Kneat

Innovative Customer Award Presentations

Innovative Customer Award Presentation #1

Cesar Tavarez
Validation Engineer, Alcon

Alcon

VALGENESIS TO KNEAT

Transition and Data Migration Project

César B. Tavárez / Yamil Casanova-Mangual
Johns Creek, GA

Alcon

VALGENESIS = VLMS1 / KNEAT = VLMS2

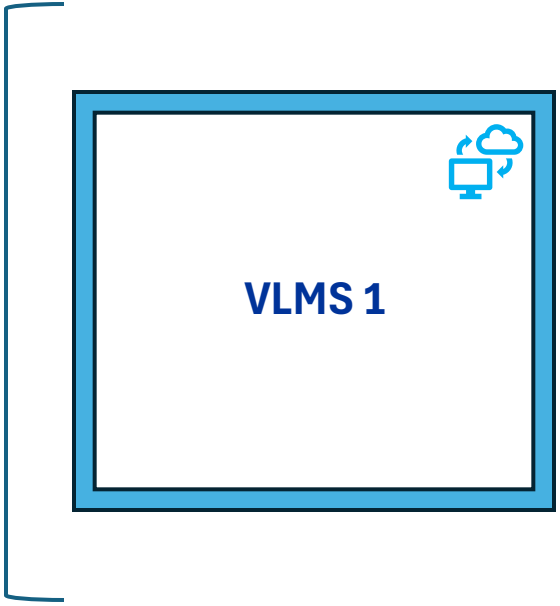
For every new software implementation, there is an equal and opposite force exerted by the user.

An English Programmer:

BACKGROUND

2017/
Paper Based
Validation

2018/
Validation Lifecycle
Management
System (VLMS)



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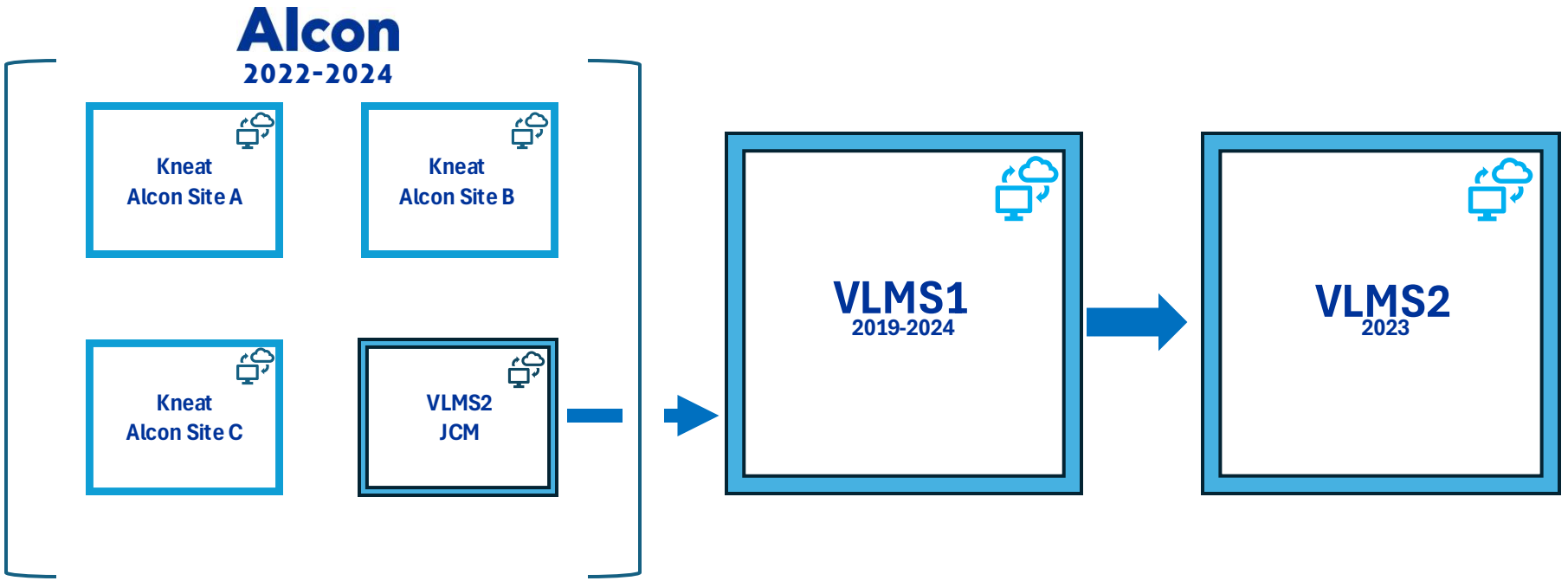


BACKGROUND

VLMS1

4 Years of

- Validation Records
- Validation Reviews
- Folder Structure

PROJECT PLAN

Implementation Plan

1. Application Implementation
   - Configuration, User Acceptance Testing and release of the application.
2. Transition Process
   - Transition of the validation program between VLMSs.
3. Data Migration
   - Transfer validation data (record, periodic reviews, and folder structure) from VLMS1 to VLSM2)
4. VLMS1 Retirement

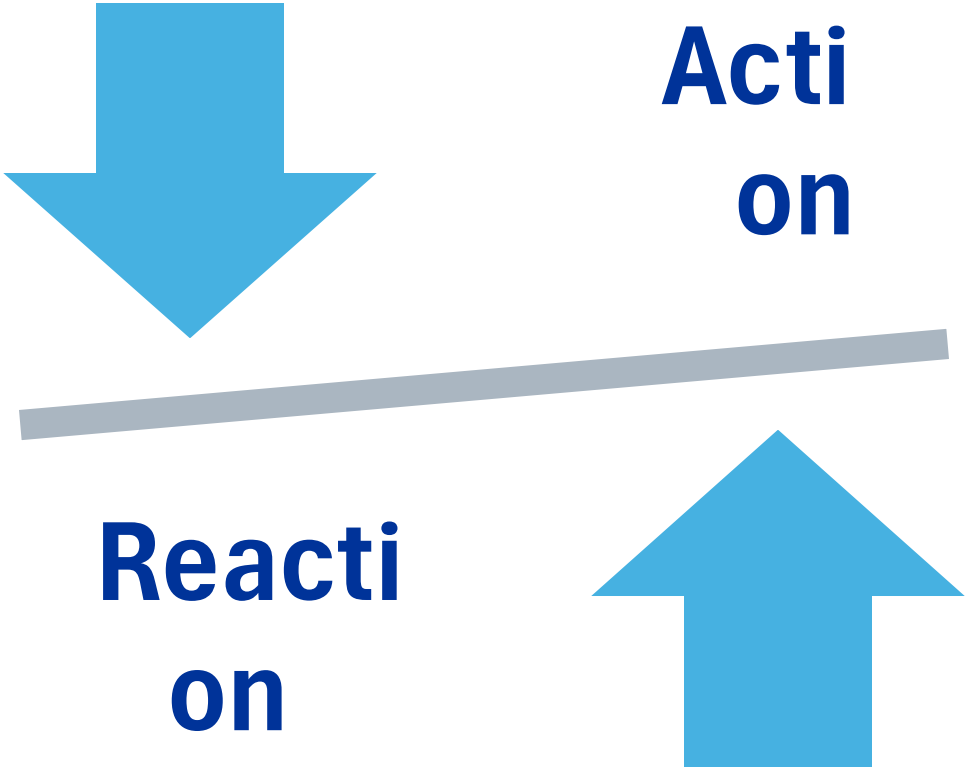
IMPLEMENTATION

1. Application Implementation
   - Configuration
   - User acceptance Testing
   - Release of the application

Step	Activity/Deliverables
1	Basic users and master users training
2	Template creation
3	System demonstration
4	PMD (Process Mapping Document)
5	RCS (Report Configuration Specification)
6	WPIV (Work Process Item Verification)
7	WPIV Report (Work Process Item Verification Report)
8	PHA (Project Handover Acceptance)

TRANSITION

1. Transition Process
   - Transition of the validation program between VLMSs.



TRANSITION

Step	Activities on VLMS 2	Activities on VLMS 1
1	• Completion of PHA and WPIV Report	General notification - Transition between VLMSs has started. Notification to the vendor of the VLMS1 about the transition plan- discuss the data migration strategy.
2		
3		
4		

MIGRATION

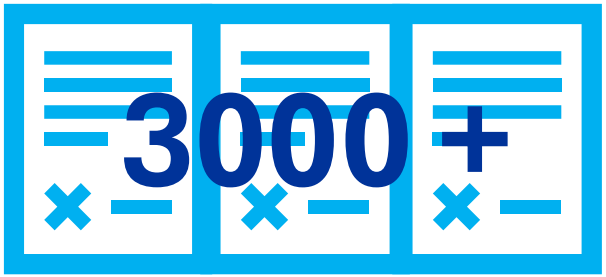
TWO MAJOR ISSUES

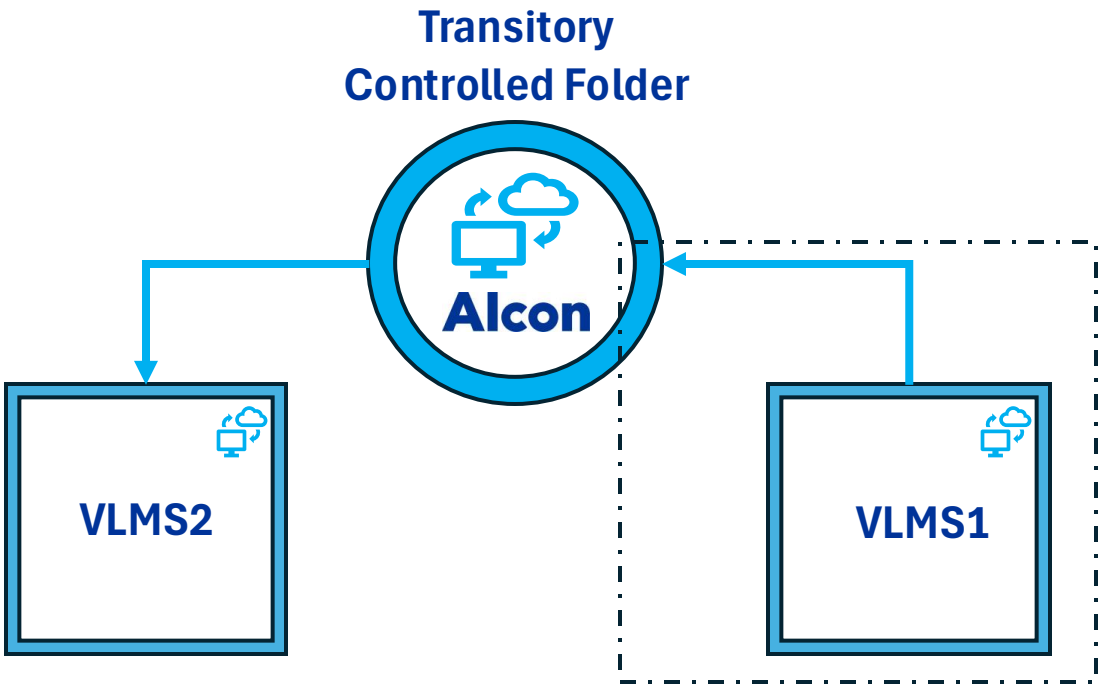
MIGRATION

Communication

1. Stablishing the basic requirement (data and folder format) for the VLMS2 to be able to migrate the data
2. Held meetings with each Tech Team independently
   - Alignment with the strategy
   - Discuss the migration plan technical details
3. Held meetings with VLMS1 and VLMS2 Tech Team together
   - Fine tune the strategy
   - Discuss specific technical aspect of the project
   - One Team (Synergy)
4. Generate a Migration Protocol
   - Written strategy
   - Pre-determined check-points

MIGRATION





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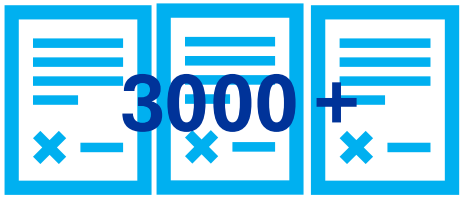
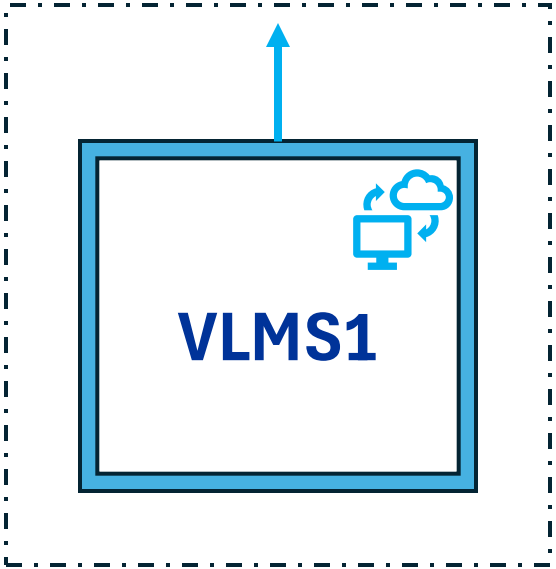
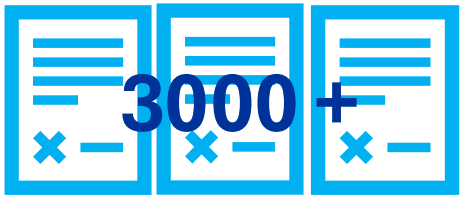
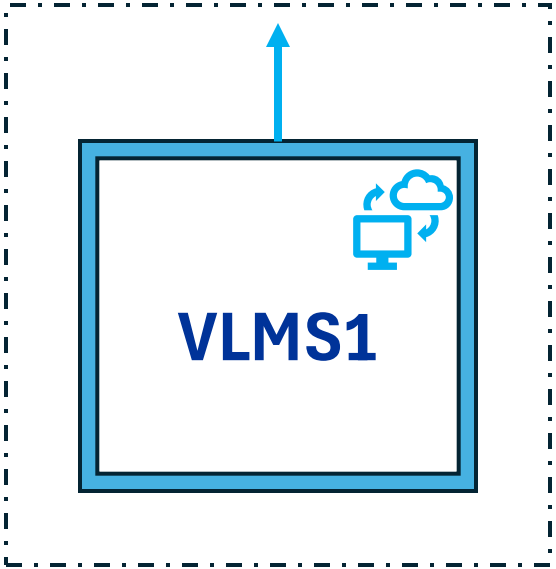




1. Data Freeze
   - Communicated to the site 6 months in advance
   - Consolidation of documents in VLMS1
   - Tracking “in execution” documents
   - Communicate that draft documents will require re-initiation in VLMS2
2. Request the use of “Off the Shelf” script to transfer the Data from VLMS1 to Alcon Transitory Controlled Folder
3. Stablishing a sampling plan to verify data accuracy

MIGRATION

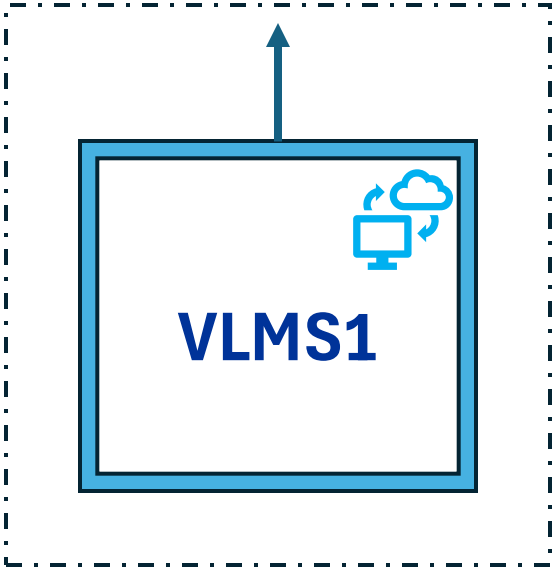




3. Stablishing a sampling plan to verify data accuracy.

1. The sample size was selected using, as a reference, the Product Quality Attributes for one of the site production platforms
   - The severity level for VLMS2 was stablished
   - Then we used our Process Validation program to determine the Minimum Reliability and Process Performance Index requirements, based on PQA/CTQ severity levels, for key process outputs
   - With the stablished severity level, the Lower Confidence Limit of the Reliability was determined to be X%
   - With a Lower Confidence Limit of the Reliability = X%, the minimum sample size was found to be N = 30, with zero defects
2. Then we selected 30 samples to monitor the migration from VLMS1 to Transitory Controlled Folder, and then from the Folder to VLMS2

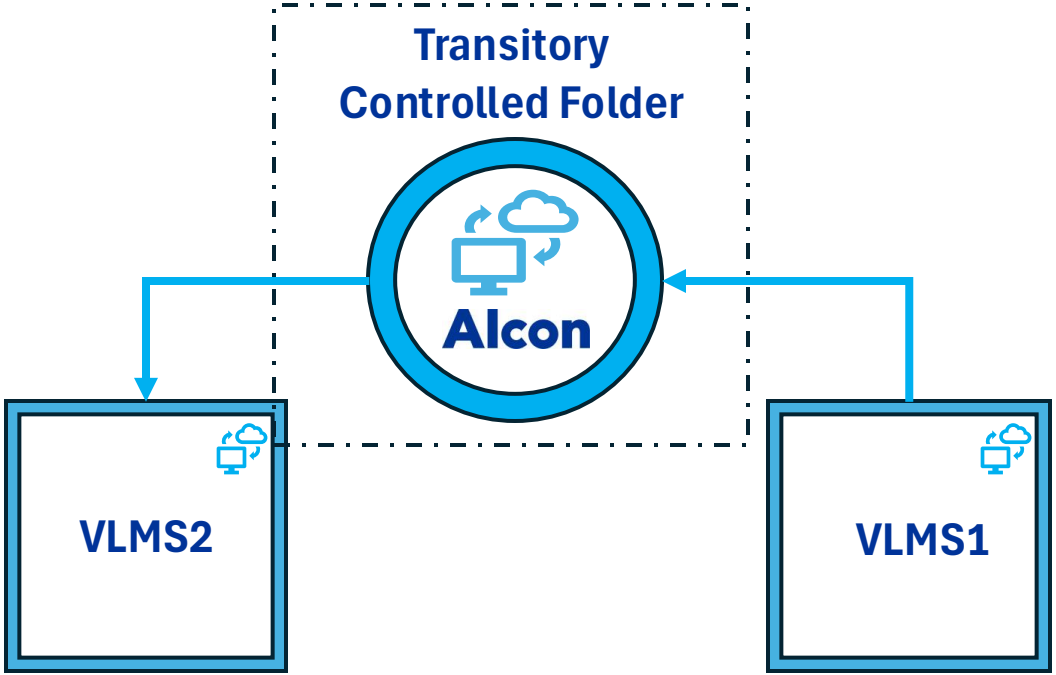
MIGRATION



3. Stablishing a sampling plan to verify data accuracy.

Compliance with Efficiency: Reduction of Project Time and the use Resources.

MIGRATION

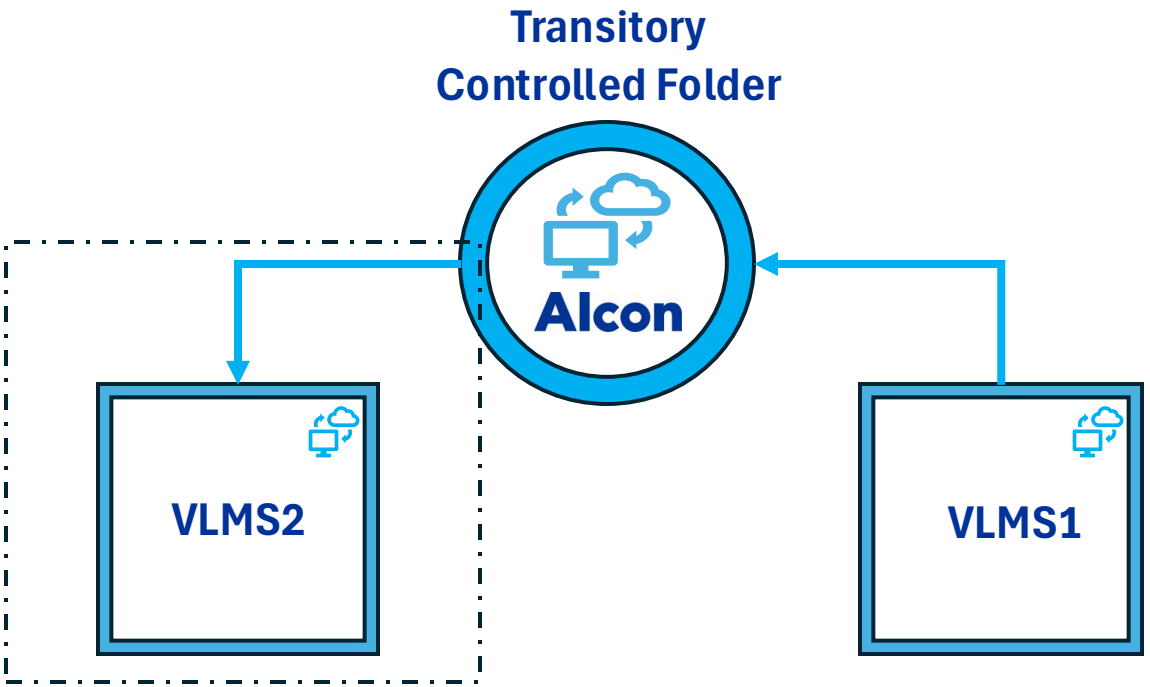


MIGRATION

Transitory Controlled Folder

1. Execute Phase 1 of the Migration Plan: VLMS1 to Transitory Controlled Folder
   - Document the VLMS1 Data Freeze
   - Request from the VLMS1 Customer Technical Services team to run the migration script in the P Environment
   - Compare the sample data between VLMS1 and the folder
2. Release for Phase 2

MIGRATION



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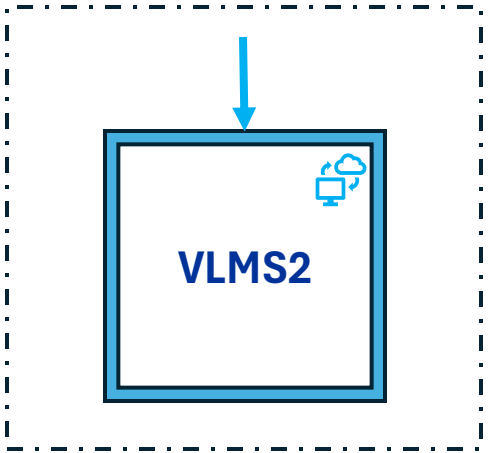
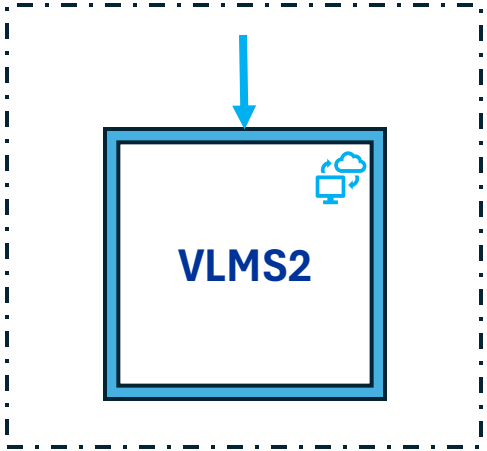


1. Execute Phase 2 of the Migration Plan: From the Transitory Controlled Folder to VLMS2.
2. 3 Steps
   - 1 DEV Environment
   - 2 VAL Environment
   - 3 PROD Environment

MIGRATION

1 DEV Environment



Two Applications

Data Mapping

Used for extracting folders, pdfs, and zipping mapped folders

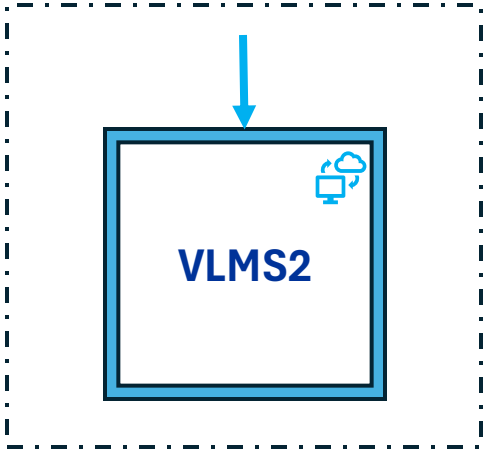
File Importing

Used for importing the File entities

1. Migration of a selection of 500 records
2. A sample of 30 random records were verified: Origen Vs Destination.
3. Both records were retrievable, record are readable, complete, have the same #, same number of pages.
4. Acceptance Criteria: 0% Discrepancy.

MIGRATION

2 VAL Environment



Two Applications

Data Mapping

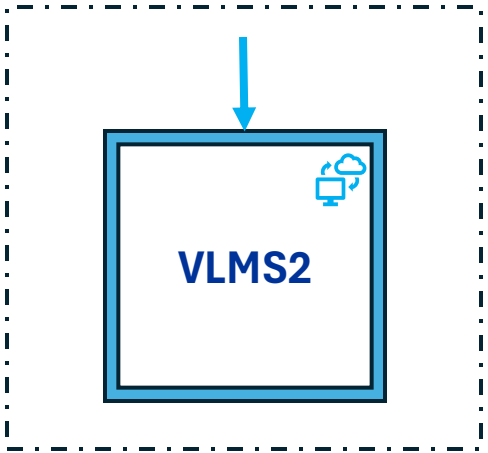
Used for extracting folders, pdfs, and zipping mapped folders

File Importing

Used for importing the File entities

1. Migration of all Record using the DATA MAPPING and FILE IMPORT APPS.
2. A sample of 30 random records were verified: Origen Vs Destination.
3. Both records were retrievable, readable, complete, have the same #, same number of pages, and same information.
4. Acceptance Criteria: 0% Discrepancy.

MIGRATION



3 PROD Environment

Two Applications:

Data Mapping

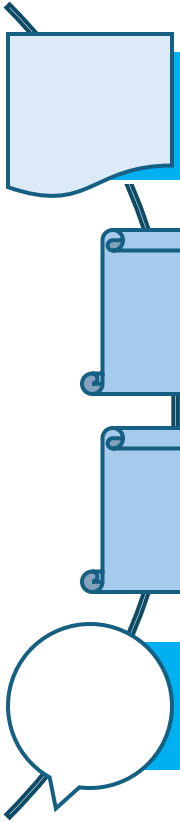
Used for extracting folders, pdfs, and zipping mapped folders

File Importing

Used for importing the File entities

1. Migration of all Record using the DATA MAPPING and FILE IMPORT APPS.
2. A sample of 30 random records were verified: Origen Vs Destination.
3. Both records were retrievable, readable, complete, have the same #, same number of pages, and same information.
4. Acceptance Criteria: 0% Discrepancy.

POST- MIGRATION / IMPLEMENTATION



Notified the site about the new Archive Folder

Provided 3 general training sections

Provided teams specific training sections

Created short instructional videos

César B. Tavárez / Yamil Casanova-Mangual

Innovative Customer Award Presentation #2

Warren Ware
Validation Engineer, Colgate-Palmolive

Validation in Consumer Health at Colgate-Palmolive

Calibration Certification and Master Database Project - Scaling KNEAT workspace functionality globally for Plant Calibration teams to strengthen GxP / 21 CFR Part 11 compliance.

Warren Ware

Validation Engineer

An End User to System Admin Journey

2015

Began in the Analytical Lab and succeeded in becoming Instrumentation SME at Morristown, TN Oral Care facility.

2020

Assisted with KNEAT pilot plant implementation at Colgate in Morristown, TN.

2024

Promoted to Validation Engineer at the Cambridge, OH Home Care facility... successfully spearheaded the KNEAT implementation and created the Calibration Certification and Master Database Project.

"I am offering my personal views in relation to my industry knowledge and KNEAT subject matter expertise, and not speaking on behalf of the Colgate-Palmolive Company or representing the Company's views."

Calibration Master Database Project

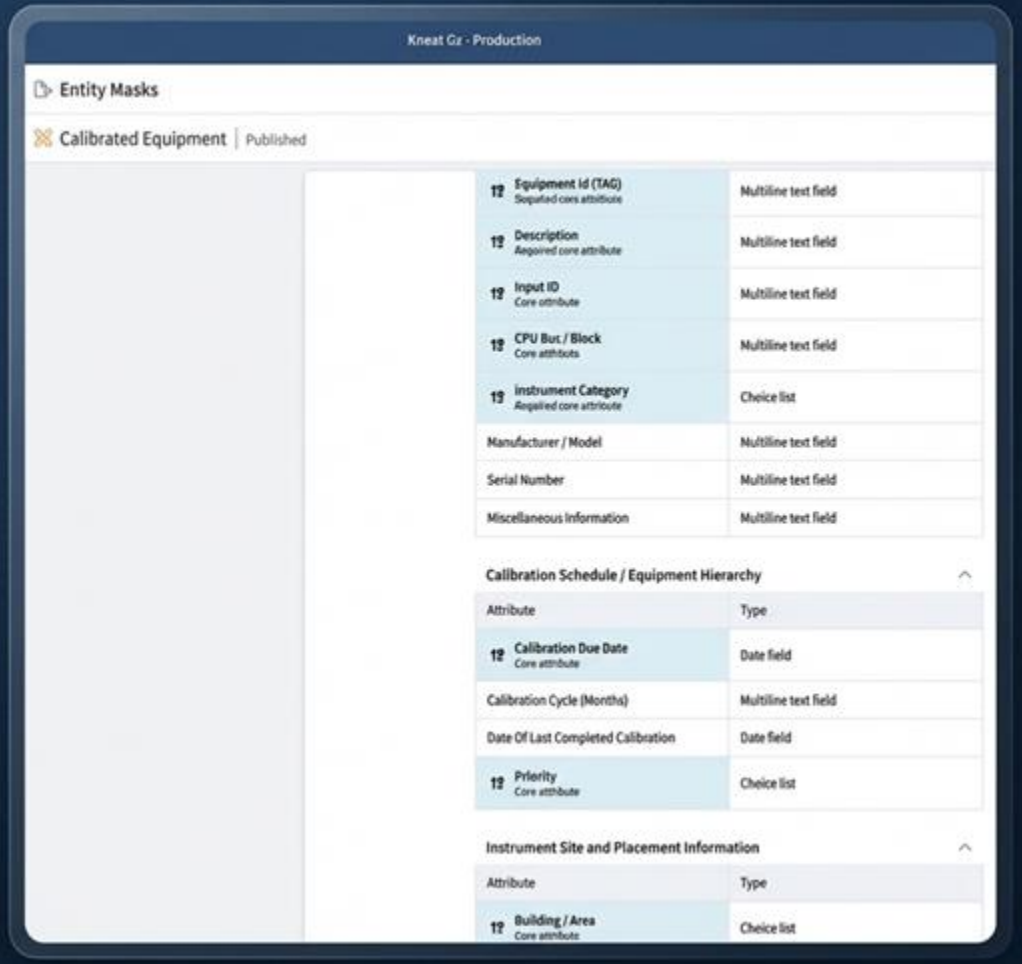
THE CHALLENGE

The calibrations department was dependent on unprotected and fragmented Google Sheets as well as paper-based calibration certificates.

Kneat

THE SOLUTION

- Fully Compliant (Global Standards)
- Secure & Centralized
- Efficient & Traceable

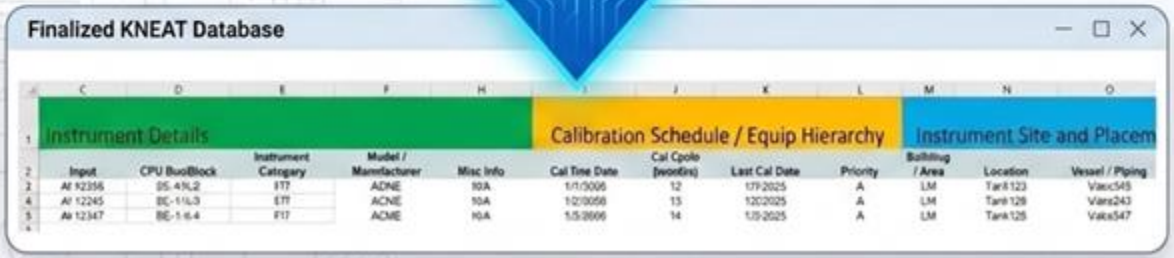


Calibration Master Database Possibilities

Created site specific Equipment Entity Mask for our Calibrated Instruments to match the fields contained in the Google sheet.

Since the Entity Mask had to be compatible with all equipment types, all possible information fields had to be included.

Methodical Data Migration and Structuring



Step 1:
Collaborate with KNEAT IT engineers.

Step 2:
Organize legacy equipment data in EXCEL to map to specific Entity Mask fields.

The Result:
Flawless transfer establishing over 650 discrete equipment entities.

Post-migration verification and reconciliation confirmed that data integrity was maintained during the transfer process.

Driving Efficiency with Standardized Document Templates

CALCERT Framework

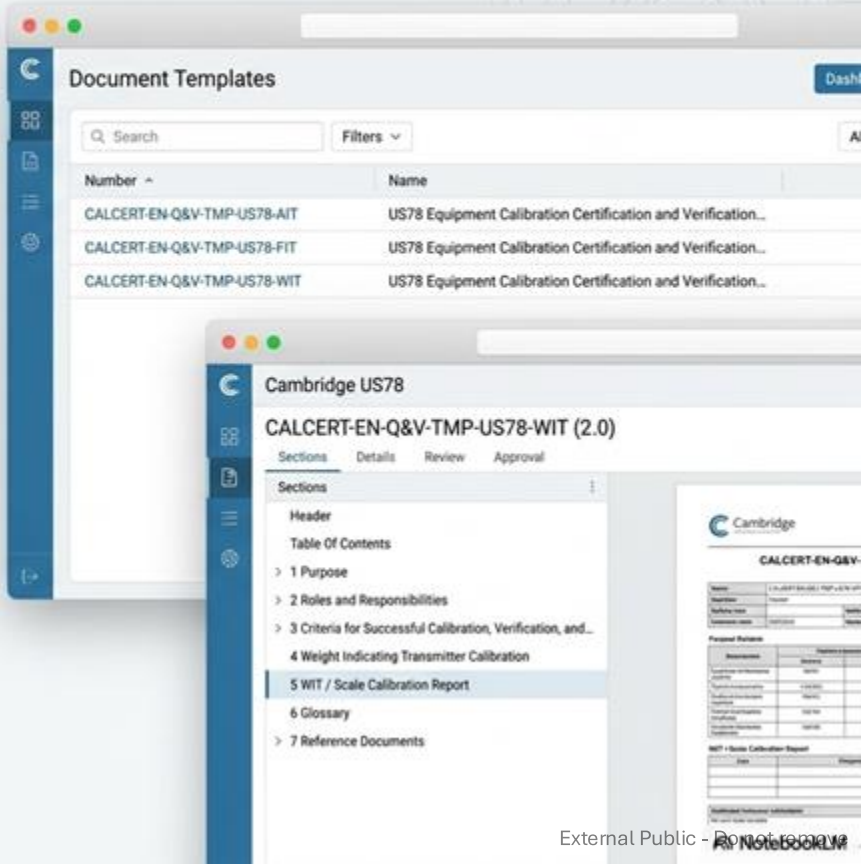
Calibration and Verification Certificate templates established for every instrument type in the Master List (AIT, FIT, WIT).

Embedded Protocols

Each template automatically contains the required work procedure, reference documents, and specific Calibration Report.

Accelerated Creation

Drastically increases efficiency in generating routine certificates by eliminating manual document assembly.



Workflow Optimization and Hard ROI

Google Drive + Paper Certificate: Legacy manual reporting and physical storage.

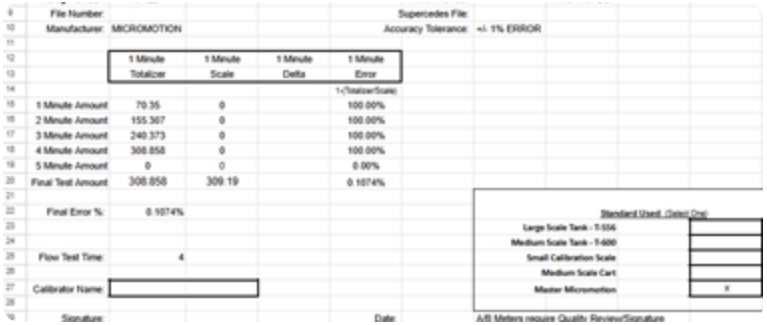
KNEAT e-certificate + electronic approvals: Streamlined digital workflow with automated data validation.

Automated Data Data Population generates significant **ROI** through raw time savings.

Optimization

Google Drive + Paper Certificate

Legacy manual reporting and physical storage process.



File Number:				Supercedes File:	
Manufacturer:	MICROMOTION			Accuracy Tolerance:	+/- 1% ERROR
	1 Minute Totalizer	1 Minute Scale	1 Minute Delta	1 Minute Error	
				1-(Totalizer/Scale)	
1 Minute Amount	70.35	0		100.00%	
2 Minute Amount	155.307	0		100.00%	
3 Minute Amount	240.373	0		100.00%	
4 Minute Amount	308.858	0		100.00%	
5 Minute Amount	0	0		0.00%	
Final Test Amount	308.858	309.19		0.1074%	
Final Error %:	0.1074%				
Flow Test Time:	4				
Calibrator Name:					
Signature:				Date:	

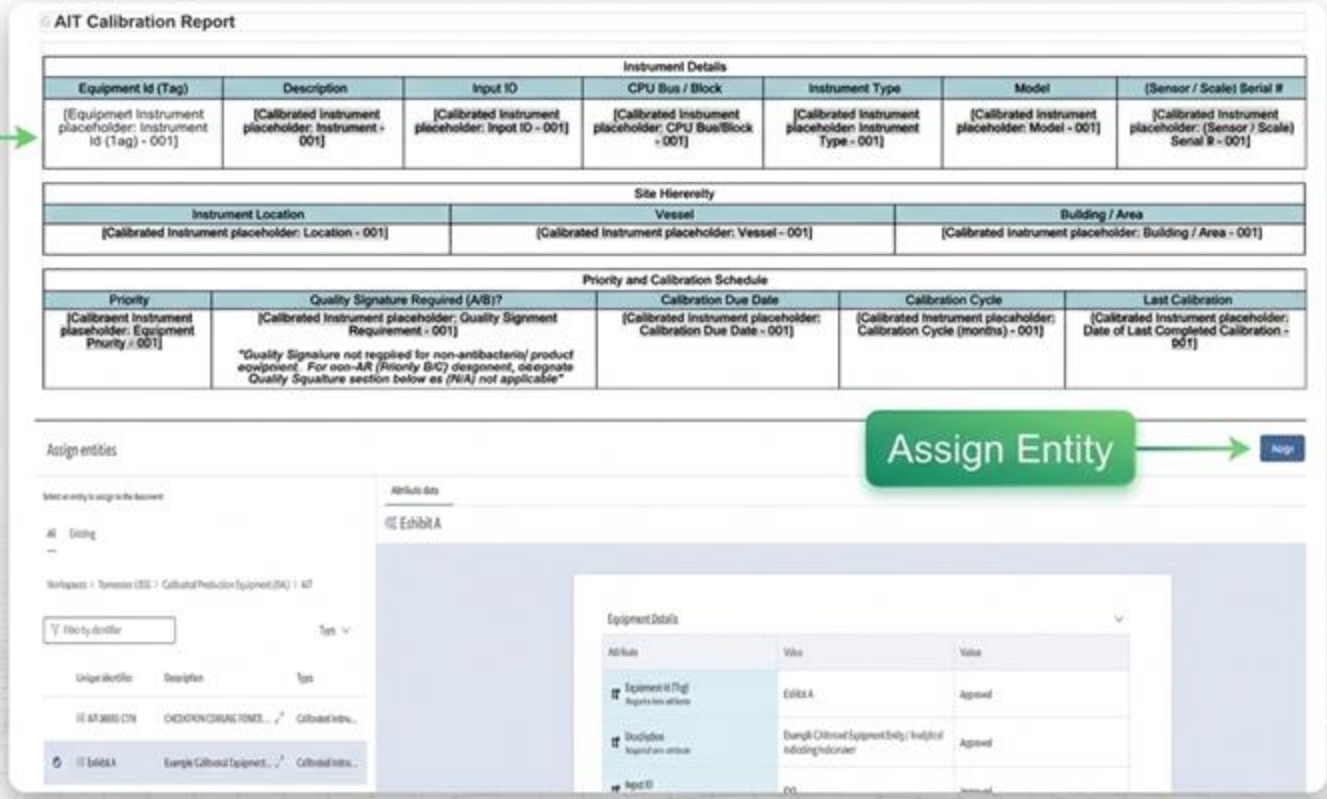
Standard Used: (Select One)	
Large Scale Tank - T-556	
Medium Scale Tank - T-600	
Small Calibration Scale	
Medium Scale Cart	
Master Micromotion	X

A/B Meters require Quality Review/Signature

KNEAT e-certificate + electronic approvals

Streamlined digital workflow with automated data population and validation.

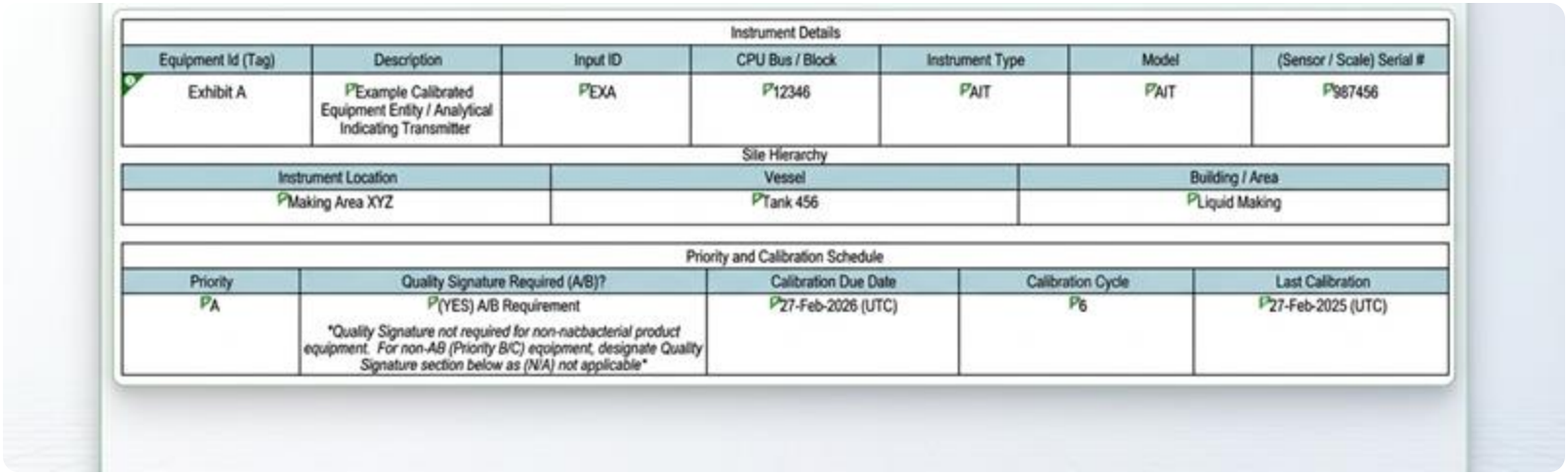
Click Here



Entity tables allow one click transfer of all equipment information from entity fields to the calibration cert/protocol.

Automated Data Population

Ensuring data integrity and traceability through validated entities



Instrument Details

Equipment Id (Tag)	Description	Input ID	CPU Bus / Block	Instrument Type	Model	(Sensor / Scale) Serial #
Exhibit A	Example Calibrated Equipment Entity / Analytical Indicating Transmitter	EXA	12346	AIT	AIT	987456

Site Hierarchy

Instrument Location	Vessel	Building / Area
Making Area XYZ	Tank 456	Liquid Making

Priority and Calibration Schedule

Priority	Quality Signature Required (A/B)?	Calibration Due Date	Calibration Cycle	Last Calibration
A	(YES) A/B Requirement *Quality Signature not required for non-nacbacterial product equipment. For non-A/B (Priority B/C) eqoipment, designate Quality Signature section below as (N/A) not applicable*	27-Feb-2026 (UTC)	6	27-Feb-2025 (UTC)

All data from Calibrated Equipment Entity is inserted into the Table

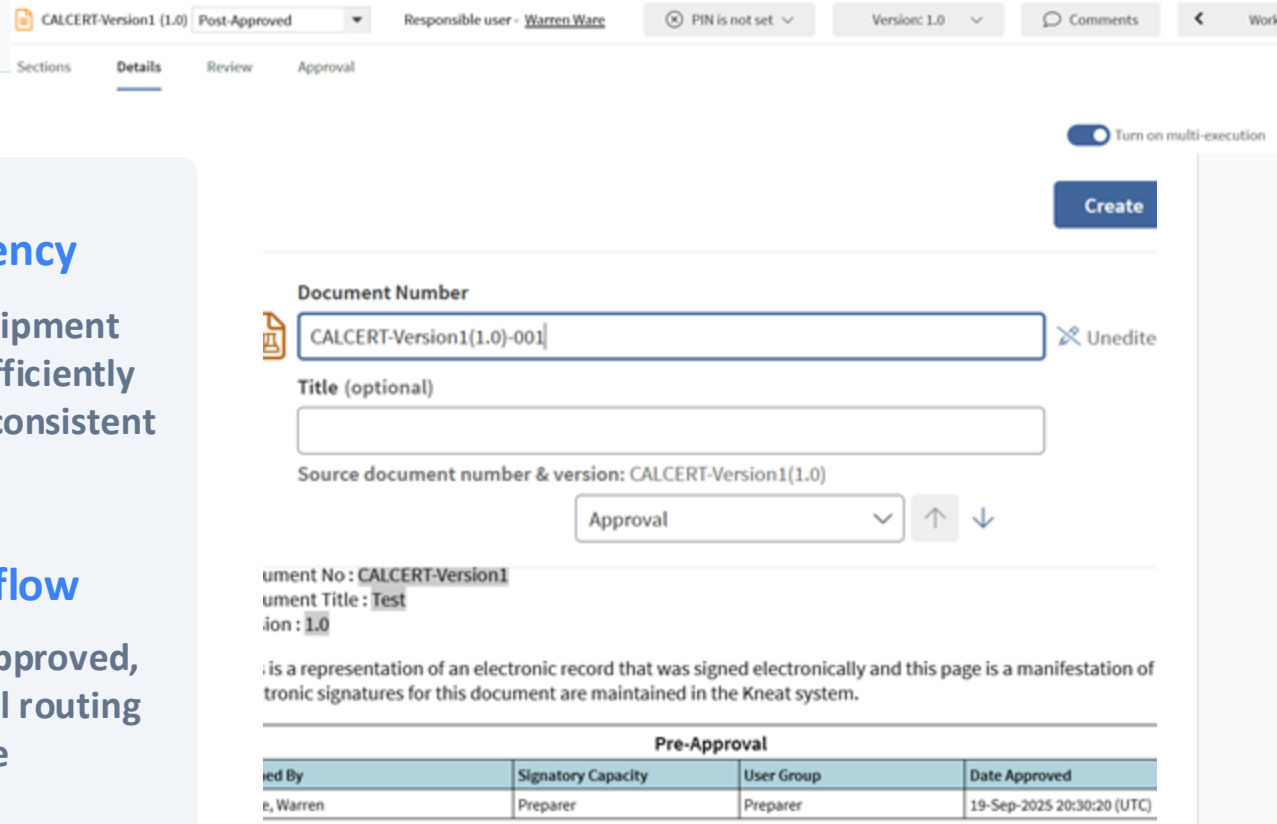
Execution Record Entity

Efficiency & Consistency

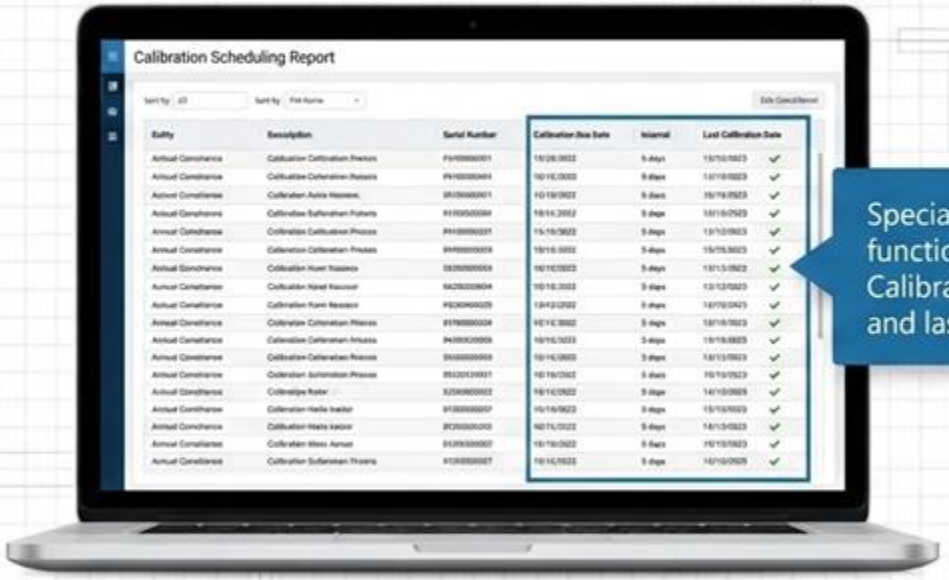
Protocols for repeated equipment calibration can easily and efficiently be reused for confident and consistent execution

Pre-Approved Workflow

Execution records are pre-approved, cutting out the first approval routing step and saving time



Proactive Compliance and Automated Reporting



Specialized and customizable functionality using specific entity Calibration due dates, intervals, and last calibrated date.

Leveraging the Calibrated Equipment Entity Report functionality and automated notifications provides clear visibility into compliance scheduling and effectively organizes equipment service workloads.

A Blueprint for Global Replication

Foundational Entity Masks

The CSV implementation directly parallels the calibration master database. By establishing rigid entity masks and templates, this architecture flexes for cross-functional use and scales globally across diverse regulatory environments, whether relying on in-house teams or external vendors.

The Architecture of Trust

1. **Communication & Cooperation:** The paramount elements of a successful cross-functional team.

2. **Shared Truth:** A robust, single workspace guarantees critical information is accurate and instantly accessible.

3. **Vetted Confidence**: Efficient routing and robust system controls (e.g., audit trail, approvals, traceability, data integrity) definitively vet data. **Technology builds the framework; the framework builds trust.**

Innovative Customer Award Presentation #3

Carly Cox
Senior Process Informatics Manager

Pfizer

Kneat Global Deployment Transformation at Pfizer

Pfizer Innovation Award Submission

Carly Cox, Senior Manager, Manufacturing Intelligence and Technology Transformation (MITT) Value Delivery, Process Modeling and Informatics (VDPMI)

Pfizer Kneat Deployments 2022-2024

- Site based workspaces with site specific deployments and templates
- Minimal alignment across sites
- Only ~30% of manufacturing sites live with average of 2 disciplines per site
- Each new site deployment takes up to 20 weeks per discipline
- No external vendor access
- No direct sharing across sites

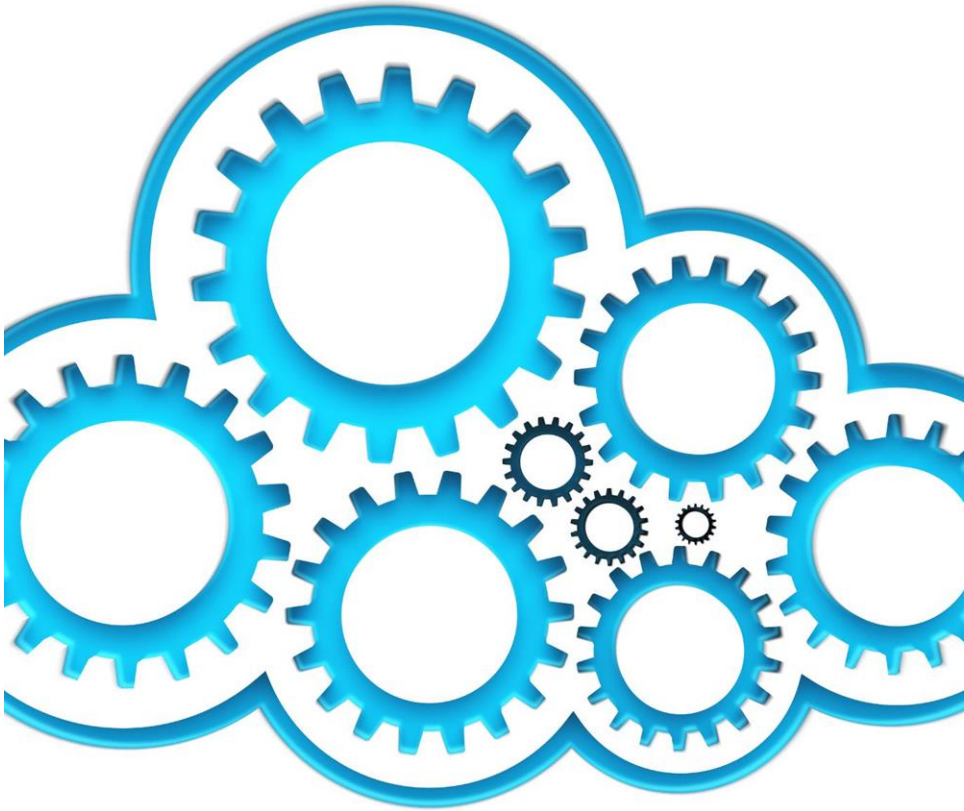
Pfizer Kneat Deployments 2025-2026

- Site based workspaces with deployment waves and global templates
- Full alignment across sites
- >90% sites live with 6 global disciplines to be fully deployed by end 2026
- 95% reduction in deployment time
- External vendor access possible without impacting internal access
- New global workspace enables sharing across sites

Pfizer

Pfizer Kneat Global Deployment Model

- Validation business processes harmonized across all manufacturing sites
- Global document templates designed and optimized to leverage Kneat features
- User groups harmonized across all Kneat disciplines
- Pilot sites complete testing of document and object templates
- Remaining sites only confirm that approval templates and folder structure within their site workspace align with the global configuration specification
- Deployments done in multi-site waves to maximize core team efficiency



Pfizer

Pfizer Use of Kneat Custom Groups

The Problem:

- Needed to restrict access for external vendors and audit support users to specific folders while still allowing regular internal users full access

The Solution:

- Created a custom group for each workspace to grant internal users folder access control permissions to ensure all documents accessible
- Created separate user group for external vendor users without this permission
- Use auditor view only and collection groups to only grant access to specific folders or documents

Pfizer Global Workspace for Test Methods

The Problem:

- Test Methods are shared across multiple Pfizer sites and validation related documents must be accessible for both viewing and execution by users at all relevant sites

The Solution:

- Created a global Test Method workspace for use by all sites
- Sites can adopt use of the new workspace without a formal deployment
- All users can access all documents within the workspace

Pfizer Kneat Innovation Summary

- Moved to global deployment waves of global templates
    - 95% reduction in deployment time
    - 9x deployments in Y4-5 vs Y1-3
    - Harmonized across sites
- Enabled external vendor access
- Global Test Method workspace allows document sharing across sites
- Continuing to improve deployment model for additional savings (e.g. consolidating disciplines)