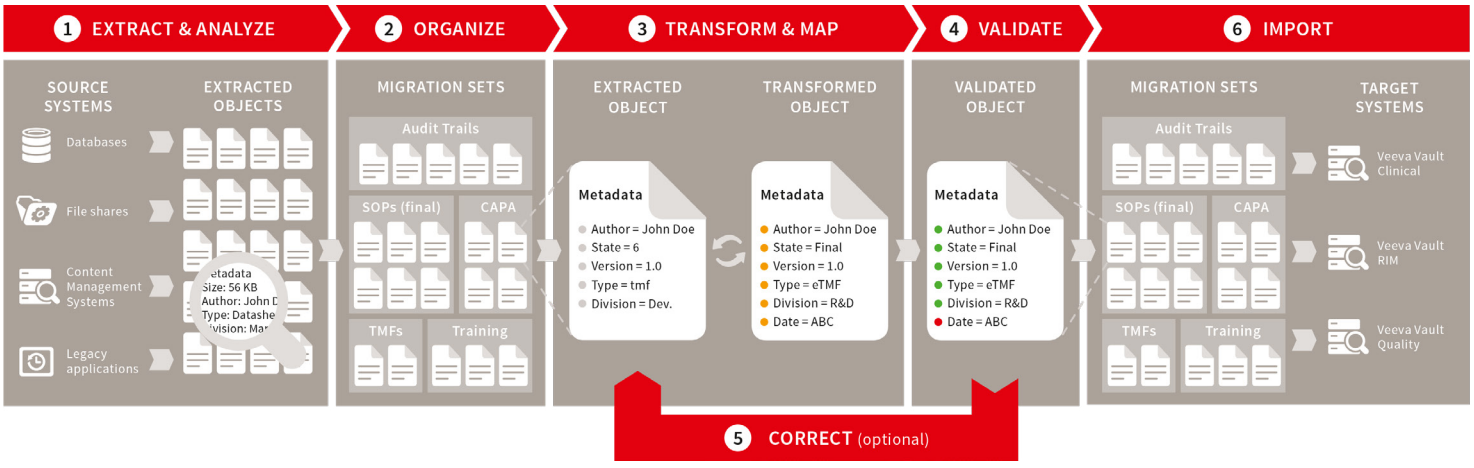
2. **Organize** the source data and break it out into manageable and meaningful sets of documents/ records.

3. **Transform and map** the source data to the target system. Object attributes (metadata) are transformed through the use of functions. Per attribute an unlimited number of functions may be inserted, allowing highly complex transformation rules.

4. **Validate and test** the transformed data against the target model before committing any data. It is crucial to address data issues before importing.

5. **Import** the transformed and validated documents including metadata into the Veeva Vault system. Ensure the documents were successfully imported into the Vault target system

All these steps can be handled independently or in parallel. Before committing any data to production, staging, testing, and dry runs should be carried out to reduce the risk of errors creeping into the new system.



Overview of the complete migration process with migration-center including validation

Migration in Action: A Case Study

Client: A leading biotechnology company with a focus on medicines for patients with serious diseases wanted to migrate part of its portfolio to Veeva Vault's RIM cloud solution. This was an important step for the global company, which already has several products on the market to treat genetic diseases and has a deep pipeline of investigational drugs aimed at addressing several other rare diseases. The company was migrating from a legacy system to a highly organized platform, which required transforming the metadata to fit into Veeva RIM.

Challenges: Among the challenges the project faced was the fact that the migration involved two separate legacy systems – one containing clinical and regulatory documents and the other involving health authority correspondence, submissions and registration data. Furthermore, because the migration only involved part of the portfolio, fme's consultants had to prepare complex data queries. Validation between the legacy and new systems was also complex due to the need for keyword searches.

In addition, because Veeva limits the daily API burst – meaning the migration of documents being imported – fme's consultants notified the client early on not to run extracts during migration to ensure a smooth transfer. In the end, fme was able to import around 14,000 documents per hour with multiple importers running in parallel.

Benefits: Because of migration-center's capabilities and the expertise of the fme migration team, the whole process – including the migration of more than 300,000 documents – was completed over a weekend. The client was able to:

- Access a powerful transformation engine, mapping rules and multiple scan queries made it possible to migrate documents with the correct mapping.
- Use a tool enhanced to enable multiple attachments to be automatically added to correspondence documents – a capability that isn't possible without migration-center.
- Access a verification tool that validates the source and target documents and their data mapping and flags anything unexpected.
- Replace corrupted documents with dummy templates in the client's desired format using migration-center's migration rules. Without migration-center it would be very difficult to identify corrupted documents and replace those records.

The migration-center: A Unique Migration Approach

One of the advantages of migration-center is that it is an out-of-the-box platform with no additional scripting or programming required, while also supporting special cases as required.

For busy life sciences companies, a challenge with migrations is the disruption to workflow as data is moved from the old platform to the new. With migration-center, data is migrated into new systems in the background without interruption to business operations, meaning users can continue to work with the old system as the migration takes place. Parallel operations are only stopped for the final run, which takes place over a weekend.

migration-center can carry out very large data volumes and, for example, has handled a migration of over 380 million documents.

Life sciences companies are urgently looking for ways to improve data quality, gain better visibility into regulatory activities, remove repetitive processes, and reduce complexity. Veeva Vault offers:

- A single cloud platform to unify registration tracking, correspondence and commitments, submission document management, dossier publishing, and regulatory submissions archiving.
- The ability to enter data and documents just once and access them in any context.
- Improved data quality due to the ability to capture accurate information directly from each region and share it globally.
- Improved visibility into activities across functions and geographies.
- Access to the complete history of regulatory submissions stored securely in the cloud.