ISEŌ
SOLUTIONS

Veeva

CUSTOMER

Industry: Life Science

Location: Switzerland

Employees: ~500

Regulatory Affairs Data Migration to Veeva Vault RIMS

RESULTS

Successful, validated migration of data & documents from the three legacy Regulatory Affairs applications OpenText Content Server (on-prem), Aris Global Register (cloud-based), and TrackWise (on-prem) into Veeva Vault RIMS (cloud-based).

PROJECT BRIEF

Business Department: Regulatory Affairs

Source Systems

- ArisGlobal Register
- Sparta Systems TrackWise
- OpenText Content Server & RegDocs

Target System

- Veeva Vault RIM Suite

CURRENT SITUATION

Our Swiss customer was facing the challenge of a complete carve-out of facilities, staff, applications, and data after the company was sold out. The necessary reorganization, segregation, and transition were a challenge themselves. A guaranteed ability to successfully pass future quality audits and to further ensure product and patient safety is key in such a program.

> "When your customer starts using a new application, it's always a big deal. If it's a regulated environment, you know that a few more qualification steps were necessary to get there. Now, as the Go Live included content to be migrated into the new application, stakes were even higher to guarantee completeness, integrity, and data quality. Consolidating 3 legacy Regulatory Affairs applications into one, considering all dependencies, duplicates, and links between data and documents is another level of Go Live."

Joachim Freitag,
Managing Partner IseoSolutions

CUSTOMER'S GOAL

✓ **Data Completeness**
Identify & extract all necessary and approved data & documents from 3 existing applications: ArisGlobal Register, TrackWise on-prem, and OpenText Content Server.
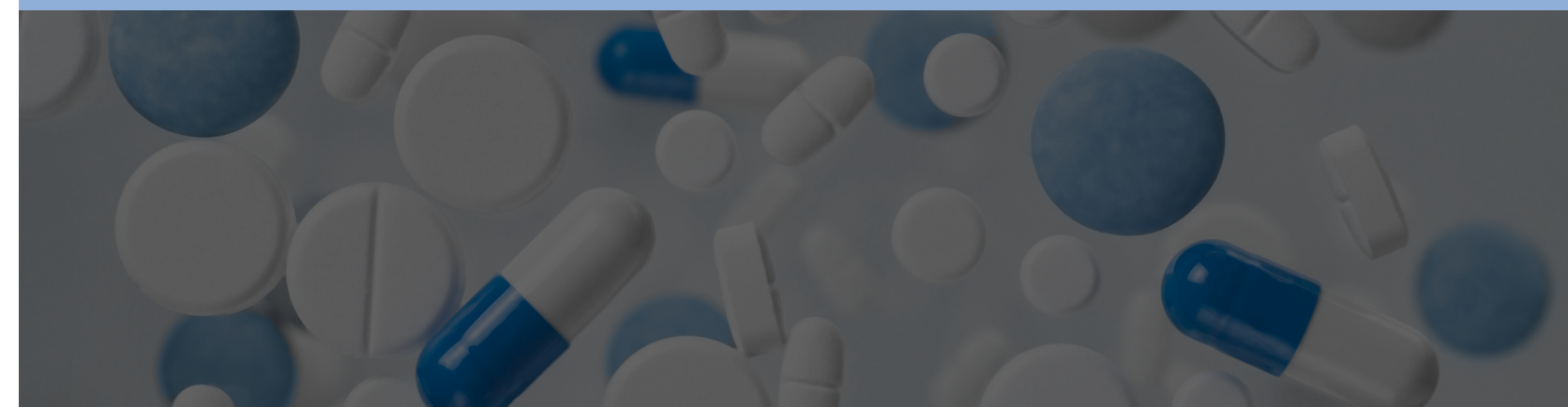
✓ **Consolidate data to be migrated**
Analyse exported data & documents, de-duplicate documents, map data to Veeva Vault RIMS data object structure, and create links between business objects using object metadata.

✓ **Ensure integrity & validation**
Import data and documents into Veeva Business Objects & test extensively to ensure a validated system after data migration.

IMPLEMENTED SOLUTION

Our data migration project required an already validated target system - configured fit for purpose according to the future requirements of our client. The legacy data and documents needed to fit into this setup and structure, so data mapping and linking was a key topic during the DryRun phase on the test servers of the 3-staged Veeva Vault RIMS cloud applications.

The extensive use of ECM functionality in the OpenText Content Server such as major and major versioning, generations (objects pointing to a specific version of a document), and the integrated OpenText Content Server de-duplication for copied documents needed to be analysed and mirrored in the target system. The custom-specific metadata and comprehensive audit trail also needed to fit into the target system.

After thorough testing of the migration scripts, the latest data extracts were consolidated in a Veeva-specific Migration Tool and imported into Veeva Vault RIMS while documenting the whole import and testing process meticulously.

RESULTS

We have managed the complete data migration project with several involved external companies, multiple key business stakeholders, and technical staff in two client companies within one year. The organization and constant alignment of tasks, activities, and deliverables for the technical migration as well as the parallel Validation Management were handled by the IseoSolutions Team. The necessary project documentation for a successful data migration validation was created, aligned, and approved electronically.

The whole project team including key customer staff, different external parties for the migration, and the Veeva target system worked very hard to make the project a success.