::: fme

Validation Package For migration-center Projects

Reduce time and complexity with custom-made document templates and property test sheets

Computer System Validation (CSV) is especially crucial in highly regulated industries like the Life Sciences industry, since their products impact public health and safety. To ensure that computerized systems and software do exactly what they are designed to do in a consistent and reproducible manner, both the European Medicines Agency (EMA) and the Food & Drug Administration (FDA) have published guidelines, which have an effect on Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP) and an impact of law.

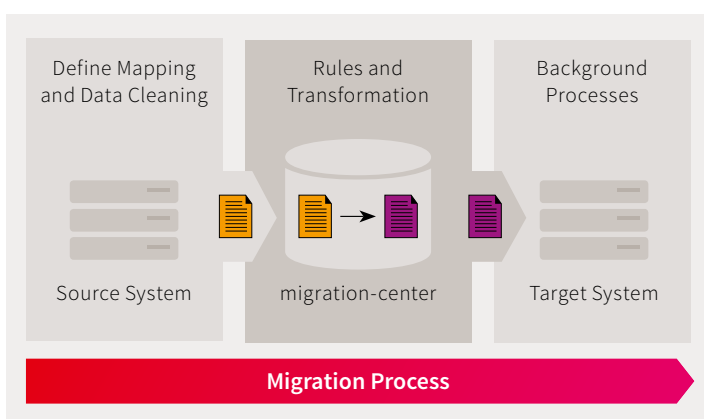## Validation In Migration Processes

If data and records are migrated to another system, the migration should to be planned, conducted, and verified in such a manner to ensure the data set is complete, consistent and accurate over its entire lifecycle. Thereby, the migration procedure should be tested or confirmed before the data is completely transferred out of the system. The validation should include checks that data are not altered in value and / or meaning during the migration process (see Good Automated Manufacturing Practice (GAMP 5) and EU GMP Guideline: Annex for Computerized Systems (Annex 11)).

Is there an »Out of the Box« validation?
The answer is NO as any migration implemented in a specific environment becomes unique. The combination of environments, configurations, rules, interfaces, business processes etc. are specific for each application. Strategies need to be set up for the individual situation of each migration project and this lies within the responsibility of the business itself.

Is it useful to validate migration-center?
The answer is NO as migration-center is the middle part of the migration process only. migration-center is not influenced by mapping definitions and background processes, but these definitions and processes will affect the data quality

Computer System Validation (CSV)

CSV establishes documented evidence which provides a high degree of assurance that a specific computer system will consistently produce results that meet its predetermined specifications and quality attributes.

The validation…
• ensures data integrity
• reduces risk and legal liability
• helps prevent software problems before reaching production / usage environments

and thus have to be validated. The best practice approach to validate a migration project is a black box test. The most important fact is that the source data will be migrated to the target system according to specified rules. The implementation details within the black box are not relevant.

The migration validation is a complex and time-consuming challenge for companies: documents have to be created, mapping sheets and rules have to be finalized, and often hundreds or even thousands of documents have to be tested to verify the migration process. In general, the companies' resources for migration projects are very limited.

Our Offering

Looking back at 10+ years of experience in migration projects in validated environments, we developed the **migration-center Validation Package**, a new and exclusive approach based on best practices that simplifies the verification process and therefore reduces the time the business is involved in migration projects. This additional package for migration-center projects consists of two basic components: A collection of needed document templates and consulting services to adapt the templates to the individual client

Define Mapping and Data Cleaning

Rules and Transformation

Background Processes

Source System

migration-center

Target System

Migration Process

validation needs. fme takes over the creation of these documents, delivers any required migration information and builds representative sample sets of documents in the form of property test sheets. The fme migration-center Validation Package can be ordered separately or as part of fme's Migration Factory solution.

List Of Document Templates

Migration Plan – The Central Document
- Defines the project team and the responsibilities of the team members
- Defines the strategy of the migration of documents and related objects
- Defines the sample sizes and the tests that need to be performed on the migrated documents

Mapping Sheets
- Define the document type, property and dictionary mapping

Migration Specifications
- Describe the implemented migration rules on a high level

migration-center Installation- & Operational Qualification
- Provides evidence that the installation of migration-center and related software was executed successfully

Technical Migration Verification Protocol
- Provides evidence that all required migration exports (scans) and imports were executed successfully
- Focuses on the comparison of the number of exported (scanned) / imported documents and the analysis of migration log files

Migration Verification Protocol (User Acceptance Test)
- Provides evidence that all relevant documents from the source system have been migrated correctly to the target system

Property Test Sheets
- The documents to be tested are preselected (according to the Migration Plan)
- Source and target metadata are shown
- Testers can easily verify the properties of migrated documents and whether the migration rules were implemented correctly

Benefits

- Reduction of time for business – through custom-made templates and the use of property test sheets

- Reduction of complexity – testers only need to compare source and target metadata on the sheets instead of comparing the metadata directly in both environments

- Compliance – solid framework for documented evidence according to guidelines ensures that the migration was planned, tested and conducted correctly

fme migration-center

migration-center is a full function and easy to deploy out-of-the-box product for highly automated, large volume content and data migrations. It is on the market since 2005 and has been certified by leading ECM platform vendors. It has proven its quality in hundreds of content migration-projects around the world, especially in highly regulated environments. **www.migration-center.com**

Your Partner For Validated Content Migrations

With our content migration and Life Sciences industry expertise, fme is your partner of choice for your validated migration projects. We look forward to your challenge!