

CEO Welcome



Eddie Ryan
CEO & Co-Founder

Kneat

Welcome

Share our knowledge around
digitalization to **deliver impact**
for our Industry

Then There was Three

Eddie Ryan

CEO, CO-FOUNDER

Experienced pharma engineer turned SaaS CEO.



Brian Ahearne

CIO, CO-FOUNDER

Expert software engineer and university lecturer.



Kevin Fitzgerald

CPO, CO-FOUNDER

Former Pfizer engineer and detail-oriented leader.



Our Purpose

Helping Life Sciences to deliver
therapies to their patients to the
highest Quality standard

Eddie Ryan

Eddie Ryan
CEO Kneat





20 Years in the Making

“One Easy to Use Zero Code
Platform for all your Validation
Workflows your way”.

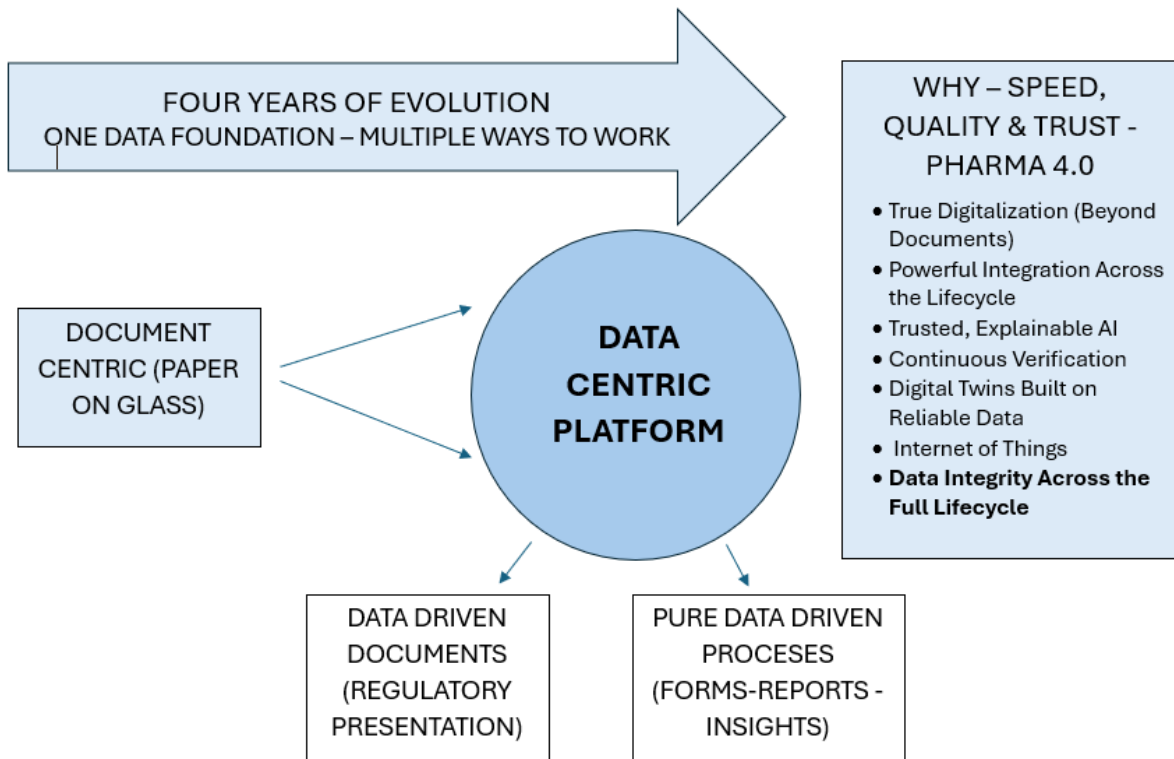
Some of Kneat's 130+ Customers



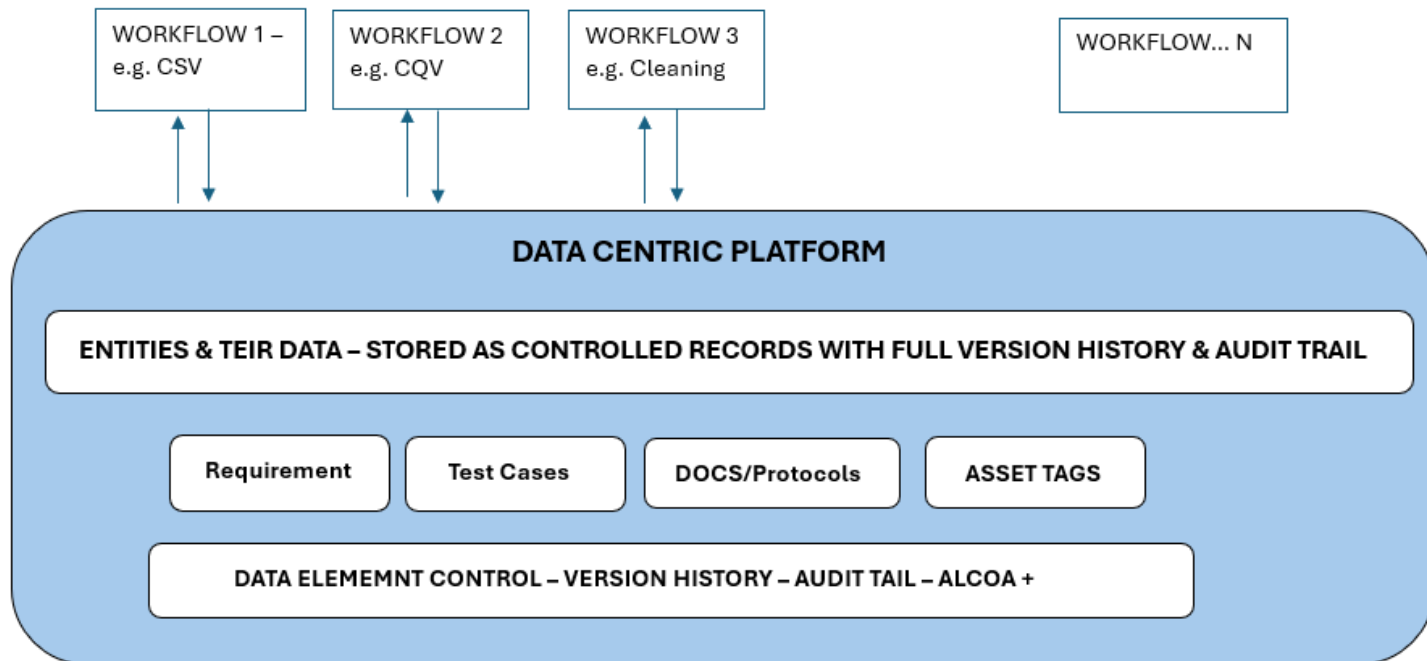
Data Integrity Is the Foundation of Patient Safety

- Everything we do is only as good as the data behind it
- Poor Data increases patient safety risk
- Regulators don't just inspect documents – they inspect trust in data
- Data → Decisions → Product → Patient

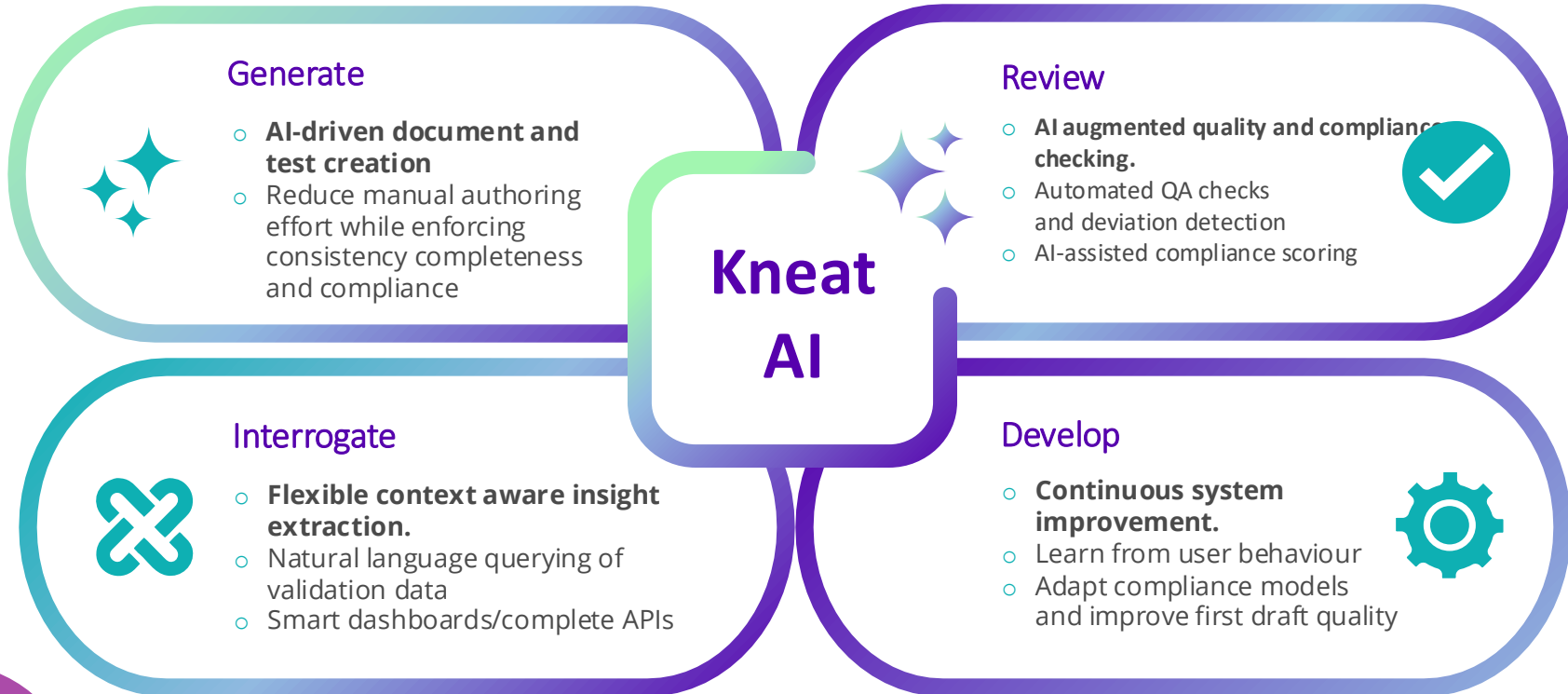
Doc Centric to Data Driven



Data Centric



GRID: AI-Driven Precision Across the Validation Lifecycle



Summary – Our Strategy



EVOLVE FROM
VALIDATION SYSTEM
OF RECORD



TO AI-ENHANCED
COMPLIANCE
INTELLIGENCE
PLATFORM



INVEST SELECTIVELY IN
EMBEDDED AI



PROTECT REGULATORY
CREDIBILITY &
CUSTOMER
OWNERSHIP

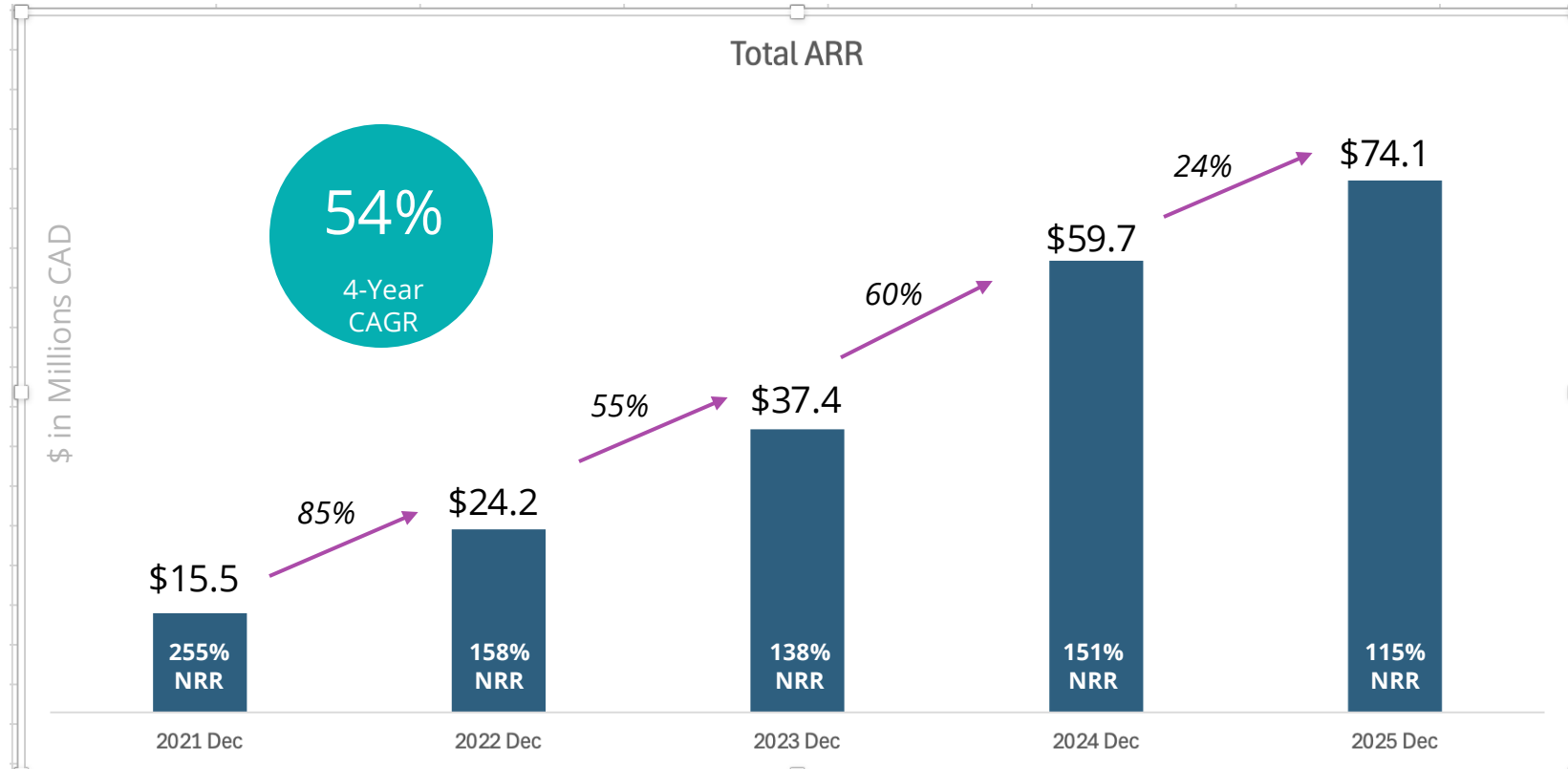
Time to Boast a Little



Some Numbers

- Global Team - 350 Employees
- 55% focused on Product Development - 191 in R&D
- Majority of top 20 big Pharma Cos.
- > 90,000 users across > 350 sites on the Kneat SaaS platform
- Strong Certified Global Partner Network

Strong Annual Recurring Revenue GRowth



Customer Success & Consultancy

- cNPS score of 70
- CSAT score of >80%

Customer Technical Support

- CSAT score of >4

Kneat Academy

- CSAT score of >4

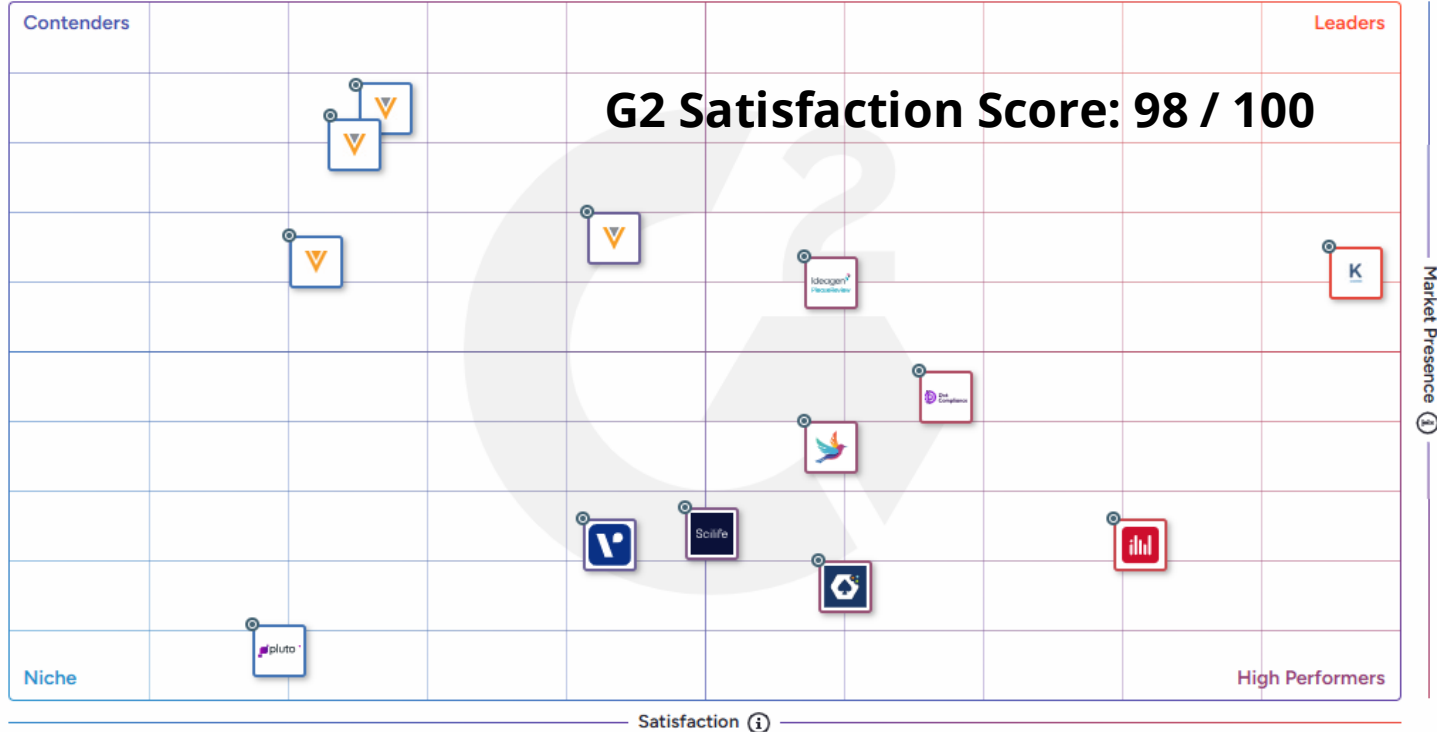
QA Compliance

- 100% Audit record - 0 Critical Findings
- On track for SOC2 Compliance in 2026



Global Recognition Award
for Customer Tech Support

Kneat Maintains Market Leadership in Pharma and Biotech Software



Compliance with increasing ESG Requirements



2024 EcoVadis Scorecard

Overall score	Environment	Labor & Human Rights	Ethics	Sustainable Procurement
53/100	Impact ●●○○	Impact ●●●●	Impact ●○○○	Impact ●○○○
Indicator scores ⓘ	Theme scores ⓘ			
Policies	Impact ●●●●	0 Insufficient	50 Good	75 Advanced
Endorsements	Impact ●○○○	0 Insufficient	0 Insufficient	0 Insufficient
Measures	Impact ●●●●	25 Partial	75 Advanced	0 Insufficient
Certifications	Impact ●●●○	0 Insufficient	0 Insufficient	0 Insufficient
Coverage	– ⓘ	Not applicable	Not applicable	Not applicable
Reporting	Impact ●●●○	0 Insufficient	25 Partial	0 Insufficient
360° Watch	Impact ●●●●	75 Advanced	75 Advanced	75 Advanced
	40/100	60/100	70/100	30/100



2025 EcoVadis Scorecard

Overall score	Environment	Labor & Human Rights	Ethics	Sustainable Procurement
63/100	Impact ●●○○	Impact ●●●●	Impact ●○○○	Impact ●○○○
Indicator scores ⓘ	Theme scores ⓘ			
Policies	Impact ●●●●	50 Good	75 Advanced	25 Partial
Endorsements	Impact ●○○○	0 Insufficient	0 Insufficient	0 Insufficient
Measures	Impact ●●●●	75 Advanced	75 Advanced	100 Outstanding
Certifications	Impact ●●●○	0 Insufficient	0 Insufficient	75 Advanced
Coverage	– ⓘ	Not applicable	Not applicable	Not applicable
Reporting	Impact ●●●○	25 Partial	50 Good	25 Partial
360° Watch	Impact ●●●●	75 Advanced	75 Advanced	75 Advanced
	61/100	65/100	74/100	49/100

Thank You!

Great presentations over
next 2 days – Customers,
Partners & Kneat Staff

Thank you very much to all
presenters for preparing
and sharing your stories
and experiences

Keynote



Benjamin B
CEO & Co-Founder

Sponsored by:



Neuroscience meets AI: Validating a Disrupted Age

Benjamin B. Bargetzi, Dublin 2026

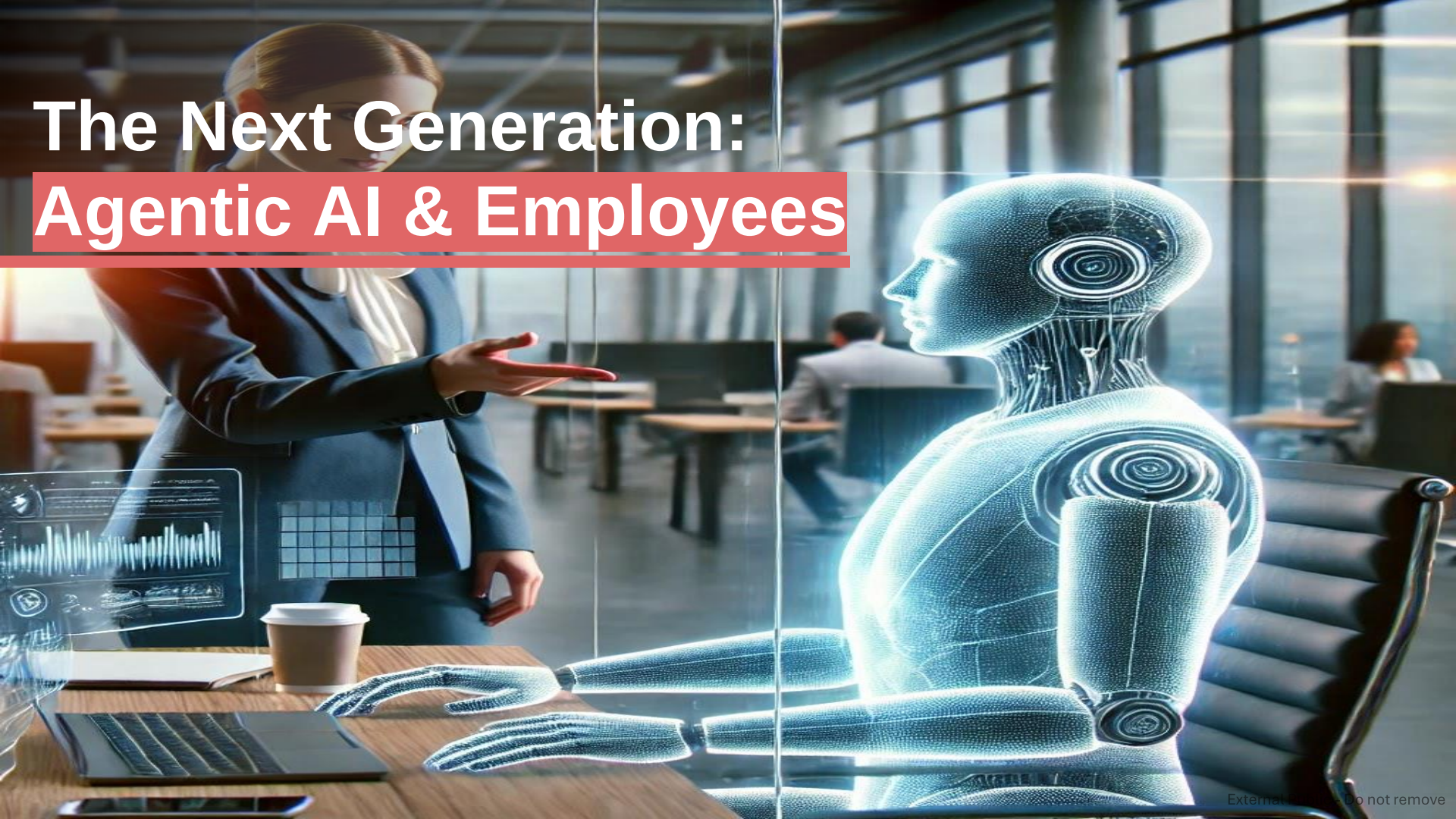
Welcome to the Second Renaissance

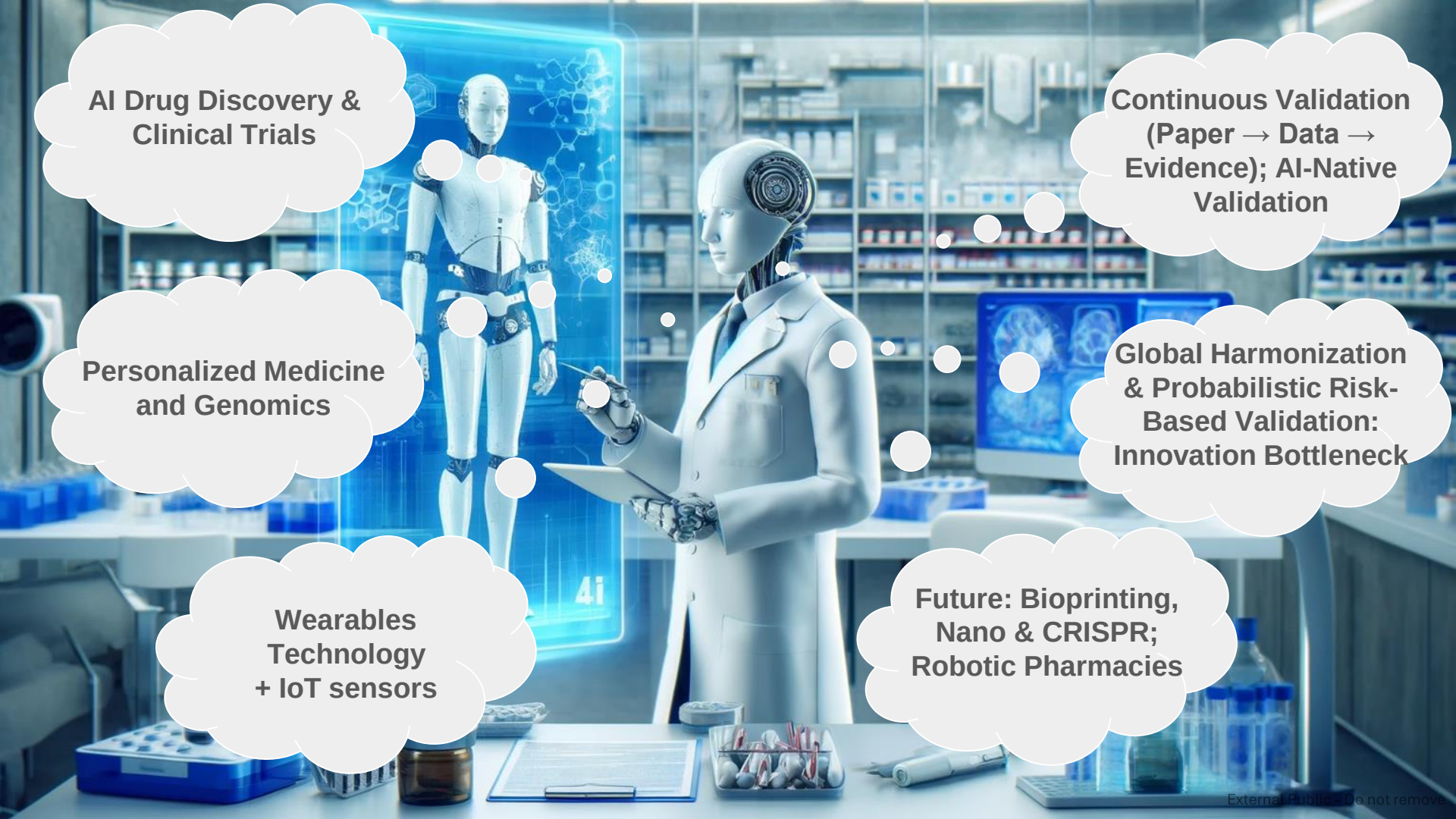




The Future beyond LLMs & GPT: **What's Next?**

The Next Generation: Agentic AI & Employees





**AI Drug Discovery &
Clinical Trials**

**Continuous Validation
(Paper → Data →
Evidence); AI-Native
Validation**

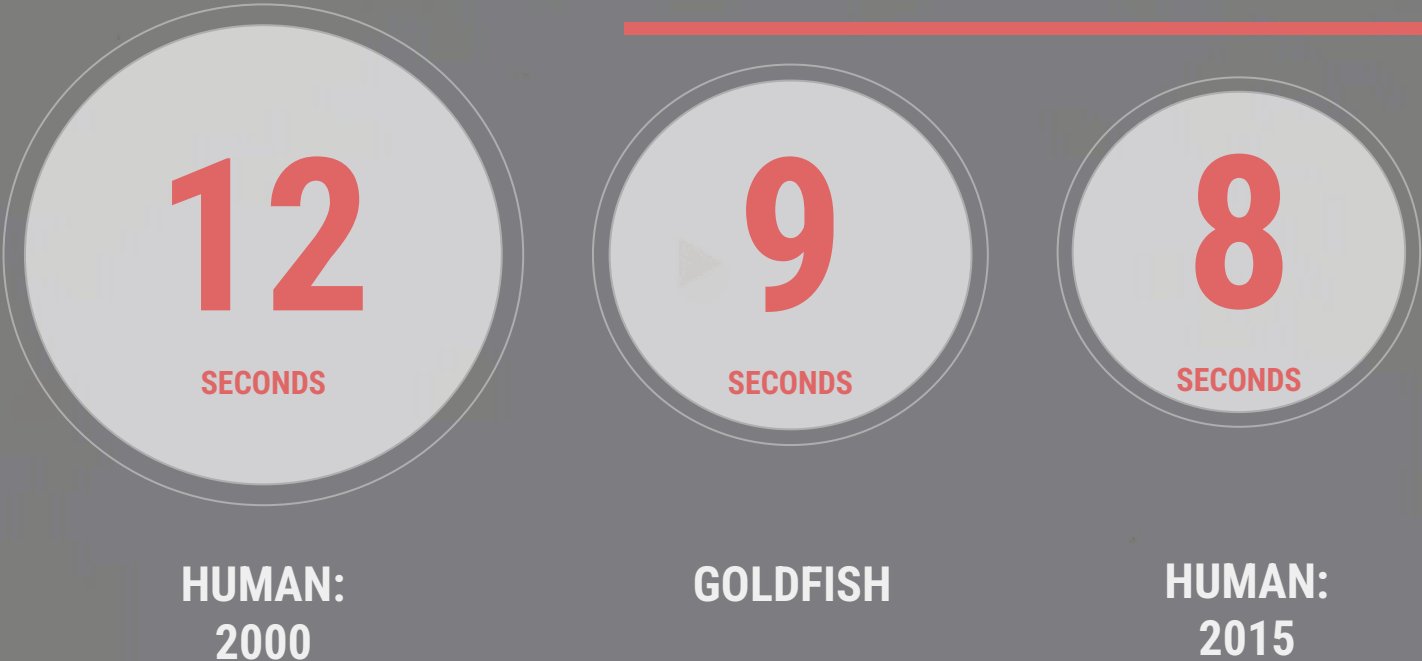
**Personalized Medicine
and Genomics**

**Global Harmonization
& Probabilistic Risk-
Based Validation:
Innovation Bottleneck**

**Wearables
Technology
+ IoT sensors**

**Future: Bioprinting,
Nano & CRISPR;
Robotic Pharmacies**

Our attention span is shrinking



The infographic consists of three light gray circles arranged horizontally. The first circle on the left contains the number '12' in large red font, with 'SECONDS' in smaller red font below it. The middle circle contains the number '9' in large red font, with 'SECONDS' in smaller red font below it. The third circle on the right contains the number '8' in large red font, with 'SECONDS' in smaller red font below it. Below each circle is a label in white text: 'HUMAN: 2000' for the first, 'GOLDFISH' for the second, and 'HUMAN: 2015' for the third. A red horizontal line is positioned above the middle and right circles.

12

SECONDS

HUMAN:
2000

9

SECONDS

GOLDFISH

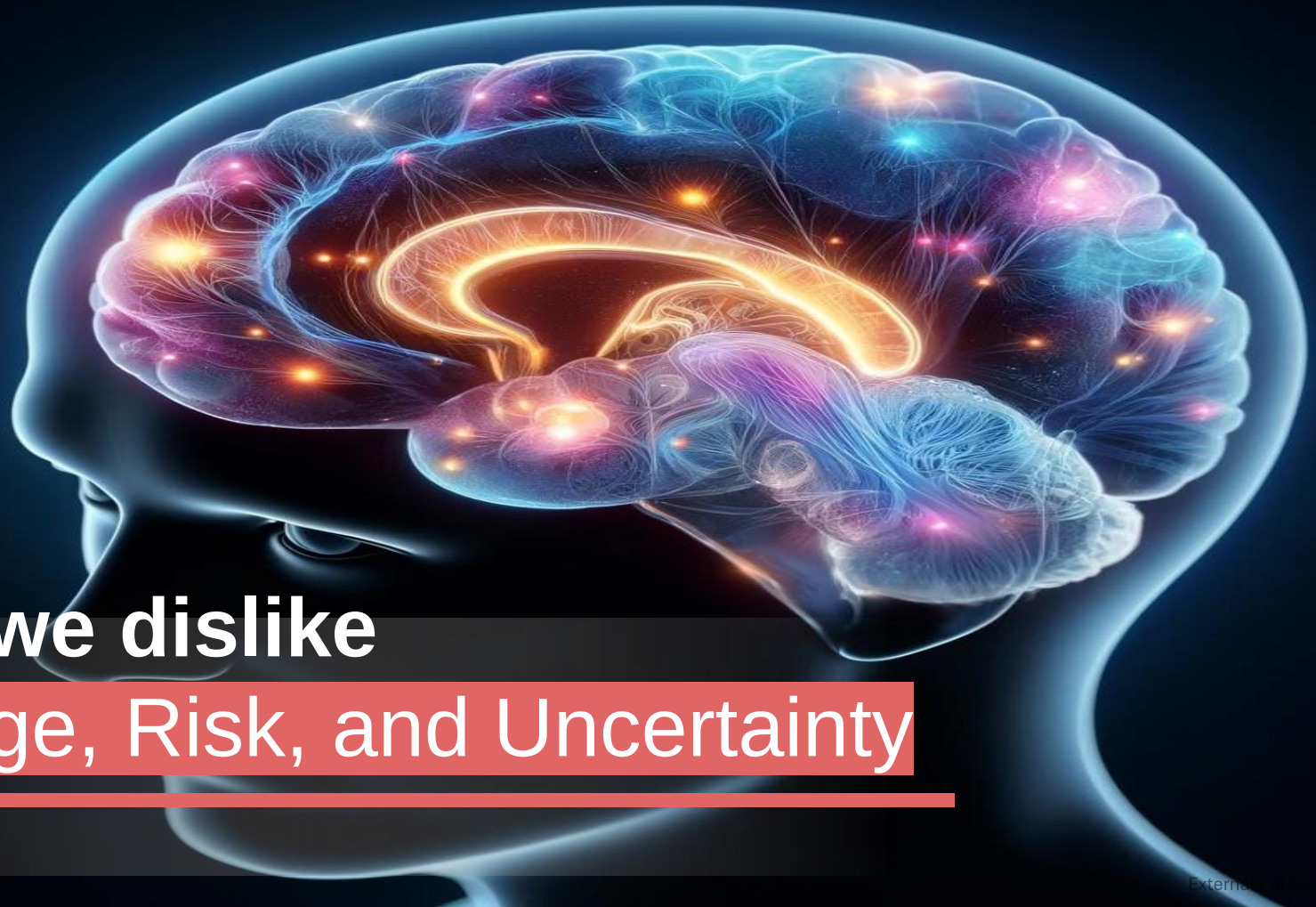
8

SECONDS

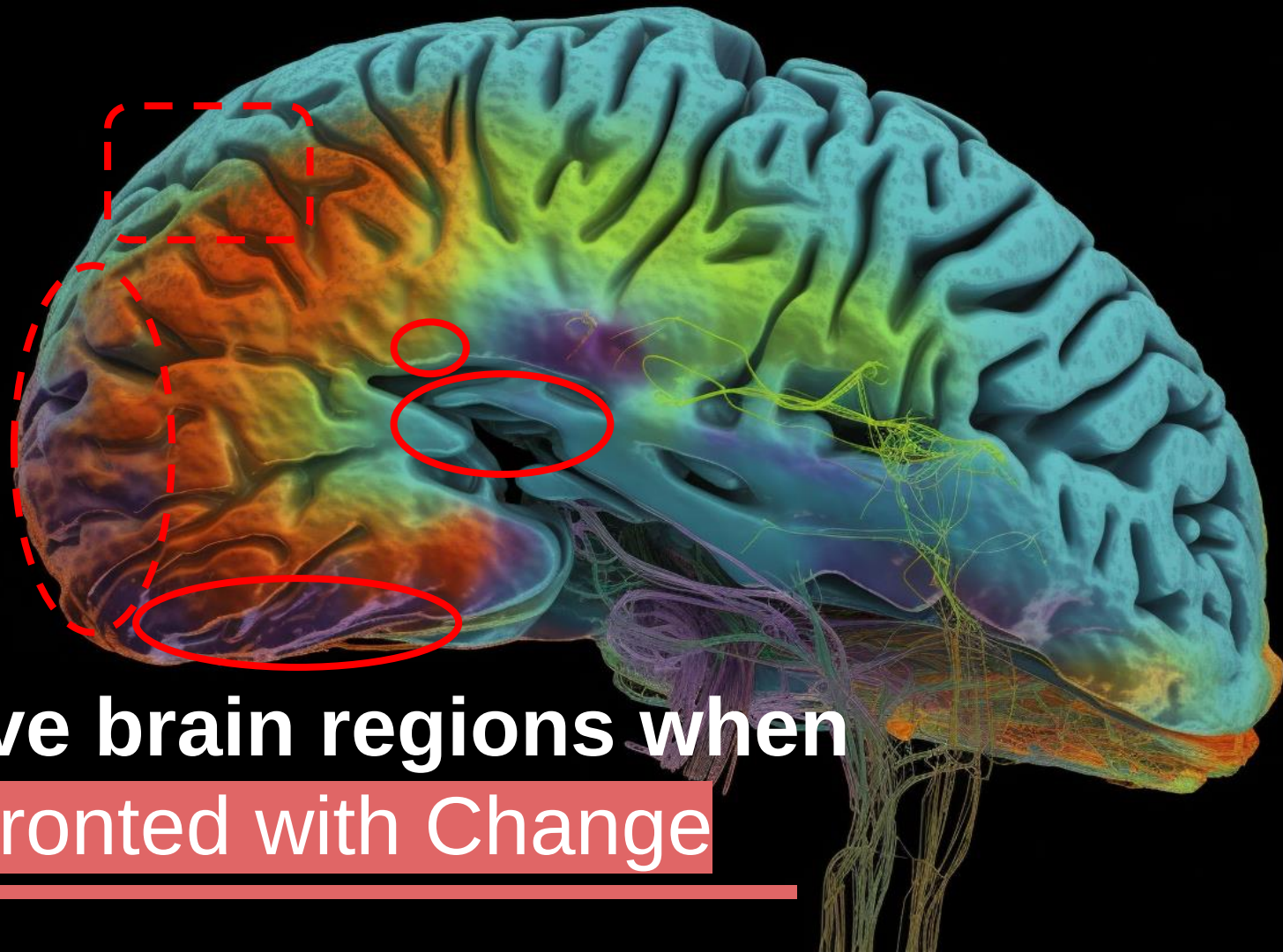
HUMAN:
2015

Diets, Duolingo, and New Year's Resolutions

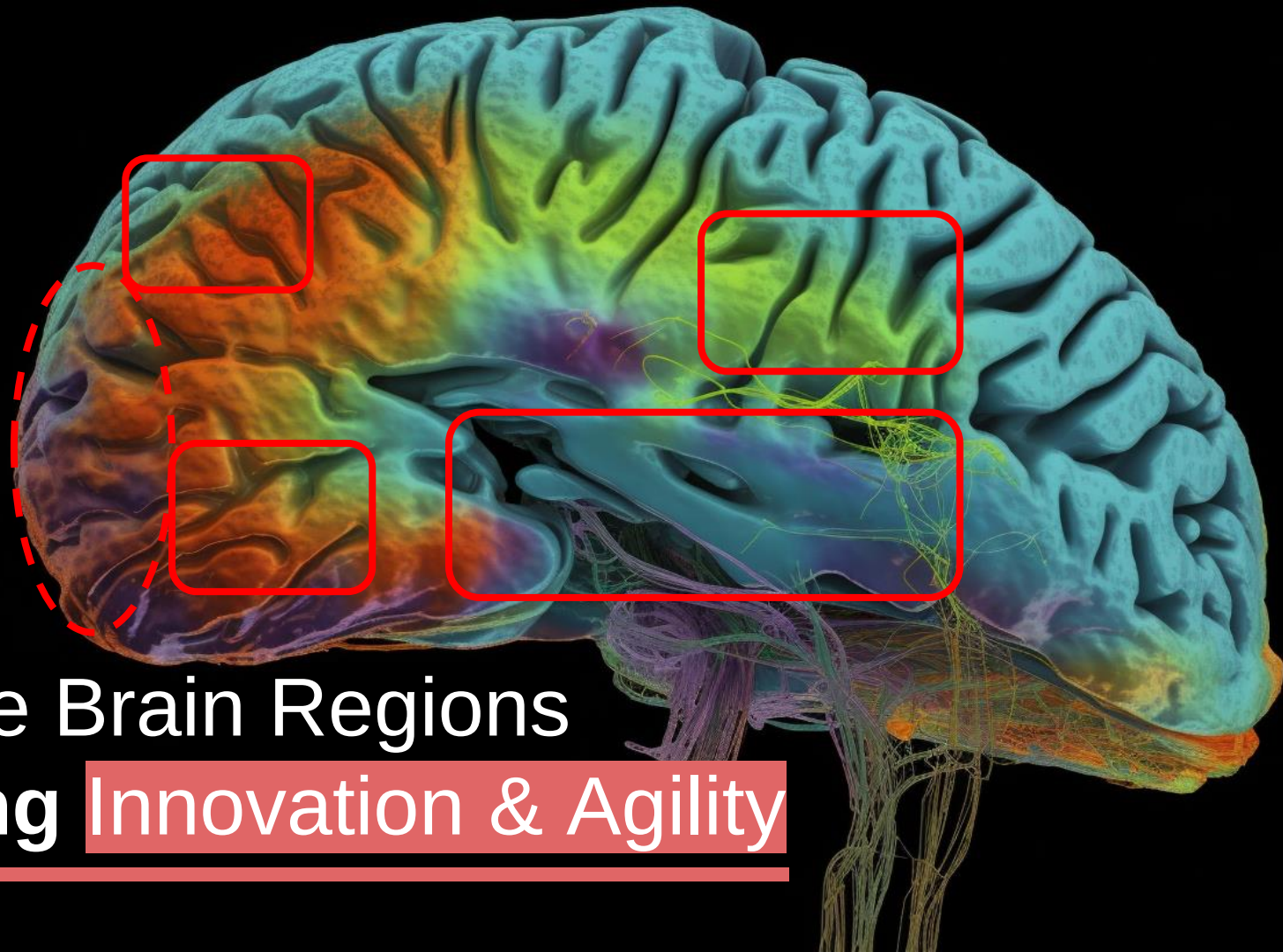




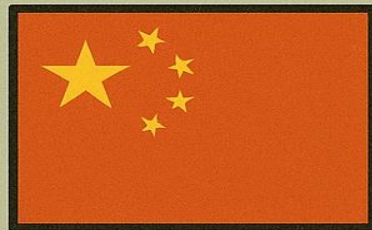
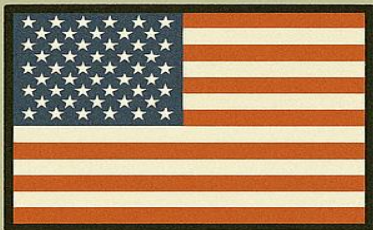
Why we dislike Change, Risk, and Uncertainty



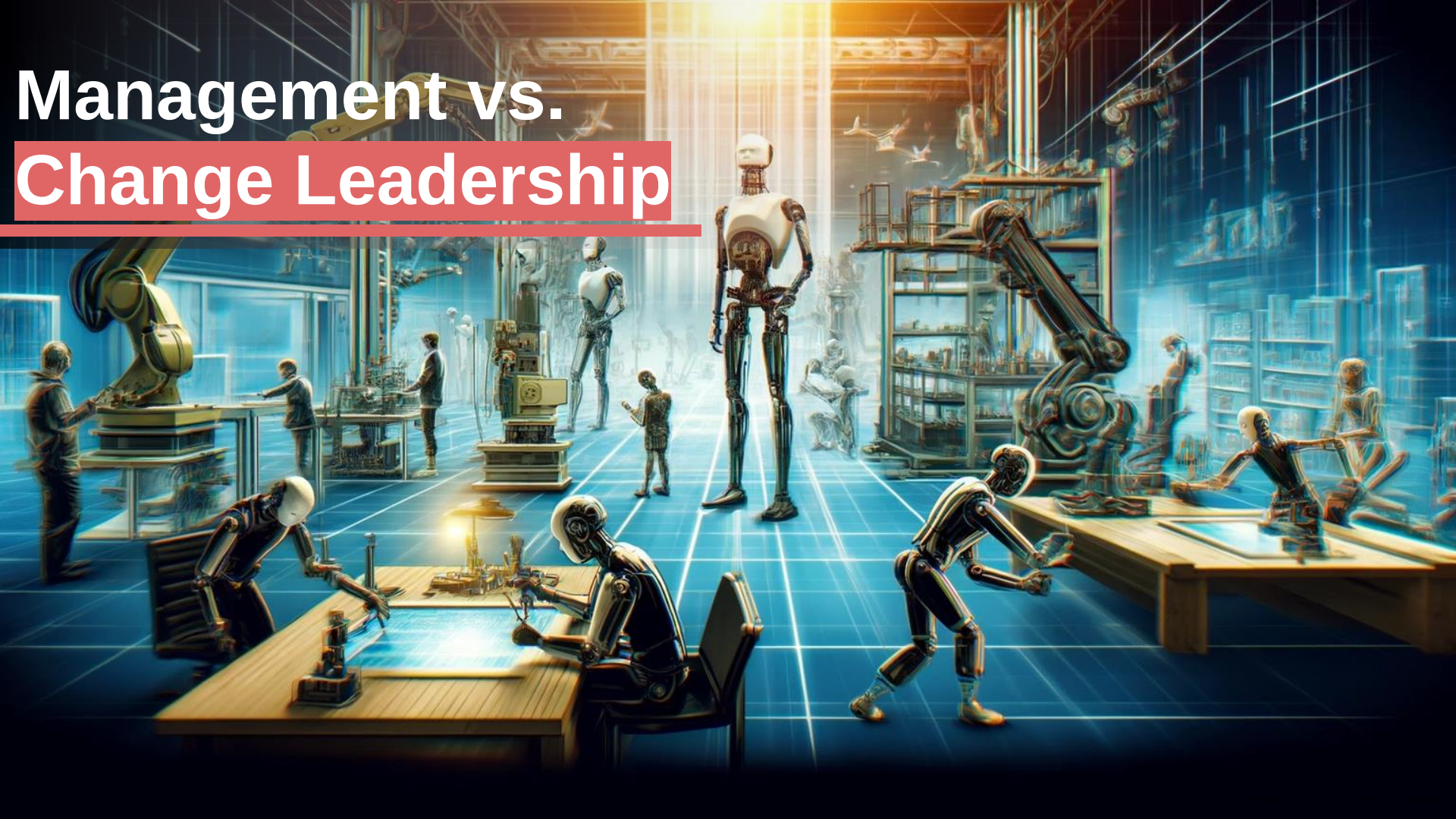
Active brain regions when
Confronted with Change

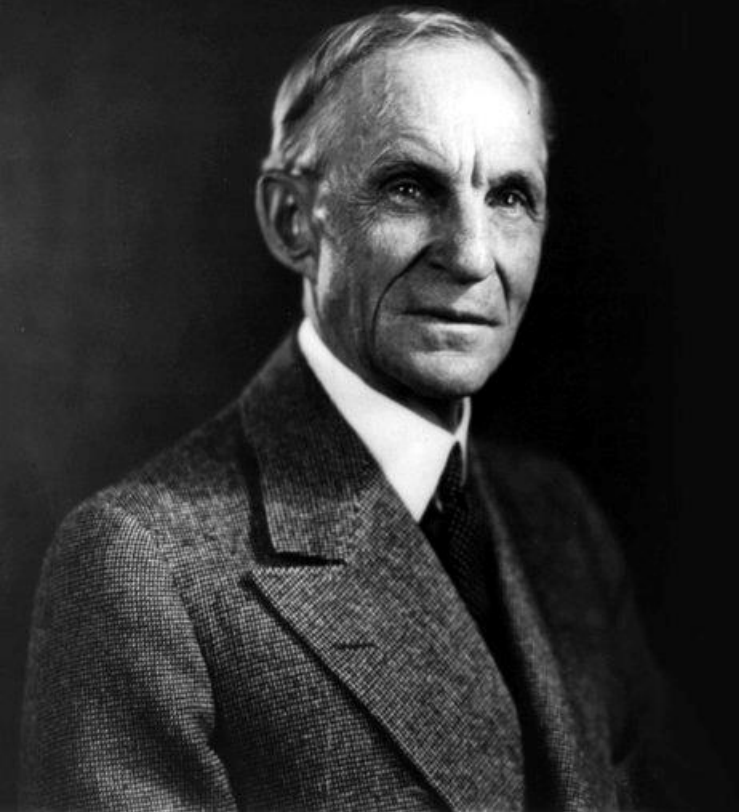


Active Brain Regions
during Innovation & Agility



Management vs. Change Leadership





“IF I HAD ASKED PEOPLE
WHAT THEY WANTED,
THEY WOULD HAVE SAID:
FASTER HORSES...”

Henry Ford

A bald eagle with its wings spread wide is flying over a vast sea of golden, fluffy clouds. The sun is low on the horizon, creating a bright, warm glow that illuminates the clouds and the eagle's feathers. The eagle is positioned in the upper left, flying towards the right. The clouds are dense and layered, with some peaks visible in the distance. The overall scene conveys a sense of freedom, ambition, and reaching new heights.

Innovation Outside The Box

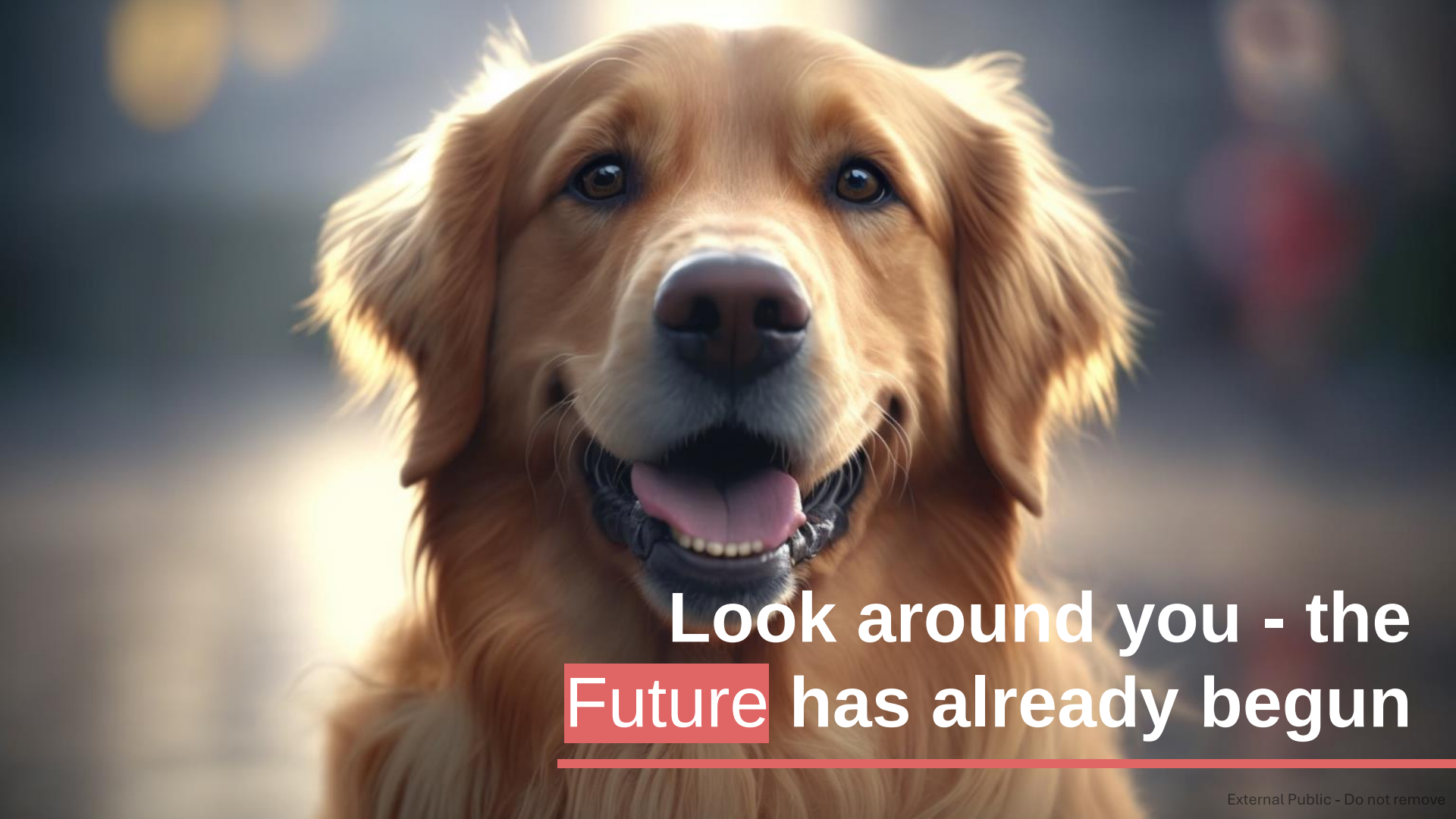
The Art of Innovation:

20% Projects & Pizza-Teams



Shock Therapy: Fear stems from inaction





**Look around you - the
Future has already begun**

DAILY: Get the World's Latest AI & Neuroscience News on LinkedIn!



Session 1.1

How Digital Validation Was a Key Enabler to MSD ONEQV

(Combining C&Q – CSV)



HOW DIGITAL VALIDATION WAS A KEY ENABLER TO MSD ONECQV (COMBINING C&Q – CSV)

Validate in Dublin

Apr 2026



Authors:

Yvonne Owens, MSD Ireland

Dave O'Connor, No Deviation by Efor



Yvonne Owens

Associate Director, Global Engineering Services
CQV Area Lead
(EMEA – Human Health & Animal Health), **MSD**



Dave O Connor

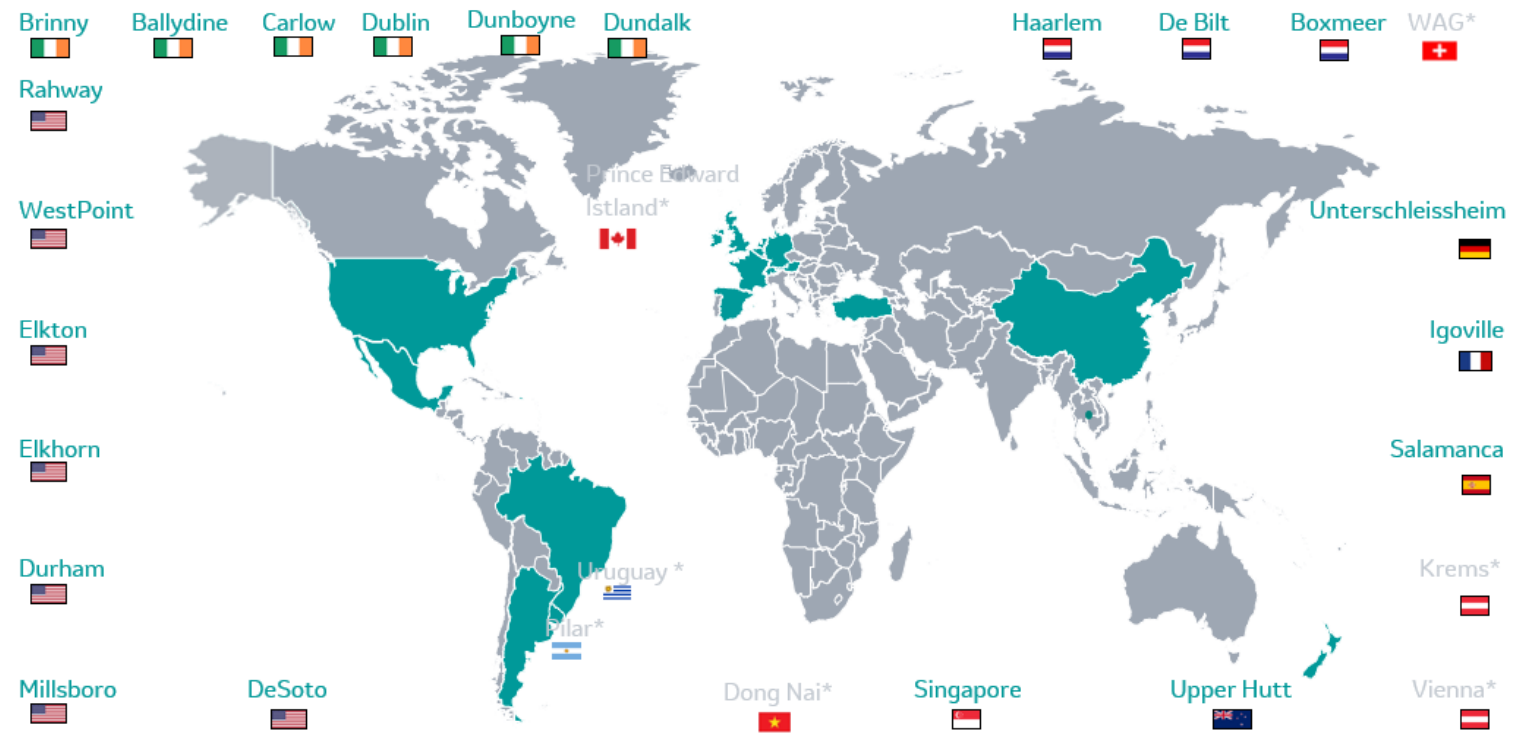
Digital Transformation Manager
No Deviation, Pte
Member of the ISPE CQV Sub-committee on
Paperless Validation

MSD Global Engineering Solutions



GES is responsible for the procurement, design, construction and C&Q of advanced manufacturing facilities and laboratories worldwide. We provide premier engineering solutions in the pharmaceutical industry through technical innovation and project management.

GES Around the World



*GES Consult only

MSD in Ireland

MSD in Ireland

50

years in Ireland

3.6k+

employees

8

locations

\$3.5B

approximate investment in our Irish
operations in the last 3.5 years

60+

number of countries we export to

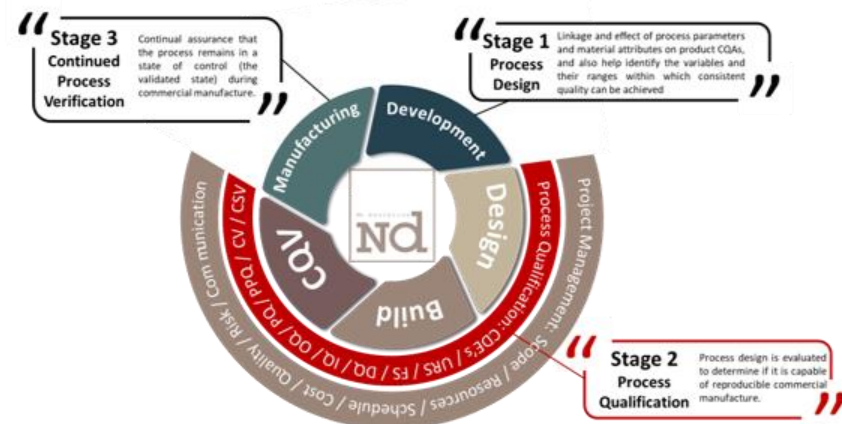
GES CQV Global Team



- Support C&Q strategy on our most strategic projects and implement new ways of working based on our experiences on previous projects.
- GES CQV leads the charge on implementing standard vendor work and digital transformation through the CQV lifecycle.

Global Validation Consulting Solutions Provider & Certified Kneat Partner

- No deviation is a patient-centric solution provider for the pharmaceutical and biotech industry for the Asia & Europe region.
- Specializing in Process Engineering, Commissioning Qualification Validation(CQV), Digitisation & Paperless Validation Solutions, Quality Compliance & Regulatory and Training & Education



ISPE Good Practice Guide

Good Practice Guide: Digital Validation

- The transition from traditional, paper-based validation to a digitally integrated framework remains a complex challenge.
- This Good Practice Guide considers how increased adoption of Digital Validation Tools (DVTs) in the life sciences industry can support a growing commitment to data integrity, operational efficiency, and regulatory compliance.
- Developed by a global team of experts in validation, regulatory compliance, quality assurance, and digital transformation, this Guide presents real-world insights, case studies, and structured methodologies to facilitate the successful integration of digital validation into business operations.

Concept Paper: Digital Validation – Future Advances

- Exploring the need for easily accessible data, the role of AI, LLMs, ML, predictive analytics, and pivoting to a more datacentric digital validation mindset.



GOOD PRACTICE GUIDE:
**Digital
Validation**



MSD: CURRENT STATUS

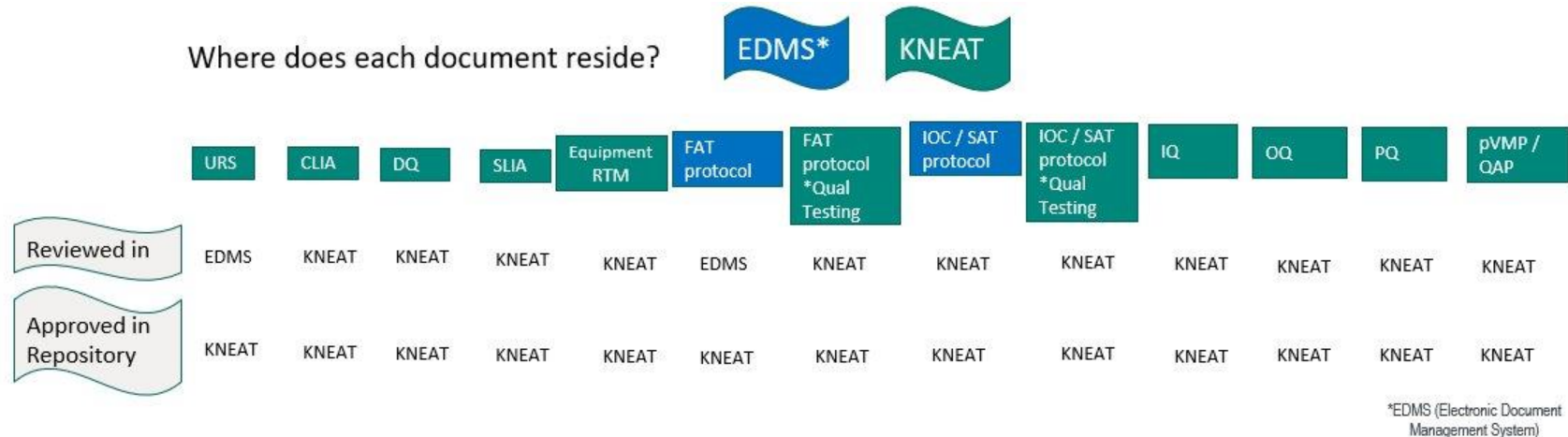
Validate Dublin



MSD : Early adoption and roll out

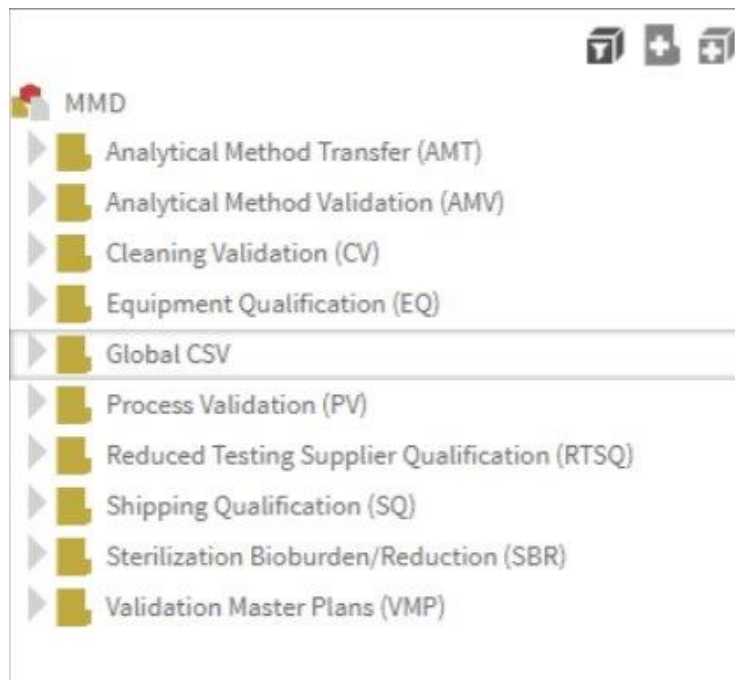


Digital Validation Roll Out



- GMP Lifecycle documents were assessed to determine suitability to digital validation platform.
- Non-GMP documents e.g FAT and IOCs (Not-Direct) were optional

Roll out to other areas over the past 5 years



- Started in CSV & EQ
- Added additional disciplines over past 5 years
- And Rolled out from Human Health to Animal Health

Animal Health Manufacturing Facilities



eVal End User Count 2026



Division & Access role	Users count
Total Users count MMD, MRL and AH	12733
MMD	11266
MRL	1924
AH	797



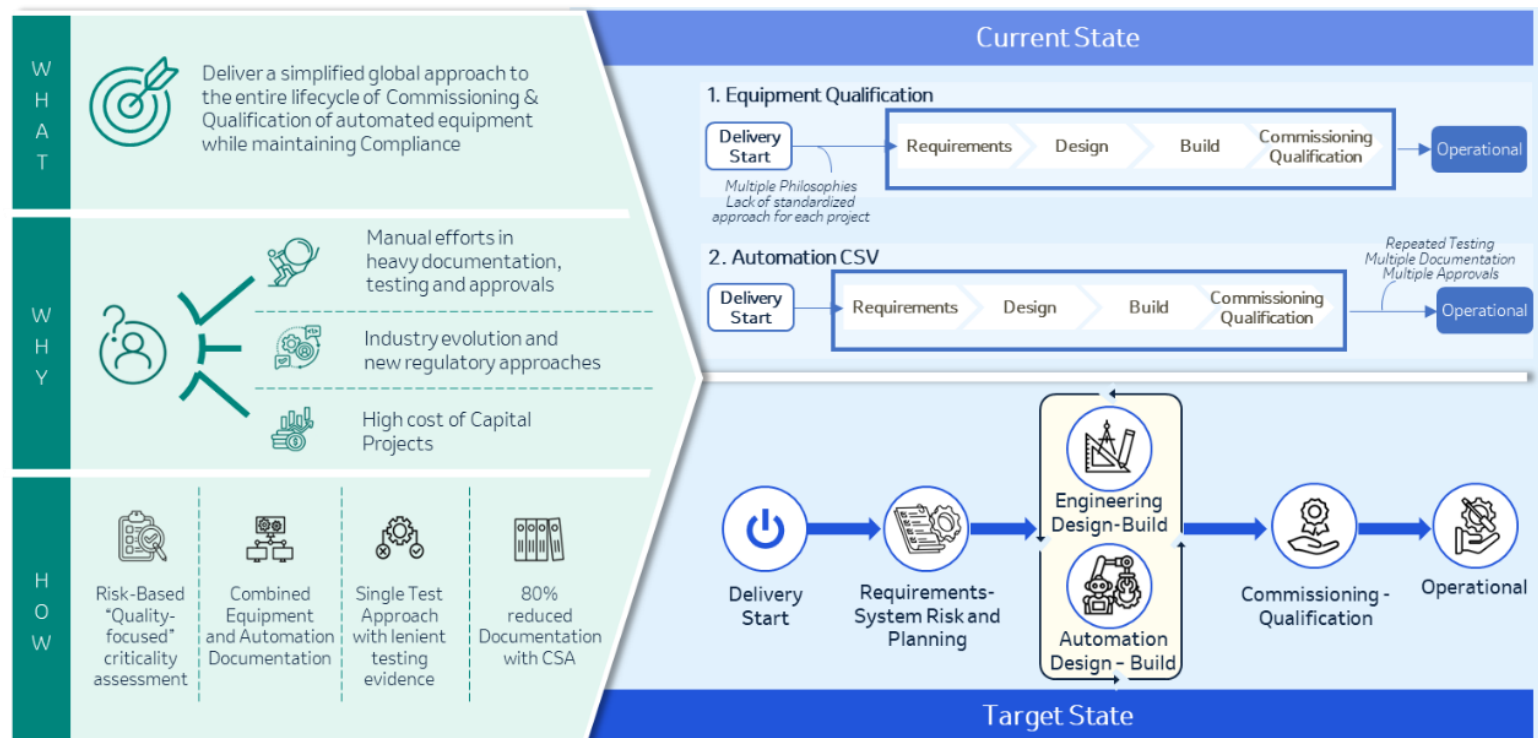


ONECQV



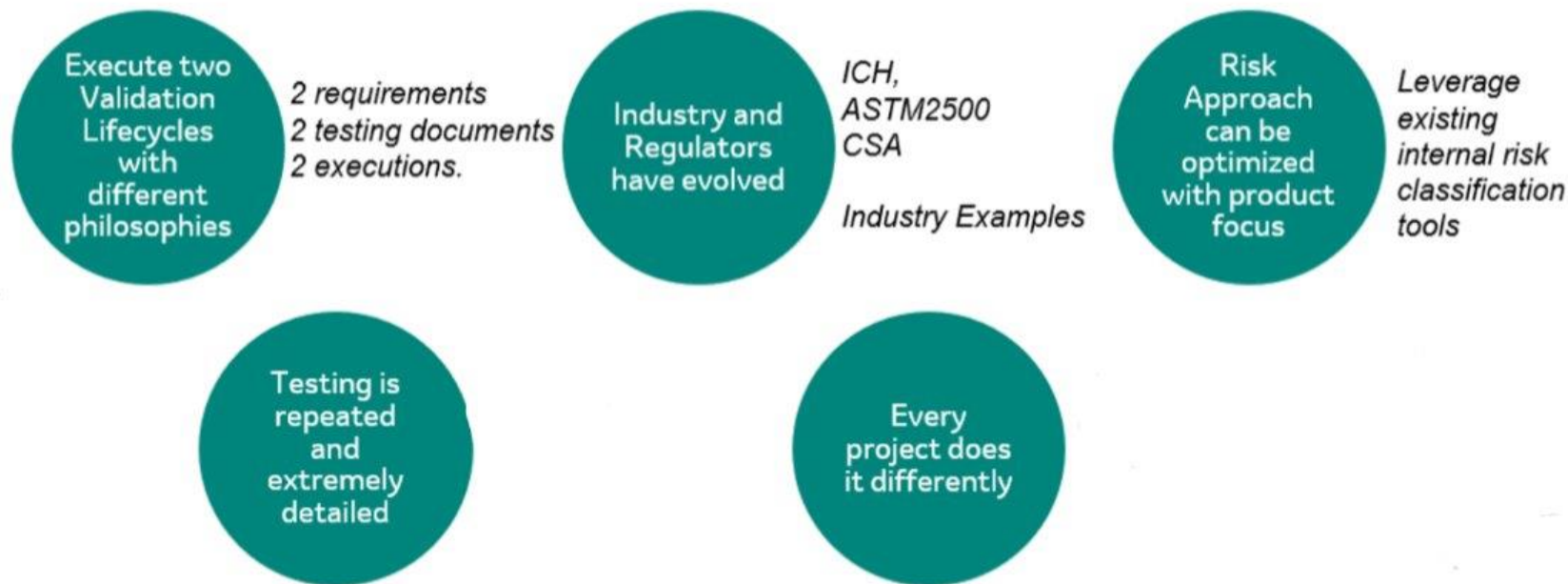
Validate Dublin

ONECQV : What, Why and How?



Problem Statement:

Current C&Q Process is compliant....however is inefficient, costly and contains repeat testing



Deliver a simplified, global approach to the entire C&Q Lifecycle

Current



Future

- | | |
|--|--|
| 1. Compliant with Quality Oversight | 1. Compliant with Quality Oversight |
| 2. Separate Equipment & Automation | 2. Combined |
| 3. Varies Project to Project | 3. One Approach – Institutionalized, governed |
| 4. Broad assessment of criticality, so everything gets “Qualified” | 4. Focused Criticality based on “true” impact to product (Does not equal take more risk) |
| 5. Repeated testing | 5. Single Test Approach |
| 6. Highly documented testing resulting 1000’s of pages | 6. 80% reduction in documentation with CSA Approach |
| 7. Vendor testing not accepted as evidence for Qualification | 7. Vendor testing accepted as evidence for Qualification |

OneCQV Mission and Vision

Mission:

Unify, simplify, and standardize the commissioning and qualification of automated equipment while maintaining compliance.

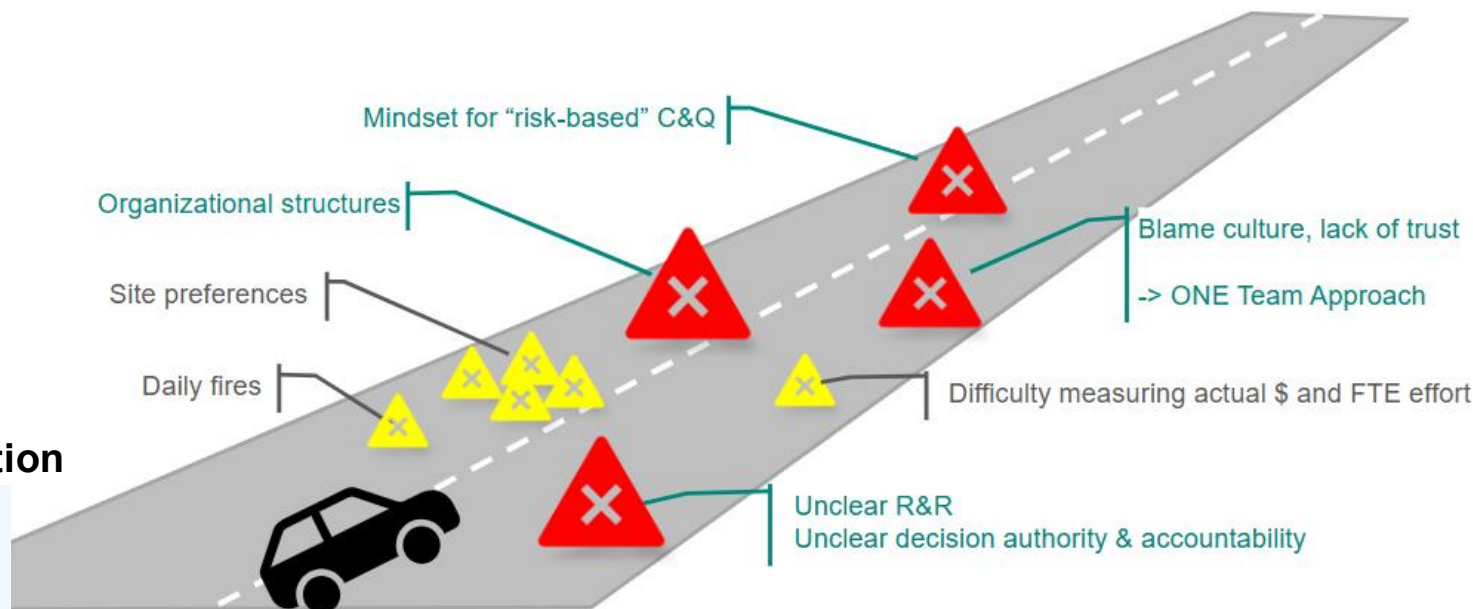
Vision

Best-In-Class C&Q

Shortest Lead Time
Competitive Cost
Agile & Digital

Current Condition

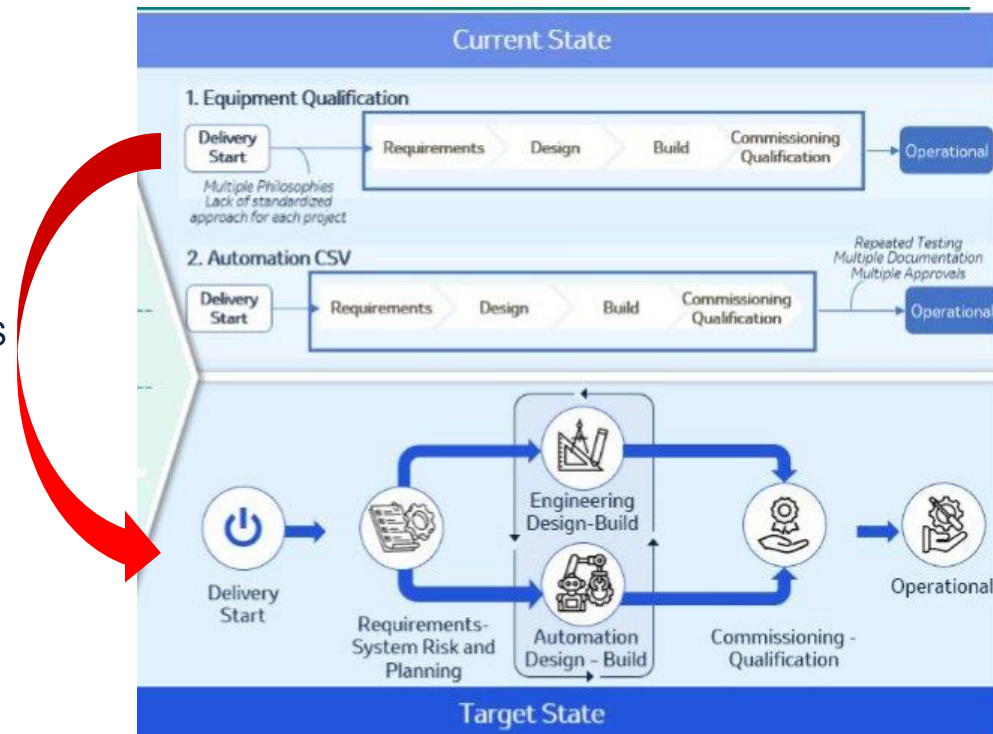
Safe
Compliant
Inefficient



Digital Validation is a catalyst for OneCQV at MSD

Digital platform allowed full access to protocols and removed silos that are present with paper.

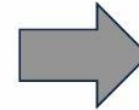
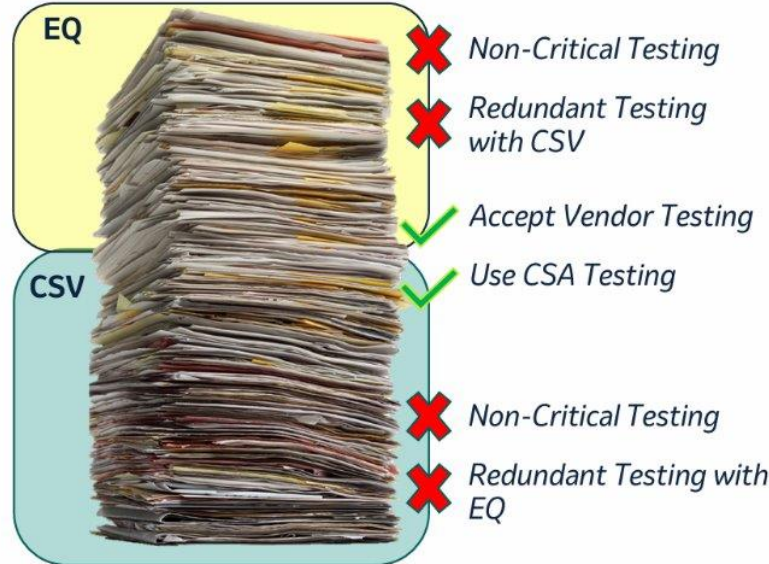
Combined (Process and Automation) URS and applying CSA risk approach to testing has eliminated repeat testing and right sized commissioning and qualification testing.



How eVal enabled us to roll out OneCQV

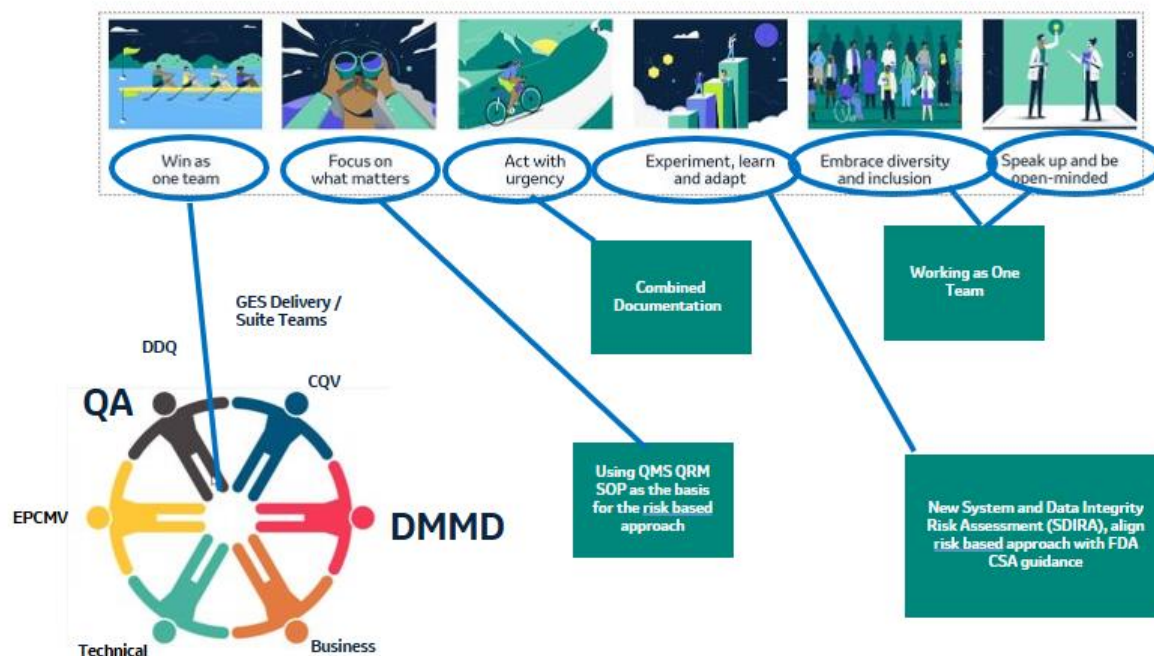
- Merge CSV and Equipment templates
- Use of Training environment to trial new templates
- Ease of global reviews – easy access for reviews and approvals (US, EMEA, Asia)
- Easy collaboration between different departments on one platform
- RTM – able to merge links to both CSV and equipment design qualification (design specs, P&ID, vendor datasheets) and testing (FAT, SAT, IOC, IOQ)
- Allowed us to have strong global governance to ensure global templates used across all sites – standardized approach
- Metrics after OneCQV rolled out – to observe return on investment

Advantages of OneCQV



Reduce equipment and automation redundancies by linking them together in a single lifecycle
Reduce rework by clarifying requirements and specifying the correct designs
Reduce paperwork and documents by focusing document rigor on higher risks to product quality

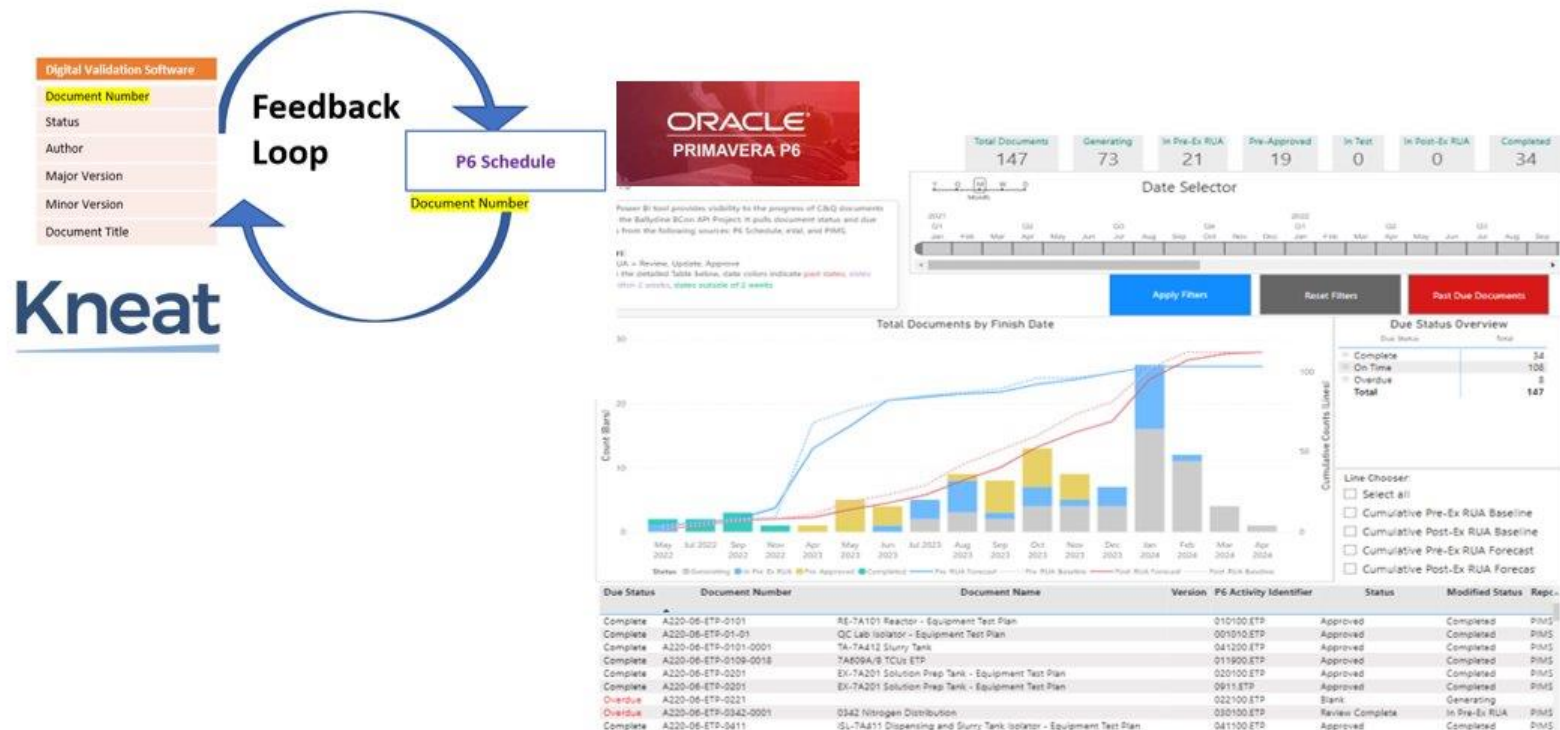
OneCQV – Better defined Roles & Responsibilities = Better Ways of Working



Current Initiatives

Validate Dublin

Digital Validation : Document Tracking Tool



Thank you



Session 1.2

Kneat Product Session eLogbooks

Lorna Whelan



Product Session: eLogbooks



Lorna Whelan

Senior Product Manager

Kneat

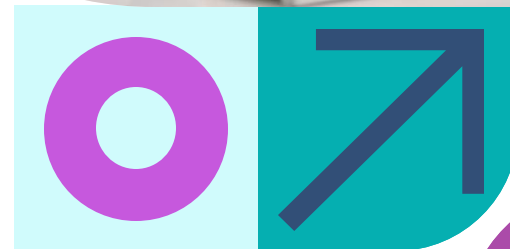
Gillian McMahon

Senior Product Owner

Kneat

Agenda

- What it is
- Benefits
- Demo



What is Kneat eLogbooks?



Product Description – Kneat eLogbooks

Description

- A secure, compliant, and user-friendly **electronic** logbook

Purpose

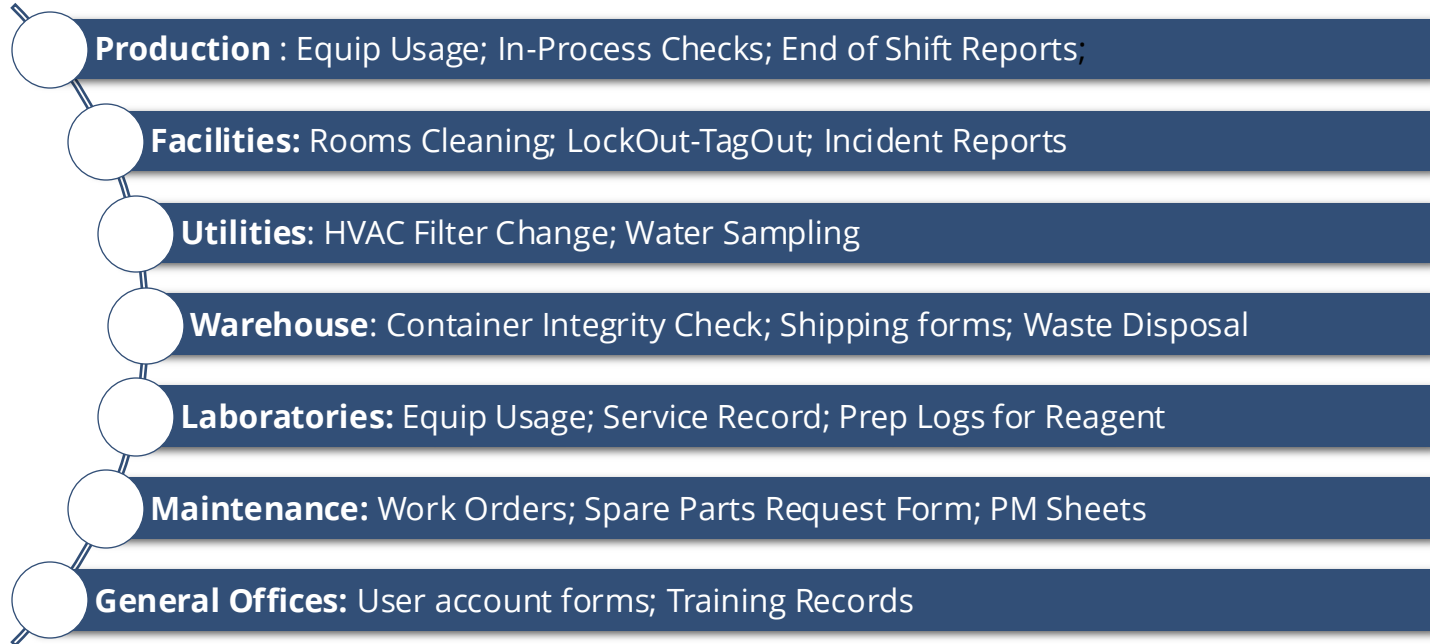
- Replace Paper **booklets** of pre-approved forms Or replace **single** forms

Users

- Production/Facilities/Utilities/Maintenance/ Labs / General Office

Examples of Paper Forms

Many manual tasks (GxP/ EHS/ Other) are still recorded on paper





Why replace Paper Logbooks ?

Risk

\$\$

Time Delays

\$\$

Storage

\$\$



Kneat eLogbook Benefits

Reduce Risk

Save Time

Save on Storage

Other

- Already have Kneat
- Ease of Adoption
- Experienced SMEs
- Excellent Customer Support

Save\$
\$

Customer Results with Kneat Gx eLogbooks

CDMO Leader

- 50% of paper logbook forms over 3 sites
- > 60% time reduction
- **\$1 MM Savings** in one year across three sites
- Requests for more digitalization

Top 20 Biotech

- Deployed in GxP Labs & Operations
- **Logbook Issuance to < 0.5 days**
- Reduction Errors
- Increased Compliance
- Aligns with Sustainability Priorities

Recipharm Advanced Bio

- Flexible and easy to use
- **Saves so much time**
- “What used to take multiple systems and manual steps, we now do directly in Kneat”

[Video Testimonial](#)

Demo



Session 2.1

Transforming Pharma Manufacturing: Sanofi's Journey Towards Digital Excellence in the Pharma 4.0 Era

Aine Fleming, VP, Head of Engineering
Specialty Care | Sanofi



sanofi



•

Building the *Future* of Manufacturing & Supply in Biopharma

Áine Fleming

Sanofi, Vice President Global Engineering Specialty Care

•

●

We are an *R&D-driven,*
AI-powered biopharma company
committed to *improving*
people's lives and *delivering*
compelling growth.

●

**Sanofi's Equation
in Manufacturing
& Supply**

TODAY

2.1 billion
units produced
annually

29,000
employees
globally

39
Manufacturing
sites globally

sanofi

TOMORROW

+30
potential new
product to launch
by 2030

+50%
increase in CAPEX
investment over two
years



How do we *Rise to the Challenge for Patients?*

Set
the Pace

Chase
Excellence

Ignite
Winning Teams

Deliver
with Purpose

We Set *the Pace*



Modular *Manufacturing*



*Our next-generation Modulus facilities are redefining the future
of Biopharma Manufacturing*

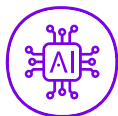


TIME Magazine
2025 BEST INVENTION

*Medical &
Healthcare category*



Most advanced and
modular
biotech sites in the
industry.



+ €1 billion invested in
two fully
AI-enabled facilities (France,
Singapore)



Manufacturing up
to **4 vaccines**
or biologics
simultaneously



Reducing changeover
times from **months** to
days.



Collaborative *Robots*

We free our teams from repetitive, exhausting tasks so they can focus on what truly matters.



Digital *Accelerator*

Our Digital Accelerator brings together dedicated teams to scale up digital innovations across our M&S global network.

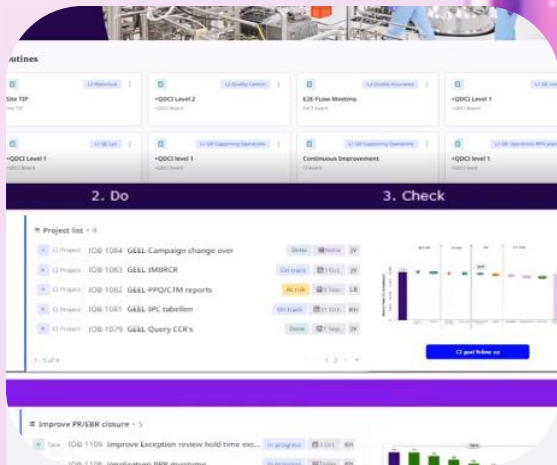


Snackable *AI*

Our plai.app provides AI and data-driven daily insights and guidance to enhance business decision-making.

We Chase *Excellence*





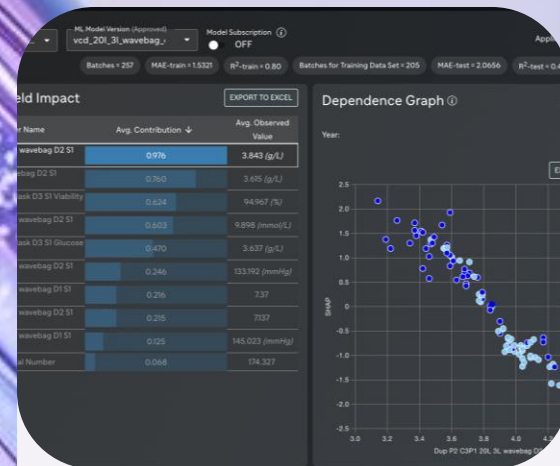
Digital Excellence Cockpit

We seamlessly manage daily routines, ensure consistent execution and leverage real-time data for performance monitoring and continuous improvement across all levels of the organization.



One Click Tech Transfers

With digital & AI advanced technologies, we run predictive simulations of entire new production processes and automate regulatory filings or quality reports generation, accelerating time to market.



Process Optimization

We harness and analyze hundreds of thousands of data points from sensors on production lines to optimize our yield performance, cycle times, service levels and inventories.

We Ignite *Winning Teams*





Sites Strong Network Stronger

We came from a fragmented constellation of manufacturing sites across the world to one integrated M&S network today.



Simplified, Standardized & Digitized

We built up SMS 2.0, the digital-native evolution of our standardized M&S processes, integrating operators and performance at the core of our systems. Paperless Validation for projects and requalifications.



Accelerate Performance Mindset

We teamed up with McLaren Racing to completely rethink our performance and competitive mindset, leveraging technology and analytics with F1 world champion engineers.

We Deliver *with Purpose*





Towards Net Zero

To play our part in mitigating climate change, we target to achieve Net Zero GHG emissions by 2045. Our reduction trajectory has been validated by the Science Based Target initiative (SBTi).



Sustainable by Design

Our eco-design approach embeds environmental sustainability at every stage of product life cycle. Today, 100% of our new medicines and vaccines follow this process.



Patients at the Center

Our Global Health Unit provides 30 most essential medicines in the 40 most vulnerable countries. To date, we reached 790,000 patients with treatments for non-communicable diseases.

2025 TIME RANKING
World's Most Sustainable Companies

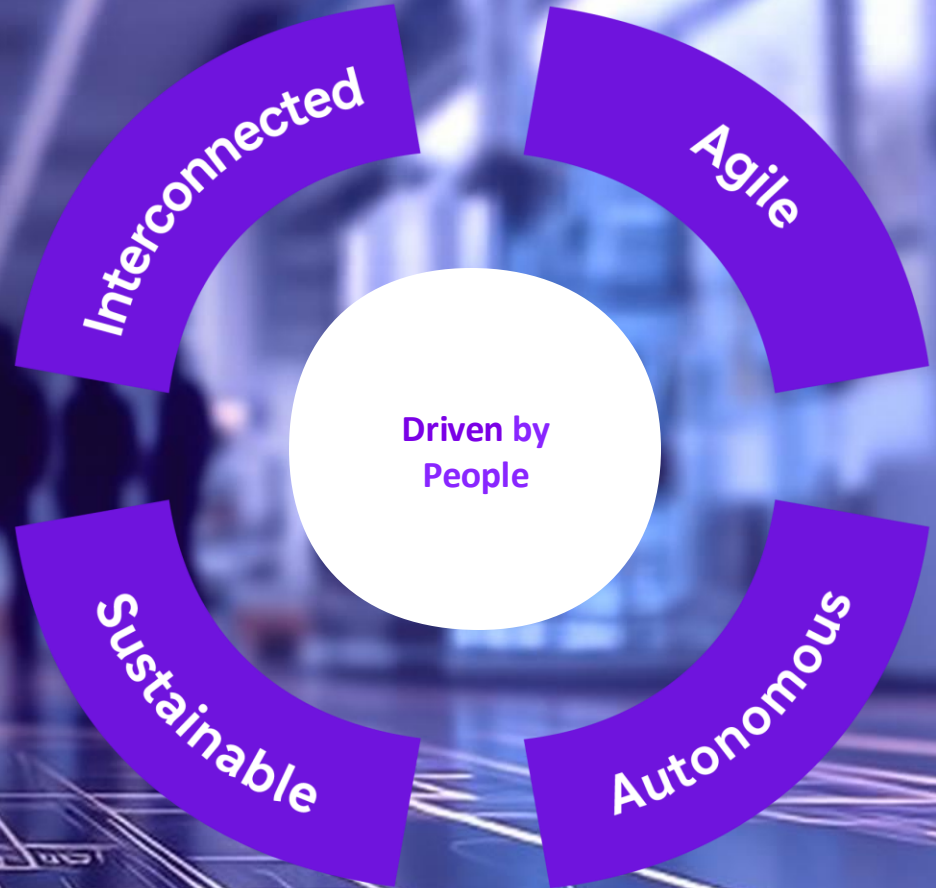
#1

Life Science Industry

#10

All Industries

We Build
Tomorrow's
Smart
Factories,
Today.



Thank
You

sanofi

Session 2.2

Kneat Product Session: Entities & CSV

Lorna Whelan & Dan Tobin



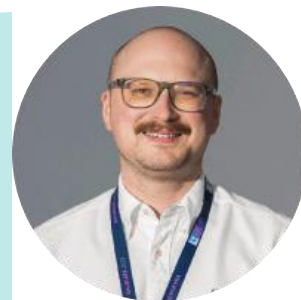
Speakers



Lorna Whelan

Senior Product Manager

Kneat



Dan Tobin

Senior Product Owner

Kneat

Agenda

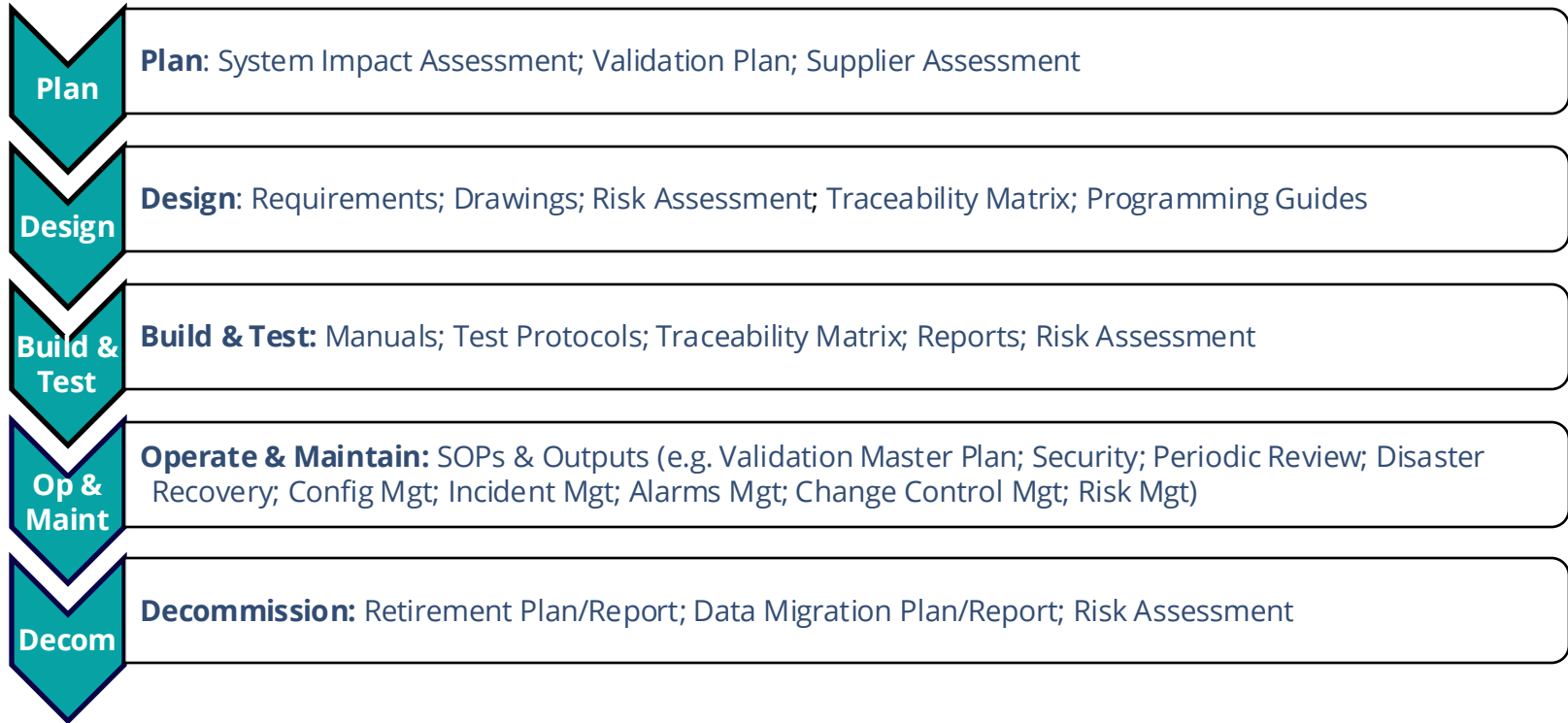
- CSV/CSA Data
- Kneat Entity Data Model
- Demo
- Next Steps



CSV/CSA Data



CSV Deliverables



*Mgt= management

Risk part of all Phases



CSA Risk-based Approach

Computer Software Assurance Guidance

Why issued?

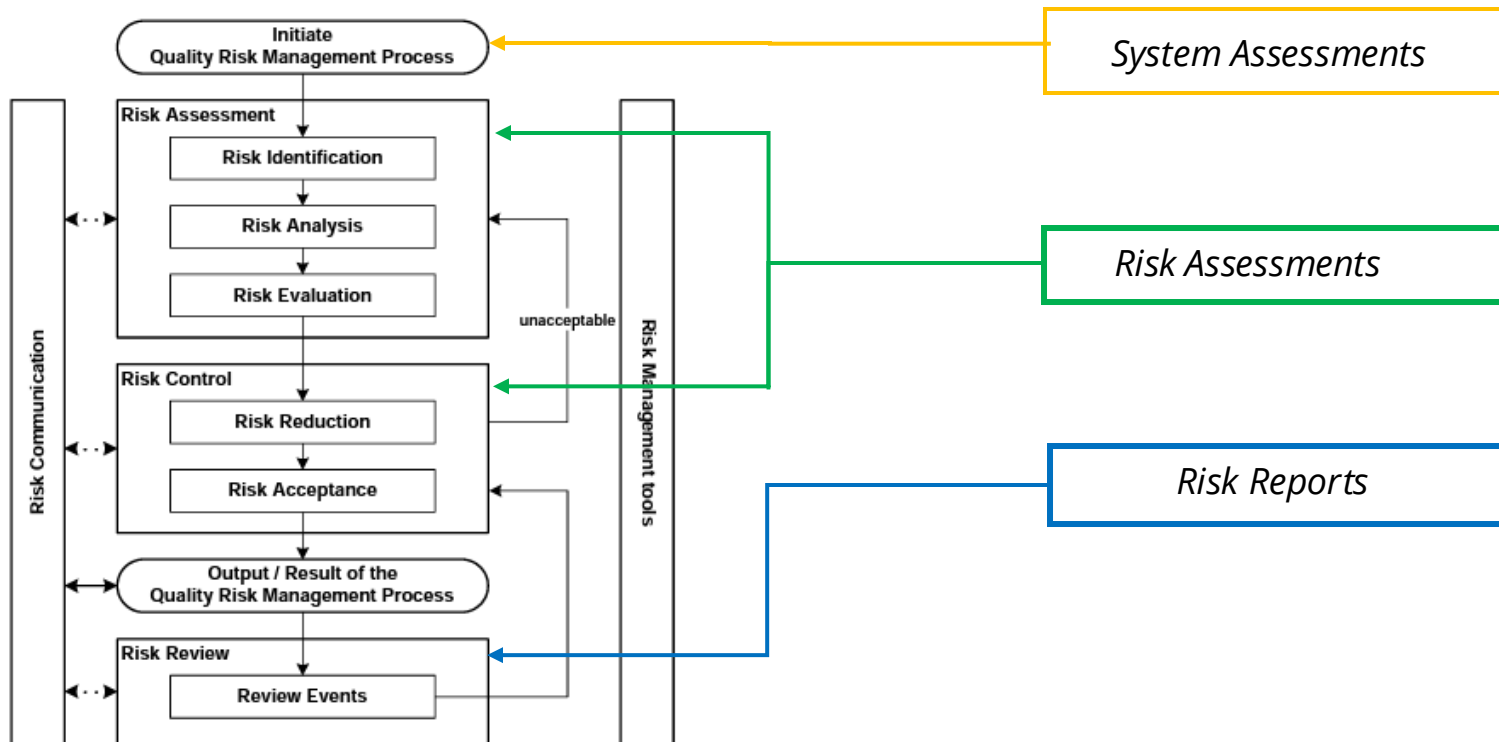
FDA wants industry to use automation, but industry was reluctant due to the perceived high **level of validation effort & thus high \$**

What is it?

CSA is a **framework**, with worked examples, on how to use Quality Risk Management (QRM) to focus CSV effort.



QRM Framework (ICH Q9)



ICH = The International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation (ICH)

Example of Risk Level driving Testing Approach

Functional Risk Assessment on GxP URS Reqs

Risk Level		Testing Approaches
High Risk	High Risk	(Robust) Scripted testing Detailed test steps & expected results (higher \$ to develop/execute)
Not High-Risk	Medium Risk	(Limited) Scripted testing Limited detail & expected results (lower \$ to develop/execute)
	Low Risk	Unscripted testing (e.g. Ad hoc) High level objective; no expected results; summary filled in by tester (lowest \$ to develop/execute)

Appropriate records should incl the intended use; Risk assessment; test results; issues; conclusion, who/when; R/A

CSA - Five Things You Need To Know

1

Risk is based on the impact to patient safety and product quality measured against requirement complexity



2

It calls for the least burdensome documentation approach



3

It can reduce paper-work by 80% with unscripted testing



4

It results in fewer issues encountered in Production



5

FDA & ISPE supported



- ✓ Improved Quality and Efficiency
- ✓ Validation Effort Reduced by 30%
- ✓ Spending More Time Challenging System

Kneat Entity Data Model

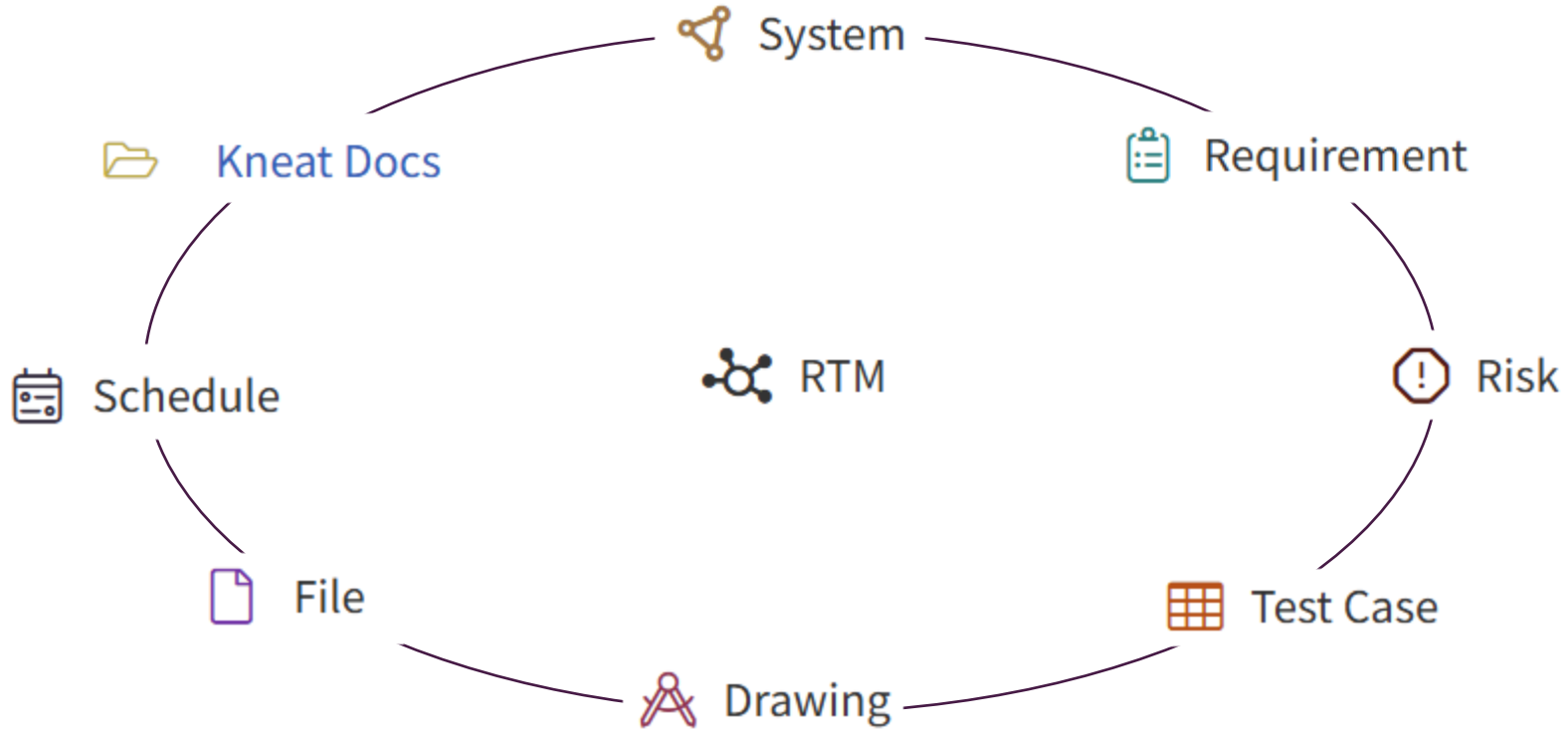


CSV Deliverables

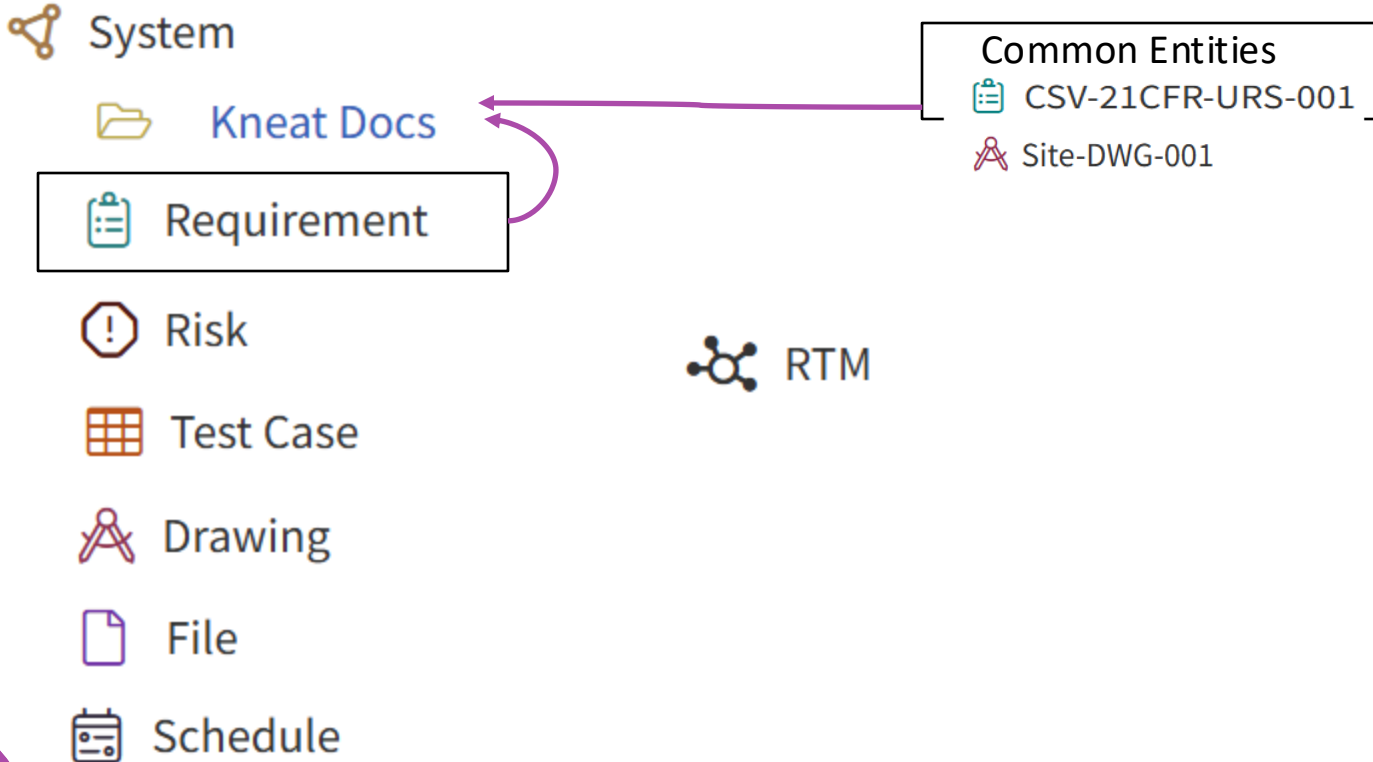


*Mgt= management

CSV Data – from Deliverables



CSV Data – from Deliverables



Plan Phase - System Impact Assessment

System Impact Assessment Document

GxP-11	Is the system used for quality trending, quality matrices and or product review?	No
GxP-12	Is this system used to maintain records of training of personnel?	No
GxP-13	Is the system used for product disposition? (Release /Reject/Disposal)	No
GxP-14	Is the system used for employee identification and access?	No

If ANSWER of any above Question is "Yes", then system is "GxP - Direct Impact " If all ANSWER of above Question is "No", then system is "Non Impact" and further assessment is not required

Impact
PPLC-Steriliser-Line1 PDI (Direct Impact)

Category 4	Configurable Software Packages (Configurable COTS) [Note: If the answer to question 4 and 6 is Yes, then category 4 is applicable]
Category 5	Custom (Bespoke) Software [Note: If the answer to question 7 is Yes, then category 5 is applicable]

Software Category
PPLC-Steriliser-Line1 PCategory 4

GxP-11	Is the system used for quality trending, quality matrices and or product review?	No
GxP-12	Is this system used to maintain records of training of personnel?	No
GxP-13	Is the system used for product disposition? (Release /Reject/Disposal)	No
GxP-14	Is the system used for employee identification and access?	No

If ANSWER of any above Question is "Yes", then system is "GxP - Direct Impact " If all ANSWER of above Question is "No", then system is "Non Impact" and further assessment is not required.

Impact
PPLC-Filter-Line1 PNi (No Impact)

System

Core System Characteristics			
Attribute	Value		Status
System Impact <i>Core attribute</i>	DI (Direct Impact)	✓	Approved
Software Category <i>Core attribute</i>	Category	✓	Approved

GxP System so **do** perform a Quality RA

Not GxP System so **do not** perform a Quality RA

Design Phase - Risk Entity

Lorna WS2 > (2) Computer Systems Validation > PLC-1 > PLC-1 Risks

+ New

Risk FMEA

▼

Entity Information	Entity Details			General Data	
Entity status & version	⬆️ Risk ID Required core attribute	⬆️ Function (being assessed) Core attribute	⬆️ ID of Function (being assessed) Core attribute	⬆️ Potential Failure Mode Core attribute	⬆️
○ ↺↻ Not Approved (0)	PLC1-Risk-001	Report data temporarily stored on PLC before being sent to EBR	PLC1-URS-001 Workspace: Lorna WS2 ✕ Add relationship	Report data is deleted/modified prior to being sent to EBR	Some PLCs, regist both

Design Phase – Risk Assessment in Kneat

2 Risk Assessment

SYSTEM: PLC-1 PLC to control Steriliser
 Product Affected: Product xxx
 Leader: Jane Doe
 Prepared By: John Smith
 Team Members: John Doe; Jane Smith; Larry Smith

Risk ID	Function (being assessed)	ID of Function (being assessed)	Potential Failure Mode	Potential Effects of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Overall Risk Level	Recommended Action Item	Occurrence (After mitigation)	Detection (After mitigation)	RPN (after mitigation)	Overall Risk Level (After mitigation)
PLC1 - Risk-001	Report data	PLC1-URS-001	Report data is deleted	Question on quality of product (as missing EBR data)	- Control 1 + - Control 2 + - Control 3	5	2	1	10	Medium	Action 1	1	1	5	Low
PLC1 - Risk-002	Report data	PLC1-URS-001	Report data is modified	Question on quality of product (as incorrect EBR data)	Control 4	5	2	1	10	Medium	Action 2	1	1	5	Low
PLC1 - Risk-003	Control XXX	PLC1-URS-002	Temperature is not controlled	Product is not sterilised	- Control 5 + - Control 6	5	1	1	5	Low	N/A	N/A	N/A	N/A	N/A

- Develop Tests – level of detail based on Risk Level in RA

1 Installation Security Checks

Test information:

Test ID	Test Description	Assessment Criteria	Specification Reference	Risk Assessment Reference
Overall Test ID: 10001	Installation Security Checks	Installation security checks are complete. All issues raised successfully and all operations correct.		

Test Script:

Step No.	Test Instruction	Expected Result	Actual Result	Pass/Fail	Deviation	Abandonment	Performed by
1	Check that the Default application pool has read access to nodes folder. Select the C:\Program Files\Boson\Boson\Right click and select Properties Select Security	The default application pool has read access permission					
2	Check that files defined for application in IS	Files shall be deployed under Binaries Application					
3	Check the Application settings. Open the IIS Manager Application Configuration settings using file in Notepad	Application settings shall be correct (see Configuration Settings)					
4	Check the connection settings. Open the IIS Manager Application Configuration settings using file in Notepad	Database connection settings shall be correct (see Configuration Settings)					
5	Check that authorization settings are the same for the application and import service. Open web.config and service.config in Notepad	Issuer and SecurityKey are the same					
6	Check the Web application settings. Open the Web.config file	Web Application settings shall be correct (see Configuration Settings)					
7	Check that the application launched	The sign pages shall be deployed					

Test Summary

Overall Pass/Fail	Comments & Deviations
Passed	

Signed by: _____

Test Sign-Off

Reviewed by: _____

Approved By: _____

Step No.

Test Instruction

Expected Result

Actual Result

Pass/Fail

Deviation

Abandonment

Performed by

Check that the Default application pool has read access to **C:\Program Files\Boson\Boson\Right click and select Properties Select Security**

The default application pool has read access permission

Check that files defined for application in IS

Files shall be deployed under Binaries Application

Check the Application settings. Open the IIS Manager Application Configuration settings using file in Notepad

Application settings shall be correct (see Configuration Settings)

Check the connection settings. Open the IIS Manager Application Configuration settings using file in Notepad

Database connection settings shall be correct (see Configuration Settings)

Check that authorization settings are the same for the application and import service. Open web.config and service.config in Notepad

Issuer and SecurityKey are the same

Check the Web application settings. Open the Web.config file

Web Application settings shall be correct (see Configuration Settings)

Check that the application launched

The sign pages shall be deployed

2.1.1 Installation Security Checks

Test ID	Test Description
SAPS-AN-PROJ-001	Installation Security Checks

Step No.	Test Instruction	Expected Result	Actual Result	Pass/Fail	Deviation	Abandonment	Performed by
1	Check that the Default application pool has read access to C:\Program Files\Boson\Boson\Right click and select Properties Select Security	The default application pool has read access permission					

2.1.1 Installation Security Checks					
Test Information					
Test ID	Test Description	Acceptance Criteria			
SAPSH-PROD-02	Installation Security Checks	Installation security checks are complete. All steps passed successfully and all deviations closed.			
Installation Security Checks					
Step No.	Test Instruction	Expected Result	Actual Result	Pass/Fail	Performed by
1	Check that the Default application pool has read access to SAPSH-Exchange\ExchangeMailBays\... folder Select the C:\Program Files\ SAP REASONING\Exchange\Reasoning Planning folder Right click on and select Properties Select Security	The default application pool has read access permission	Deviation Found ID: SAPSH-PROD-02-001	Fail	Mark Foley (Mark.Foley) New York, 14-May-2020 09:11:54 (UTC)

Attribute	Value	Status
Test Case Id Required core attribute	PLC1-Test-001	Not Approved
Description Core attribute	Test the transfer of Report data from PLC to ArchestrA	Unsaved changes
Test Type Core attribute	Scripted	Not Approved

Build & Test Phase – Traceability Matrix

Reset
→ PLC-1 > PLC-1 Risks
Include sub folders for selected items ☒

- Lorna WS2
 - (1) Equipment Qualification
 - (2) Computer Systems Validation
 - PLC-1
 - Kneat Docs
 - PLC-1 Drawings
 - PLC-1 REQs
 - PLC-1 Risks**
 - PLC1-Risk-001
 - PLC1-Risk-002
 - PLC1-Risk-003
 - PLC-1 Tests
 - PLC1-SCHEDULE-001
 - (3) eLogbooks

Requirement traceability matrix (RTM)

Traceability relationships (+3)

Report last updated: 15-Apr-2026 08:53:26 (UTC-05:00, CDT)

Unique identifier	Entity type	Description	Traceability relationships	Traceability relationships (+1)	Traceability relationships (+2)	Traceability relationships (+3)
PLC1-Risk-001 Not Approved Workspace: Lorna WS2	Risk FMEA	Report data temporarily stored on PLC before being sent to EBR	PLC1-URS-001 Not Approved Workspace: Lorna WS2	- PLC1-Risk-002 Not Approved Workspace: Lorna WS2 - PLC1-Test-001 Not Approved Workspace: Lorna WS2		
PLC1-Risk-002 Not Approved Workspace: Lorna WS2	Risk FMEA	Report data temporarily stored on PLC before being sent to EBR	PLC1-URS-001 Not Approved Workspace: Lorna WS2	- PLC1-Risk-001 Not Approved Workspace: Lorna WS2 - PLC1-Test-001 Not Approved Workspace: Lorna WS2		
PLC1-Risk-003 Not Approved Workspace: Lorna WS2	Risk FMEA	TX Steri Boundary (start & end)	PLC1-URS-003 Not Approved Workspace: Lorna WS2	- PLC1-FS-002 Not Approved Workspace: Lorna WS2 - PLC1-Test-004 Not Approved Workspace: Lorna WS2 - PLC1-URS-002b Not Approved Workspace: Lorna WS2	- PLC1-DDS-002 Not Approved Workspace: Lorna WS2 - PLC1-Test-005 Not Approved Workspace: Lorna WS2 - PQ-001 In Pre-Approval (Current) Workspace: Lorna WS2	PLC1-Test-006 Not Approved Workspace: Lorna WS2

Copy RTM

Copy RTM button will only copy items from the current page. Please navigate to the other pages to copy more items.

Benefits of Kneat Entity Data Model for CSV

- Configurability – build entities to suit your Validation process
- Data Governance – build Standardised entities ensuring consistency, saving time
- In-app CSA – build & manage Risks within your validation system
- Save Time - reduce transcription errors; re-use of entities
- Efficient Design– agile editing outside docs; real-time Traceability Matrices
- Change Management – audit history per entity ; assess impact of change on systems
- Share data – integrations and data export

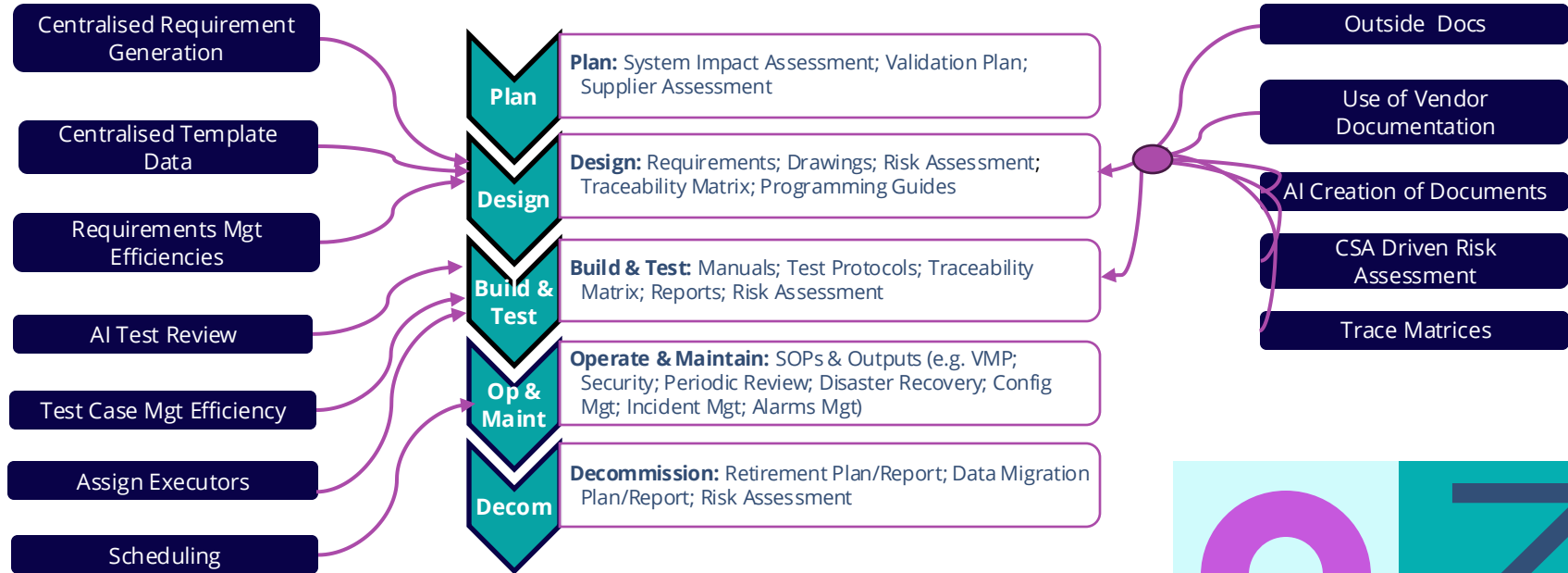
Demo



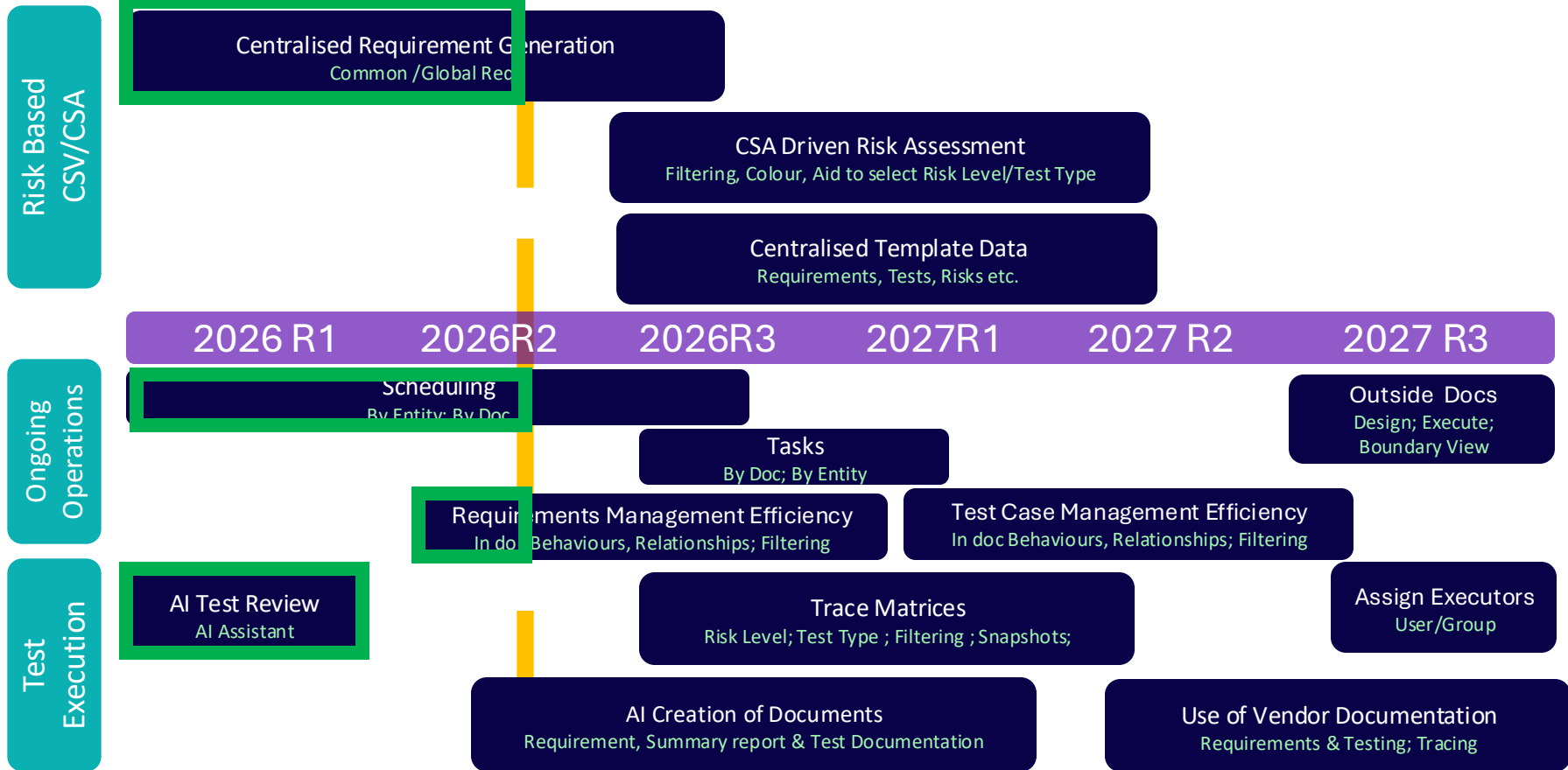
Next Steps



Features coming soon – as affecting CSV deliverables



Kneat GX CSV/CSA Roadmap 2026/2027



Q&A

Innovative Customer Award Presentations



Innovative Customer Award Presentation #1



Cesar Tavaréz

Validation Engineer, Alcon

Alcon

VALGENESIS TO KNEAT

Transition and Data Migration Project

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



VALGENESIS = VLMS1 / KNEAT = VLMS2



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

An English Programmer:



BACKGROUND



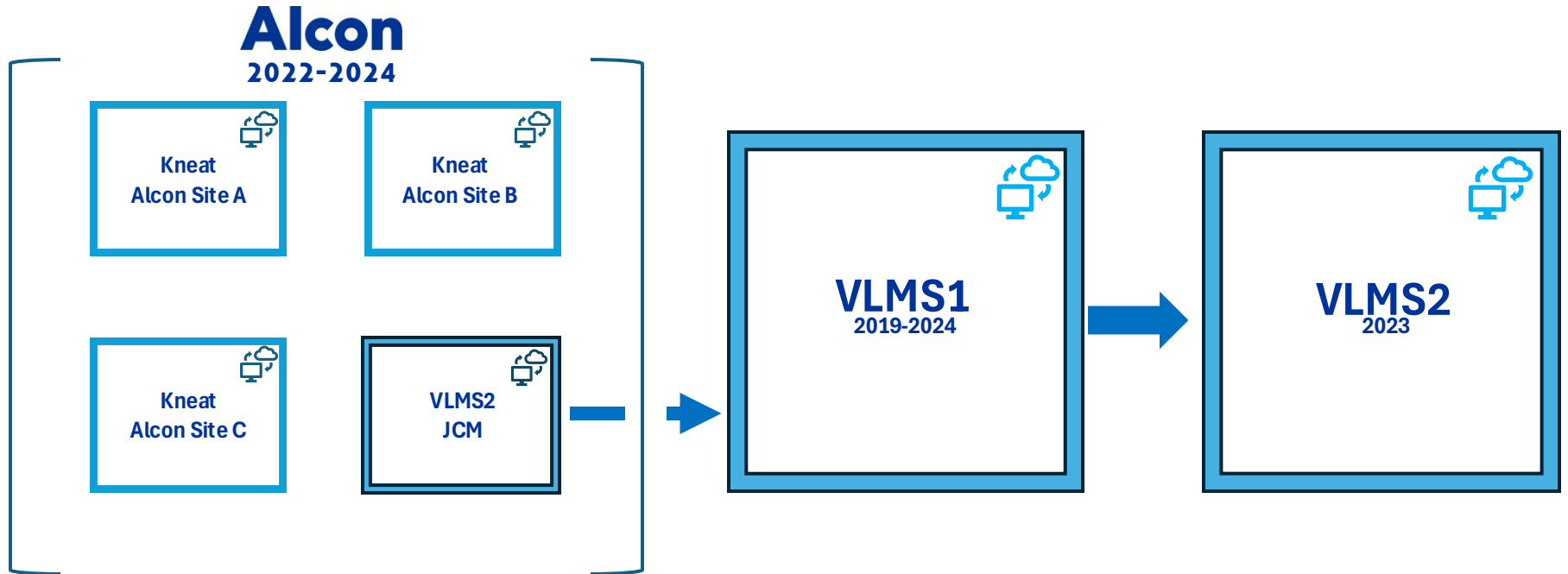
**2017/
Paper Based
Validation**



**2018/
Validation Lifecycle
Management
System (VLMS)**



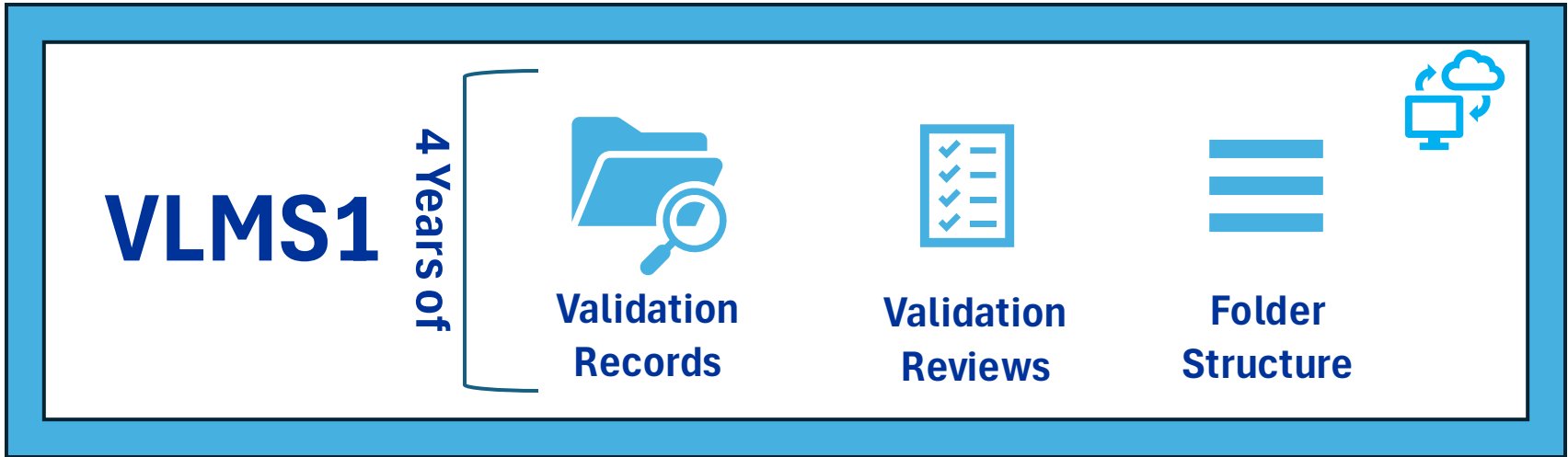
BACKGROUND



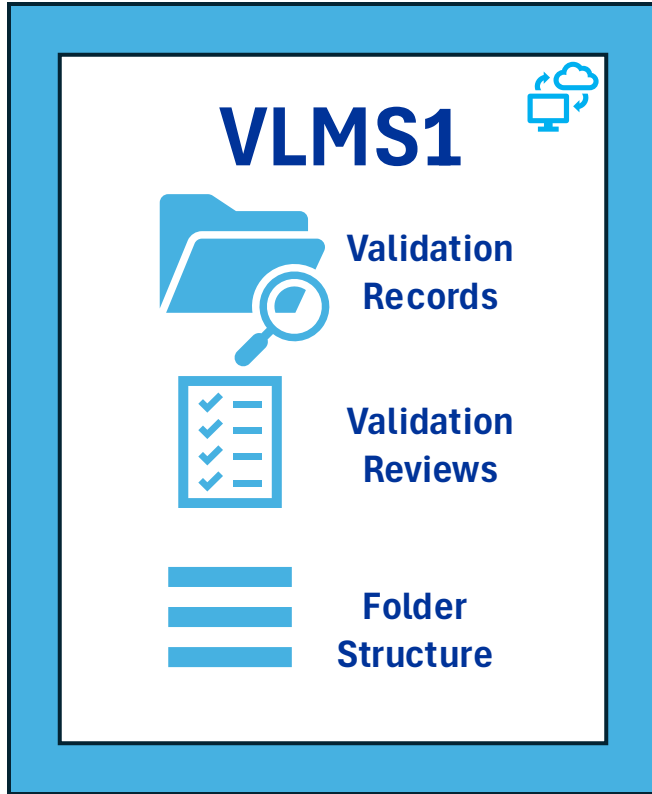
Transition and Data Migration Project



BACKGROUND



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 VLMS2)
4. VLMS1 Retirement



IMPLEMENTATION

1. Application Implementation

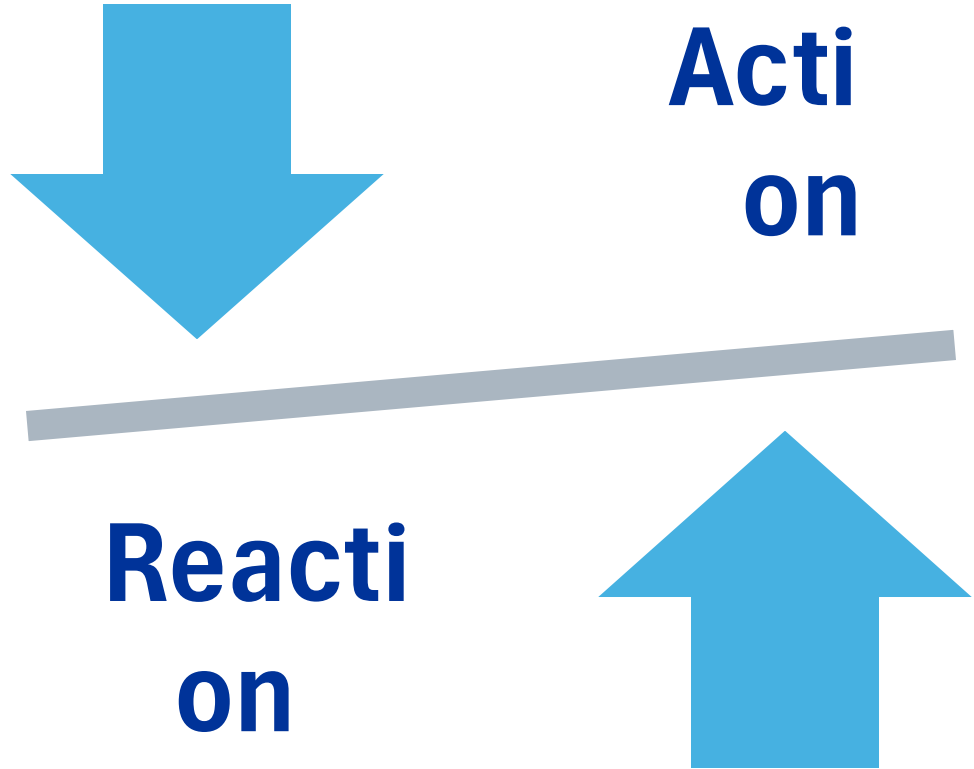
- Configuration
- User acceptance Testing
- Release of the application

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



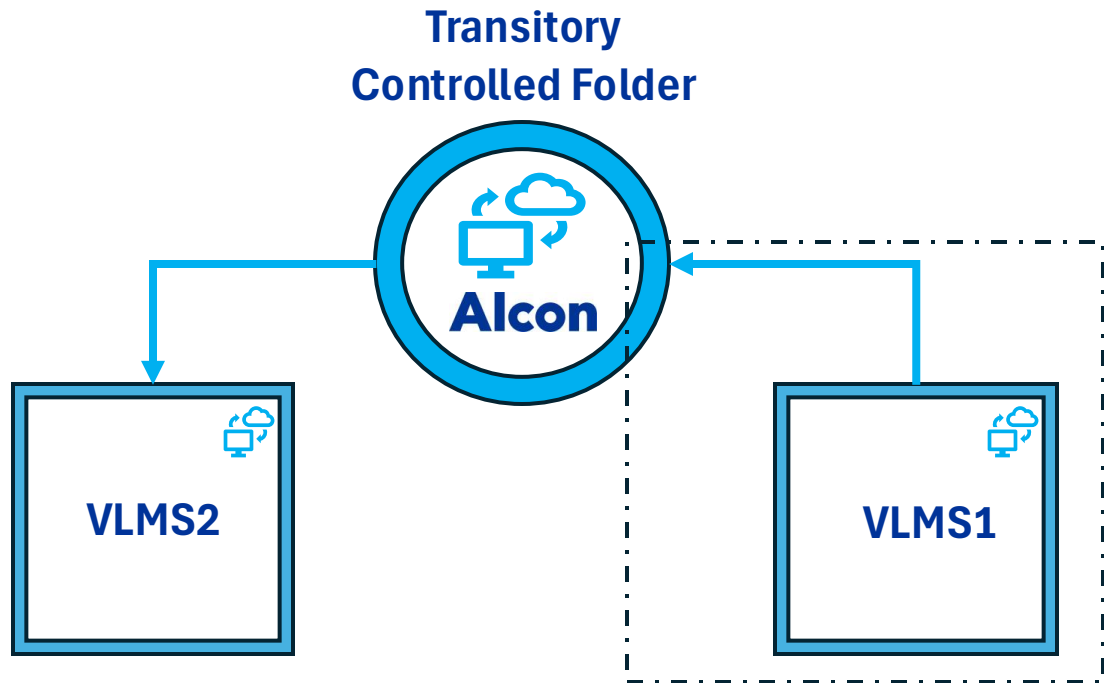
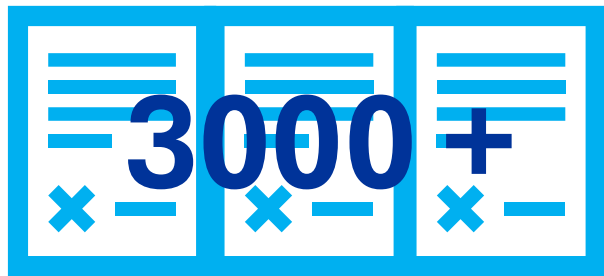
MIGRATION



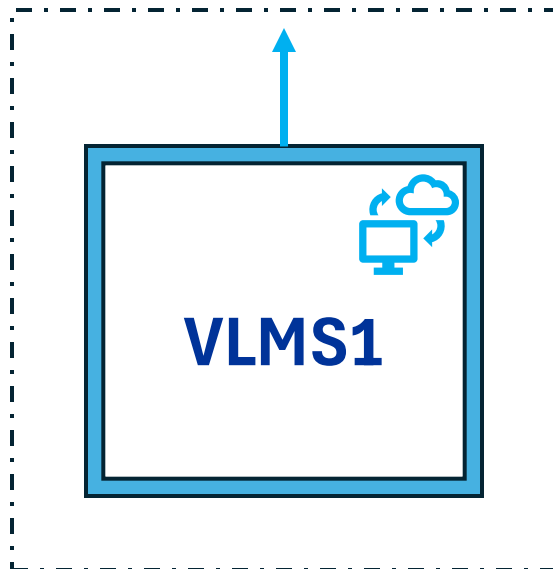
1. Establishing the basic requirement (data and folder format) for the VLMS2 to be able to migrate the data
2. Held meetings with each Tech Team independently
 - Alignment with the strategy
 - Discuss the migration plan technical details
3. Held meetings with VLMS1 and VLMS2 Tech Team together
 - Fine 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



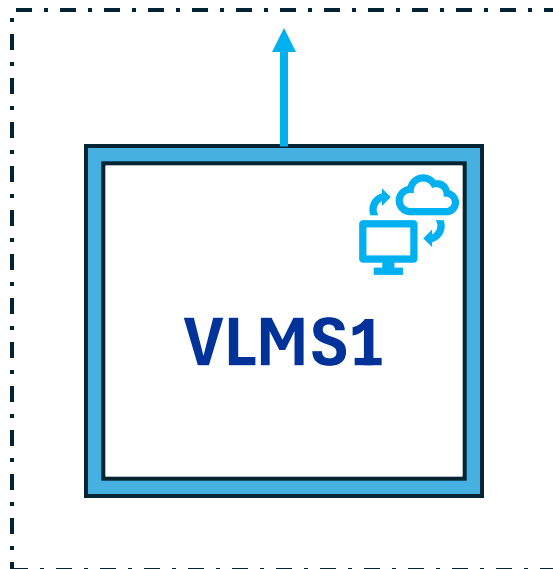
MIGRATION



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. Establishing a sampling plan to verify data accuracy



MIGRATION

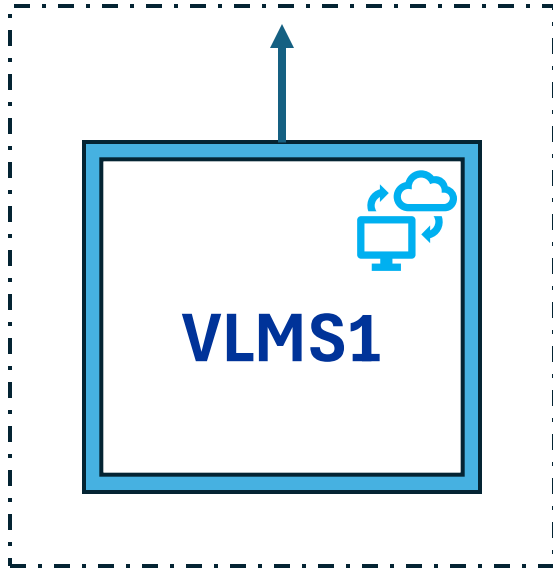


3. Establishing a sampling plan to verify data accuracy.

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 established
 - 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 established 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.

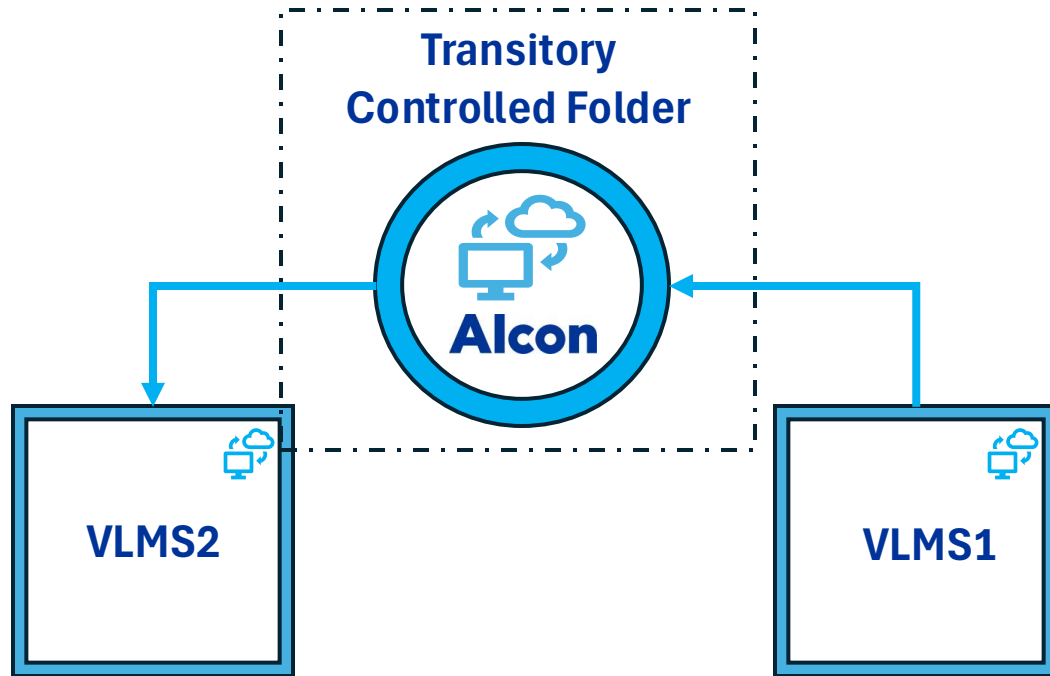


Compliance with Efficiency: Reduction of Project Time and the use Resources.

Transition and Data Migration Project



MIGRATION



MIGRATION



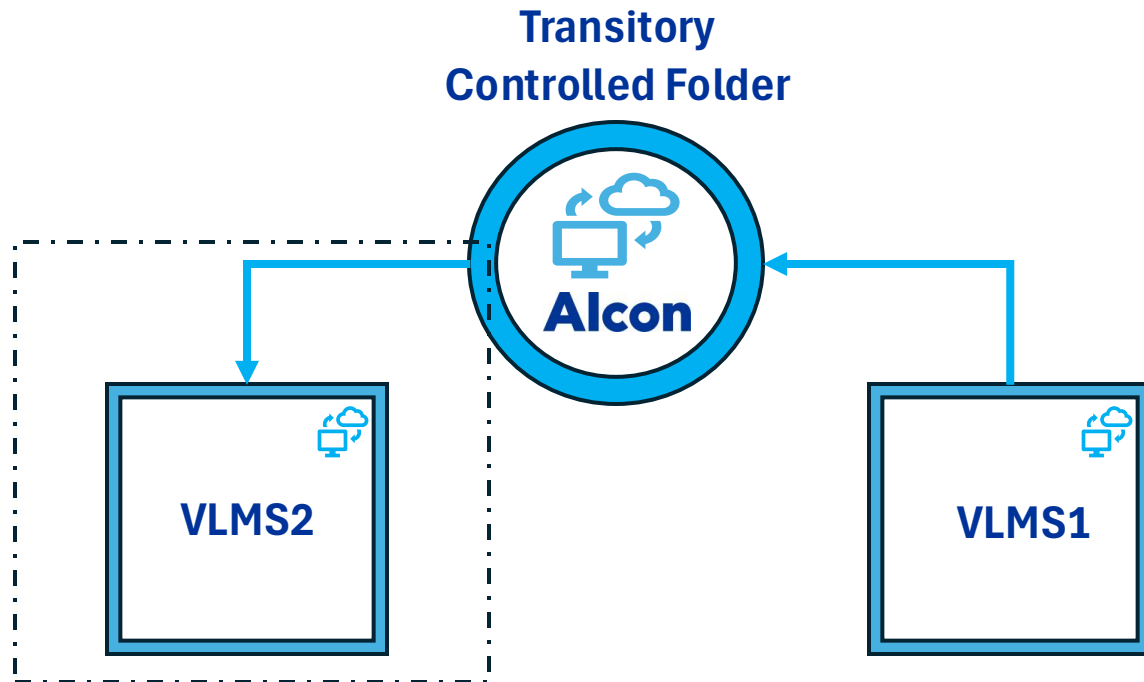
Transitory Controlled Folder



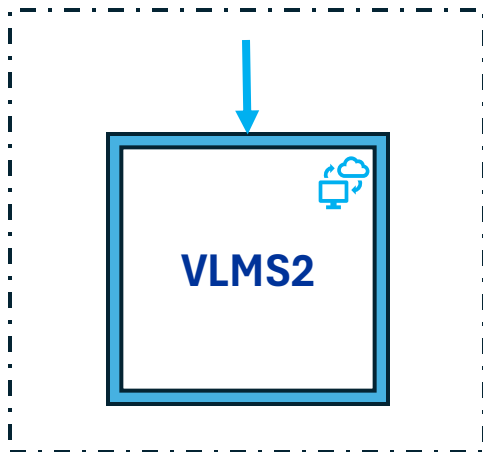
1. Execute Phase 1 of the Migration Plan: VLMS1 to Transitory Controlled Folder
 - Document the VLMS1 Data Freeze
 - Request from the VLMS1 Customer Technical Services team to run the migration script in the P Environment
 - Compare the sample data between VLMS1 and the folder
2. Release for Phase 2



MIGRATION



MIGRATION



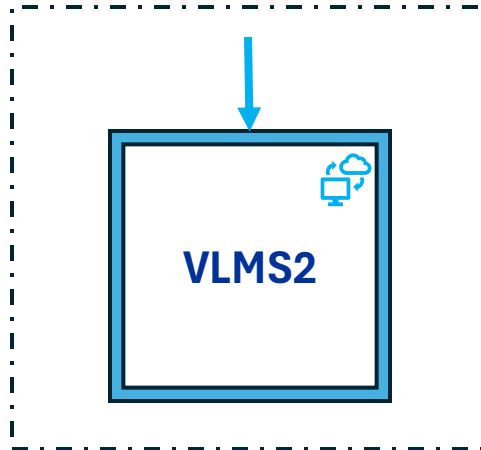
1. Execute Phase 2 of the Migration Plan: From the Transitory Controlled Folder to VLMS2.
2. 3 Steps
 - 1 DEV Environment
 - 2 VAL Environment
 - 3 PROD Environment



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

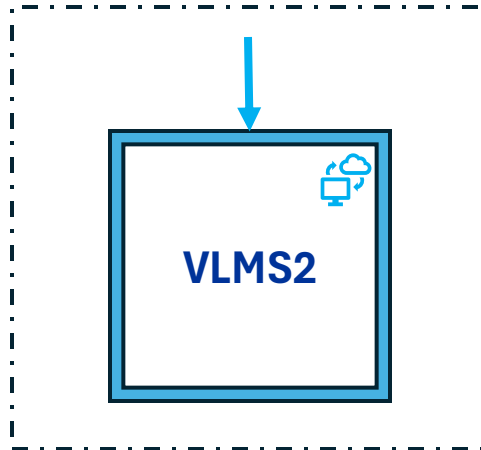
1. Migration of a selection of 500 records
2. A sample of 30 random records were verified: Origin Vs Destination.
3. Both records were retrievable, record are readable, complete, have the same #, same number of pages.
4. Acceptance Criteria: 0% Discrepancy.



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: Origin 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

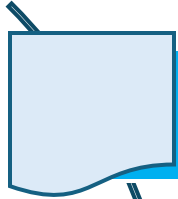
VLMS2

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

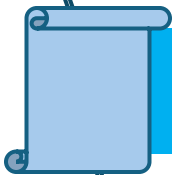
Transition and Data Migration Project



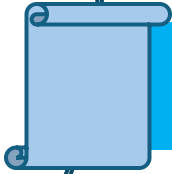
POST- MIGRATION / IMPLEMENTATION



Notified the site about the new Archive Folder



Provided 3 general training sections



Provided teams specific training sections



Created short instructional videos



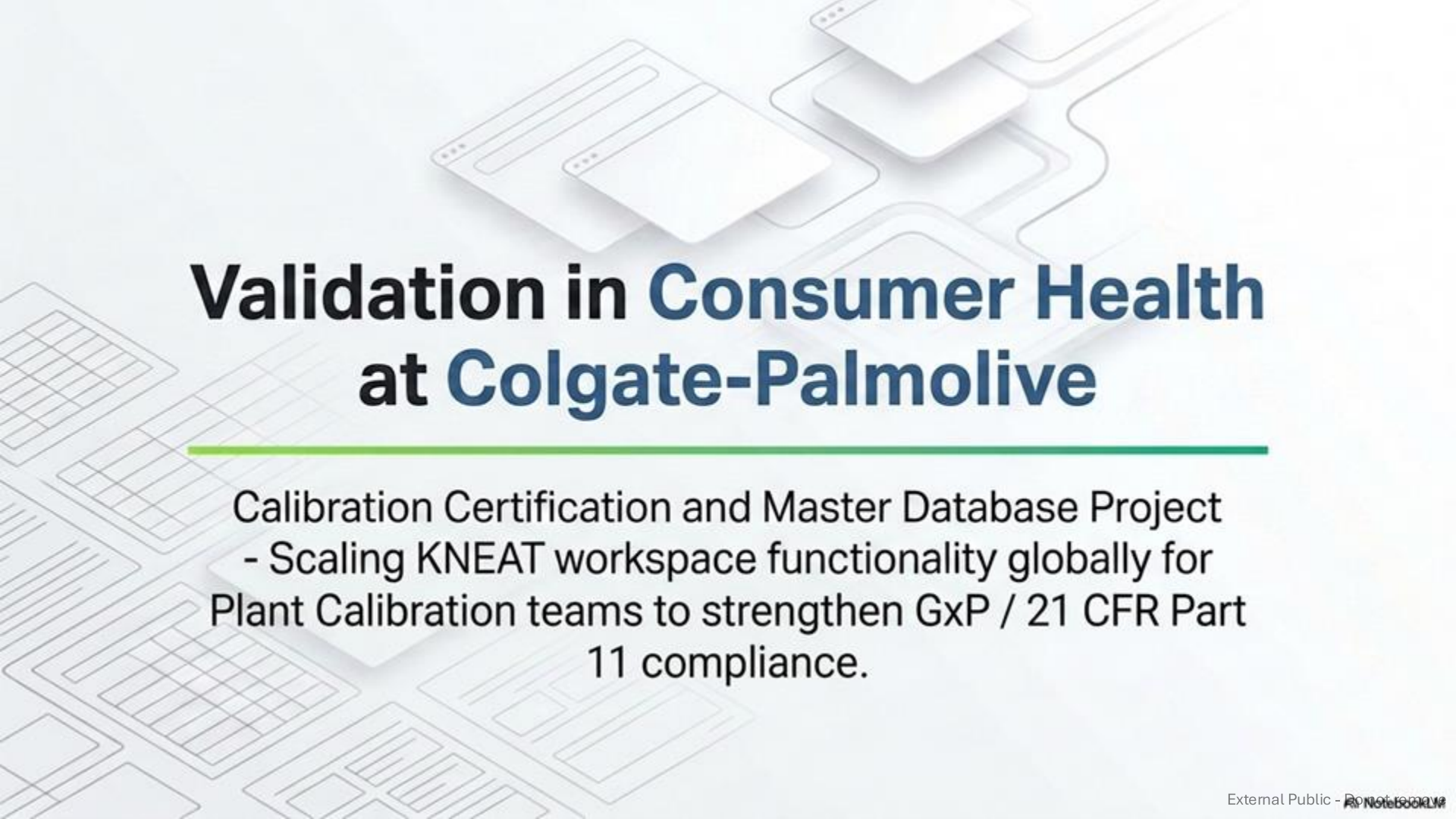
Innovative Customer Award Presentation #2



Warren Ware

Validation Engineer, Colgate-Palmolive





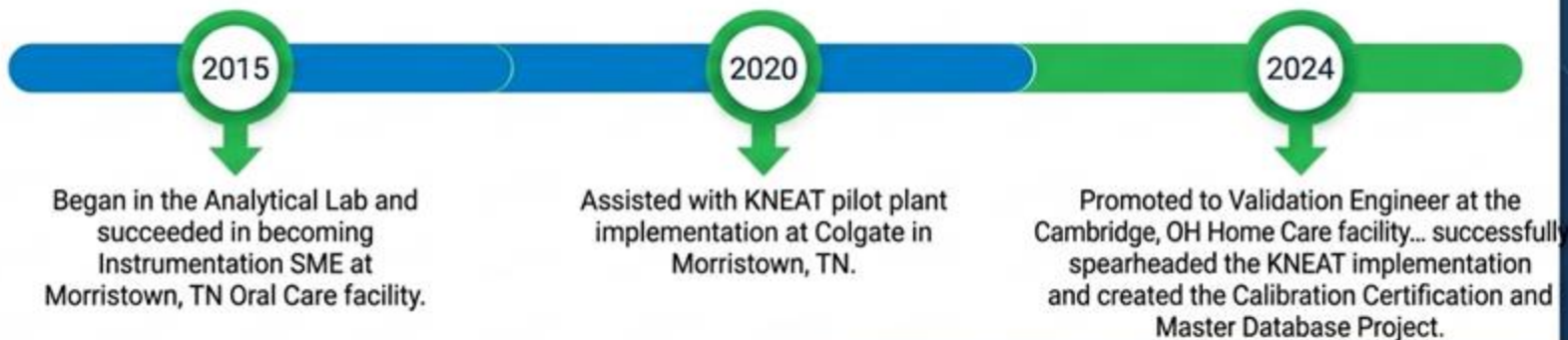
Validation in Consumer Health at Colgate-Palmolive

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



"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.



THE SOLUTION



Fully Compliant
(Global Standards)



Secure &
Centralized



Efficient &
Traceable

Kneat Gr - Production

Entity Masks

Calibrated Equipment | Published

12	Equipment Id (TAG) <i>Required core attribute</i>	Multiline text field
12	Description <i>Required core attribute</i>	Multiline text field
12	Input ID <i>Core attribute</i>	Multiline text field
12	CPU Bus / Block <i>Core attribute</i>	Multiline text field
12	Instrument Category <i>Required core attribute</i>	Choice list
	Manufacturer / Model	Multiline text field
	Serial Number	Multiline text field
	Miscellaneous Information	Multiline text field

Calibration Schedule / Equipment Hierarchy

Attribute	Type
12 Calibration Due Date <i>Core attribute</i>	Date field
Calibration Cycle (Months)	Multiline text field
Date Of Last Completed Calibration	Date field
12 Priority <i>Core attribute</i>	Choice list

Instrument Site and Placement Information

Attribute	Type
12 Building / Area <i>Core attribute</i>	Choice list

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

Legacy Equipment Data



Facilities ID (TAG)	Instrument ID	Equipment ID (TAG)	Calibration Due Date	Calibration Cycle (Months)	Date of Last Completed Calibration	Priority	Building / Area	Location	Vessel / Piping	Structure Reference
1	12345	12345	1/1/2025	12	12/1/2024	A	Building / Area	Tank 123	Vessel 123	Structure 123
2	12346	12346	2/1/2025	12	1/1/2025	A	Building / Area	Tank 124	Vessel 124	Structure 124
3	12347	12347	3/1/2025	12	2/1/2025	A	Building / Area	Tank 125	Vessel 125	Structure 125
4	12348	12348	4/1/2025	12	3/1/2025	A	Building / Area	Tank 126	Vessel 126	Structure 126
5	12349	12349	5/1/2025	12	4/1/2025	A	Building / Area	Tank 127	Vessel 127	Structure 127
6	12350	12350	6/1/2025	12	5/1/2025	A	Building / Area	Tank 128	Vessel 128	Structure 128
7	12351	12351	7/1/2025	12	6/1/2025	A	Building / Area	Tank 129	Vessel 129	Structure 129
8	12352	12352	8/1/2025	12	7/1/2025	A	Building / Area	Tank 130	Vessel 130	Structure 130
9	12353	12353	9/1/2025	12	8/1/2025	A	Building / Area	Tank 131	Vessel 131	Structure 131
10	12354	12354	10/1/2025	12	9/1/2025	A	Building / Area	Tank 132	Vessel 132	Structure 132

Step 1:

Collaborate with KNEAT IT engineers.

Step 2:

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

Finalized KNEAT Database



Instrument Details					Calibration Schedule / Equip Hierarchy				Instrument Site and Placement		
Input	CPU Bus/Block	Instrument Category	Model / Manufacturer	Misc Info	Cal Time Date	Cal Cycle (months)	Last Cal Date	Priority	Building / Area	Location	Vessel / Piping
AI 12355	DS-416.2	IT7	ACNE	ROA	1/1/2025	12	1/1/2025	A	LM	Tank 123	Vessel 123
AI 12345	DS-116.3	IT7	ACNE	ROA	1/2/2025	13	1/2/2025	A	LM	Tank 128	Vessel 243
AI 12347	BE-116.4	IT7	ACNE	ROA	1/3/2025	14	1/3/2025	A	LM	Tank 125	Vessel 347

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).



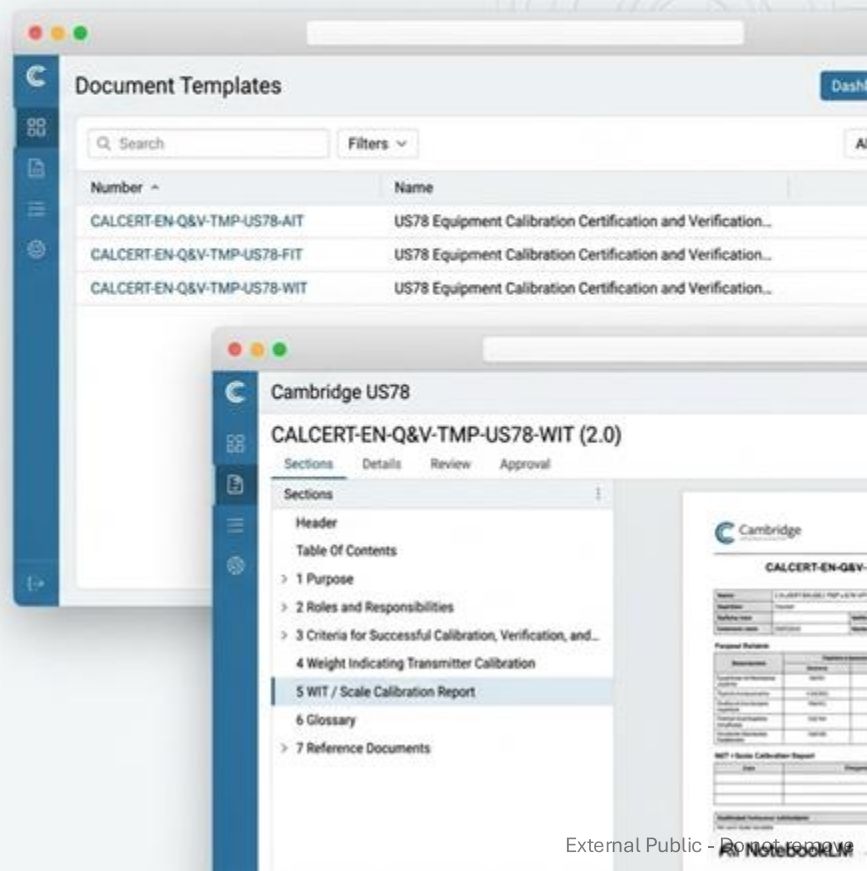
Embedded Protocols

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.

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

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

The screenshot shows the KNEAT application window. The title bar includes standard macOS window controls (red, yellow, green buttons) and a search icon. The main content area is divided into two sections. The top section, titled 'Instrument Details', contains a table with the following data:

Support ID / Tag	Description	Input ID	CPU Bus / Stock	Instrument Type	Model	Serial / Scale Serial #
Extrud A	P3Extruder Colletted Extruder-Surf1 Extrud Y1 Extruder Extruder Recorder	P3CAM	P31348	Print	Print	Print488

The bottom section, titled 'Site Inventory', contains a table with the following data:

Instrument Location	Serial	Binding / Stock
P3Printing Area XYZ	P31348	P3Print/Stock

Below these tables is a section titled 'Partly and Calibration Schedule' containing a table with the following data:

Partly	Quality Equations Required (REQ)	Calibration Due Date	Calibration Cycle	Last Calibration
PA	P313CAM Requirement "Quality Signature not required for non-scheduled product signature. For non-scheduled Parts EQ signatures designate Quality Signature order below as N/A not applicable"	P313CAM-2020-07-01	PA	P313CAM-2020-07-01

Optimization

Google Drive + Paper Certificate

Legacy manual reporting and physical storage process.

9	File Number:				Supersedes File:	
10	Manufacturer:	MICROMOTION			Accuracy Tolerance:	±1.1% ERROR
11						
12		1 Minute	1 Minute	1 Minute	1 Minute	
13		Totalizer	Scale	Delta	Error	
14						1/(Totalizer/Scale)
15	1 Minute Amount	70.35	0			100.00%
16	2 Minute Amount	155.367	0			100.00%
17	3 Minute Amount	240.373	0			100.00%
18	4 Minute Amount	308.858	0			100.00%
19	5 Minute Amount	0	0			0.00%
20	Final Test Amount	308.858	309.19			0.1074%
21						
22	Final Error %:	0.1074%				
23						
24	Flow Test Time:	4				
25						
26	Calibrator Name:					
27						
28	Signature:				Date:	

Standard Used: (Select One)

Large Scale Tank - 1.554	
Medium Scale Tank - 1.400	
Small Calibration Scale	
Medium Scale Cart	
Master Micromotion	11

All Meters require Quality Reviewer Signature

KNEAT e-certificate + electronic approvals

Streamlined digital workflow with automated data population and validation.

Google Drive + Paper Certificate



Instrument Details						
Equipment Id (Tag)	Description	Input ID	CPU Bus / Block	Instrument Type	Model	(Sensor / Scale) Serial #
[Equipment Instrument placeholder: Instrument Id (Tag) - 001]	[Calibrated Instrument placeholder: Instrument - 001]	[Calibrated Instrument placeholder: Input ID - 001]	[Calibrated Instrument placeholder: CPU Bus/Block - 001]	[Calibrated Instrument placeholder: Instrument Type - 001]	[Calibrated Instrument placeholder: Model - 001]	[Calibrated Instrument placeholder: (Sensor / Scale) Serial # - 001]
Site Hierarchy						
Instrument Location		Vessel		Building / Area		
[Calibrated Instrument placeholder: Location - 001]		[Calibrated Instrument placeholder: Vessel - 001]		[Calibrated Instrument placeholder: Building / Area - 001]		
Priority and Calibration Schedule						
Priority	Quality Signature Required (A/B)?		Calibration Due Date	Calibration Cycle	Last Calibration	
[Calibrated Instrument placeholder: Equipment Priority - 001]	[Calibrated Instrument placeholder: Quality Signature Requirement - 001]		[Calibrated Instrument placeholder: Calibration Due Date - 001]	[Calibrated Instrument placeholder: Calibration Cycle (months) - 001]	[Calibrated Instrument placeholder: Date of Last Completed Calibration - 001]	
<i>"Quality Signature not required for non-antibacterial product equipment. For non-AB (Priority B/C) equipment, designate Quality Signature section below as (N/A) not applicable"</i>						

Select an entity to merge in the document

All Casting

Workforce & Training (ITE) > Cultural Production Equipment (PAC) > 429

V. M. Kozlov

Table 4

Unique Identifier	Description	Type
-------------------	-------------	------

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Exercise Cultural Encounters... Cultural notes...

Keywords: *depression, mood, self-esteem, self-concept, self-evaluation, self-perception, self-regard, self-worth, self-image, self-identity, self-idea, self-view, self-construction, self-formation, self-development, self-growth, self-maturation, self-actualization, self-fulfillment, self-achievement, self-actualization, self-fulfillment, self-achievement*

DE EDITORIAL

Equipment Details

Address

446

Costs

11

Range

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	P12346	PAIT	PAIT	P987456
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	
PA	P(YES) A/B Requirement *Quality Signature not required for non-microbial product equipment. For non-AB (Priority B/C) equipment, designate Quality Signature section below as (N/A) not applicable*		P27-Feb-2026 (UTC)	P6	P27-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

CALCERT-Version1 (1.0) Post-Approved Responsible user - Warren Ware PIN is not set Version: 1.0 Comments

Sections Details Review Approval

☒ Turn on multi-execution

Create

Document Number



CALCERT-Version1(1.0)-001

Unedit

Title (optional)

Source document number & version: CALCERT-Version1(1.0)

Approval



Document No : CALCERT-Version1

Document Title : Test

Version : 1.0

This is a representation of an electronic record that was signed electronically and this page is a manifestation of the original record. Electronic signatures for this document are maintained in the Kneat system.

Pre-Approval

Prepared By	Signatory Capacity	User Group	Date Approved
Warren, Warren	Preparer	Preparer	19-Sep-2025 20:30:20 (UTC)

Serial Number	Calibration Due Date	Interval	Last Calibration Date
F100000001	11/28/2022	9 days	11/19/2022 ✓

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

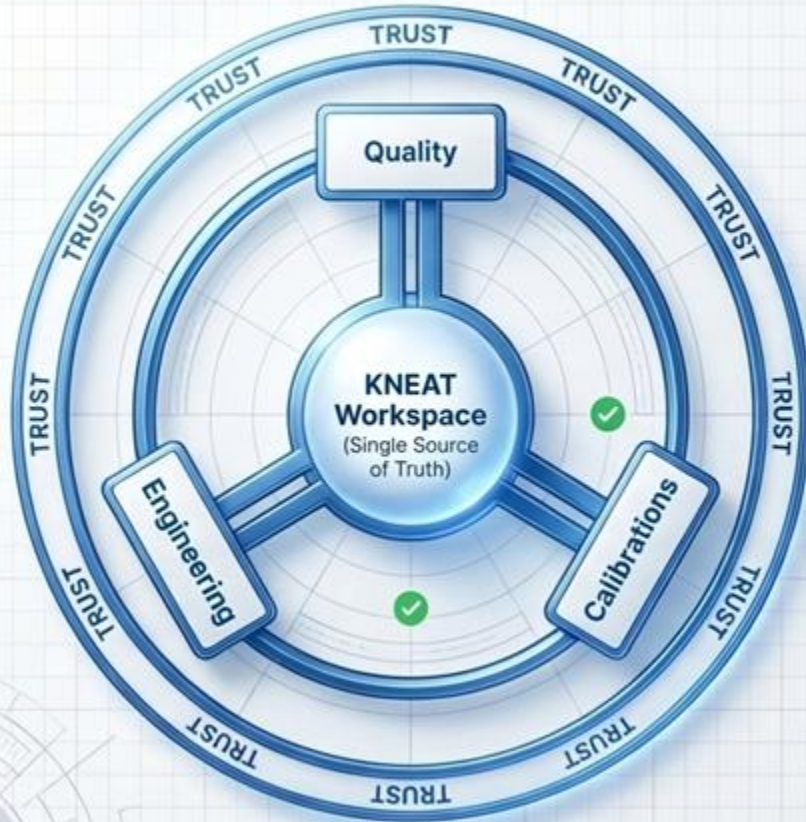
External Public - Do not remove

A Blueprint for Global Replication



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





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



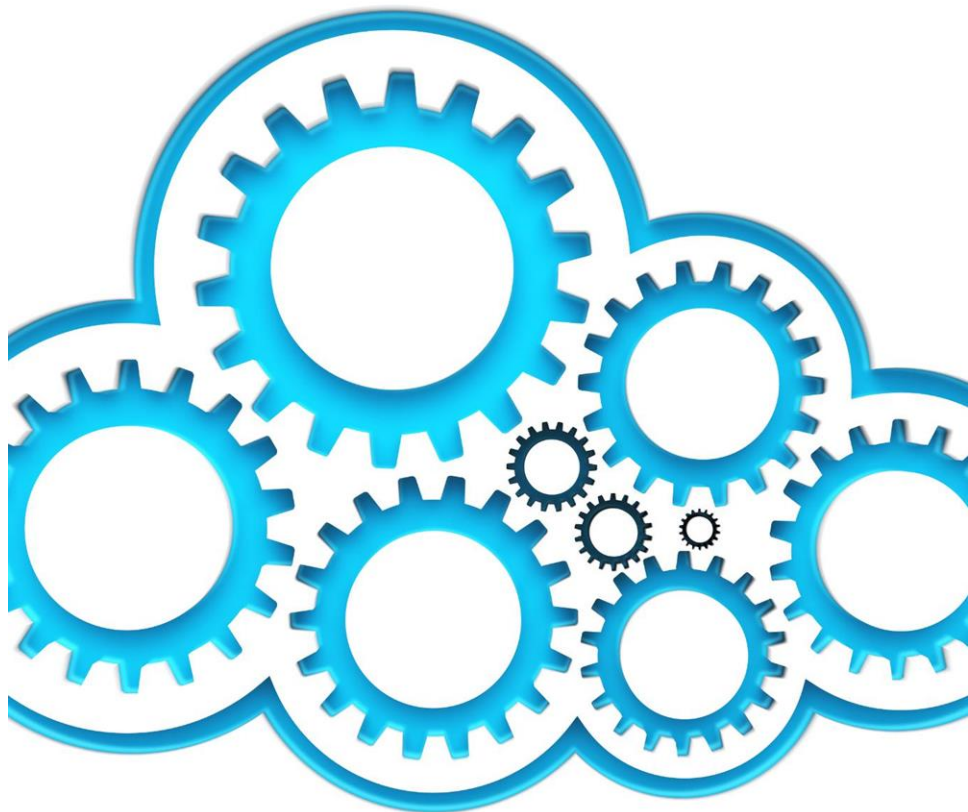
Pfizer Kneat Deployments 2025-2026

- 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 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 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)



Day 2 2026 Partner Awards



Speaker



Carey Ziegler
Manager, Partner Success

Kneat

Kneat Partner Program



[Kneat.com/ Find A Kneat Partner](https://Kneat.com/FindAPartner)

Session 4.1

Practical use of Kneat to standardize and simplify validation across global MODA-ES deployments

Fokke Zijlstra | Holocene Projects
B.V. (Lonza)



From SOP to Execution

Why MES transformations succeed or fail in execution, not on paper

Practical use of Kneat to standardize and simplify validation across global MODA-ES deployments

Fokke Zijlstra – Dublin Validation Conference 2026



The real test starts when validation begins

- DEV can look stable
- Test scripts can be approved
- Documentation can be complete
- But execution reveals the truth

Lonza



Validation does not create problems, it exposes them

- Infrastructure differences
- Timing issues
- Configuration gaps
- Environment-specific behavior

Lonza



So, the real question is not: are we documented?

The real question is: are we executable?

- Can we rehearse it?
- Can we trace it?
- Can we recover from failure?
- Can we prove control?

Lonza

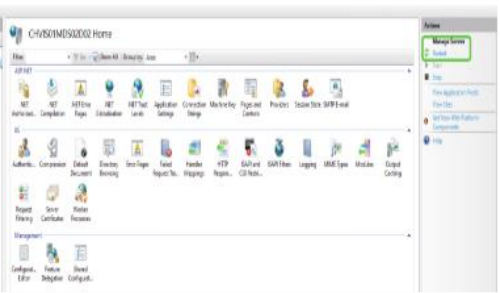


Real Example from Kneat

These instructions do more than control execution

- They train local administrators
- They build technical understanding
- They transfer knowledge to the site
- They improve readiness when issues occur

3 Verify that IIS is running, by opening the internet information Service (IIS) Manager
If restart is not green , click on start



20 Go to IIS and verify / update the Moda App and Workflow Pools created with the install.
Ensure that the .Net CLR Version is v4.0 according SCS.

if not the case select the App Pool and click on Basic Settings and update to .Net CLR Version v4.0/

Verify / Update the Identity for the Application Pool.
It needs to be Local System.

if not select the appropriate application pool and click on advanced settings and set the identity on local system.

Recycle the application pools.

example:

Application Pools

This page lets you view and manage the list of application pools on the server. Application pools are associated with worker processes, control...

Name	Status	.NET CLR V...	Managed Pool...	Identity	Applications
NET-v4.5	Started	v4.0	Integrated	ApplicationPoolIdentity	0
NET-v4.5 Classic	Started	v4.0	Classic	ApplicationPoolIdentity	0
CHAI_DEVFlowRight	Started	v4.0	Integrated	LocalSystem	1
DefaultAppPool	Started	v4.0	Integrated	ApplicationPoolIdentity	1
Moda_CHAI_DEVAppPool	Started	v4.0	Integrated	LocalSystem	2

Lonza



A Real-World Upgrade Scenario

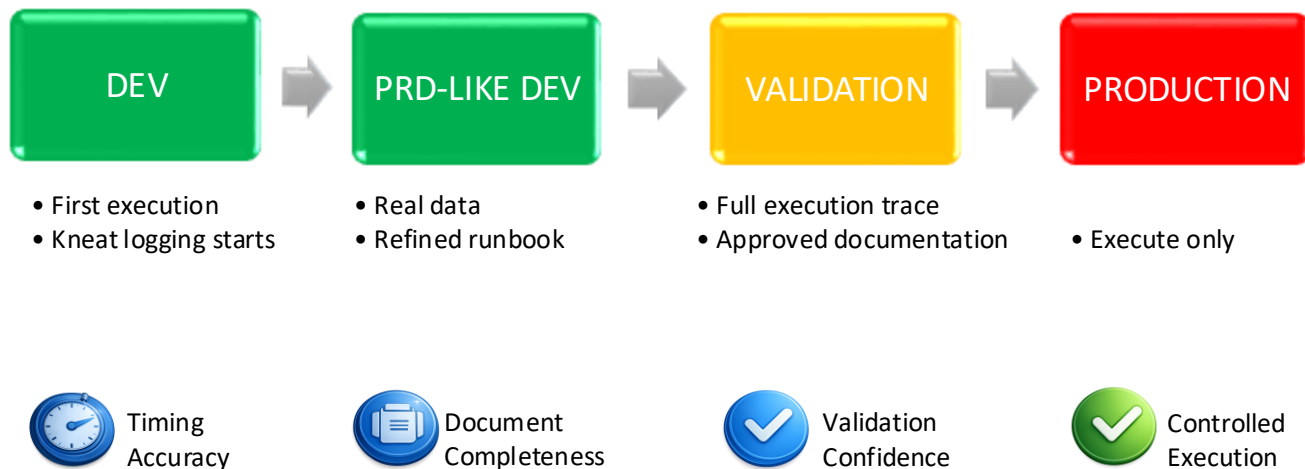
- Major MODA-ES site upgrade
- Large production database
- Production-like rehearsal environments
- Single production downtime window



Lonza



Preparation Phase, Engineering a Predictable Production Upgrade



Lonza



Start	Completed		6:00	6:15	23:00	23:15	0:15	Shutdown application on both nodes and contact TCS to start database Backup		Application Node 1/2	17/feb/26	6:00	6:13	0:13
	Completed		6:15	10:00	23:15	3:00	3:45	TCS Starts with the Backup of databases	RITMD478147	Databases Backup	17/feb/26	6:13		

14:00 Incident

- 14:00
- The installer stopped.

Lonza



- Upgrade scripts executed
- 18 completed
- 6 remaining

Lonza



One character in a password.



Password adjusted

Installer executed again

Upgrade completed successfully

Lonza

MODA

EBR

LIMS

Key Lesson

Control is not the absence of issues.

Control is knowing how to respond.



What made this controllable

This was not control because nothing went wrong

This was control because we knew how to respond

- We rehearsed the upgrade
- We traced every step
- We understood the dependencies
- We controlled the recovery

Planned Leadtime		
		These tasks can be done before
0:30	SG-TMP-5549	TC - MODA-ES - IP - MODA-ES BASIC SERVER
0:30	SG-TMP-5549	TC - MODA-ES - IP - MODA-ES BASIC SERVER
0:30		Coffee Break Team Geleen
0:30	SG-TMP-5549	TC - MODA-ES - IP - MODA-ES BASIC SERVER
0:30	SG-TMP-5549	TC - MODA-ES - IP - MODA-ES BASIC SERVER
0:30	SG-TMP-5549	TC - MODA-ES - IP - MODA-ES BASIC SERVER
0:15	SG-TMP-5550	TC - MODA-ES - IP - MODA-ES VISUAL STUDIO
0:15	SG-TMP-5550	TC - MODA-ES - IP - MODA-ES VISUAL STUDIO
		Draft Summary report, prepare closure of CO
		Copy all needed software , moda-es , .ne
		Tasks During Shut down
0:15		Shutdown application on both nodes and
3:45		TCS Starts with the Backup of databases
0:45	SG-TMP-9352	TC - MODA-ES - IP - MODA-ES 4.x De-installat
0:45	SG-TMP-9352	TC - MODA-ES - IP - MODA-ES 4.x De-installat
1:00	SG-TMP-5557	TC - MODA-ES - IP - MODA-ES 4.0 De-installat
1:30	SG-TMP-9601	TC - MODA-ES - IP - MODA-ES 4.2 PREREQUIS
1:30	SG-TMP-9601	TC - MODA-ES - IP - MODA-ES 4.2 PREREQUIS
0:30		Coffee Break Team Geleen
2:00	SG-TMP-5552	TC - MODA-ES - IP - CLEAN INSTALLATION OF
2:00	SG-TMP-5552	TC - MODA-ES - IP - CLEAN INSTALLATION OF
0:30		Lunch Break Team Geleen
3:00	SG-TMP-5553	TC - MODA-ES - IP - MODA-ES HOTFIX/MINO
0:30		Hand over to team in Houston

Lonza

MODA

EBR

LIMS

Because at the end of every validated system, there is a patient who depends on it.



AI Vision & Roadmap



Speakers



Ruairi McGarry

Product Manager

Kneat

Gillian McMahon

Senior Product Owner

Kneat

Agenda

- The Strategy
- Data Privacy/Security
- AI Roadmap & Deep Dive
- Demo With Gillian



The Strategy



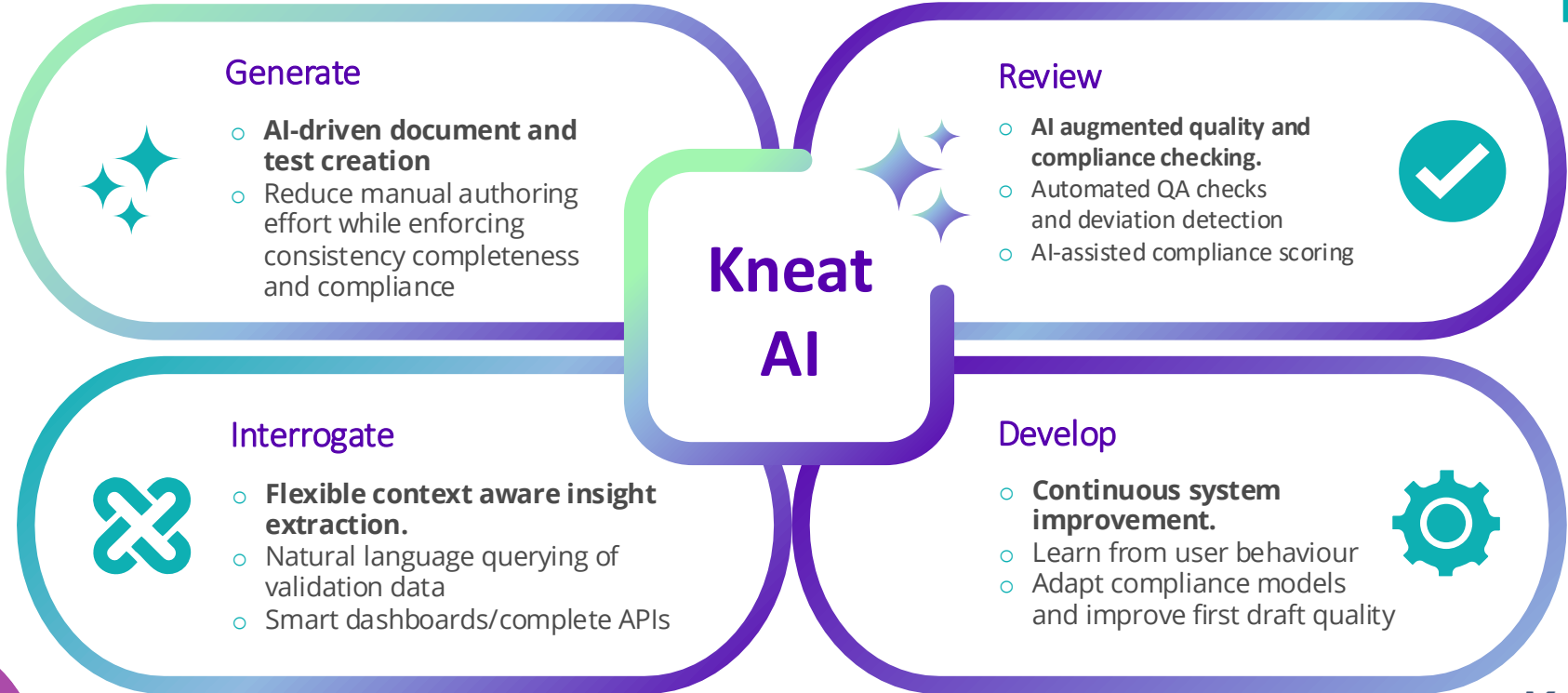
AI Enhances Kneat Gx Efficiency Further

Life Sciences requires AI that is controlled, compliant, and grounded in data integrity

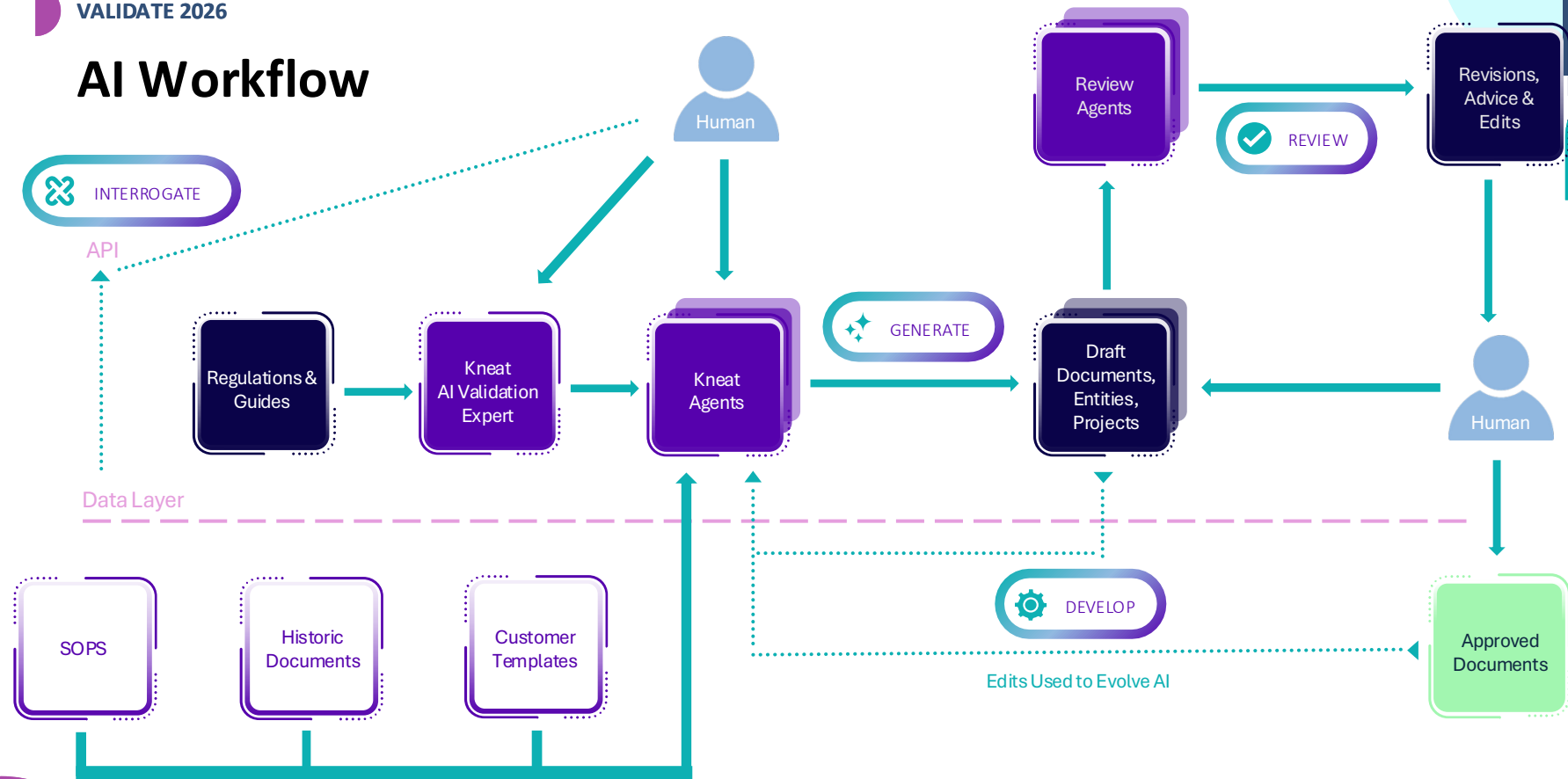
Benefits

- Faster content (protocols/reports) generation
- Faster right first-time review cycles
- Instant comprehensive data insights
- Enhanced compliance standard
- Shorter cycle times

GRID: AI-Driven Precision Across the Validation Lifecycle



AI Workflow



Data Privacy/Security





What's Core

- Maintaining Customer IP
- Data Segregation
- Access Control
- Never Training Foundation Models



AI Roadmap & Deep Dive



Kneat AI: Current and Upcoming Capabilities

Available

Early 2026

AI Kneat Expert

Ask questions and receive instant guidance on the platform's features and functionality.

Data API

Large-scale data accessibility to support owned AI initiatives.

AI Translated UI

Multilingual user experience through AI-driven translation of the platform interface.

AI Review Assistant

Automatically identifies and prioritizes items that require human review, increasing efficiency and reducing manual effort.

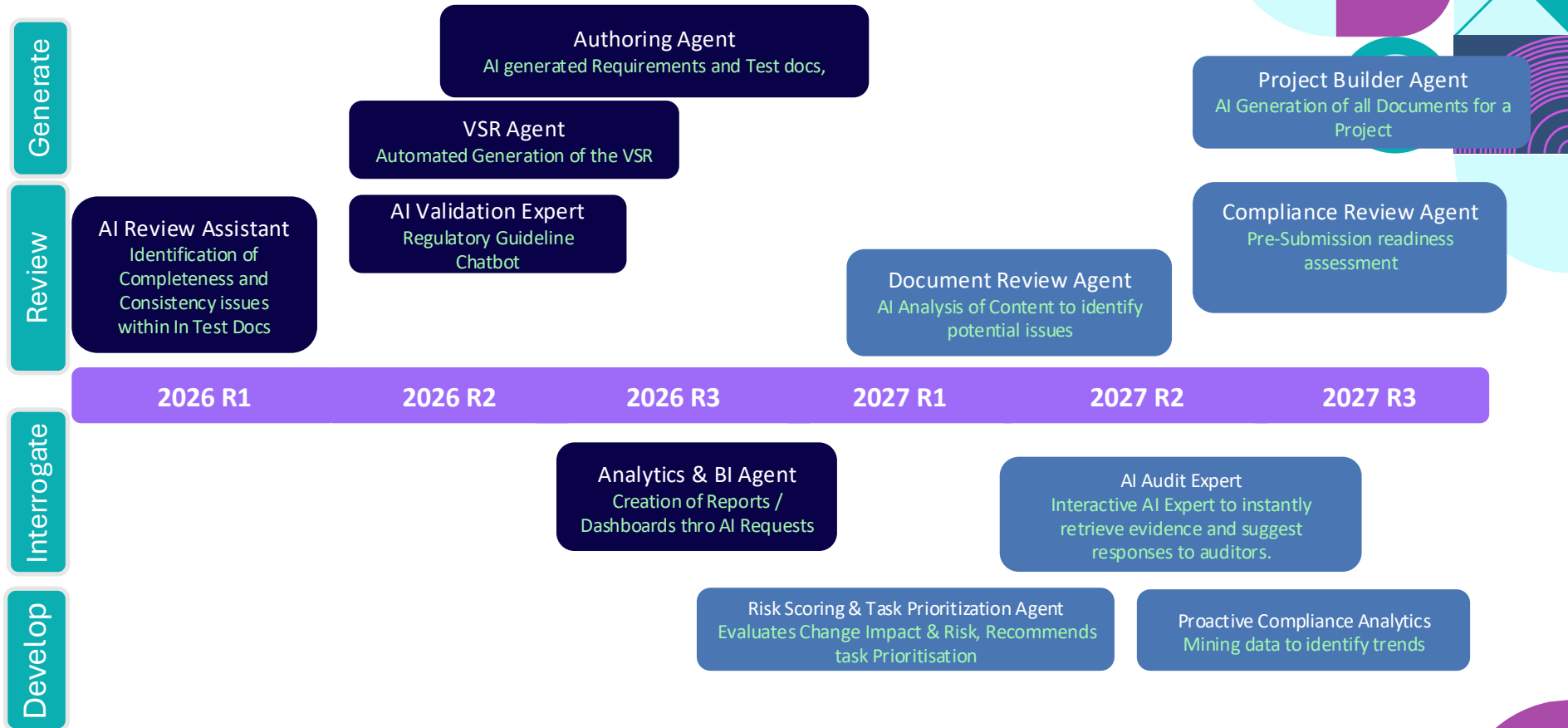
Validation Summary Report Agent

Query data using everyday language, making analytics more intuitive and accessible.

Authoring Agent

Create and refine documentation, reports, and validation content automatically, ensuring consistency, accuracy, and compliance.

Kneat Gx AI 2026/ 2027



Validation Summary Review Agent

Structured, Inspection-ready overview of validation protocols:

- Issue Summary
- Test Summary
- Executive Summary



AI Validation Expert

Rapid access to global life science regulatory guidance while maintaining clear boundaries as a knowledge navigator not a decision-making authority.

How it works

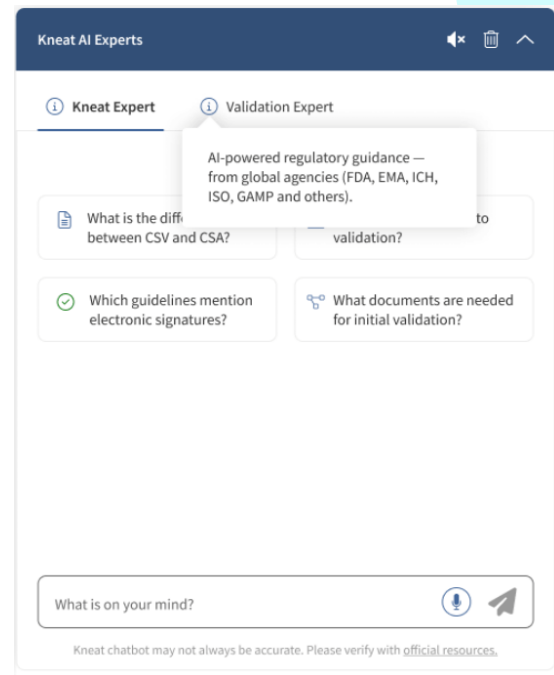
The system retrieves and presents precise, traceable excerpts from approved sources (FDA, EMA, ICH, ISO, GAMP, etc.), delivering contextual insights with Harvard-style citations while operating strictly within a governed knowledge base.

High Level Capability

It centralises fragmented regulatory frameworks into a single, searchable interface that accelerates validation workflows, improves visibility, and enhances understanding through accurate, source-backed guidance.

Primary Value

- Reduces time, inconsistency, and risk in regulatory navigation
- while strengthening audit readiness,
- preserving SME accountability, and
- ensuring all outputs remain compliant, controlled, and transparent.



Authoring Agent

*An AI-Assisted Validation Authoring Capability,
fully integrated within the Gx application*

High Level Capability

- Secure use of customer-owned validation documentation as inputs,
- Automation of drafting, extracting requirements and test cases, and
- Standardising terminology to ensure consistency and alignment with regulatory expectations.

Primary Value



Reduces manual effort
& document review cycles



Improves global consistency



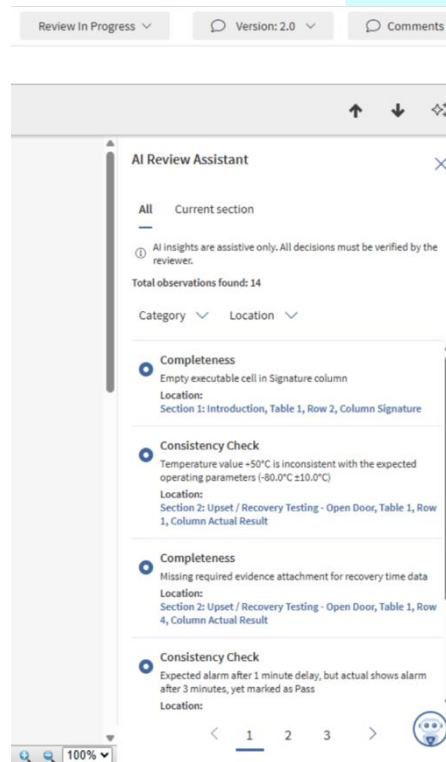
Enables teams to focus on
higher-value validation &
quality decisions

AI Review Agent

Improve accuracy and reduce time spent reviewing content

Automatically flag what needs your attention most, letting you focus on critical decisions rather than routine checks and review.

- ✓ Flag blank cells
- ✓ Missing evidence/attachments
- ✓ Logical mismatches
- ✓ Data inaccuracies



DEMO

Session 5.1

Pfizer's Kneat Deployment Journey

Gisele Fahmi &
Vasilios Tsatsaias | Pfizer



Pfizer's Kneat Global Deployment Journey

From Local Complexity to Global Scale

Gisele Fahmi | Vasilios Tsatsaias



April 2026

Scaling Kneat Globally at Pfizer: Faster, Lower-Cost, and Repeatable

50% Faster Deployment

Parallel wave execution replaces site-by-site rollouts

45% Lower Deployment Cost

Streamlined process, standardized delivery

90% Training Improvement

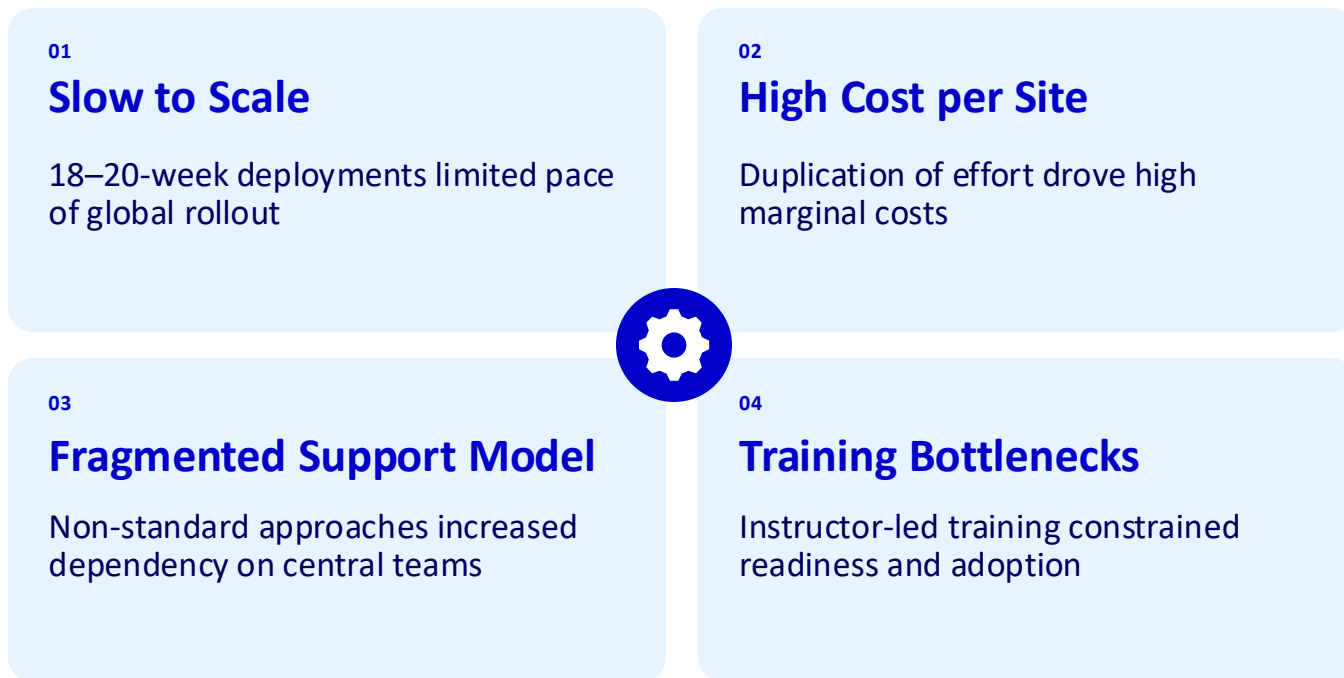
Self-service, scalable enablement model

Built to Scale Globally

Governed, repeatable operating model

A standardized global deployment model that accelerates site onboarding, reduces cost, and establishes a blueprint for future digital platforms.

As Kneat adoption expanded, the original deployment approach became slower, more expensive, and increasingly complex



What worked for individual sites did not work at a global scale

A site-by-site deployment model created duplication, cost, and capacity constraints as adoption expanded.

Resetting the Model to Enable Global Scale

Following the realization that site-by-site deployments could not scale globally, Pfizer convened a cross-functional alignment workshop to intentionally redesign how Kneat would be deployed, governed, and supported at scale.

Design Principles for Global Scale

1

Establish Clear Decision Ownership

The Global Process Owner was designated as the single decision maker, with defined escalation paths for unresolved or high-risk items.

2

Design for the Ideal Future State

Decisions were made based on what would scale globally, rather than optimizing for current local practices or constraints.

3

Move to a Global Discipline Model

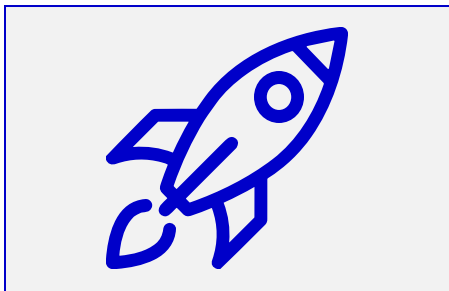
A single global discipline approach was selected to reduce complexity, enable reuse, and support consistent deployment across sites.

This workshop marked the start of Pfizer's transformation toward a deliberately designed global operating model

Transformation Pillars

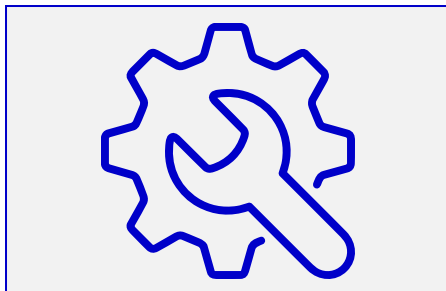
The global operating model was delivered through three integrated transformation pillars.

Deployment



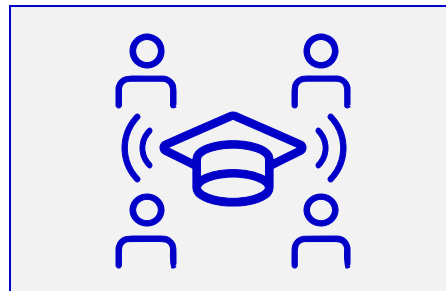
Repeatable, wave-based
rollout

Support Model



Clear ownership and
structured escalation

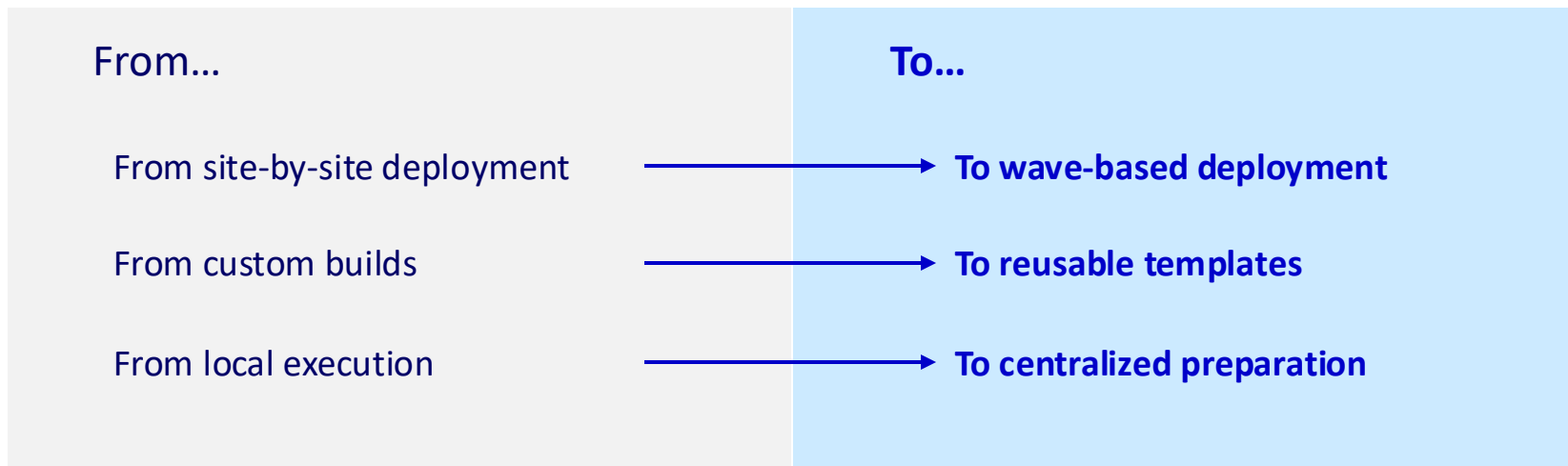
Training



Scalable, self-service
enablement

Deployment Transformation

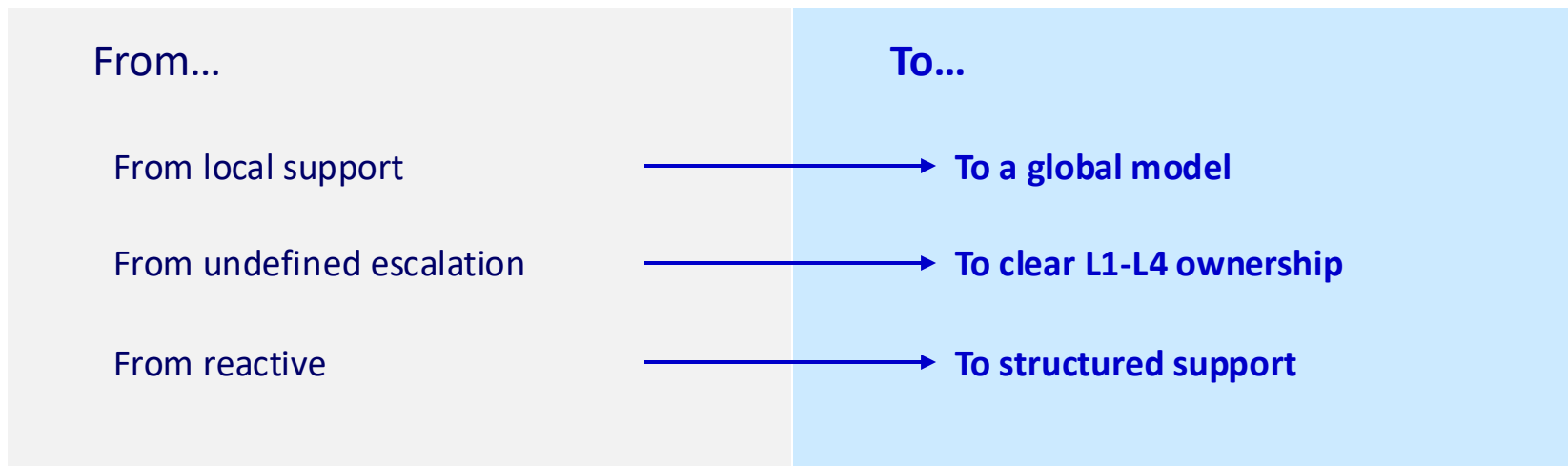
The first lever to unlock global scale



Deployment became repeatable, simplified, and scalable by design.

Support Model Transformation

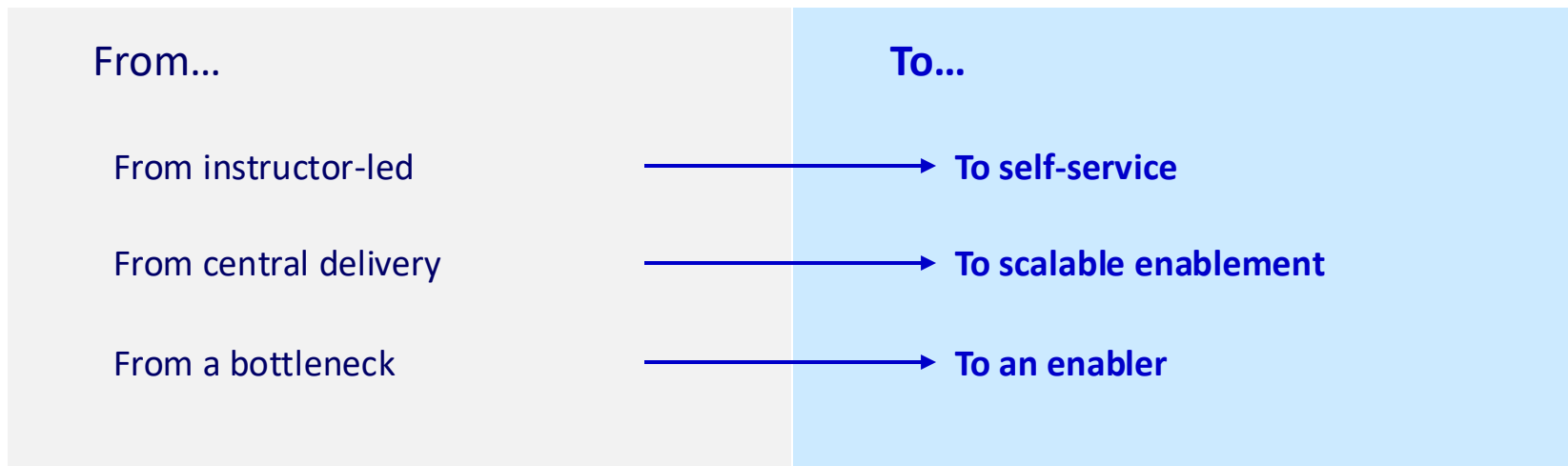
Evolving support to sustain a global operating model



The support model ensured scale could be sustained without increasing complexity.

Training Transformation

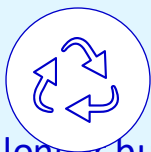
Evolving training to support a simplified, scalable deployment model



Training reinforced scale by making adoption faster, simpler, and repeatable.

What Changed for Sites

Less Setup Effort



Sites no longer build from scratch—reusable templates and centralized prep reduced upfront work

Clearer Roles & Expectations



Defined ownership and escalation simplified how sites engage and get support

Focus on Adoption



Standardized templates reduced site-specific variation

Impact

Speed

50%

Faster Deployments

Parallel wave execution
replaced sequential rollouts

Cost

45%

Lower Deployment Cost

Reduced duplication and
marginal effort per site

Adoption

90%

Improvement in Training
Reach & Readiness

Self-service enablement
scaled adoption globally

Together, these changes enabled faster onboarding, lower cost, and sustainable global scale.

“Coming together is a beginning, staying together is a process, and working together is a success.”

—Henry

Ford

“Great things in business are never done by one person; they’re done by a team of people.”

—Steve Jobs

Questions?

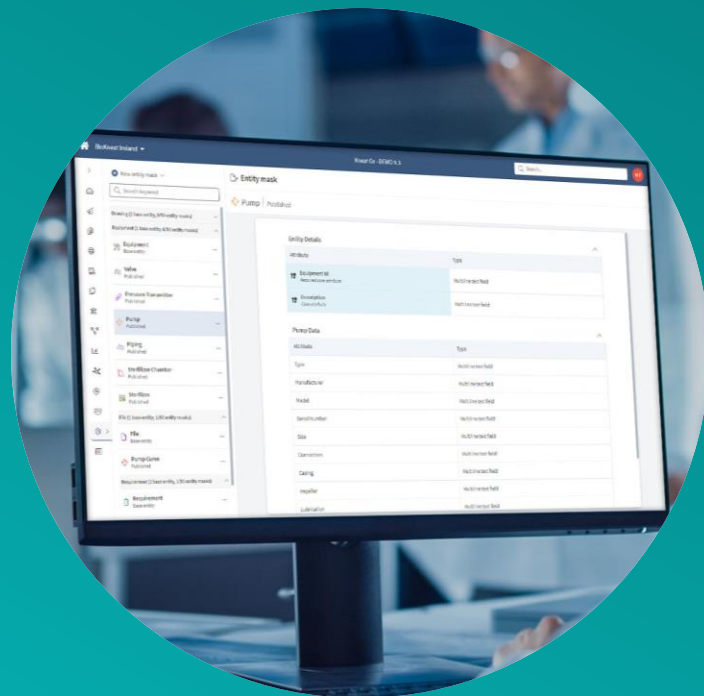


Thank You



Session 5.2

Kneat Integrations



Speakers



Joe Azzarella

Senior CSE,

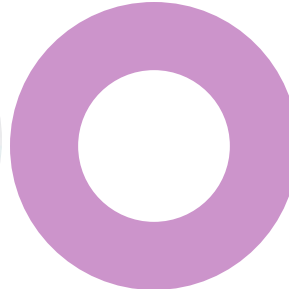
Kneat



Denis Bartley

Senior Integration Engineer

Kneat



Fintan Coady

CQV Specialist ORP Lead,

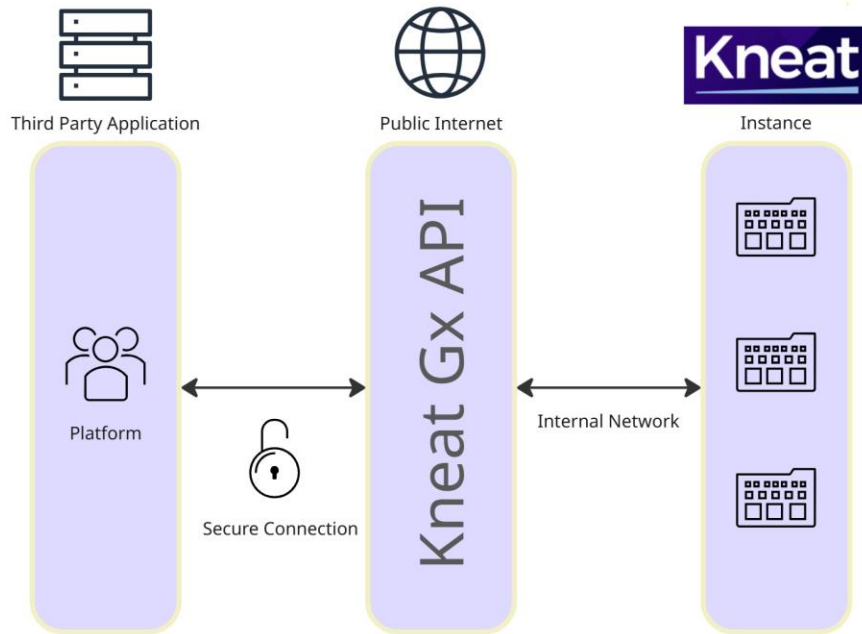
PM
GROUP

Kneat Open APIs

Connecting Kneat to Your World

- Your validation data lives in Kneat. Your business runs on data from across your ecosystem. Today we show you how they connect.
- Kneat's APIs are designed to fit your workflows, not define them.
- Kneat's APIs put automation and integration in your hands to connect your validation data to the workflows and tools that drive your business.

What is an API – Application Programming Interface



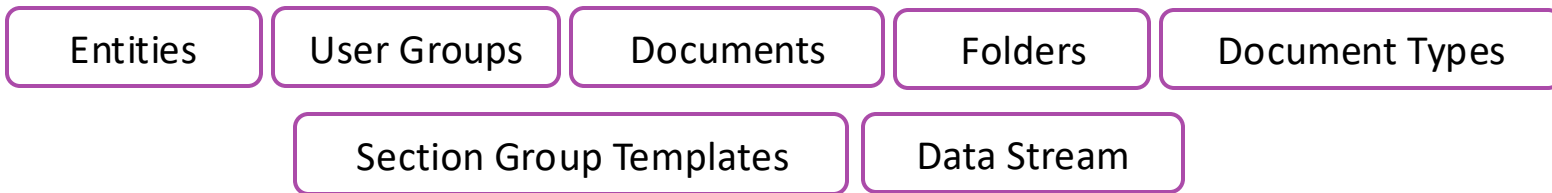
Kneat Gx API provides a standardised set of rules and requests that allows systems to communicate and exchange data efficiently and securely.

Integrations provide:

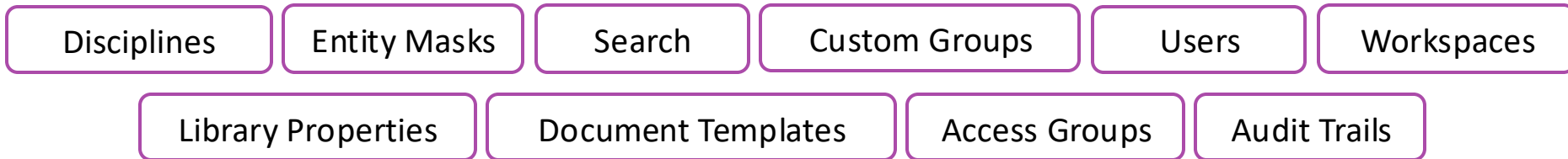
- Reduce Manual Effort
- Enable automated workflows
- Embed Kneat into your ecosystems
- Time-To-Value

Current API Feature Support

New API Additions and Enhancements



Foundation APIs



Integrations Built With Kneat API



The Industry Problem – Drowning in Data

The Concept of DRIP

- As we transition to a Pharma 4.0 world, we are drowning in data (values in databases, PDF files with extensive information, values from instrumentation, etc.). This allows us to be **Data Rich**.
- This data is not easily identifiable or transferred to our systems of choice. Being able to answer a simple question should not require using the correct system with the right query if that option is available at all. This leaves us **Information Poor** in situations where we need immediate answers.
- This combination leaves us **Data Rich and Information Poor (DRIP)**.

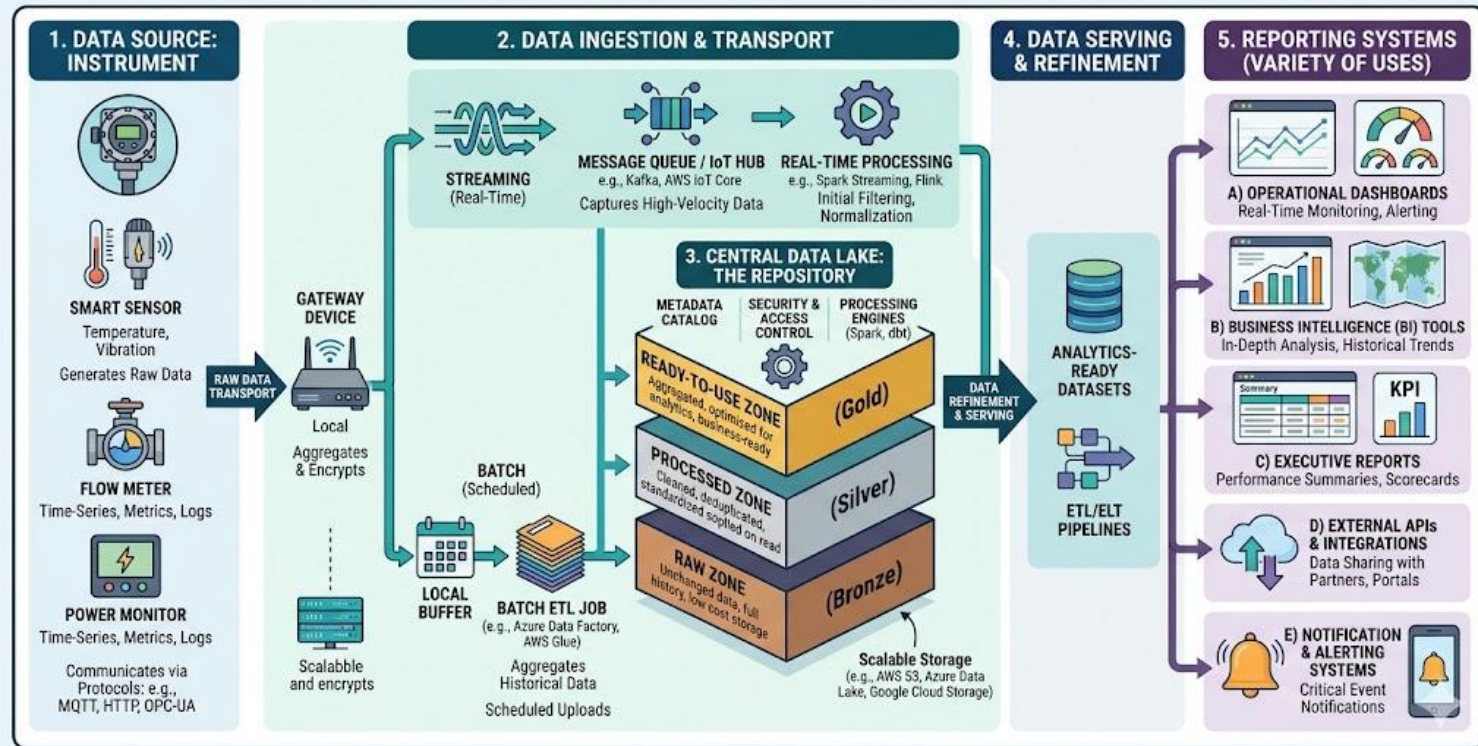


The Industry Problem – Drowning in Data

DRIP Challenges

1. Data Ingestion & Transport Chaos
2. Governance & Security Nightmare
3. Multiple Versions of the Truth
4. Hidden Costs & Wasted Resources
5. Sluggish & Unreliable Reporting

END-TO-END DATA PIPELINE: INSTRUMENT TO DATA LAKE TO REPORTING SYSTEMS





*A 20-minute query is a report.
A 10-second query is a conversation.*



Kneat's Solution to DRIP – Data Stream

What is Data Stream?

- Retrieve your KPI data through the Kneat API
- Data is updated every 24 hours
- Supports automated retrieval of data
- Contact your CSM/CSE for more information on how to access Data Stream in the future

Kneat Gx Data Stream

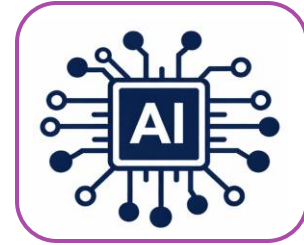
How the data can be used!



Data Warehouse / Data Lake



Reports



Artificial Intelligence

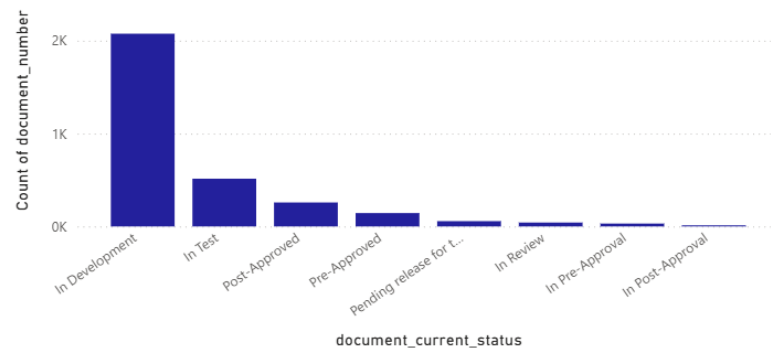
Kneat Gx Data Stream

Document Time Estimate Overview

Issue Count	Average Issue Resolution Time (days)
570	38.34
Protocol Count	Average Protocol Execution Time (days)
3130	47.34

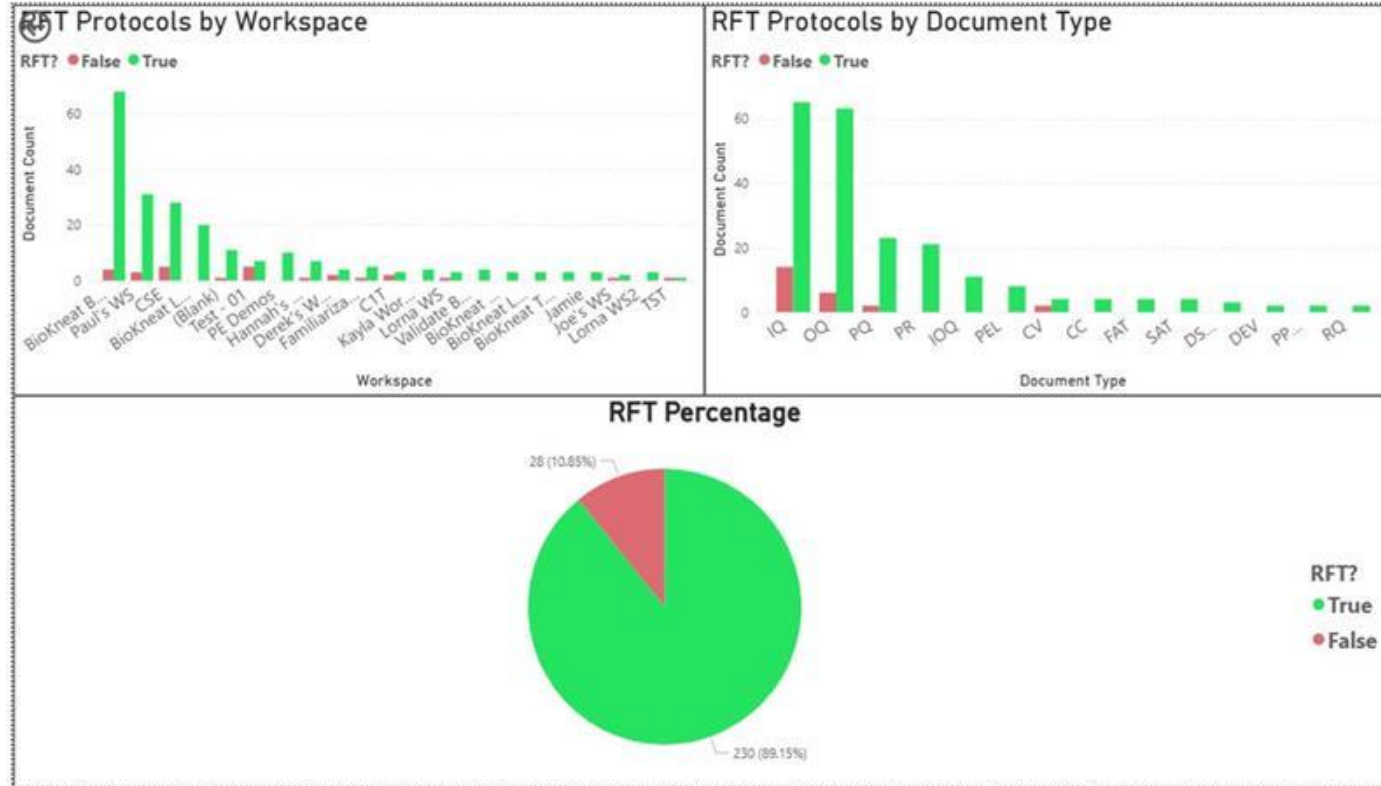
Count of Protocol Docs by Status

Issue? ☒ False



Kneat Gx Data Stream

Protocol Count per Document Status



“Your Validation, Your Way”

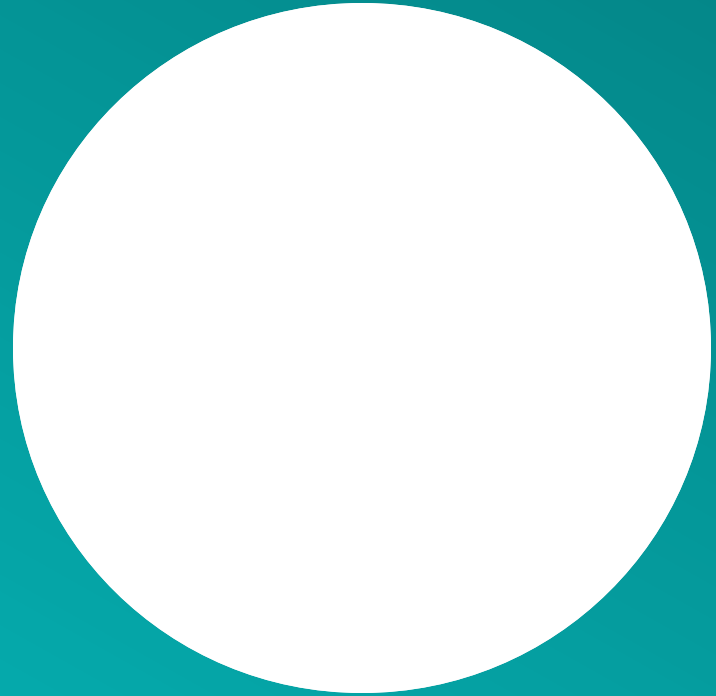


“Connectivity, Your Way”

Kneat Integrations

Panio's Digital Dashboards

Fintan Coady | PM Group



Panios Digital Platform & Unified Watchtower

Electronic Validation

Digital validation management, protocol execution, and real-time readiness tracking across all CQV activities.

Automation Project Tracking

Automation change monitoring and tracking, with oversight of automation change requests including MES integration, supported by operator dashboards and seamless data exchange for end-to-end operational visibility.

Document Management System

Controlled documents, SOPs, training materials, and regulatory compliance in a single validated system.

Change Control/ Deviation EQMS

Deviation, CAPA, and change control management with closure tracking post-handover for sustained compliance.

Unified Dashboard "Watchtower"



Risk register & action tracker: •
Training readiness status
• Tech transfer visibility
• Cross-stream KPIs in real time

01.

Foundation

Governance and digital platform establishment

02.

Population

Workshops, SIPOCs, comprehensive risk register

03.

Integration

System linkage, dashboard cadence

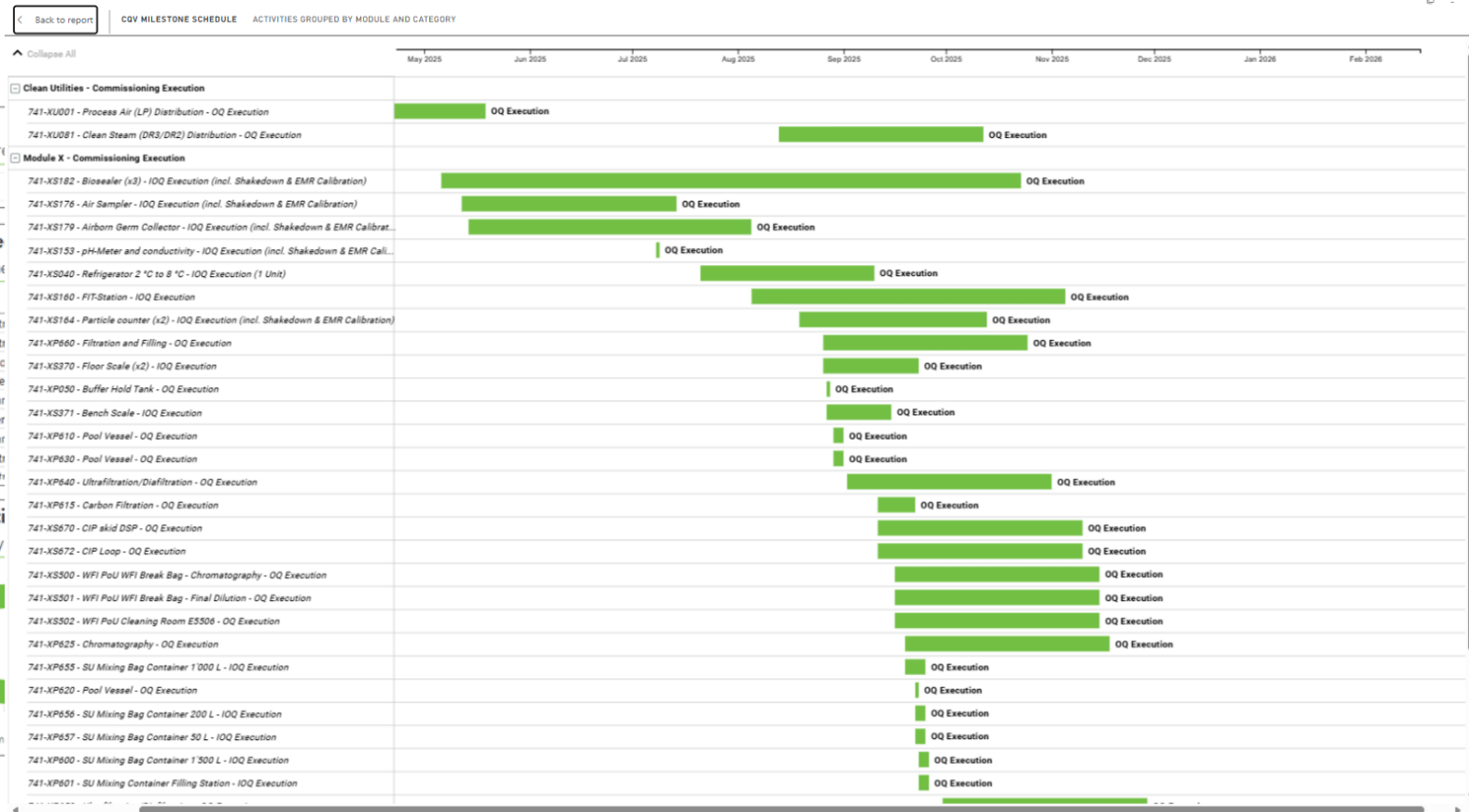
04.

Optimisation

Continuous improvement post Day One

We deliver a facility not just built, but truly ready to run from Day One.

CAPEX Overview Single source of truth





Module:

21.05.2025 > Week 21

Breakdown

Select to filter results

All

Status

Filter

In progress

Critical

Critical path



Document List

Data acquired from KNEAT application

number	title	version	modifiedDate	status	link
CLIA - MP016-01	Component Level Impact Assessment for LOG-0002-01	0.3	5/1/2025 4:04:22 PM	InDevelopment	link
CUCTP-MP016-02	Clean Utility Commissioning Test Protocol for MP016-LOG-001-02	0.1	4/4/2025 9:44:18 AM	InDevelopment	link
CUIOQ - MP016-LOG-001-03	Clean Utility Installation Operational Qualification Test Protocol for MP016-LOG-001-03	0.1	3/14/2025 12:32:11 PM	InDevelopment	link
DQ-MP016-01	Design Qualification for LOG-	0.3	5/13/2025 1:29:30 PM	InDevelopment	link

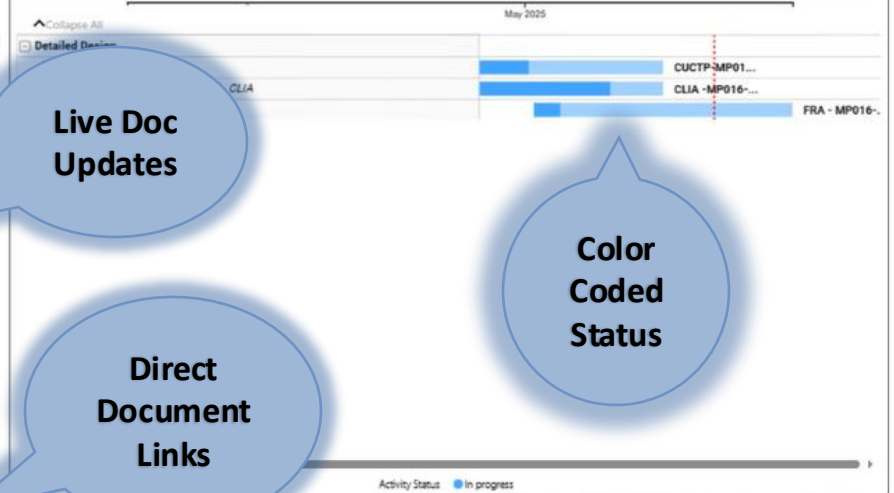
Document History

Data acquired from KNEAT application

number	issuedDate	status	version	link
CLIA - MP016-01	4/8/2025 3:07:31 PM	Review Closed	0.1	link
DQ-MP016-01	4/9/2025 1:35:57 PM	Review Closed	0.1	link
FRA - MP016-02	4/15/2025 3:52:32 PM	Review Closed	0.1	link
FRA - MP016-02	4/16/2025 12:25:38 PM	Review Closed	0.2	link
FRA - MP016-02	4/16/2025 12:32:07 PM	Review Closed	0.3	link
FRA - MP016-02	4/21/2025 10:35:23 AM	Review Closed	0.4	link
FRA - MP016-02	4/23/2025 8:45:44 PM	Review Closed	0.5	link
URS - MP016-01	4/28/2025 10:30:12 AM	Approved	1.0	link
BTM - MP016-01	4/28/2025 10:45:40 AM	Approved	1.0	link

Schedule

Activities grouped by module and category



Live Doc Updates

Color Coded Status

Direct Document Links

Project Timeline



Handover Risks and Progress Tracking


 Module: **Risk Register** 16.04.2026 > Week 16
 Last data update: 30 Mar 2026 

S Status

Closed	Issue (PCN)	Open
--------	-------------	------

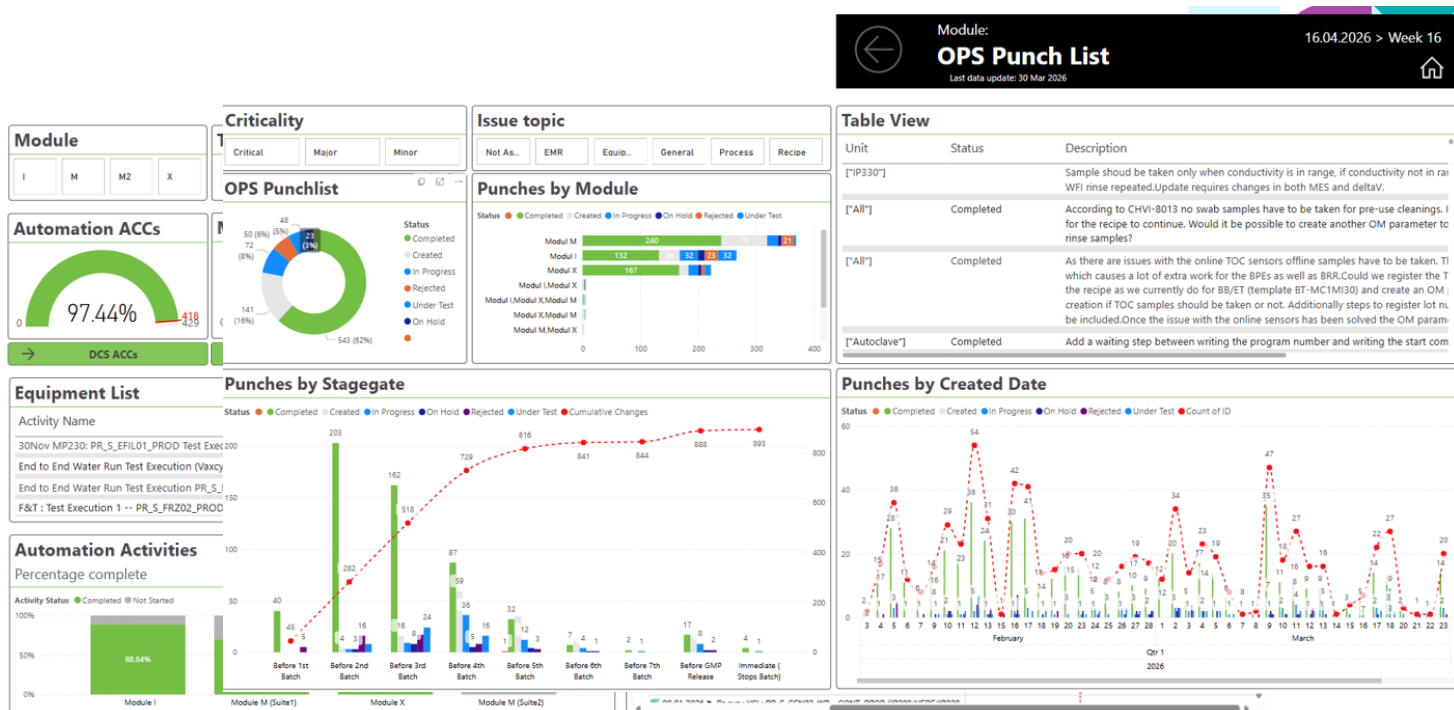
R Risk Matrix - Risks

Risk count - by probability and impact

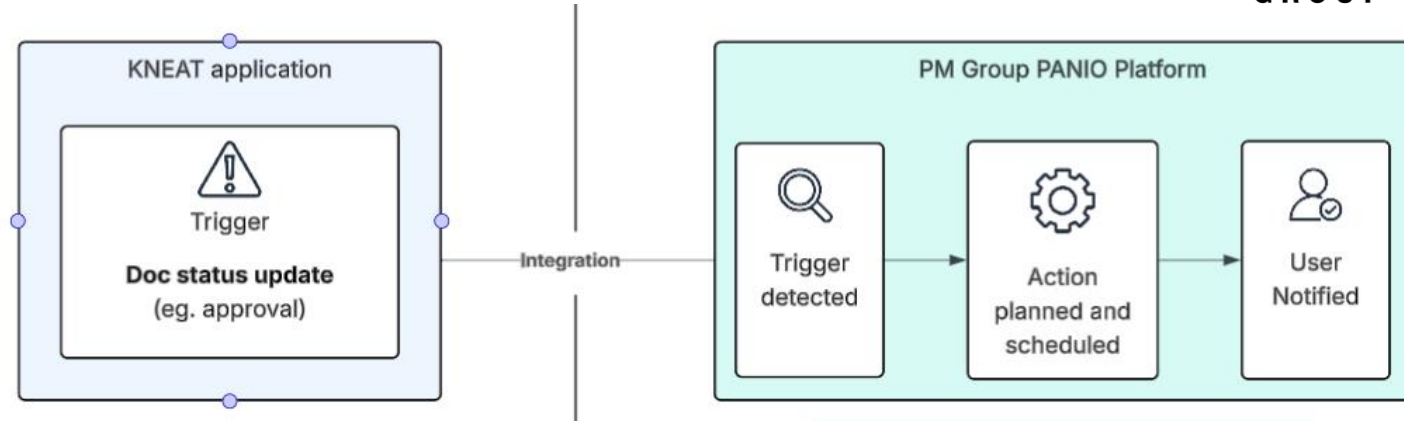
Likelihood	Header	1 Low	2 Medium	3 High	4 Very High	5 Extreme
1 Rare	0	0	1	0	1	
2 Unlikely	3	3	2	1	6	
3 Possible	7	2	10	8	7	
4 Likely	0	0	4	1	2	
5 Almost Certain	1	0	1	0	2	
Total	11	5	18	10	18	

Table 1 - New centrifugation process		14 - Tech Transfer Process											
Hover over to see details		Workstream											
ID	Title	Process / MSAT Lead											
		Discipline											
		Process Readiness											
		Category											
		Peters		(Blank)									
		Risk lead Lanza		Risk lead Vaxcyte									
2	Scale	14Aug2025: Results of PD runs show no issue with KI precipitation in terms of P5 quality or quantity. Risk to be closed. 3APR25: test ongoing in PD, 6 serotypes (5T3 was repeated); centrifugation of the KI precipitate went smoothly 28JUN24: tests ongoing in PD, 3 out of 5 serotypes tested, centrifugation for these went smoothly 25JAN24: An experiment is scheduled for process development, subsequently the development focus will be more on the continuous unit operations that are considered more challenging. Demo runs executed towards Q4 of 2024 will include up to 5 selected serotypes to demonstrate the pr...											
3	CPP	<table> <thead> <tr> <th>Type</th><th>Initially proposed Risk Response / Mitigation action</th><th>Type</th><th>Current risk Response / Mitigation action</th></tr> </thead> <tbody> <tr> <td>Mitigation</td><td>Vaxcyte (P. Davey) to perform test runs with their qualified down scale model</td><td>Mitigation</td><td>Carry out test runs in PD</td></tr> </tbody> </table>				Type	Initially proposed Risk Response / Mitigation action	Type	Current risk Response / Mitigation action	Mitigation	Vaxcyte (P. Davey) to perform test runs with their qualified down scale model	Mitigation	Carry out test runs in PD
Type	Initially proposed Risk Response / Mitigation action	Type	Current risk Response / Mitigation action										
Mitigation	Vaxcyte (P. Davey) to perform test runs with their qualified down scale model	Mitigation	Carry out test runs in PD										
4	New centrifugation process												
5	New centrifugation process												
		of PS Intermediate											
6	Microfluidizer (process)	As a result of changing the process from homogenizer to Microfluidizer there is a risk that sizing of PS differs from clinical production facility or that unforeseen technical issues occurs with this new equipment which would lead to different quality / quantity of PS or need for technical development.	end PQ	2	Open								
7	Initial buffer supply	As a result of a delayed start of the Buffer project there is a risk that the buffer supply to Vibe-X is not operating/ available on time which would lead to delay in commissioning/ production	end IQ	3	Issue (PCN)								
8	Cross	As a result of re-evaluation of risks by Swiss Medic to have different serotypes	end DQ	3	Open								

Punches and Changes



Periodic Review and Approval triggers



Live Prompts for Periodic Tasks- Integrations with Kneat & Scheduling tools allows PM Group Dashboards to trigger alarms for user against emerging reviews, re-qualifications & re-approvals.

- **Detect** triggers from external apps (KNEAT API).
- **Validate** events
- **Plan** actions using custom logic (rules, prioritization, dependencies).
- **Persist** planned actions with state tracking.
- **Notify** users with context-rich messages (email, Teams)
- **Track** execution and feedback (status updates, re-planning, audit logs).

Digital Factory and APIs

Diğer

[illegible]

Type	Stock																														
Available when required																															
	<table><tr><th>Component</th><th>Component Description</th><th>Stock</th></tr><tr><td>704583</td><td>Hy-Soy 11.34 KG</td><td>46,546.32</td></tr><tr><td>704585</td><td>CysL-HCl-H2O pH 1KG</td><td>3,971.59</td></tr><tr><td>704587</td><td>NaOH 5M 2.5L</td><td>5,412.15</td></tr><tr><td>704623</td><td>Deoxycholate-Na 1KG</td><td>4,101.89</td></tr><tr><td>704626</td><td>Fernstool, Manifold Parker, Typ E</td><td>702.00</td></tr><tr><td>704633</td><td>TUA-I-0.5"-1m-BB-TU</td><td>16,641.00</td></tr><tr><td>704635</td><td>TUA-III-0.375"-1m-GG-WS</td><td>3,230.00</td></tr><tr><td>704636</td><td>TUA-III-0.5"-1m-GG-WS</td><td>54,450.00</td></tr><tr><td>704637</td><td>TUA-III-0.5"-3m-GG-WS</td><td>17,064.00</td></tr></table>	Component	Component Description	Stock	704583	Hy-Soy 11.34 KG	46,546.32	704585	CysL-HCl-H2O pH 1KG	3,971.59	704587	NaOH 5M 2.5L	5,412.15	704623	Deoxycholate-Na 1KG	4,101.89	704626	Fernstool, Manifold Parker, Typ E	702.00	704633	TUA-I-0.5"-1m-BB-TU	16,641.00	704635	TUA-III-0.375"-1m-GG-WS	3,230.00	704636	TUA-III-0.5"-1m-GG-WS	54,450.00	704637	TUA-III-0.5"-3m-GG-WS	17,064.00
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Coverage with Stock																															
Release as planned																															
Reschedule to																															
Unplanned Coverage																															

Material Supply

Component Description	PO Placed	PO Confirmed	Quality Release Ready	Available Stock	First Category	VAX PO Number	Open Requirement
K2-HP04 ph EPBP SKG							
14165263							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG
14165264							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG
14165265							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG
14165266							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG
14165267							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG
14165268							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG
14165269							
13.12.2025	1	1	1	0	Pending quality release	POCH00131	0.03 KG



Module: **Material availability**

Last data update:

Available Stock

Availability Date	Initial Stock	UoM	Safety Stock	Component *
28.09.2025	10,738.03	KG	0	704740
31.10.2025	0.00	PC	0	705000
31.12.2025	0.00	KG	0	704732
04.01.2026	0.00	PC	0	705124
07.01.2026	0.00	PC	0	704782
07.01.2026	0.00	PC	0	705341
04.02.2026	1,538.21	KG	0	704623
09.02.2026	0.00	KG	0	704754
Total	7,577,315.32		0	



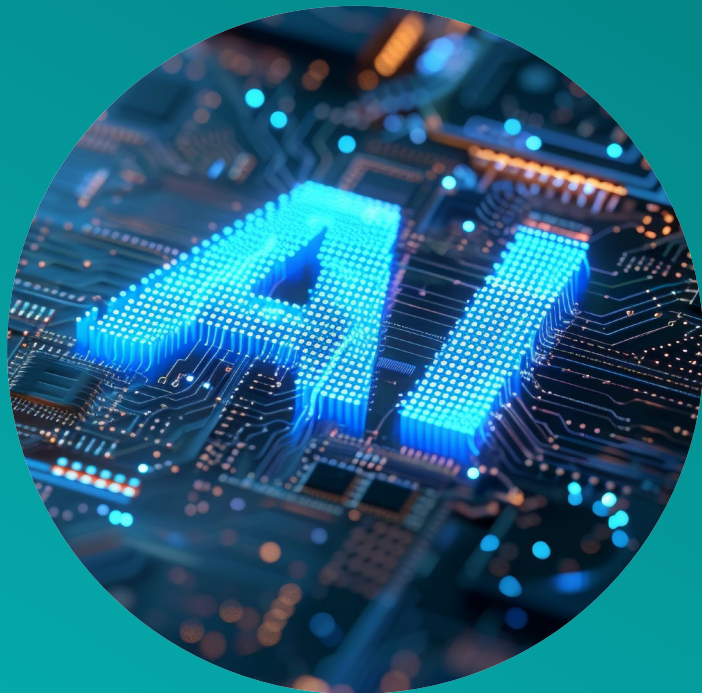
375K (23.8%)

13.42K (78.18%)

PO Overview					
Campaign	Product	Consumer	Requested Delivery Date	Vendor	Vendor Art. Description
ENG	PS	Module I	10.12.2025	Brunswick Chemie	SODIUM CARBONATE, 99.5%, ANHYDROUS, EXTRA PURE, CAS 497-19-8
GMP	PS	Module I	1.02.2026	Chemie Brunswick AG	Na-carbonat 25KG
GMP	PS	Module I	8.01.1900	Sartorius Stedim Biotech GmbH	FTU-III-0.2m2-0.2um-PTFE-0
GMP	PS	Module I	8.01.1900	Sartorius Stedim Biotech GmbH	FTU-III-0.2m2-0.2um-PTFE-0
GMP	PS	Module X&I	25.03.2026	Sartorius Stedim Biotech GmbH	FTU-III-0.2m2-0.2um-PTFE-0
GMP	PS	Module X&I	25.03.2026	Sartorius Stedim Biotech GmbH	FTU-III-0.2m2-0.2um-PTFE-0
GMP	PS	Module X&I	4.03.2026	Life Technologies BPD UK Ltd	TUA-III-0.5"-3m-GG-T8
GMP	PS	Module I	8.01.2026	Interlechnik Eize GmbH & Co. KG	TUA-XX-1-1.60-88-T8-CHV12
GMP	PS	Module I	8.01.2026	Interlechnik Eize GmbH & Co. KG	TUA-XX-1-1.60-88-T8-CHV12
Total					

Session 6.1

AI in Validation & Quality: What's Real, What's Next?



Moderator



Donal O'Sullivan
CPO, Kneat

Kneat

Panelists



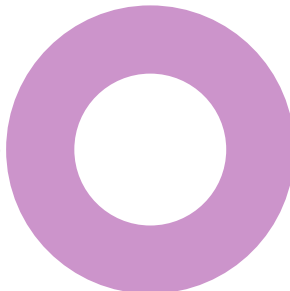
Emily Petrelis

Head of Site Facilities, Engineering
and Global Pharma Validation
Nestlé Health Science



Roisin Hickey

GMP Consultant
Qualirus



Dori Gonzalez-Acevedo

CEO & Founder
ProcellaRX



Phil Jarvis

CQV and Digital
Validation Manager Europe
No deviation



Session 6.2

Main Challenges Slowing Your Digital Validation (and How Top Teams Are Solving Them)



Panelists



Darragh Boyle

Manager, Consulting

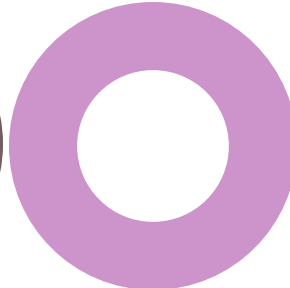
Kneat



Clare Hehir

CSM

Kneat



Andy Clarke

Director,
Customer Success

Kneat



Gisele Fahmi

Director, Content & Risk
Management
Solutions Lead,



Session Overview

"A panel-led, slide-light conversation shaped by your responses to our opening poll"

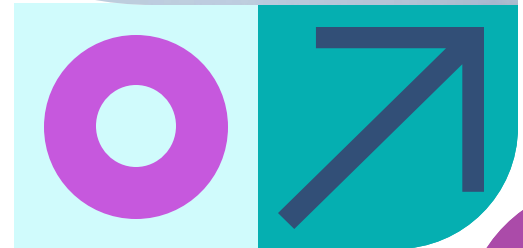
- **Poll Input:** Your responses define where we start
- **Panel Insights:** Guided by lived experience
- **Flexible Flow:** We follow the topics that matter most to you!



Poll

What is the biggest challenge slowing your Digital Validation rollout today?

- **A)** Scaling the solution
- **B)** Accelerating Go-Live / Launch
- **C)** Optimising Our Use of Kneat
- **D)** Global rollout strategy
- **E)** Knowledge / Training



Panel Discussion

Scaling Digital Validation



Scaling Digital Validation



Before scaling, do we have:

Validated process model

User roles and permission structure

Validation approach – what disciplines?



Understand what needs to be standardised vs. localised

Global: workflows, data definitions, system configuration, validation strategy

Local: site specific SOP, local regulatory add-ons, language, local risk assessments

Scaling Digital Validation



Creating a global governance model

Global process owner; digital validation steering committee; change control process; Site SME; Harmonised training model



Rollout

Site readiness assessment; Gap analysis; Hypercare period post go-live



Embracing Digital

Share success stories; create Communities of Practice

Scaling Digital Validation

2025 State of Validation: In your opinion, what are the leading benefits of digitalizing validation? Rank all answer choices in order of preference, with 10 being the highest.



Enabling global standardization:
Respondents place strong emphasis on **enabling global standardization** and **having a system of record**, highlighting a desire to harmonize validation processes and eliminate site-level silos.

Panel Discussion

Accelerating Go-Live



Accelerating Go-Live (Past Experience)

Highly specific
templates

No internal
communication

Lack of buy in –
preference for
other products etc.

Untrained access
to system

Accelerating Go-Live (Where we see Success)



RIGHT FIRST-TIME
TEMPLATES



STAKEHOLDER
ALIGNMENT – RIGHT
PEOPLE IN PLACE



COMMUNICATION
PLAN



SUPPORT STRUCTURE



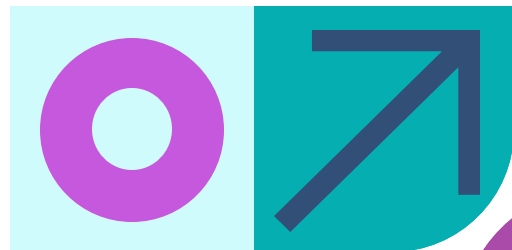
FUTURE PLANNING
(THINK OF NAMING)



TRAINING &
ONBOARDING



CONTROLLED
PERMISSIONS

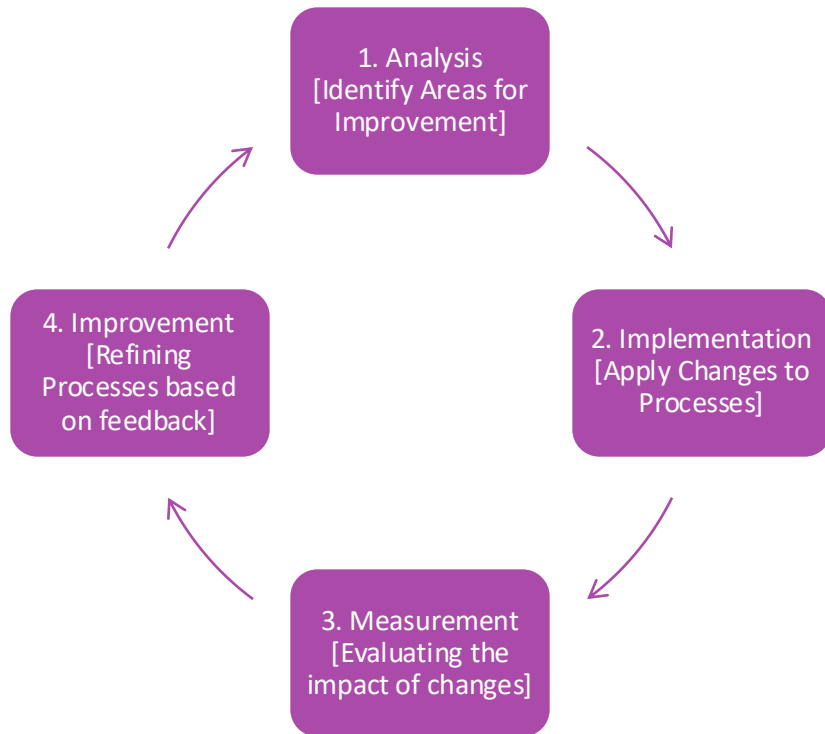


Panel Discussion

Kneat Optimization Strategies



Kneat Optimization Strategies



Optimization is a Continuous Cycle

Measure your improvements

Don't Stop There

Kneat Optimization Strategies

What does optimizing mean for you?

Early

- Deploying
- Establishing Governance
- Migrating

Maturing

- Harmonizing
- Optimizing Processes
- Expanding
- Connecting / Integrating

Prioritize the opportunity



Gather feedback from stakeholders



No “one size fits all”,



Don't boil the Ocean



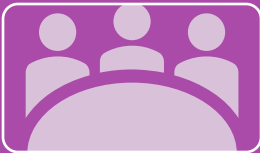
Kneat Optimization Strategies

Key Success Factors



Have a Success Plan

- 5W1H: What, Who, Where, When, Why, How?
- Document it, agree it and communicate it



Identify the Team & Execute

- Engage Key Stakeholders, early and often
- Ensure the right Kneat Expertise



Measure the Success

- How successful was the optimization
- Were goals from the success plan achieved



Continue to Improve & Enable

- Establish improvement processes
- Seek continuous feedback
- Enable Users

Panel Discussion

Global Rollout Strategy



Operationalising Global Kneat

Success is embedding Kneat as the global validation operating model

- **Key Challenges:**

- Kneat is "Live" but not yet operationalised
- Strong process at pilot site but weaker globally
- Sites using it differently
- Templates not standardised
 - updates become laborious and difficult to manage
- Benefits not fully realised
 - speed and consistency

Operationalising Global Kneat

Success is embedding Kneat as the global validation operating model

- Supporting users in different regions and time-zones
- Ability to triage what is application question from a useability question
- Upgrade Support and Roles

Operationalising Global Kneat

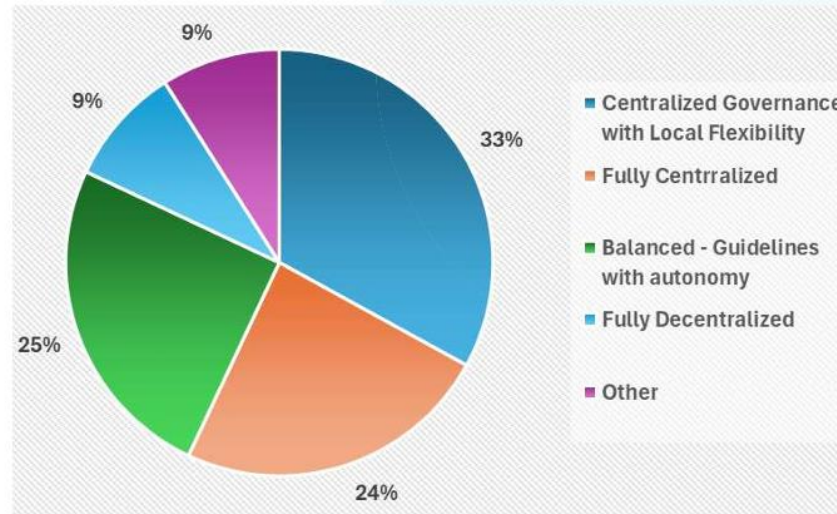
Success is embedding Kneat as the global validation operating model

- Centralised IT Support
- Standardised Validation approach
- Global Templates
- Governance
 - Global Business Owner
 - Global System Owner (CSV Owner, CQV Owner, CV Owner)
 - Global IT Owner

Operationalising Global Kneat

2024 State of Validation Report: Governance

Q: Do you have a global approach for governance of the digital validation system, or do you let sites configure the system to their specific needs?



Panel Discussion

Knowledge/ Training



Knowledge / Training

- **Kneat Academy**
- Standardised training courses covering the fundamentals of the application across all user levels.
- Data reporting enables our customers to track training levels, consumption rates, version control which provides 360 view on user competency levels – critical for platform user uptake.
- Simulated platform - Access End User training at your own convivence, progressing through as your workload permits.
- Reduction in duration of End User course (2026 = 4 hours)
- Number of languages provided (Audio translation included from June 2026)
- Kneats extensive partner network facilitates extensive reach, including time-zone, onsite, and process specific training etc.

Knowledge / Training

- **New Booking Form**

- New User-friendly simplified booking process – [Form](https://Kneat.com/academy/academy-booking-form/) (Kneat.com/academy/academy-booking-form/)
- Automation – example - users can be locked to specific versions

- **E-Learning Courses**

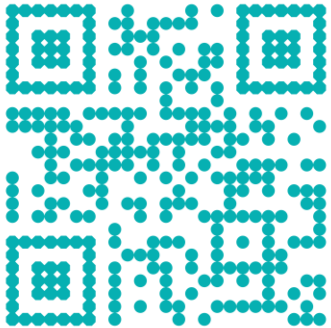
- Review & Approval training – 10 minutes
- Administration training – 30 - 40 minutes
- Entities Training – 2 hours
- End User - 4 hours (2026 End User – April 2026)
- Plus an additional optional “Advanced” module (May 2026)

- **Instructor Led Training Courses**

- Review & Approval training – 10 minutes
- Administration training – 30 - 40 minutes
- Entities Training – 2 hours
- End User - 4 hours (2026 End User – April 2026)
- Plus an additional optional “Advanced” module (May 2026)

Have you signed up?

Kneat's **Free Health Check** can baseline your process against industry best practices and provide a roadmap for optimized performance



Session 7.1

Driving Cost Reduction for C&Q Capital Projects with Digital Validation

Patrick Mullin | Sanofi



Driving Cost Reduction for C&Q in Capital Projects with Digital Validation

Patrick Mullin

The views and opinions expressed by the speaker are their own and should not be attributed to their employer.

Presentation Topics

Act 1: Capital Context

Act 2: Core Problem in CQV

Act 3: Interpretation and Translation

Act 4: Measurement

Act 5: Digital CQV

Act 6: Structured Data

Act 7: Future Trajectory

Act 8: Capital Impact

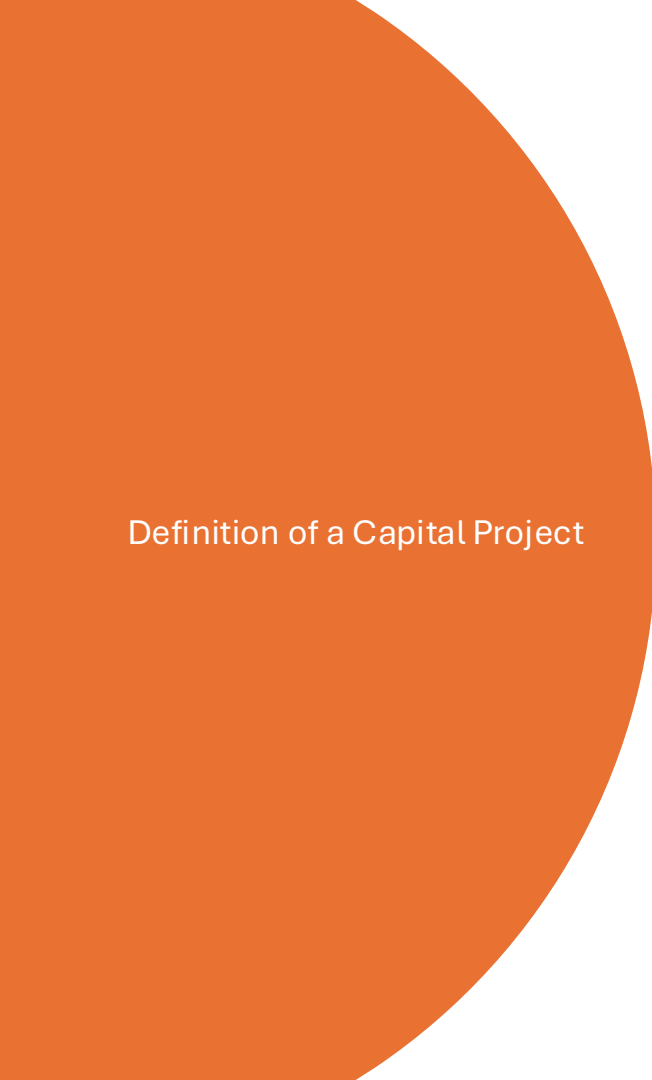


Act 1 – Capital Context

Core Message:

CQV Operates within a larger capital delivery system

**CQV Project Costs
= Baseline Effort + Interpretation + Rework**



Definition of a Capital Project

A Capital project is a long-term capital investment intended to build, add to, or improve a capital asset characterized by its large scale and high-cost relative to other investments.



How Big are Modern Mega Capital Projects?

J&J \$2 B build in Wilson, NC

Lily \$27 B across 4 mega sites

Amgen \$1 B in Holly Springs, NC

Sanofi \$2.5 B for Insulin production in
Germany and China

Sanofi \$1 B in Vitry-sur-Siène

Novo Nordisk \$4.1 B in North Carolina

Capital Project Structure: Engineering



Feasibility



Basic Design



Detail Design



Construction



Startup and Commissioning



Qualification



Validation

Industry Benchmark: Capital Project Schedule

Schedule Duration as % of Total Project Duration			
	Low	Average	High
Basic Design	8	10	12
Detail Design	17	24	33
Construction	40	55	61
Startup and Commissioning	18	22	30
Qualification	13	16	21
Validation	3	4	5

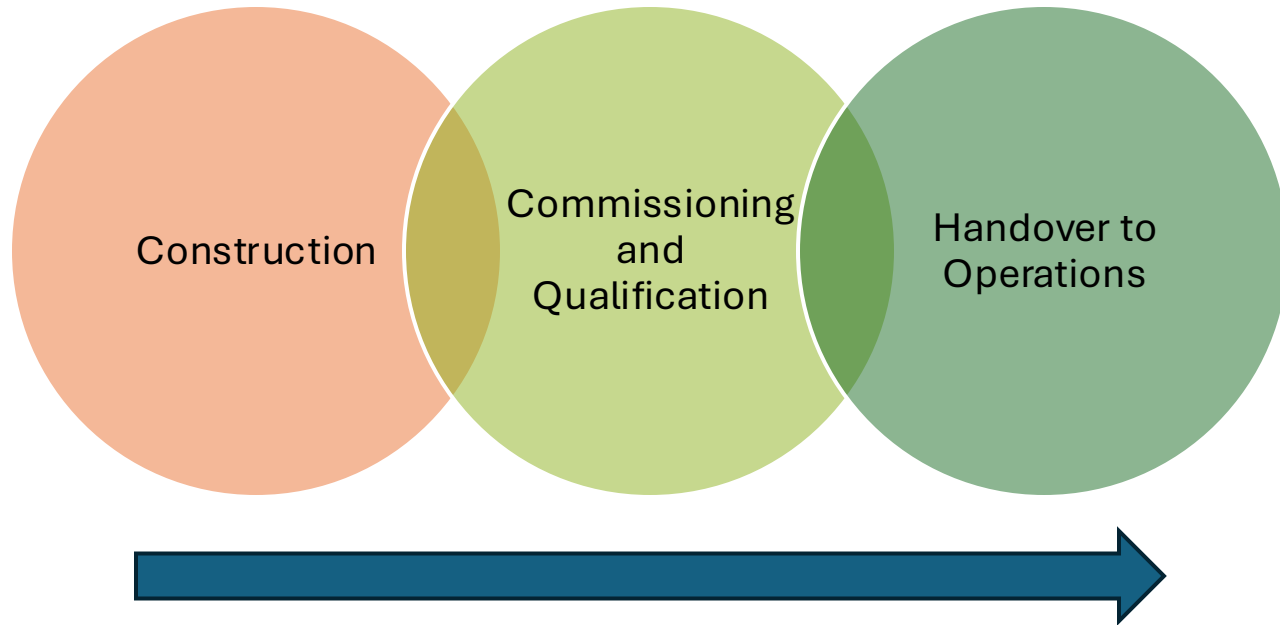
- [How data can improve pharmaceutical construction project performance | Turner & Townsend \(turnerandtownsend.com\)](https://turnerandtownsend.com)

Industry Benchmark: Capital Project Costs

Cost as % of Total Project Cost			
	Low	Average	High
Engineering	5.5	12	25
Construction Management	3.5	12.5	24.5
General Conditions	0.5	4.5	12.5
Process Equipment/Piping	15.5	30.5	43.5
Clean/Process Utilities	1	5.5	18
Mechanical/Electrical/Plumbing (MEP)	3	7.5	17.5
Civil Structural/Architectural	4.5	13.5	32.5
Automation	1	3	10
Commissioning and Qualification	.5	4	11
Electrical and Instrumentation	1	6.5	11.5

- [How data can improve pharmaceutical construction project performance | Turner & Townsend \(turnerandtownsend.com\)](https://turnerandtownsend.com)

Typical Construction and C&Q Workflow



Typical C&Q Digital Savings



DIGITAL CONTENT

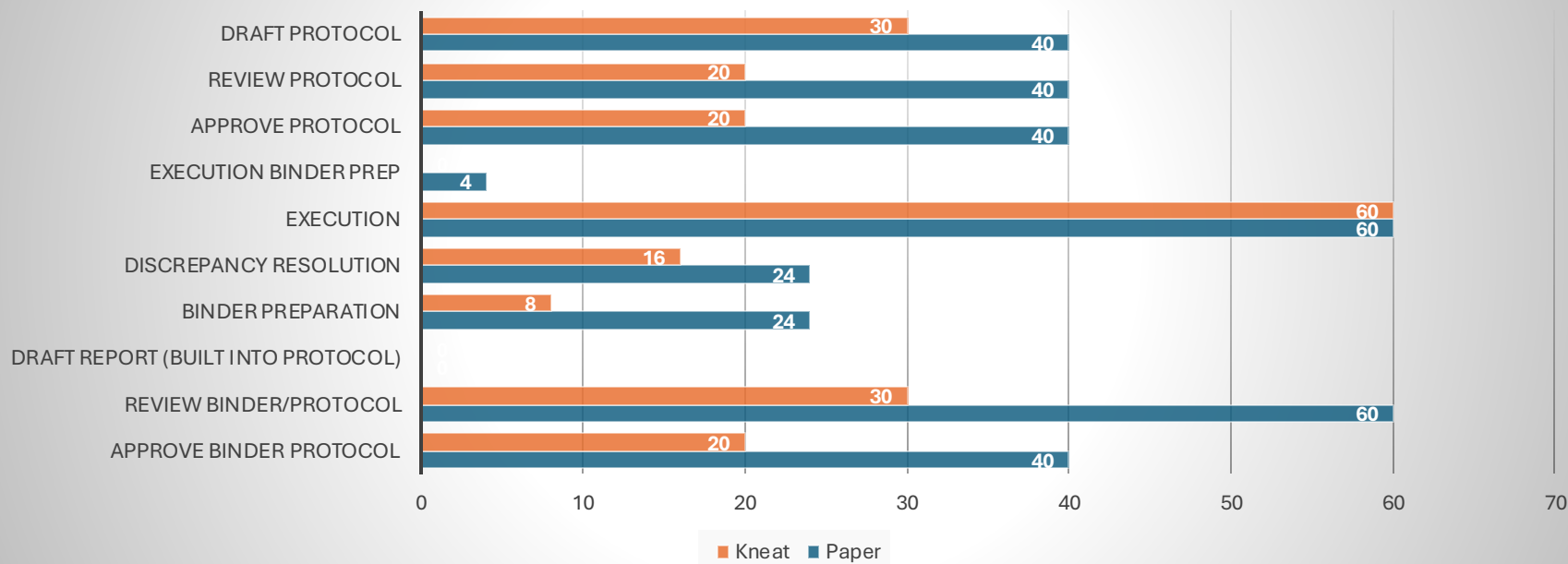


DIGITAL EXECUTION

C&Q Savings Using Kneat

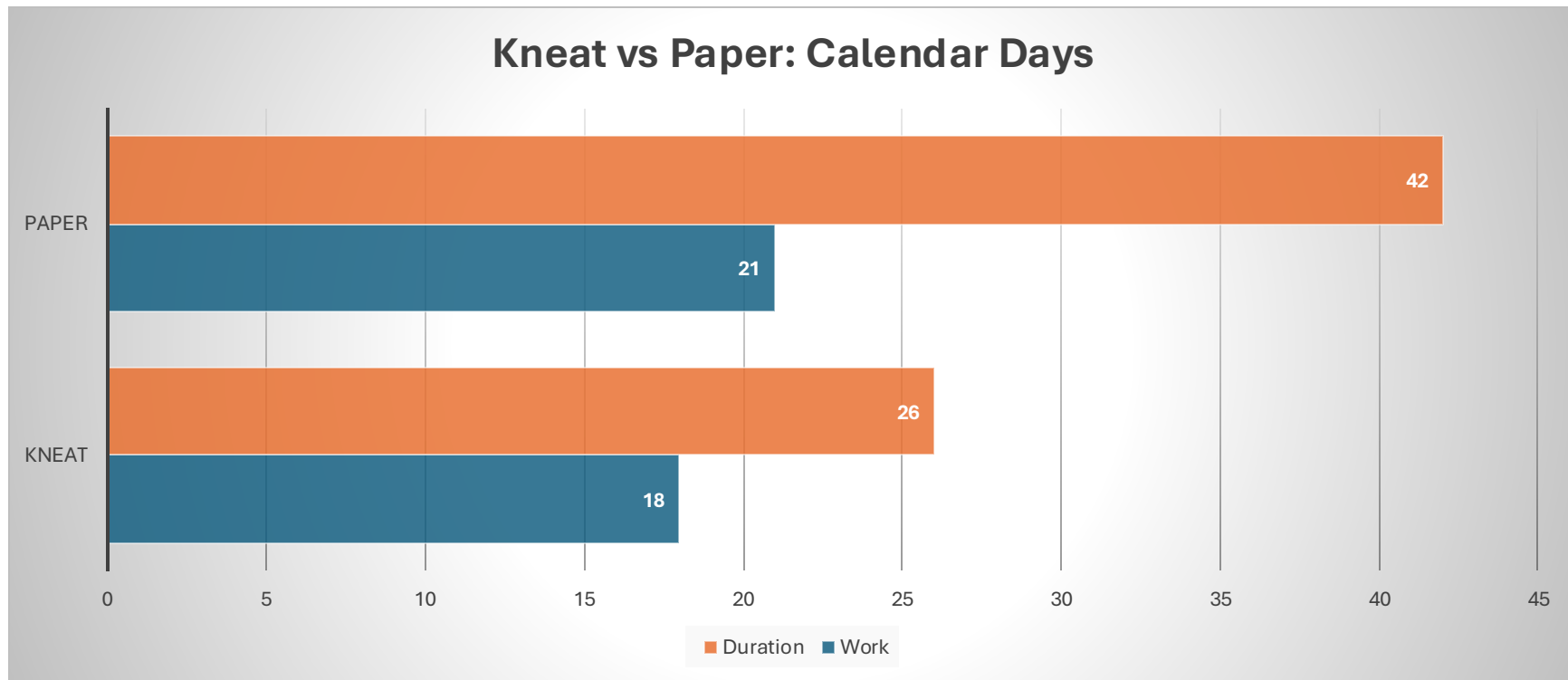
Comparison

Kneat vs. Paper Comparison (Calendar Hours)



C&Q Savings Using Kneat

Comparison

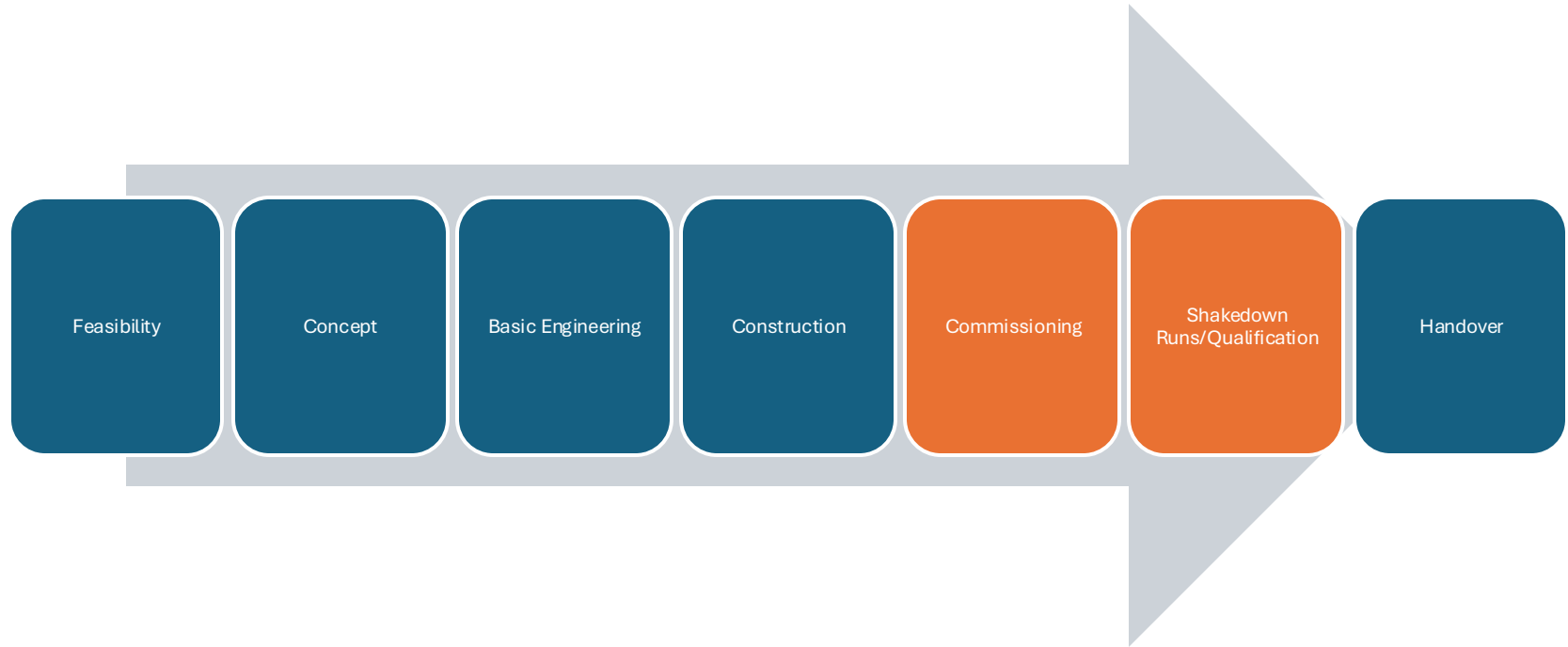


Typical C&Q Digital Savings Over Time

Content	Paper	2019	2022	2025
Complex Equipment Protocol	50-60 hours	30-40 hours	10-15 hours	< 4 hours
Protocol Clone	5-10 hours	< 5 hours	< 2-3 hours	minutes



Typical Engineering Project Workflow



Typical C&Q in Engineering Digital Savings



Integrated documents
Across Engineering Lifecycle
and C&Q Documents



Digital Leveraging Strategies



Digital Engineering Change
Management

Typical C&Q in Project Management Digital Savings



Pacing with Construction

Where are future digital C&Q Savings?



Steering Committee



Project Management



Engineering



Quality



Finance

Meet Project Controls



Project Controls

“All Commissioning and Qualification activities supporting large Capital Projects must be digitized.”

Act 2 – Core Problem in CQV

Core Perception:

“Why is CQV always late and over budget?”

Core Message:

CQV reveals issues late in the project lifecycle, and it is this timing that drives rework, cost, and schedule amplification.

CQV Project Costs
= Baseline Effort + Interpretation + Rework

CQV Occurs at the Point of Integration

- CQV is where systems are tested together and real performance is confirmed.
 - Design and construction is complete
 - Automation is deployed
 - Testing happens under real conditions across disciplines





CQV and Late Discovery

- When issues are discovered late, the resulting rework drives cost and schedule amplification
 - Issues are identified only at execution
 - Resolution requires investigation, correction, and retesting
 - Work already completed may need to be revisited
 - Impact increases as the project approaches completion

Is Protocol Centric Enough?

- Protocol Centric CQV – paper based or digital – performs well as an expression of ISPE Baseline Guidance for Commissioning and Qualification, or Annex 15, and others.
- The pace of today's capital projects, and the tolerance for issues discovered in CQV, is demanding that we do more, faster, and with less.
- Can we do better?



Act 3 – Interpretation and Translation

Core Message:

Interpretation is a major embedded component of CQV work.

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Interpretation as Digital Topic of Interest

- Recent AI partnered workflows demonstrate that interpretation effort can be reduced
- Separating interpretation from baseline effort and rework is the first step in applying new digital technologies in CQV



CQV Work Includes Significant Interpretation

- MSAT translates scientific conclusions into therapeutic promises.
- Engineering translates business needs into technical solutions
- CQV Translates technical solutions into a compliance solutions
- **Interpretation and translation in Biotech and Pharma is our foundational activity.**



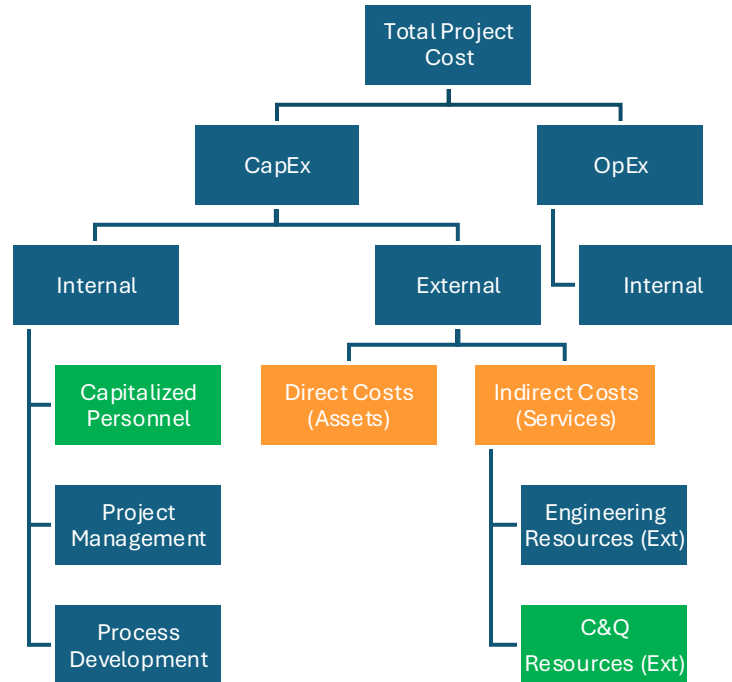
Act 4 – Measurement

Core Message:

Earned Value Management (EVM) is the key approach that successful project managers and project controls professionals use to assess the health of a project.

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Project Controls Finance Hierarchy (Simplified)



Patrick's Metrics for Project C&Q

- Total Cost of C&Q as a Percentage of a Project's Direct Costs
- Cost per Protocol



C&Q Savings in Project Controls

- Benchmarking Resources
- Monitoring Execution Progress
- Performance Comparisons Across Projects
- Evaluating the strength of a C&Q services proposal

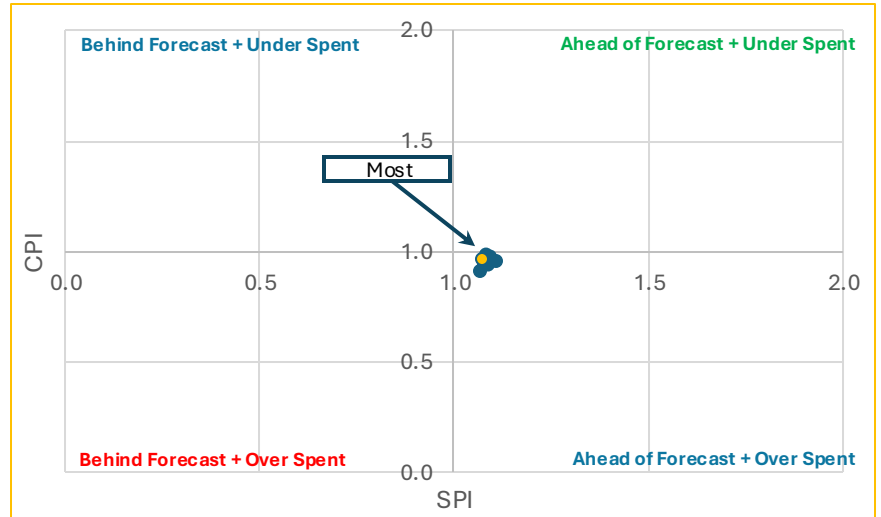
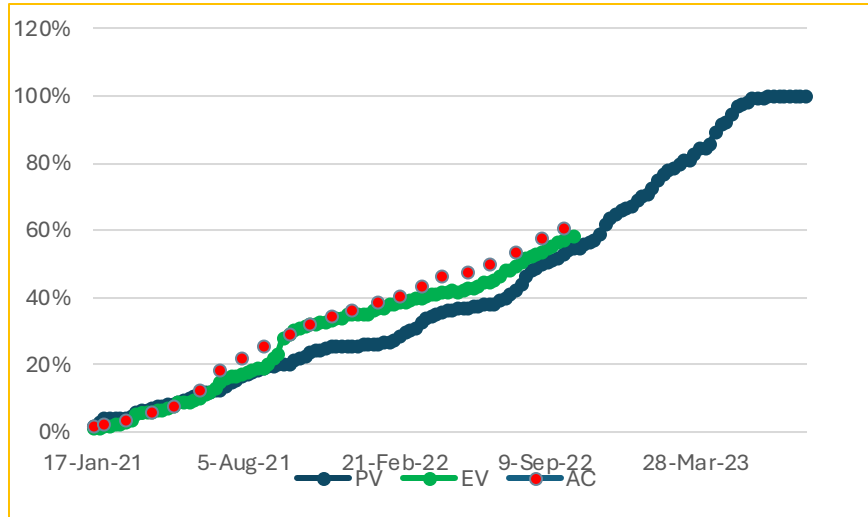


Benchmarking Resources

- “How long will it take to commission and qualify these assets?”
- Project Management wants to know how long.
- Project controls wants to know how many resources.

Resources Required	21 +												
	20												
	19												
	18												
	17												
	16												
	15												
	14												
	13												
	12												
	11												
	10												
	9												
	8												
	7												
	6												
	5												
	4												
	3												
	2												
	1												
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	
Work Hours	168	152	168	176	176	160	176	176	160	176	152	168	
Total Hours	168	320	488	664	840	1000	1176	1352	1512	1688	1840	2008	
# Resources	42	22	14	11	8	7	6	5	5	4	4	3	

Monitoring Progress – Earned Value Analysis



Act 5 – Digital CQV

Core Message:

Digital CQV improves execution structure and visibility

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Digital CQV Today

- We have come a long way in a few short years
 - Paper to Glass
 - Templates and Libraries
 - Reuse and Cloning
 - Rigid Data Integrity Rules
 - Inspection Readiness
- **Key Message:** Digital CQV has improved execution and enabled reuse, reducing both variability and baseline effort.

Act 6 – Structured Data

Core Message:

Structured data reduces interpretation at its source

CQV Project Costs
= Baseline Effort + Interpretation + Rework

What is Structured Data?

- In a CQV context, structured data means capturing key information – in structures called entities in Kneat – in a consistent and reusable format.
 - The original intended use of entities was to facilitate retrieval and sharing of data across a lifecycle workflow – and to report out on the qualified state of a system or process.
 - In a new development, driven by AI, structured data can also be used to facilitate and significantly reduce interpretation in the CQV space.



Example of Structured Data In Use

Structured Data (Entities)

- System
- Equipment
- Requirement
- Test Case
- Risk

Interpreted Data

- User Requirements
- System Impact Assignment
- System Risk Classifications
- Execution strategies

Generated Outputs

- URS
- SIA/SRA
- Protocol/Reports
- Trace Matrixes

How Structured Data Reduces Typical AI Limitations

- Gen AI is effective at interpreting information, but its reliability depends on how the information is structured and provided.
 - Context limitations can lead to drift across long workflows
 - Information is often stored in documents or images – not structured formats – and is subject to additional layers of interpretation
 - Retrieval across multiple documents can be inconsistent
 - Output clarity depends on clarity and consistency of inputs



Machine Readable Content Enables Consistent Interpretation at Scale

- Machine readable formats make structured CQV data directly usable across systems, enabling consistent and repeatable interpretation.
 - Human readable documents require repeated interpretation
 - Machine-readable formats preserve structure and relationships
 - Enables consistent generation and reuse of CQV content



Act 7 – Future Trajectory

Core Message:

Interpretation becomes increasingly compressible

CQV Project Costs
= Baseline Effort + Interpretation + Rework

From Document Centric to Data Centric

- In review, CQV today is now evolving from document centric to data centric workflows built on structured lifecycle information.
 - Documents become outputs, not primary work products
 - Lifecycle data drives requirements, risk, and testing
 - Interpretation, now separated from the baseline CQV work product, is now highlighted as a significant cost saving opportunity.



Impact to Capital Projects

- A data driven CQV model, empowered with digital interpretation strategies, enables more consistent, efficient, and predictable project delivery.

- More consistent document generation across the lifecycle
- Reduced duplication and rework
- Improved alignment between design, risk, and testing
- Shortened, and more predictable, baselines



Act 8 – Capital Impact

Core Message:

Evolving CQV data structures enable meaningful cost reduction

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Two Paths When We Thought There Was Only One

2025:

Reporting-Focused
Adoption of Structured
Data

- Data lakes, Dashboards
- Improved Visibility and Tracking
- Better Reporting
- Limited Cost Improvements

2026 and beyond:

Managed Interpretation
with Structured Data

- Interpretation captured once and reused
- Lifecycle documents generated from structured inputs
- Reduced duplication and inconsistency
- Improved baselining and execution

A wireframe robot in a blue-tinted, digital style is shaking hands with a person in a dark suit. The background is a blurred cityscape at night with bokeh light effects. The robot's body is composed of a grid of lines, and its head has a circular sensor on the side.

Driving Down Cost in Capital Projects

- CQV cost reduction depends on how we structure and manage the work – not just how we execute it.
- Today: Protocol Centric CQV (Digital)
 - Interpretation repeated across the lifecycle
 - Limited data extraction
 - Limited alignment with measurement (EVM)
 - **Outcome: 5-7% of direct project cost**
- Incremental Improvement with Data Centric Only Approach
 - Entity enabled elements
 - Better data available for reporting and dashboards
 - Improved visibility (e.g. real time RTM tracking)
 - **Outcome: 4-5% of direct project cost**
- Structured Data and Managed Interpretation
 - Interpretation captured once and reused
 - Machine-readable lifecycle data
 - Consistent AI document generation
 - Improved baselining and execution
 - **Outcome: 3-4% of direct project cost**

Questions:



T₁

H₄

A₁

N₁

K₅

S₁

Session 7.2

How Alcon Utilizes Kneat as a Catalyst for Harmonization





How Alcon is Using Kneat as a Catalyst for Harmonization

April 2026

Nathan Raschke

Sr Manager, Analytical
Science and Technology –
ASPEX and FWN

Daniel Weingand
Manager, Analytical Science and
Technology – GWS

Alcon
SEE BRILLIANTLY





Agenda

- Alcon Background
- Problem Statement
- Approach/Work
- Outcome/Future
- Q&A

Alcon Background

***a** legacy **of** innovation*



Alcon's over *75-year history* of success rests on a foundation of industry expertise, leading brands and a winning mindset.

We aspire to lead the world in innovating *life-changing vision* products because when people see brilliantly, they live brilliantly.

We are an *innovation leader* with 1,800 dedicated Research and Development (R&D) associates, more than 100 projects in our development pipeline, and one of the *largest R&D commitments* in the market. In 2023, we invested over \$828 million in R&D.

Our legacy is rich with *industry firsts*. We rely on and value strong customer relationships. Our future will build on that record.

Alcon

Positioned #1 or #2 across product categories

Surgical

Implantables

Consumables

Equipment/Other

Vision Care

Ocular Health¹

Contact Lenses²

Key Brands

Clareon. PanOptix.
IOL

Clareon. Vivity.
IOL

Clareon. Monofocal
IOL

HYDRUS[™]
MICROSTENT

Alcon
CUSTOM PAK



INTREPID[™] PHACO TIPS

CENTURION[™]
VISION SYSTEM

constellation[™]
VISION SYSTEM

SMARTCataract

LEGION

ARGOS[®]
with Image Guidance by ALCON[®]

wavelight

Systane[®]
LUBRICANT EYE DROPS

Pataday.



OPTI-FREE

CLEAR CARE

rocklatan[™]
(netarsudil and latanoprost
ophthalmic solution) 0.02%/0.005%

rhopressa[™]
(netarsudil ophthalmic
solution) 0.02%

EYSuVIS[™]
(loteprednol etabonate
ophthalmic suspension) 0.25%

DAILIES
TOTAL 1[®]

PRECISION 1[®]

TOTAL 30[®]
ONE-MONTH-REPLACEMENT CONTACT LENSES

2023
Sales

\$1.7B

\$2.7B

\$0.9B

\$1.6B

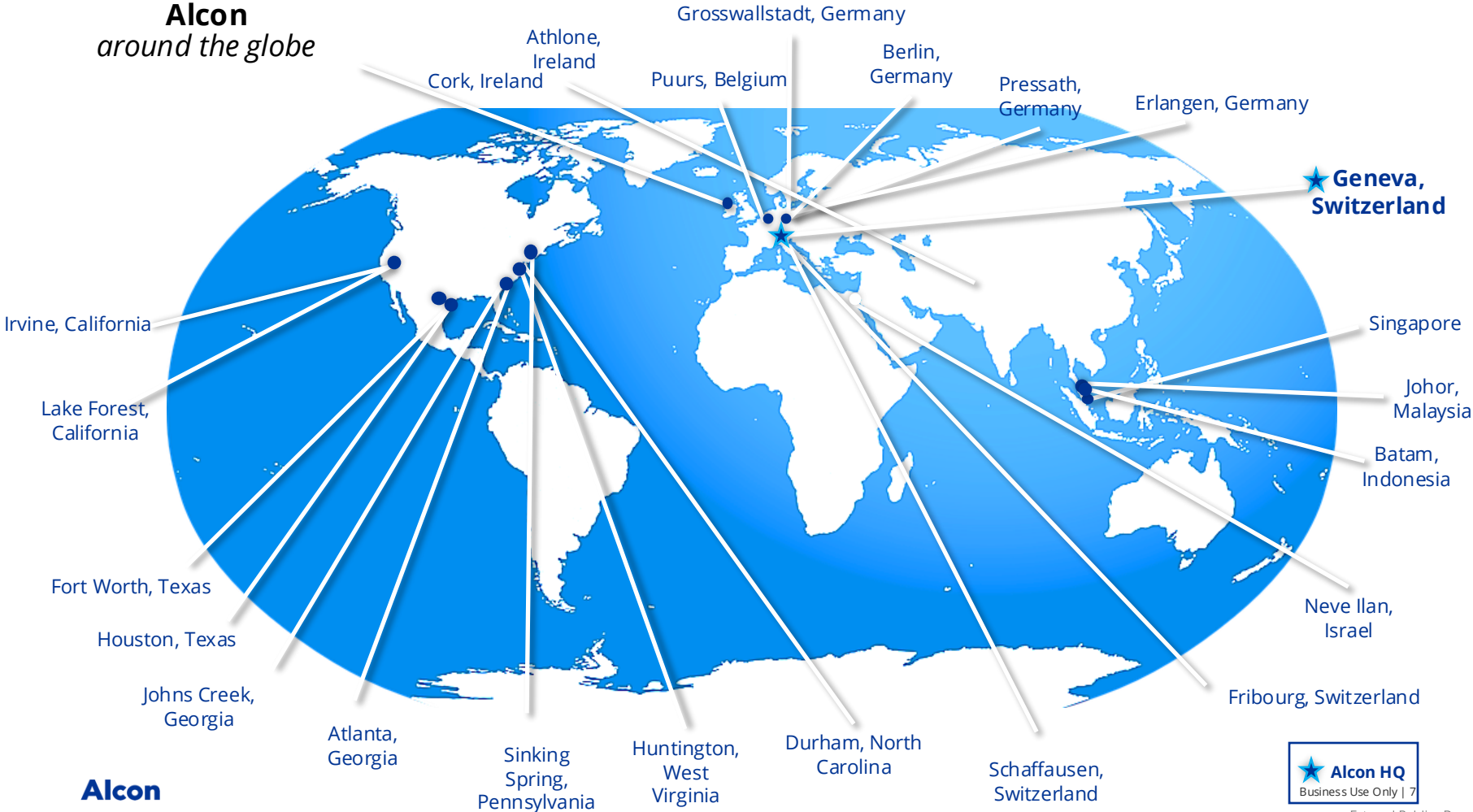
\$2.4B

1. Market position excludes Rx.

2. #2 in branded contact lenses; excludes private label and myopia management solutions.



Alcon
around the globe





Mission & Objective

Build Roadmap to Digital Lab



Data Lifecycle Management

Analyzing for Continual Improvement
Smarter - Faster - Better



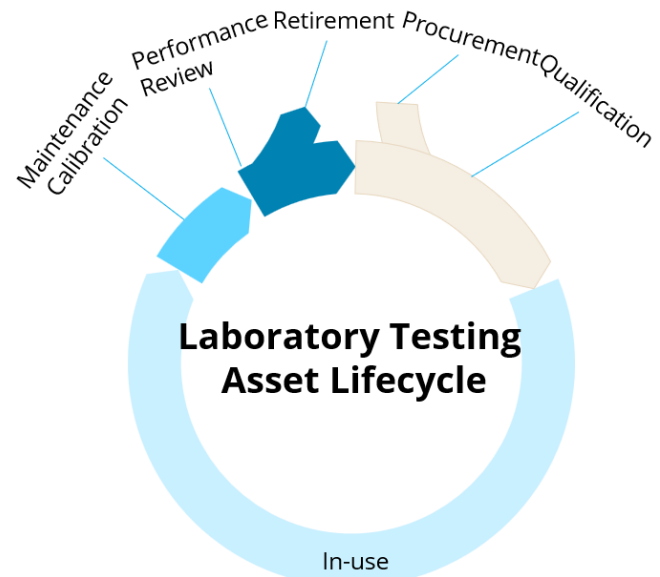
Steps within the Qualification Phase of the Asset Management Lifecycle



Lab Testing Assets

Life Cycle Phases

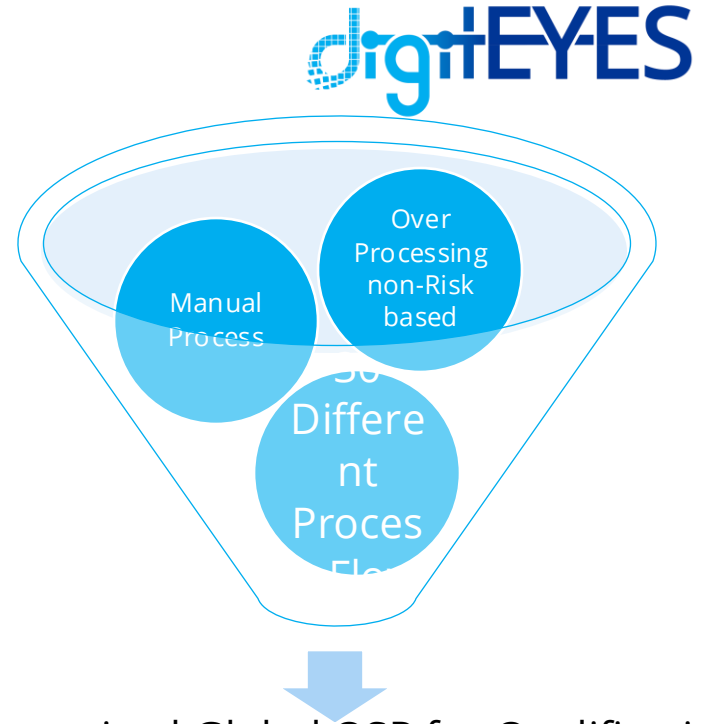
- Procurement
- Qualification
- In Use
- Maintenance
- Performance Review
- Requalification
- Retirement



Problem Statement

Problem Statement

- Many different business processes
 - Definitions
 - Roles and responsibilities
 - Approval process
- Differing interpretation of regulations by site
- Manual Process
 - No standard template
 - No Electronic tool



Harmonized Global QSP for Qualification
& Maintenance phases of the Labs Asset
Management Lifecycle

Solution and Approach

Kaizen

- Goal: One Alcon business process that satisfies the regulation with no overwork.
 - Common interpretation
 - Lexicon/Language
 - Process Map
 - Pain Point Identification
 - Establish Templates
 - Deploy Tool

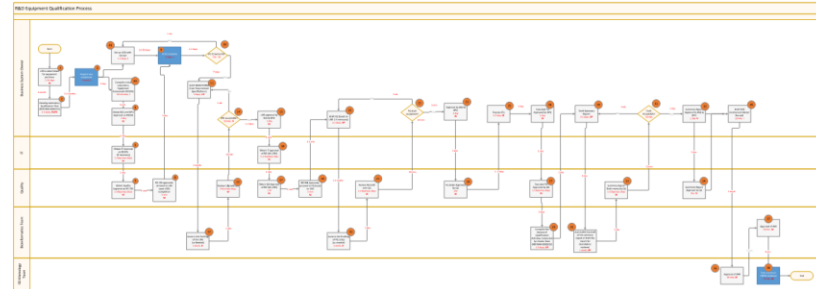
Alcon around the Globe with 14 Sites Participating



Kaizen Event - Step 1 Current State Analysis



- Analyzed end-to-end **current state process maps** for each function/site
- Captured **process element** waste type, value contribution & completion time, and **wait time** between elements



Kaizen Event – Step 2

Pain Point Analysis



Identified & categorized pain points with potential solutions

- Identified 117 Pain Points in Qualification
- Identified 47 Pain Points in Maintenance
- Brainstormed 419 potential solutions!

Kaizen Top Pain Points

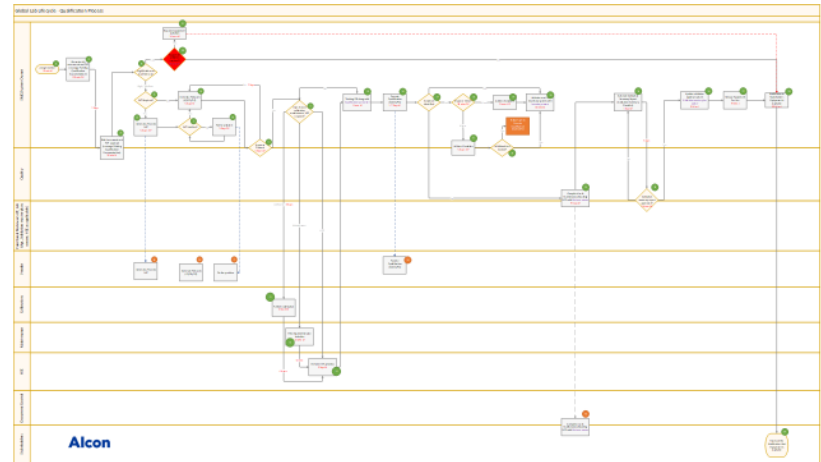
- Procedure inadequate
- Complex forms
- Electronic system needed

Kaizen Event – Step 3

Development of Future State



- **Developed & integrated end-to-end future state process maps** from each function
- **Examined potential improvements** addressing waste type, value contribution & completion intervals
- **Analyzed Outcomes**
 - Reduced process element & wait times
 - Improved process element outcomes

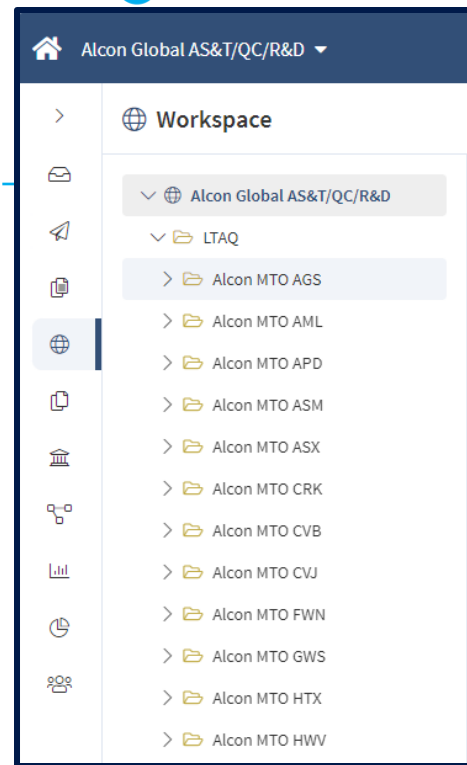


Action Plan

- Publish Quality System Procedure and Template Design
- KNEAT Build process
 - Timing was simplified due to harmonized process
- Template Permissions/User Access

Use KNEAT as Electronic system to support the harmonized process

- Develop
- Implement
- Adopt



Outcome

Waste elimination

- Number Approval
- Physical movement - Risk of loss or missing
- Wait Time

Measured Benefits

- Overall Reduction in Time: 54.2%
- Total Save Time: 100 Days
- Value Added Efficiency: 22%

Ongoing Maintenance

- Global Network
- Procedure and Template Updates
- License Distribution

Lessons Learned

- Roll out with sites and changes
- Financial impact not accounted for
- When to engage site functions (QA, Users, Finance)
- Up front work with down stream payoff.

Next Steps

- Expansion to Method Validation Life Cycle
- Partnering with KNEAT for Product Enhancement
- Interface with other Lab Systems



Q & A

Session 8.1

Digital Validation at Eli Lilly

Jeff Denault | Eli Lilly



Kneat Gx for Analytical Instrument Qualification (AIQ)

Validate 2026, Dublin, Ireland

**Jeff Denault, Ph.D.
Eli Lilly and Company**

Agenda

01 Analytical Instrument Qualification (AIQ)

02 Kneat Deployment

03 Kneat Multi-Execute Test Documents

04 Kneat Folder Structure

05 Kneat Entities

Eli Lilly and Company



Founded 1876

Pharmaceutical chemist Eli Lilly; HQ Indianapolis, IN; offices in 18 countries, products sold in ~125 countries



50,000+ Employees

Global leader in diabetes, obesity, oncology, and immunology therapeutics



World's Most Valuable Pharma

First healthcare company to reach \$1T market cap (Nov 2025). Ranked #4 by revenue among biomedical companies



Expanding Pipeline

Growing oncology and immunology portfolios; oral GLP-1 orforglipron submitted in US and 40+ countries



Manufacturing Investment

Expanding global capacity with new facility builds to meet growing demand across therapeutics



Eli Lilly Manufacturing Sites - 2019

 Existing Sites



Eli Lilly Manufacturing Sites - Today

■ New/Planned Sites ■ Existing Sites



Analytical Instrument Qualification (AIQ)

Project Team

Leadership



**Joseph
Heyward**



**Jeff
Denault**

Quality & Compliance



**Theresa
Nieto**



**Ashlee
Brommer**

IT & Systems



**Keith
Parsons**



**Josh
Ellis**

Site Implementation



**Stephanie
Ligoci**



**Surbhi
Shelar**



**Heidi
Studebaker**



**Chris
Howe**



**Josh
Ellis**



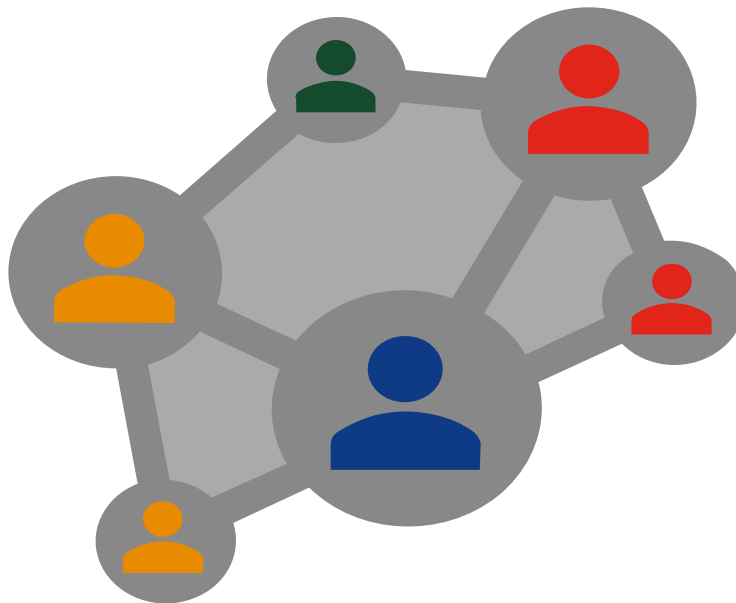
**Rob
Walker**



**Rob
Gleeson**



**Amanda
Austerman**



Analytical Instrument Qualification Standardization

GOAL



Standardize QC lab instrument qualification using Kneat templates and electronic documentation

Qualification of the same instrument using the same qualification package

Global validation of instrument application software for replicate deployment

HOW



Create a reusable deployment model to maximize efficiency at each site

Standardize key process points while leveraging naturally variable elements

Global Design Qualification, Vendor Evaluation, Qualification Plan, Multi-Execute Documents, CSV Requirements, Test Cases

WHY

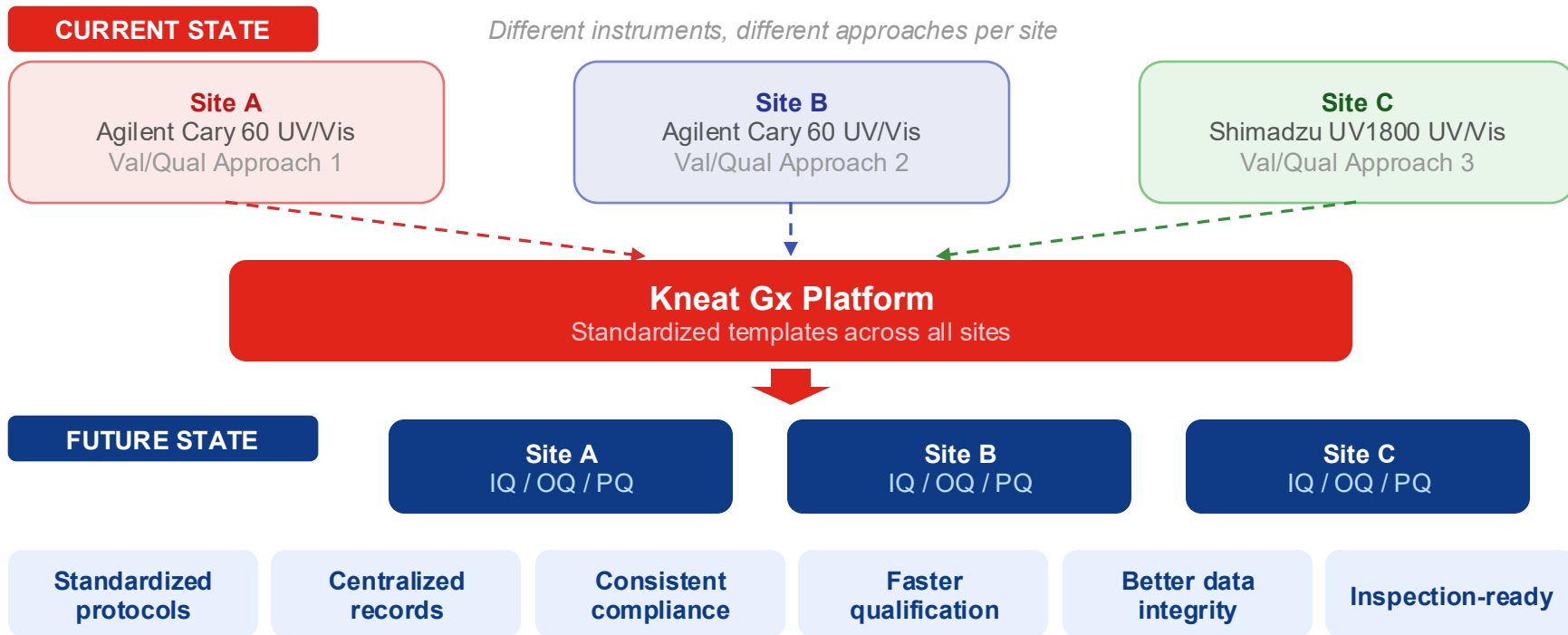


Advance operational excellence to support seamless, scalable network expansion

14+ new manufacturing sites (2020 forward)

New Lab Execution System

One Platform, One Standard: Global AIQ Through Kneat



Standardization and Electronic Documentation

Standardized Protocols

Harmonize Qualification Plans and test documents, IQ, OQ, and PQ, across all sites for consistent global execution

Centralized Records

Consolidate all qualification documentation into a single digital platform, eliminating paper-based records and scattered file systems

Consistent Compliance

Enforce uniform compliance standards across all sites through standardized templates and automated validation controls

Faster Qualification

Standardized documentation and workflow eliminate design rework. Pre-approved test documents minimize review and approval cycles.

Better Data Integrity

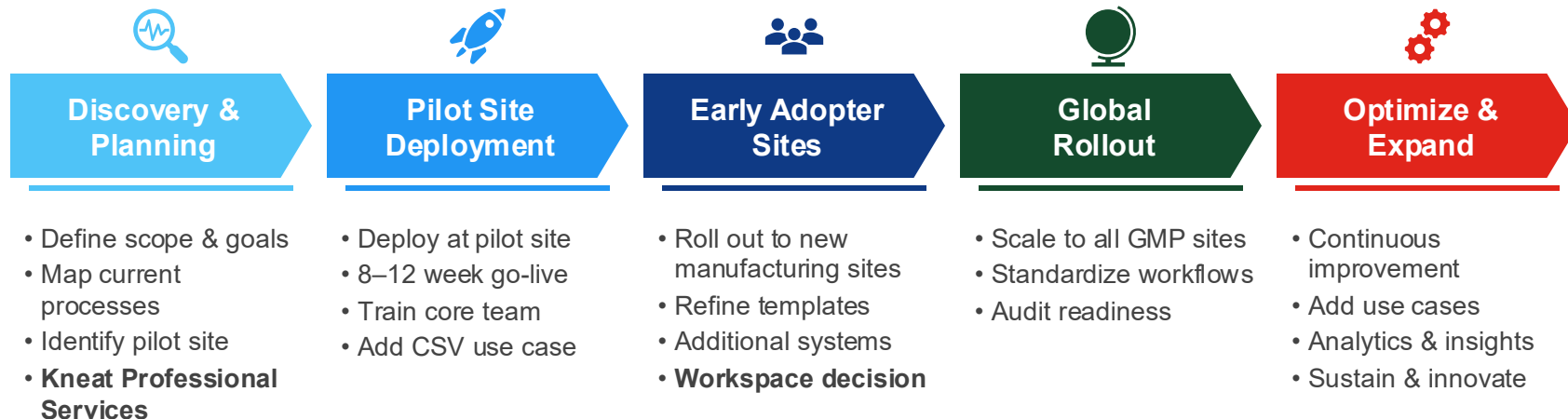
Enforced data entry controls ensure ALCOA+ compliance across activities

Inspection-Ready

Real-time access to centralized qualification history ensures immediate compliance evidence during inspections

Kneat Deployment

Kneat Implementation Roadmap



One Workspace

Consistent Standards Across Every QC Lab



Kneat Features Availability

- Cross-reference across documents (updated)
- Execution forms shared globally
- Computer system validation visibility
- Full entity utilization across the function (can use but cannot modify entities across workspaces)



Streamlined Access & Governance

- AIQ team: single access vs. 20+ workspaces
- Managed training and role-based access
- Template approval and user groups harmonized



Consistency & Standards

- Consistent folder structure across sites
- Standardized naming conventions
- Harmonized workflows and templates



Shared Learning & Collaboration

- Sites can view other sites' documents
- Best practices shared across network
- Accelerated onboarding for new sites

Risks & Mitigation Strategies

Site-to-Site Culture Differences

Varying digital maturity and resistance to change across global sites

Rapid New Site Onboarding

Onboarding new facilities while standardizing AIQ processes in parallel

QA & IT Alignment

Coordinating cross-functional alignment between QA and IT teams

System Capabilities

Not "paper under glass" — must learn the Kneat limitations and requirements

Champion Network

Appoint site-level champions to drive adoption and tailor change management to local maturity levels

Deployment Playbook

Deployment playbook to define roles and responsibilities and expectations for Global rollout

Joint Governance

Cross-functional steering committee with shared KPIs and a unified decision-making framework

System Capabilities

Leverage Kneat platform features — entities, electronic signatures, and dynamic cross-references — to eliminate design gaps

Design Challenges: Murphy's Law

If something can go wrong in document design, it will. Issues that have been encountered:

- **Choice Lists with No Choices** — Drop-down fields deployed empty or with incomplete options (mitigated by Kneat)
- **Witness Column with No Signature Column** — Witness column cannot be executed unless accompanying Signature column is included in the test document
- **Outdated Cross-References** — Document links pointing to superseded versions (flags)
- **No Comment Space / Columns** — Missing fields for explanation, deviations, or contextual observations
- **Locked Sections** — Protected template areas that cannot be updated when requirements change, requiring full document revision cycles

Kneat Execution Records

Kneat Multi-Execute Test Documents



Global Qualification Packages

Create Global Qualification Packages using Execution Records.

Keep multi-execute test document in pre-approved status for version control and traceability.



Consistent Execution

Drive consistency in documentation and execution with standardized templates. Ensure uniform quality outcomes across every site.



Parent Design Caution

Leverage Kneat library properties and parameterized design constructs. Structure test cells so site-specific details are isolated and configurable.



Rapid Startup

Fewer document designs and approvals needed. Enable consistent, repeatable qualification deployments that scale with network growth.



Folder Structure Navigation

Organize folder structures for rapid execution record creation. Mitigate navigation challenges with scattered multi-execute test documents across sites.

Test Document Design (Pre-Approved Test)

Insert Object Value

The scope of this Installation Qualification includes the installation of the **<Enter Instrument Name Here>** with the COTS system software, configured per the applicable System Overview and Configuration (SOC) document, and connected for data collection and management.

Insert Document Value

The scope of this Installation Qualification includes the installation of the **<Enter Instrument Name Here>** with the COTS system software, configured per the applicable System Overview and Configuration (SOC) document, and connected for data collection and management.

For the folder design structure, with all multi-execute test documents in one location, the use of the library property field requires the use of “Insert Document Value” NOT “Insert Object Value”

Use of the “Insert Document Value” will enable use of the Document Properties Report for the execution records.

Kneat AIQ Folder Structure

AIQ

Kneat Gx - Production

Search...

JD

Workspace

Recents

AIQ

Global Computer System Validation

Instrument Qualification

AIQ Global Protocols

#Functional Requirements

AIQ Balance

AIQ Total Organic Carbon

AIQ UV-VIS Spectrophotometry

#Master Executable Protocols

AIQ IQ Test Case Entity

AIQ Agilent Cary 60 UV-VIS

AIQ Agilent Cary 3500 UV-VIS

AIQ Mettler Toledo XPR Balances

AIQ Pipettes

AIQ Veolia Sievers M9

Site 1

Site 2

Site 3

AIQ > Instrument Qualification

+ New Manage access Update document types

Group by Filter (0) Navigation mode

Unique identifier ↑	Description	Type
Folder (6)		
#AIQ Global Protocols	Global documents	Analytical Instrument Qualification
Site 1	Site qualification execution documents	Analytical Instrument Qualification
Site 2		Analytical Instrument Qualification
Site 3		Analytical Instrument Qualification
Site 4		Analytical Instrument Qualification
Site 5		Analytical Instrument Qualification

All local site qualification folders are in the same workspace with folder naming to facilitate easy navigation to global documents

AIQ

Kneat Gx - Production

Search...

JD

Workspace

Recents

AIQ

Global Computer System Validation

Instrument Qualification

#AIQ Global Protocols

#Functional Requirements

AIQ Balance

AIQ Total Organic Carbon

AIQ UV-VIS Spectrophotometry

#Master Executable Protocols

AIQ IQ Test Case Entity

AIQ Agilent Cary 60 UV-VIS

AIQ Agilent Cary 3500 UV-VIS

AIQ Mettler Toledo XPR Balances

AIQ Pipettes

AIQ Veolia Sievers M9

Site 1

Site 2

Site 3

AIQ > Instrument Qualification > #AIQ Global Protocols

+ New

Manage access

Update document types

Group by

Filter (0)

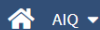
Navigation mode

Unique identifier ↑	Description	Type
Folder (7)		
#Functional Requirements		Analytical Instrument Qualification
#Master Executable Protocols		Analytical Instrument Qualification
AIQ Agilent Cary 60 UV-VIS		Analytical Instrument Qualification
AIQ Agilent Cary 3500 UV-VIS		Analytical Instrument Qualification
AIQ Mettler Toledo XPR Balances		Analytical Instrument Qualification
AIQ Pipettes		Analytical Instrument Qualification
AIQ Veolia Sievers M9		Analytical Instrument Qualification

Functional User Requirements

Multi-execute test documents

Vendor Protocols and Global Qualification Plans



AIQ ▾

Kneat Gx - Production

JD

Workspace

🕒 Recents

🌐 AIQ

➤ 📁 Global Computer System Validation

▼ 🌐 Instrument Qualification

▼ 📁 #AIQ Global Protocols

▼ 📁 #Functional Requirements

➤ 📁 AIQ Balance

➤ 📁 AIQ Total Organic Carbon

➤ 📁 AIQ UV-VIS Spectrophotometry

▼ 📁 #Master Executable Protocols

📊 AIQ IQ Test Case Entity

➤ 📁 AIQ Agilent Cary 60 UV-VIS

📁 AIQ Agilent Cary 3500 UV-VIS

📁 AIQ Mettler Toledo XPR Balances

📁 AIQ Pipettes

📁 AIQ Veolia Sievers M9

➤ 📁 Site 1

➤ 📁 Site 2

➤ 📁 Site 3

AIQ > Instrument Qualification > #AIQ Global Protocols > #Master Executable Protocols

+ New ▾

Manage access

Update document types



Group by ▾

🔍 Filter (0)

Navigation mode ▾

Unique identifier ↑	Description	Type
▼ Document (3) <i>Sorted by process document order</i>		
○ IQOQPQ-Agilent Cary 60 UV-VIS		IQOQPQ
IQOQPQ-Agilent Infinity III HPLC		IQOQPQ
IQOQPQ-Veolia M9 TOC		IQOQPQ
▼ Test Case (1)		
AIQ IQ Test Case Entity		Test Case

Multi-execute test documents

Test case entities





AIQ ▾

Kneat Gx - Production

Search...

JD



Workspace



Recents



AIQ

Global Computer System Validation

Instrument Qualification

#AIQ Global Protocols

#Functional Requirements

#Master Executable Protocols

AIQ Agilent Cary 60 UV-VIS

AIQ Agilent Cary 3500 UV-VIS

AIQ Mettler Toledo XPR Balances

AIQ Pipettes

AIQ Veolia Sievers M9

Site 1

Site 2

Site 3

Site 4

Site 5

AIQ > Instrument Qualification > #AIQ Global Protocols > AIQ Veolia Sievers M9

+ New ▾

Manage access

Update document types



Group by ▾

Filter (0)

Navigation mode ▾



Unique identifier ↑

Description

Type

Status



AIQ Vendor Qualification Protocol (1)



Veolia M9 ver 001

Vendor Qualification Protocol (File entity)

AIQ Vendor Qualification Protocol

Approved (✓2)



Document (2)

Sorted by process document order



AIQ-VQP-Veolia Sievers M9

Vendor Qualification Protocol evaluation

AIQ-VQP

Approved (1.0)



AIQ-QP-Veolia Sievers M9

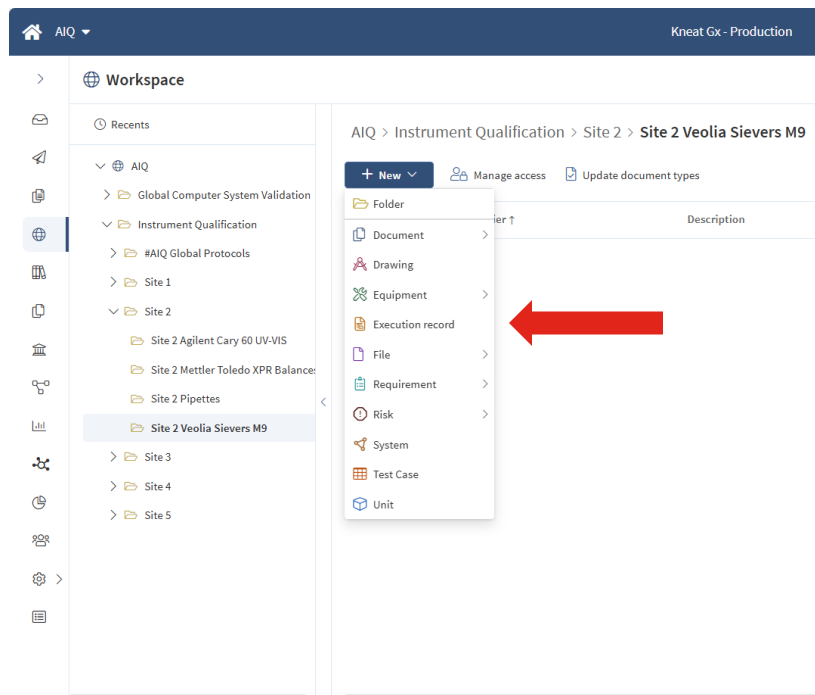
Global Qualification Plan

AIQ-QP

Approved (1.0)



Creation of an Execution Record



Finding the Multi-execute Test Document

The screenshot displays the Kneat Gx - Production interface. At the top, there is a dark blue header with a home icon, 'AIQ', and a search bar. The main content area is titled 'Select approved content' and includes a 'Create' button and a 'Cancel' button. Below the title, a message states: 'Select approved content to apply to the execution record. Previous execution data will not be included in the new record.' A breadcrumb path is shown: '... > Site 2 > Site 2 Veolia Sievers M9'. A green oval highlights this path. Below the breadcrumb, there is a search bar labeled 'Filter by identifier' and a 'Type' dropdown menu. A table with columns 'Unique identifier' and 'Description' is present, but it contains the text 'No Items to display'. To the right of the table, there are three horizontal progress bars. The middle progress bar is highlighted with a blue checkmark icon. Below the progress bars, a message reads: 'Please select an approved test document.'

Navigate to Multi-execute Test Document “Repository”

The screenshot displays the Kneat Gx - Production interface. At the top, there is a dark blue header bar with a home icon, 'AIQ' dropdown, 'Kneat Gx - Production' text, a search bar, and a user profile icon 'JD'. Below the header, a modal dialog titled 'Select approved content' is open. The dialog has 'Create' and 'Cancel' buttons in the top right. Inside the dialog, there is a message: 'Select approved content to apply to the execution record. Previous execution data will not be included in the new record.' Below this, a breadcrumb path shows 'Site 2 > Site 2 Veolia Sievers M9'. A dropdown menu is open, showing 'AIQ' and 'Instrument Qualification'. A large red arrow points to 'Instrument Qualification'. Below the dropdown, there is a table with columns 'Unique identifier' and 'Description'. The table is empty, showing 'No Items to display'. To the right of the table, there are three document selection cards. The middle card is selected, indicated by a blue border and a checkmark icon. Below the cards, the text 'Please select an approved test document.' is displayed. The left sidebar contains various icons for navigation. The bottom right corner has a small circular icon with a face.

Navigate to Multi-execute Test Document “Repository”

The screenshot displays the Kneat Gx - Production interface. At the top, there is a dark blue header bar with a home icon, 'AIQ' dropdown, 'Kneat Gx - Production' text, a search bar, and a user profile icon 'JD'. Below the header, a modal dialog titled 'Select approved content' is open. The dialog has 'Create' and 'Cancel' buttons in the top right. Inside the dialog, there is a sub-header 'AIQ > Instrument Qualification'. Below this, there is a filter section with 'Filter by identifier' and a 'Type' dropdown. A table with two columns, 'Unique identifier' and 'Description', lists several items. A red arrow points to the first item, '#AIQ Global Proto...'. To the right of the table, there are three document selection cards. The middle card is selected, indicated by a blue border and a checkmark icon. Below the cards, the text 'Please select an approved test document.' is displayed. The bottom of the interface shows a sidebar with various icons and a footer with the Lilly logo.

Select approved content

Create Cancel

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

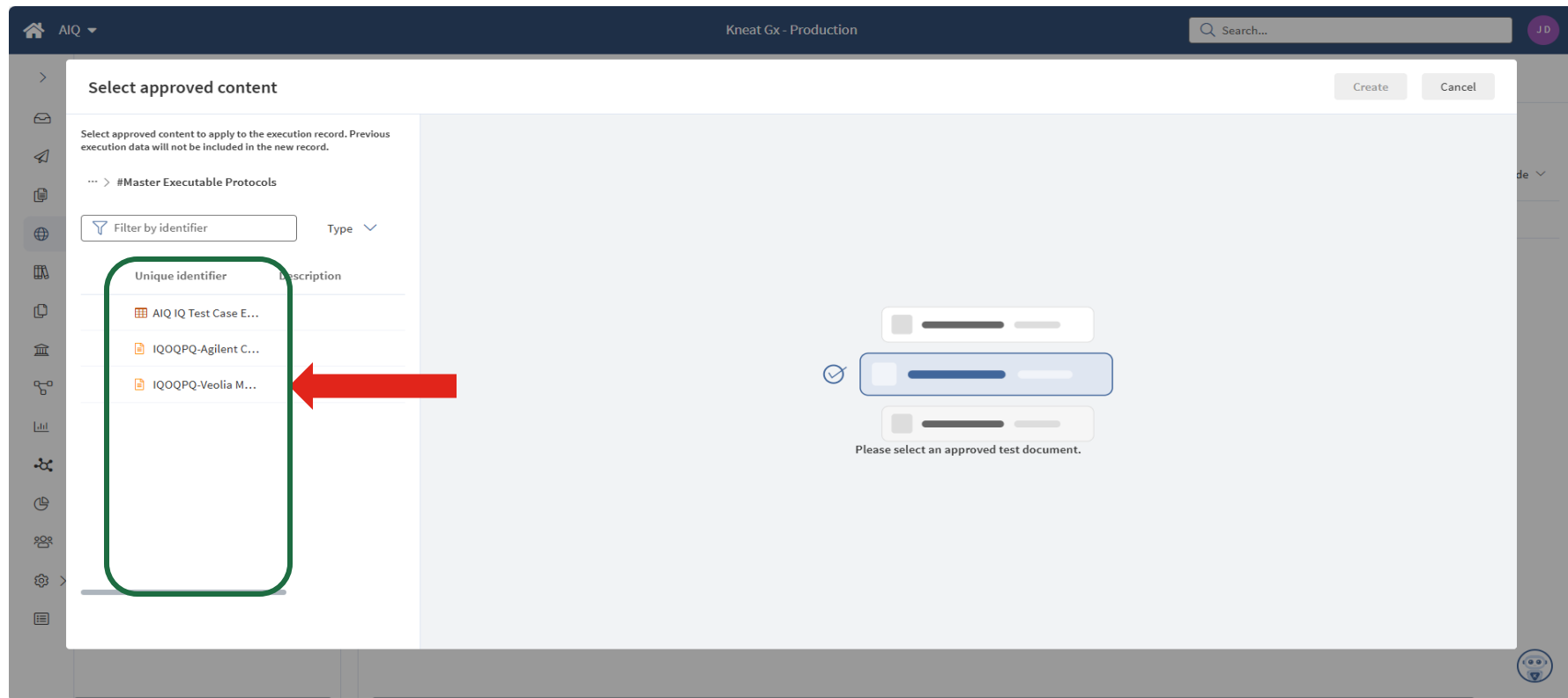
AIQ > Instrument Qualification

Filter by identifier Type

Unique identifier	Description
#AIQ Global Proto...	
Site 1	
Site 2	
Site 3	
Site 4	
Site 5	

Please select an approved test document.

Multi-execute Test Documents



Select approved content

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

... > #Master Executable Protocols

Filter by identifier Type

Unique identifier	Description
AIQ IQ Test Case E...	
IQQPQ-Agilent C...	
IQQPQ-Veolia M...	

Please select an approved test document.

Execution Record Creation

AIQ

Kneat Gx - Production

Search...

JD

Select approved content

CreateCancel

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

... > #Master Executable Protocols

Filter by identifier

Type

Unique identifier

Description

AIQ IQ Test Case E...

IQOQPQ-Agilent C...

IQOQPQ-Veolia M...

Document Number

IQOQPQ-Site 2 Veolia M9 TOC(1.0)-001

Edited

Title (optional)

Source document number & version: IQOQPQ-Veolia M9 TOC(1.0)

Approval

Approval

↑

↓

Approval

IQOQPQ-Veolia M9 TOC

Document TitleValue

Workspace : AIQ

Document No : IQOQPQ-Veolia M9 TOC

Document Title : Document TitleValue

Version : 1.0

This is a representation of an electronic record that was signed electronically and this page is a manifestation of the electronic signature. The electronic signatures for this document are maintained in the Kneat system.

Pre-Approval			
Signed By	Signatory Capacity	User Group	Date Approved
Denault, Jeffrey	Approver	Approver	02-Apr-2026 03:28:56 (UTC)

Post-Approval

JD

Lilly

Kneat Entities

Kneat Entities



Structured Data Objects

- Requirements, file, risks, test cases as entities
- Replace static documents with live data
- Enable traceability and cross-referencing



Reusability Across Processes

- Link entities across validation types
- URS entities reused in CSV and Qualification processes



Impact Analysis

- Change one entity, see all affected items
- Automated downstream impact assessment
- Reduces change control cycle time



Analytics-Ready Data

- Structured data enables real-time dashboards
- Track validation KPIs across the network
- Data-driven continuous improvement

Kneat Entity Types and Masks



Requirements Entities

Functional and CSV requirements traced through the full validation lifecycle

CSV requirements mask based on regulations and Lilly procedures

Functional requirements mask based on compendia and Lilly procedures



File Entities

Attachments, SOPs, screenshots, and evidence files linked directly to qualification records

- Vendor Qualification Protocol
- Data Flow Diagram
- Process Data Flow Map

Mask developed based on relevant metadata from vendor protocols



Risk Entities

QRM entries linked to vulnerabilities and test cases for risk-based validation

Utilization of the Kneat default QRM mask



Test Case Entities

Structured test scripts with defined steps, expected results, and pass/fail criteria

- Installation Qualification
- Operational Qualification
- Performance Qualification
- Computer System Validation

Kneat Entities Utilization



Entity per Row Table

Use Entity per Row for BOTH entity attribute entry and design data entry for a specific system



Entity Creation

Creation of entities using Entity per Row tables



Minimal Updates

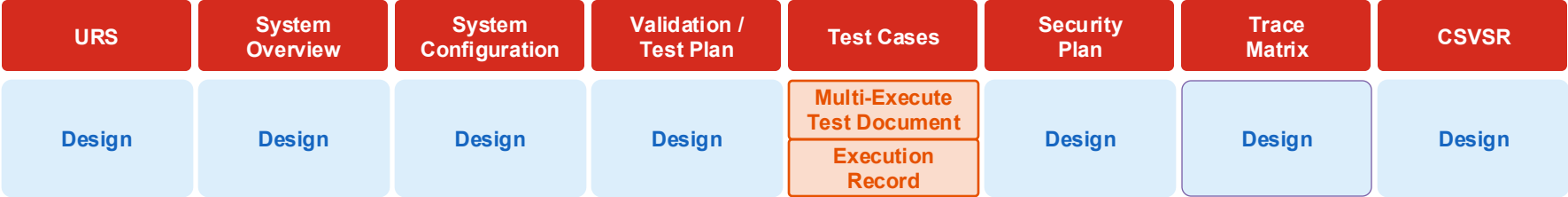
One entity per instrument type, not per instrument — minimizes required updates across the system



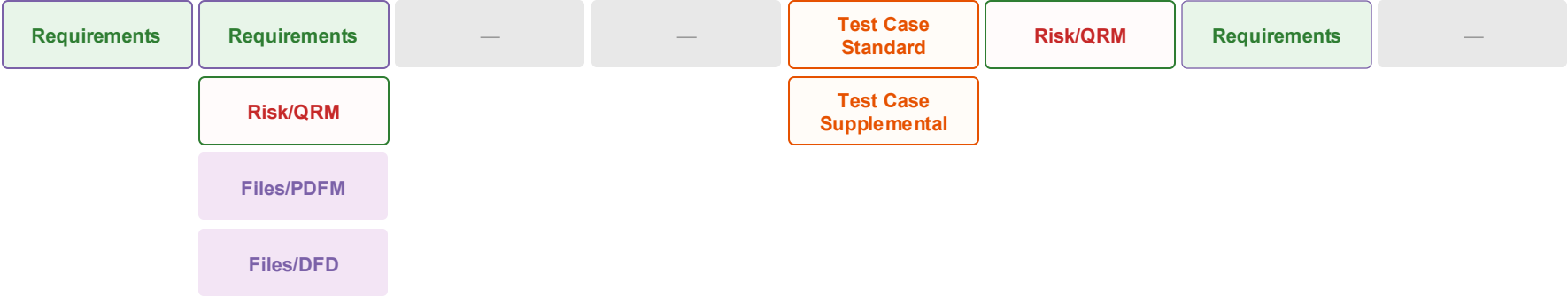
RTM Limitation

RTM (Requirements Traceability Matrix) cannot be used with this entity approach

Computer System Validation

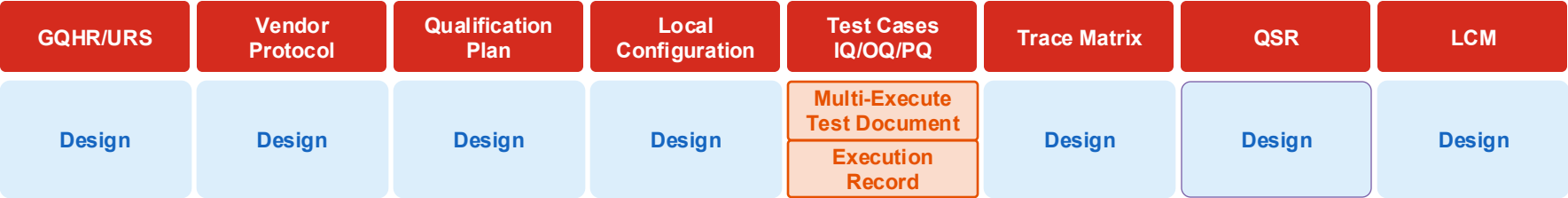


Kneat Entities Used

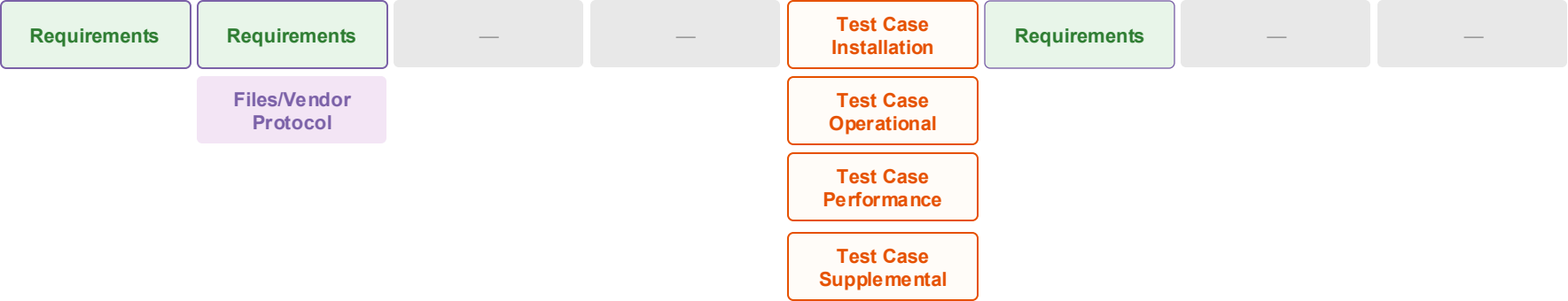


● Requirements ● Risk/QRM ● Test Cases ● Files

Functional Qualification



Kneat Entities Used



Entity per Row. Partial attributes and design

2 Vendor Qualification Protocol

Entity Per Row Table – All content contained in the Entity

Attribute Design

File Id	Vendor	Instrument Model	Version	Language	True copy
✓ Veolia M9 ver 001	✓ Veolia	✓ M9	✓ 001	✓ English	✓ Yes

Entity Per Row Table – Table content contains partial attribute and partial design columns

File Id	State	Requirements Tested	Status
✓ Veolia M9 ver 001	✓ Initial Qualification	All	All meet

Entity per Row. Partial attributes and design

2 Vendor Qualification Protocol

Entity Per Row Table – All content contained in the Entity

Attribute Design

File Id	Vendor	Instrument Model	Version	Language	True copy
✓ Veolia M9 ver 001	✓ Veolia	✓ M9	✓ 001	✓ English	✓ Yes

Entity Per Row Table – Table content contains partial attribute and partial design columns

File Id	State	Requirements Tested	Status
✓ Veolia M9 ver 001	✓ Initial Qualification	All	All meet

Entity Per Row Table – Table content contains partial attribute and partial design columns

User Requirements Specifications			
Requirement Id	Description	Vendor Test	Meets Requirement
✓ TOC-F01	✓ Must discriminate between organic and inorganic carbon.	Operational test, page 22	Yes
✓ TOC-F02	✓ ≤ 0.050 mg/L of carbon	Operational test, page 23	Yes
✓ TOC-F03	✓ The response efficiency (rE) of the system suitability solution must be NLT 85% and NMT 115%.	Operational test, page 30	Yes
✓ TOC-F04	✓ The precision of the TOC measurement must meet NMT 2.0% RSD.	Operational test, page 31	Yes

Next Steps



Expand to Additional Sites

- Deploy Kneat Gx to legacy QC laboratories
- Continue rollout to new QC labs globally
- Standardize AIQ processes across all sites



Global Qualification Packages

- Create Global Qualification Plans
- Build multi-execute test documents
- Cover full suite of instruments in Lilly QC labs



Increase System Utilization

- Develop software revision evaluation process and document revision assessments in Kneat
- Expand platform usage beyond core AIQ



Measure and Demonstrate ROI

- Develop and track key performance indicators
- Collect user feedback across sites
- Optimize templates based on metrics

Acknowledgements

Thao Phan & Jason Hasenour

System Owners

Stephanie Ligoci & Colleen Tigani

Execution Form & Entity process development

The AIQ Team

Working through process changes

Session 8.2

Implementation & Adoption: Strategies & Tactics



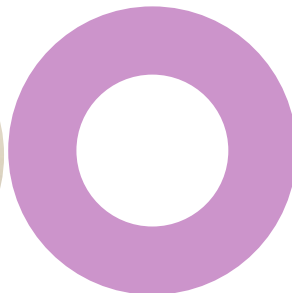
Moderator & Panelists



Tim Akin
CSM



Warren Ware
Validation Engineer



Aoife Hamilton
CQV Lead



GE HealthCare



Lindsay Settecasi
Director of
Digital Validation



VERISTA

Session 9.1

Audit Readiness in a Digital Environment



Moderator & Panelists



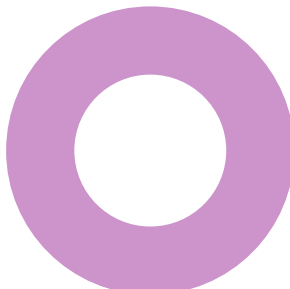
Sarah Grogan

Senior Customer
Success Manager
Kneat



Patrick Mullin

C&Q Lead
Sanofi



Yvonne Burazer

Associate Director
Takeda



Denis Kelleher

Validation Engineer
Gilead



Session 9.2

Data Integration Platform – Implementation & Validation Challenges

Grzegorz Janczewski | Rezon Bio



Data Integration Platform

➤ Implementation and validation challenges



Table of contents

01 Rezon Bio Overview

02 Data-driven organization

03 Challenges vs Reality

04 Good practices & Solution

05 Kneat Gx user experience



➤ End-to-End CDMO solutions for scalability, speed & quality

Cell line development



High-yield mammalian cell lines tailored for fast timelines & manufacturability*

Clinical & commercial drug substance GMP manufacturing



Flexible capacity, inspection-ready operations, highly competitive pricing

Drug product development



Expertise aligning formulation, device, and packaging strategies with clinical needs

Drug substance process development



Scalable upstream and downstream processes built for robustness

Analytical capabilities



Development and Quality Control: Phase-appropriate method development, CQA-driven assay strategies, qualified release testing.

Drug product GMP manufacturing



Ready-to-fill formulations, supply of vials or assembly of drug devices*

Supporting Services

- ✓ Device development
- ✓ Tech transfers (analytical/process)
- ✓ PAI support
- ✓ Regulatory support
- ✓ Process characterization
- ✓ PPQ

* Delivered by trusted and qualified external partners

➤ Integrated state-of-the-art facilities & services



Phase-appropriate services, spanning from cell line development to commercial supply. Mirrored equipment, processes, and analytical approaches enable seamless scale-up to serve clients worldwide.

Clinical development & manufacturing

➤ Gdańsk, Poland

- ✓ AI-supported manufacturing lines
- ✓ Fast, first-in-human batches
- ✓ Analytical & process development for quality, robustness & scalability
- ✓ FDA, EMA, ANVISA, MHRA approved
- ✓ Up to 2×1,000L SU scale



Commercial scale GMP manufacturing

➤ Warsaw-Duchnice, Poland

- ✓ Extensive capacity supports increasing scale
- ✓ Fast & flexible scheduling
- ✓ Cost-efficient
- ✓ Quick multi-product turnover
- ✓ FDA, EMA approved
- ✓ Up to 2×2,000L SU scale



Disclaimer

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Table of contents

01 Rezon Bio Overview

02 Data-driven organization

03 Challenges vs Reality

04 Good practices & Solution

05 Kneat Gx user experience



Why data-driven?

Market saturation

CDMO market is growing

... so as the number of competitors

Growing expectations

Clients expect more

... and faster

Cost pressure

Budgets are smaller

... but the workload is growing

Staying competitive requires data-driven organization



Removing data access barriers



Increasing cross org data visibility

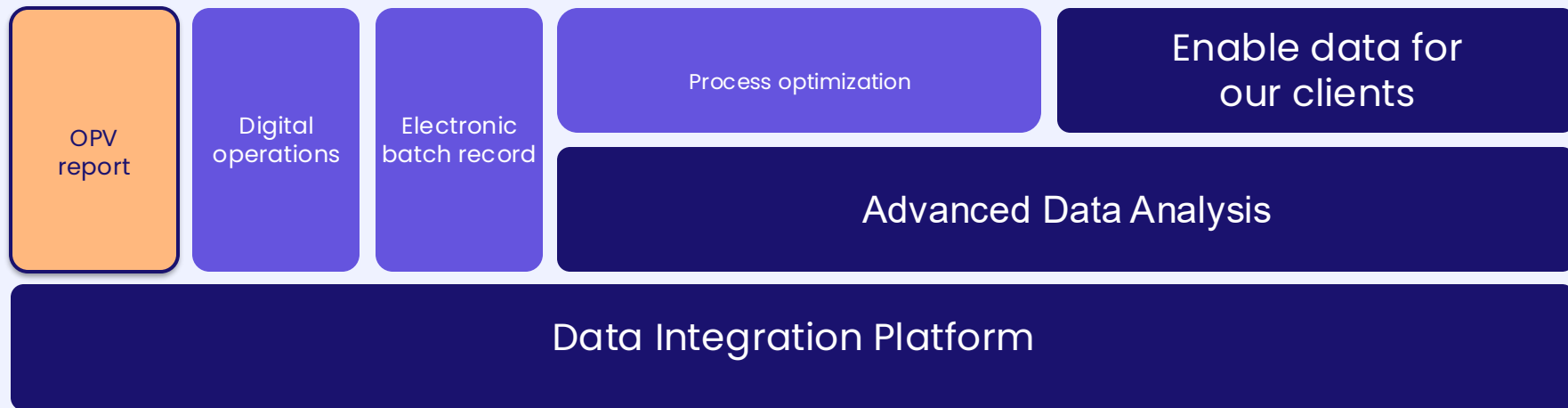


Preparing for the era of Artificial Intelligence





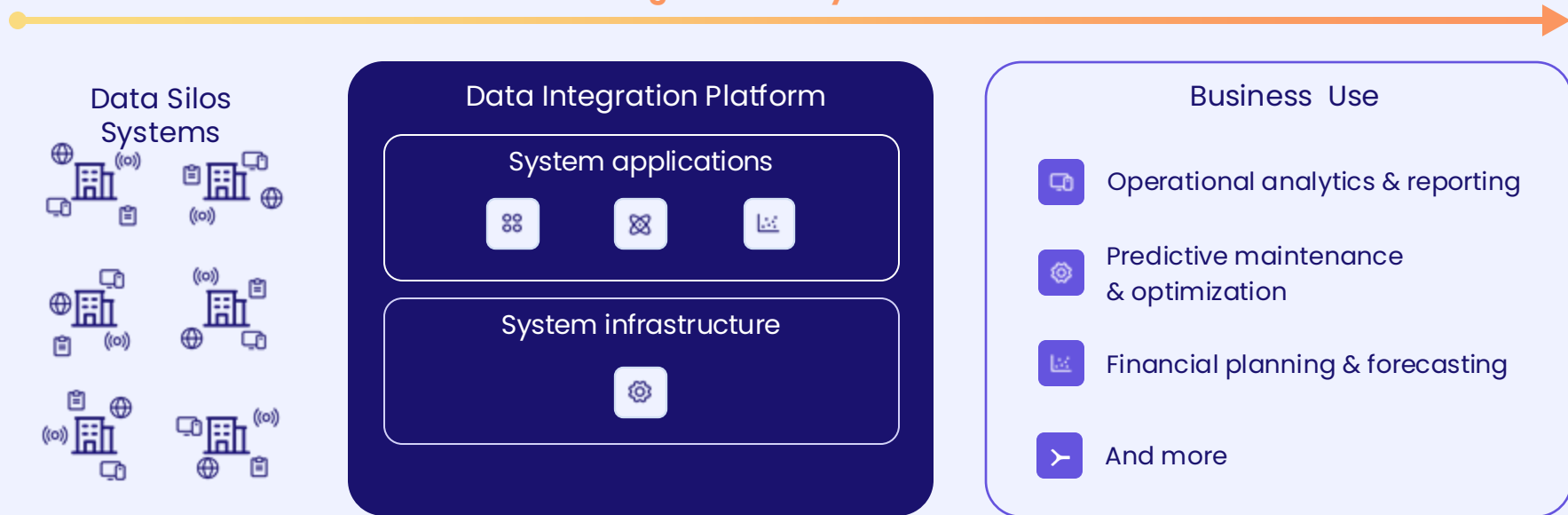
From idea to operational reality



Business purpose and intended use



Digital Maturity Growth



System architecture

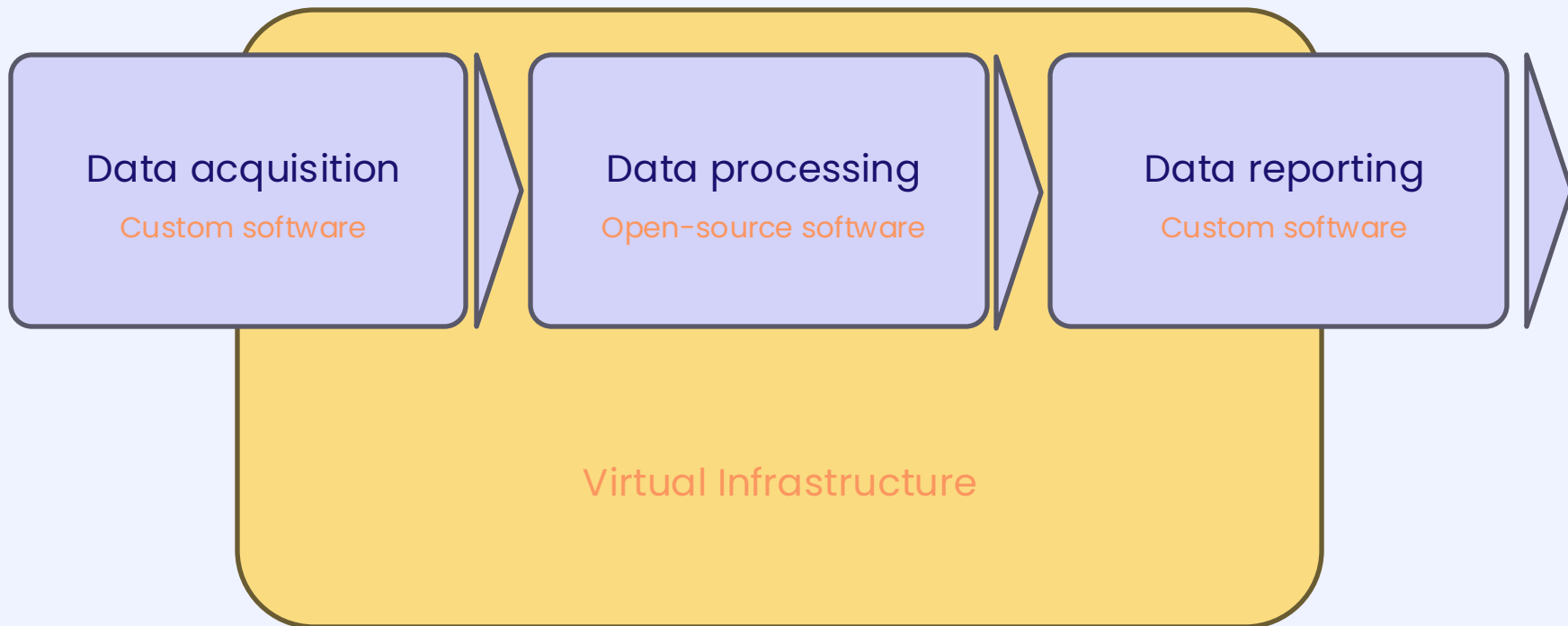




Table of contents

01 Rezon Bio Overview

02 Data-driven organization

03 Challenges vs Reality

04 Good practices & Solution

05 Kneat Gx user experience



Challenges

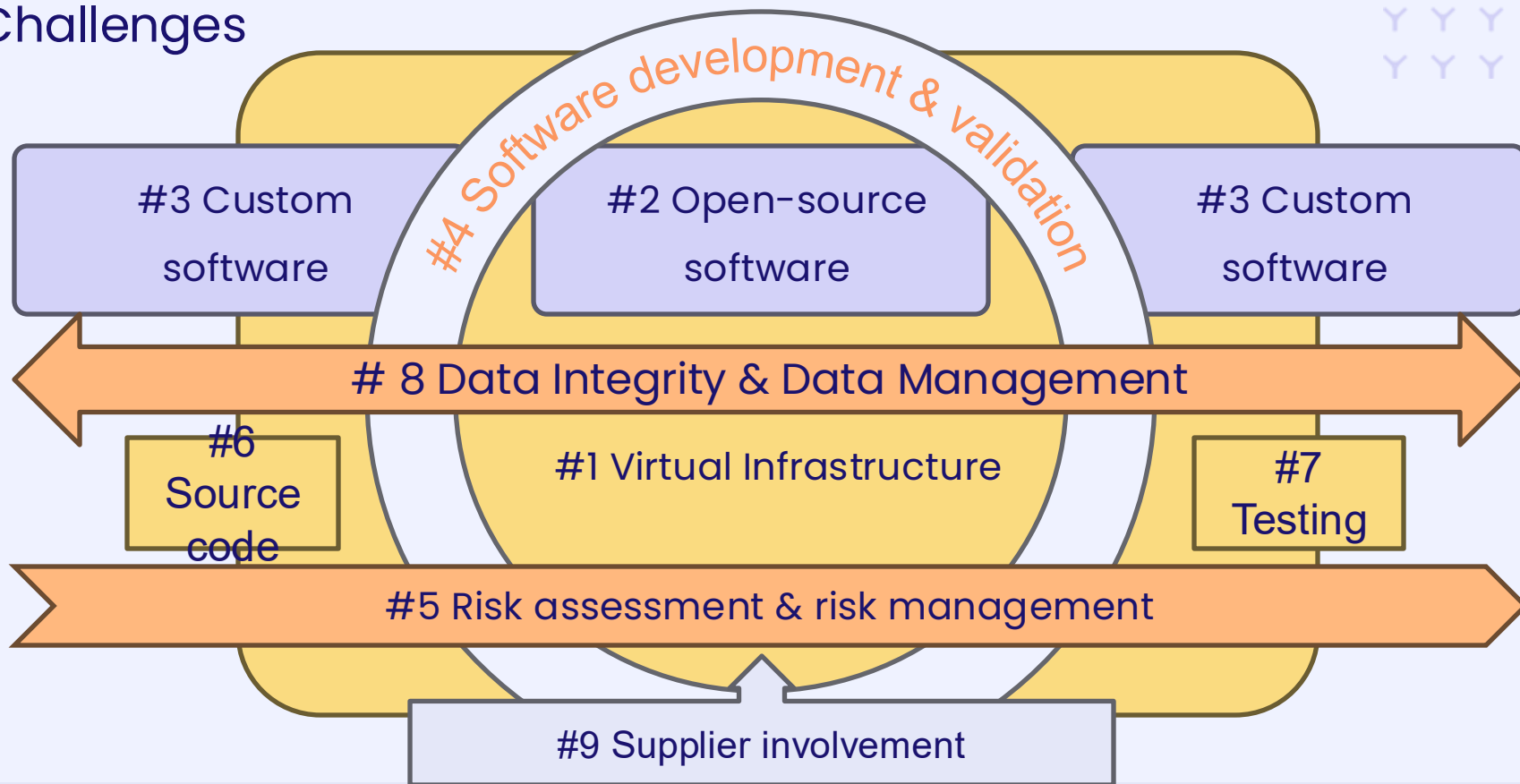




Table of contents

01 Rezon Bio Overview

02 Data-driven organization

03 Challenges vs Reality

04 Good practices & Solution

05 Kneat Gx user experience

#1 Virtual infrastructure



ISPE GAMP Good Practice Guide: IT Infrastructure Control and Compliance, Second Edition
Appendix 12 – Virtualization: Compliance and Control

- "... infrastructure platforms and components may be qualified independently of the validation of the dependent systems, as long as the infrastructure is properly specified, verified, controlled, and maintained"
- „ ... risks are unique to the virtualized environment and will require specific risk assessments to be conducted ..."
- "... procedures should be specific to the virtualized environment"





#1 Virtual infrastructure

Initial risk assessment
–
complexity and GxP
impact.

Information security
risk analysis
–
potential vulnerabilities.

User requirements
–
20 requirements for
network and
infrastructure.

Specifications

- Data Platform Infrastructure specification
- Data Platform Infrastructure deployment specification

Maintenance processes

restore and disaster recovery,
change and patch
management,
access management

#2 Open-source software



ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix D4, Section 24.3.3. Third-Party Software

- "Note that commercial software may contain open-source components ..."
- "Evaluation of software control for OSS is similar in scope and approach to that of purchased software"
- "...a risk assessment should be performed to determine the business and GxP risk..."
- "Such software should be implemented in accordance with the appropriate life cycle activities as for commercial software ..."



#2 Open-source software



Functional Risk Assessment

- Risk assessment for every OSS

Specification

- each OSS is specified and configured

Version control

- installed On Prem,
- patches are fully under control

Vulnerability

- OSS not exposed to the internet,
- each OSS was assessed by Information Security team

Testing

- limited to the intended use
- appropriate to the results of functional risk assessment

#3 Custom software



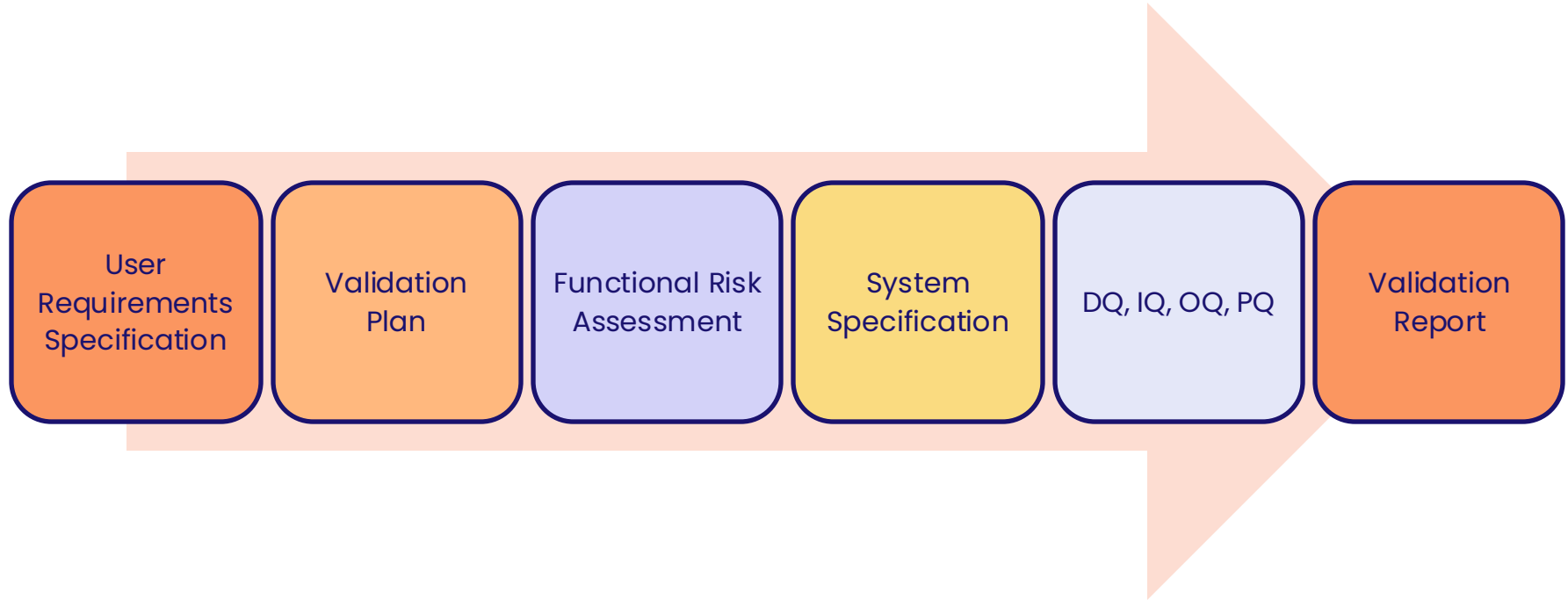
ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix D8 Agile Software Development

- "Agile is not a reason to accept the lower level of quality or GxP compliance."
- "For agile, testing is always performed (...) an untested product is not shippable."
- "The regulated user must ensure the computerized system is fit for intended use."
- "Evidence of this may be generated and maintained in tools and supporting systems"



Solution

#3 Custom software



#4 Software development & validation



Eudralex Volume 4 Annex 11

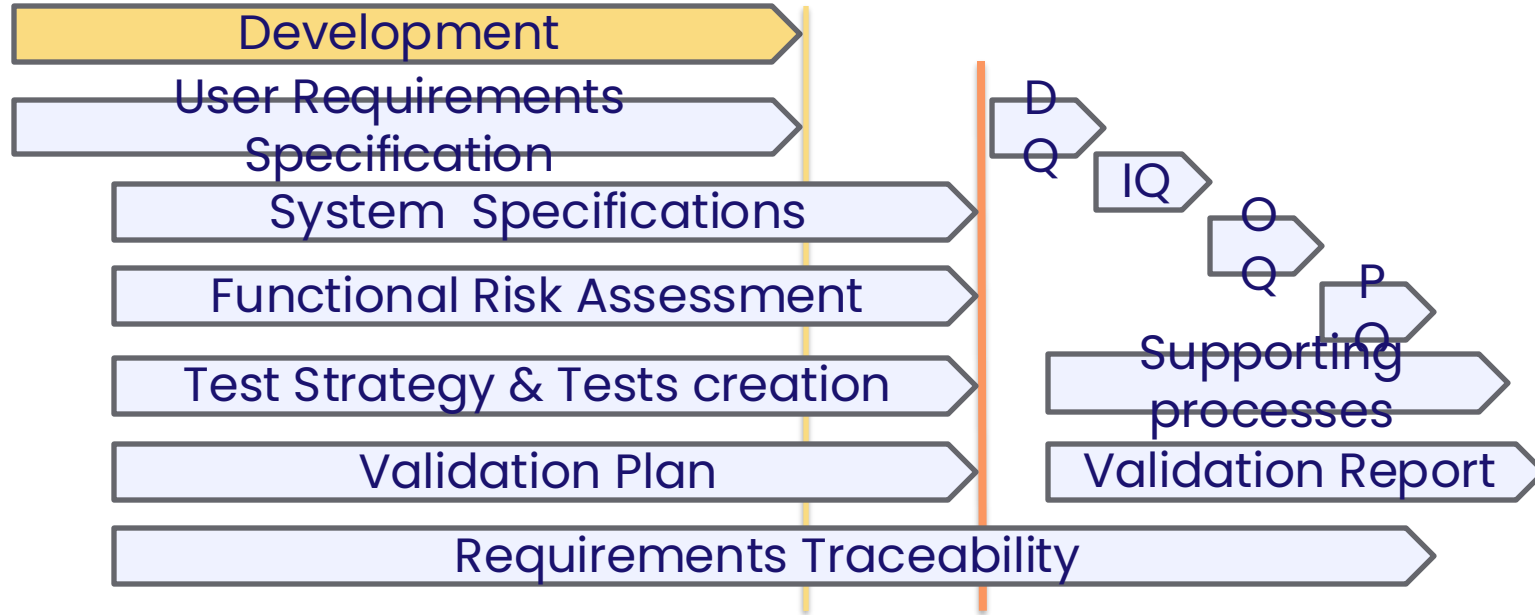
- 4.6 "For the validation of bespoke or customised computerised systems there should be a process in place that ensures the formal assessment ...".

Eudralex Volume 4 Annex 15

- 1.2 "Qualification and validation activities should only be performed by suitably trained personnel who follow approved procedures."
- "Verification of the correct installation [IQ] against pre-defined criteria"



#4 Software development & validation



#5 Risk assessment & risk management

ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix M4 Categories of Software and Hardware

- There are two main ways to use the categories:
 - Whole-system assessment
 - Functional risk assessment
- Functional risk assessment
 - Increasing risk of failure occurrence from standard to custom software
 - Increasing risk of failure detection from standard to custom software



#5 Risk assessment & risk management

Occurrence and detectability depends on function implementation types:

Category 3

- Standard function
 - the risk should not be high

Category 4

- Configurable function
 - the risk might be medium

Category 5

- Custom-made function
 - the risk should not be low

#6 Source code



ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition

- Appendix D4: Management, development, and review of software
 - "The [source code] review should be performed by at least one independent person with sufficient knowledge"
- Appendix M12: Critical thinking
 - "Information and test evidence in the form of artifacts within (...) automated test tools have the same status as formal documentation,,
- Appendix D9: Software tools
 - "Tools, like system supporting IT processes, are all GAMP category 1"
 - "Such tools and systems supporting system life cycle, IT processes and infrastructure should not be subject to specific validation"
 - "GAMP and FDA Case for Quality program strongly encourage the use of software lifecycle management tools"
 - "Tools should have sufficient controls to preserve the data/records"



#6 Source code



Microsoft Azure DevOps

Code
Management

Code
Review

Code
Approval

Code
Review
Good
Practices
document

#7 Testing



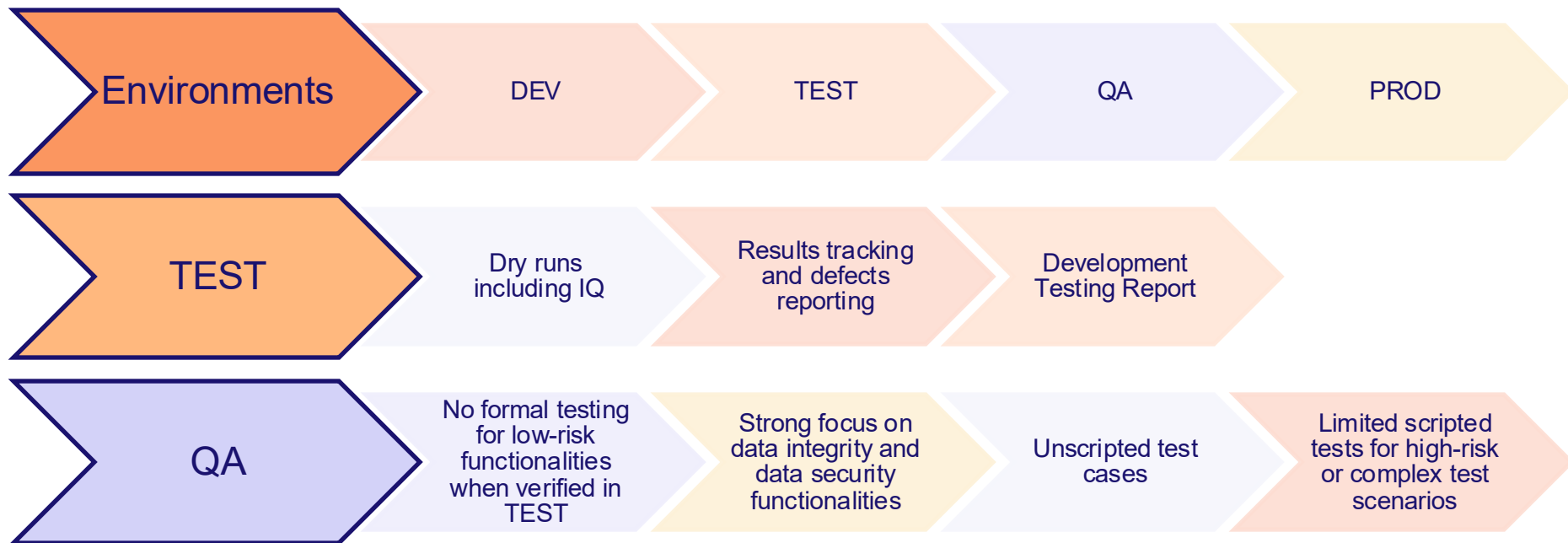
ISPE GAMP 5 Guide: A-Risk-Based approach to Compliant GxP Computerized Systems, Second Edition
Appendix D5: Testing of computerized systems

- "Testing may take place in different environments during a project: development, formal testing, operational.
- "The test environments (...) need to be functionally equivalent for the testing to be representative..."
- "...there is no benefit to repeating testing already performed in another, but still adequately controlled environment just because it was not the formal test environment,"



Solution

#7 Testing



#8 Data integrity

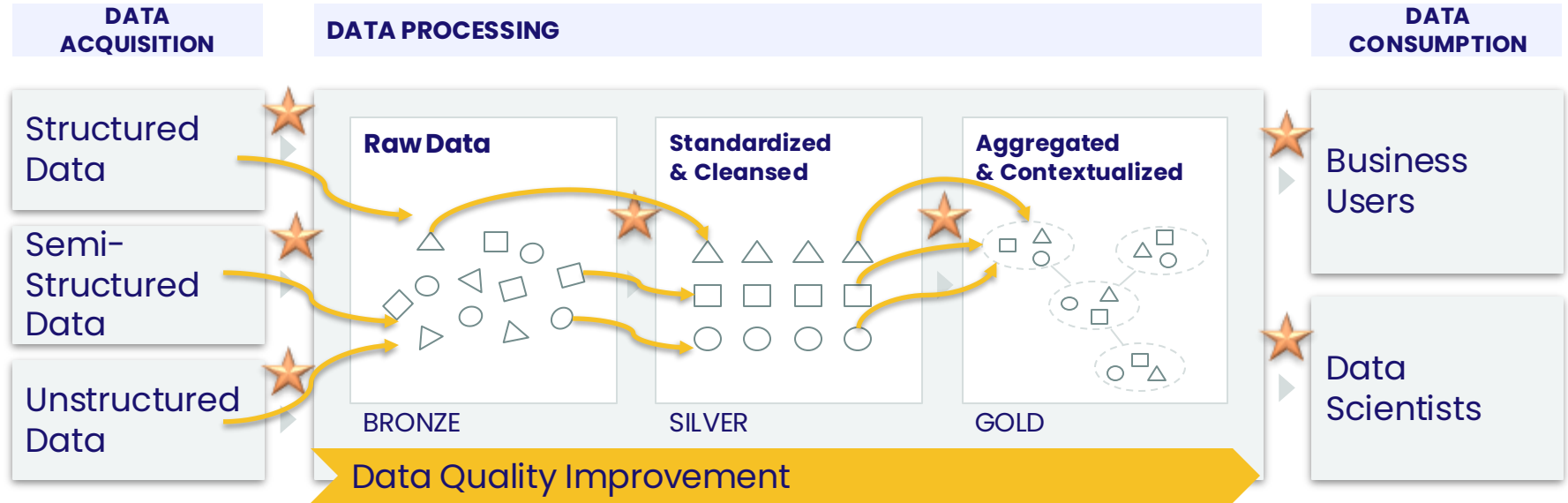


Eudralex Volume 4, Annex 11

- 4.8 If data are transferred to another data format or system, validation should include checks that data are not altered in value and/or meaning during this migration process.



#8 Data integrity & data management



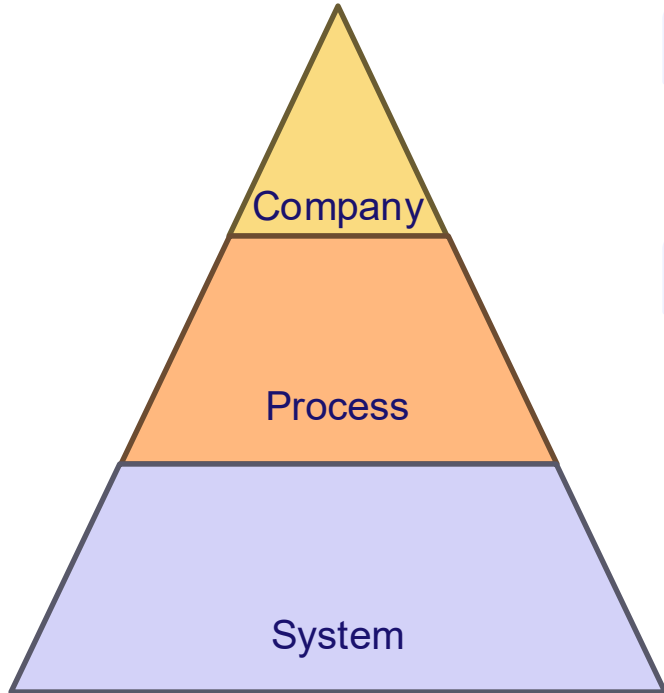
#8 Data integrity & data management



- MHRA (UK) GMP Data Integrity Initiatives
- WHO Guidance on Good Data and Records Management Practices
- PIC/S PI-041 Data Integrity Guidance
- FDA Guidance on Data Integrity and Compliance with CGMP
- EMA Guideline on computerised systems and electronic data in clinical trials
- ISPE Records and Data Integrity Guides
- DAMA Data Management Body of Knowledge



#8 Data integrity & data management



Company

- New unit within IT department
"Data Intelligence & Data Platforms"

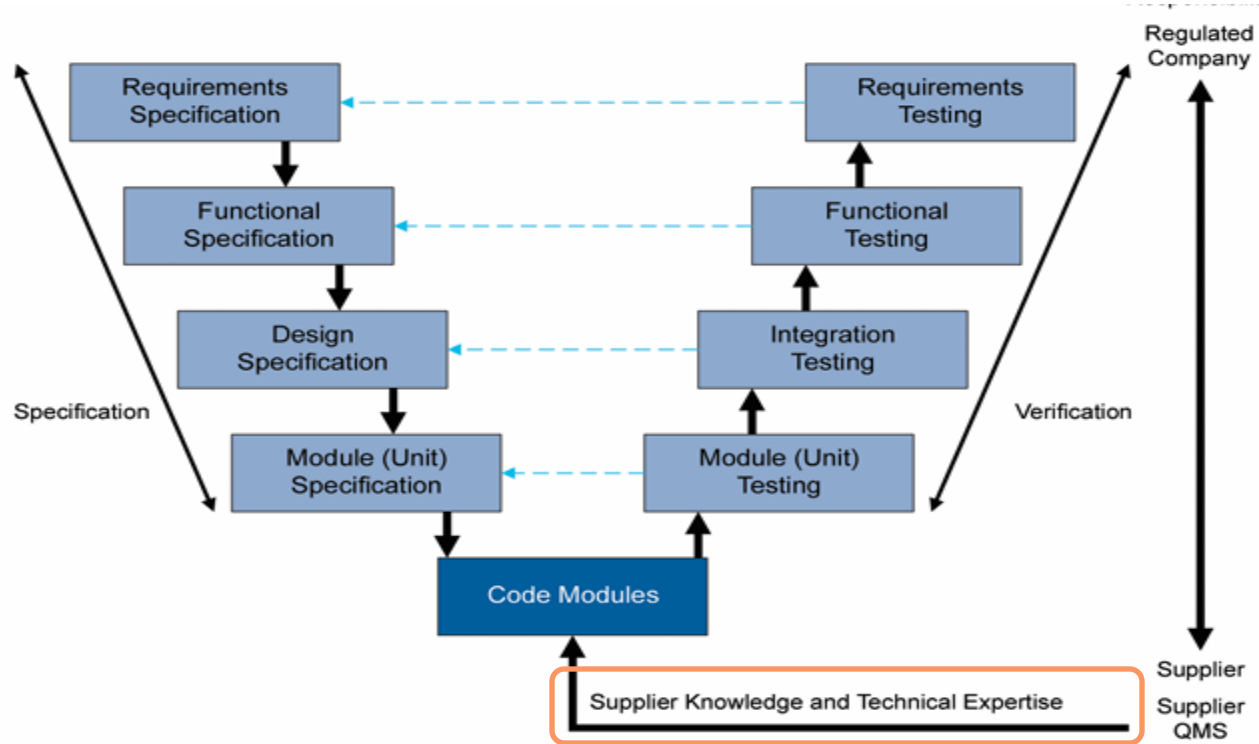
Process

- Data policy and procedures update

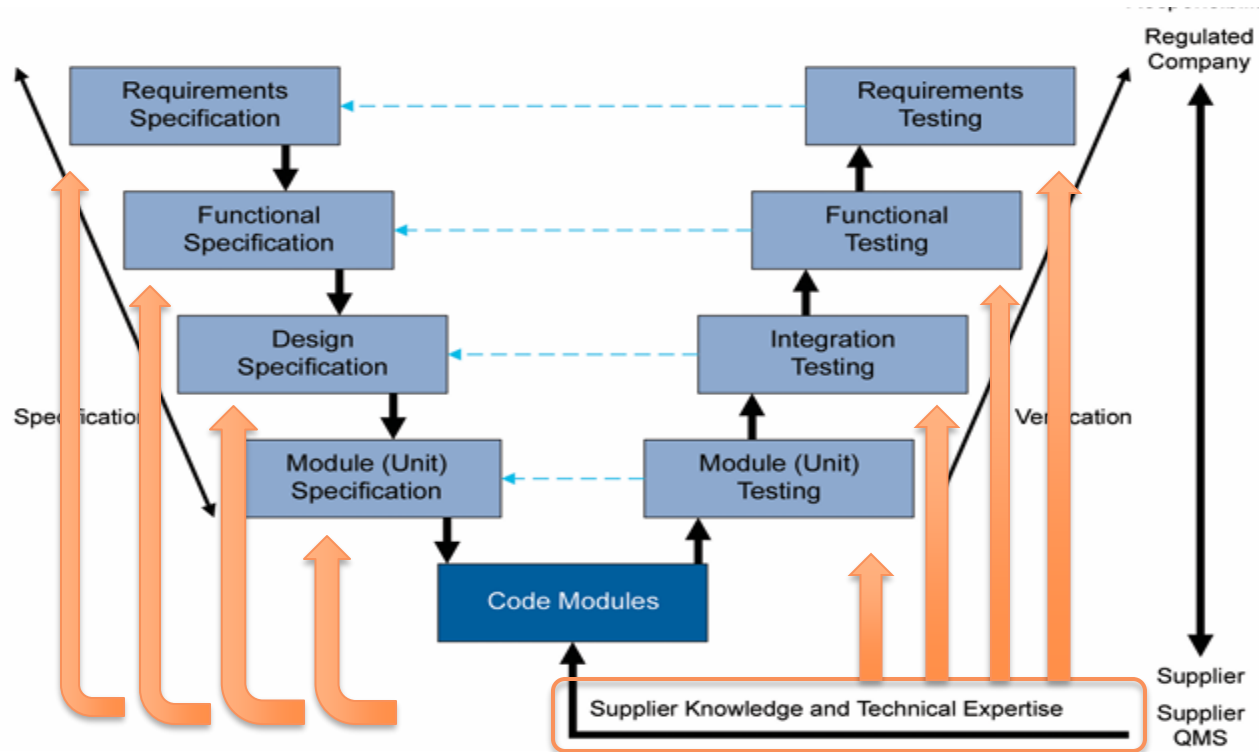
System

- Data integrity control points and mapping

#9 Supplier involvement



#9 Supplier involvement





Takeaways

1. Regulations do not limit your validation process – your procedures do.
2. A risk-based validation approach is crucial for custom software.
3. You are not alone; your supplier can provide significant support.
4. Data integrity and data management must be ensured at



Table of contents

01 Rezon Bio Overview

02 Data-driven organization

03 Challenges vs Reality

04 Good practices & Solution

05 Kneat Gx user experience



Kneat Gx experience

- SPECs – we have started in SharePoint and documents were moved to Kneat Gx (import from Word) for review, corrections, and approval.
- FRA – created in Excel and attached to Kneat Gx. I regret not using Risk Entities.
- Traceability – Kneat Gx is a useful tool to create the requirements traceability (but we made a mistake)
- RTM – fully generated by Kneat Gx, over 1200 rows
- Test cases – created in SharePoint and moved to Kneat Gx test protocols
- Review & approval process – very efficient, users were satisfied
- User license consumption – improved due to active / inactive switch
- User experience – positive for both Standard Users and Review & Approval User

Thank you! Questions?



Where dedication delivers
program success

Grzegorz Janczewski

CSV Manager, IT Department



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05-850 Duchnice, Poland



Learn
more at
www.rezonbio.com

Session 10.1

Smart Commissioning in a Pharma 4.0 Smart Factory

Darren Crowe | AstraZeneca



VALIDATE 2026

Smart Commissioning in a Pharma 4.0 Smart Factory: A Digital CQV/CSV Ecosystem



Darren Crowe
Technical Lead, CQV & CSV



Kneat

INTRODUCTION – DARREN CROWE

3 |



Validation/Manufacturing Engineer
Maintenance/Validation Engineer

8 Years



Plant/Project Validation Engineer (CQV)

9 Months



NPI Validation Engineer (Automation & Tooling)

3 Years



Senior Specialist QA, (QAV)
Packaging Validation Lead

Validation & CQV Manager

5 Years



Validation & CQV Lead – Current

2 Years



Apprenticeship Electrical Maintenance,

3 Years



FdEng Manufacturing & Management Engineering
2 Years

BEng Honours Degree in Mechanical & Manufacturing Engineering
3 Years

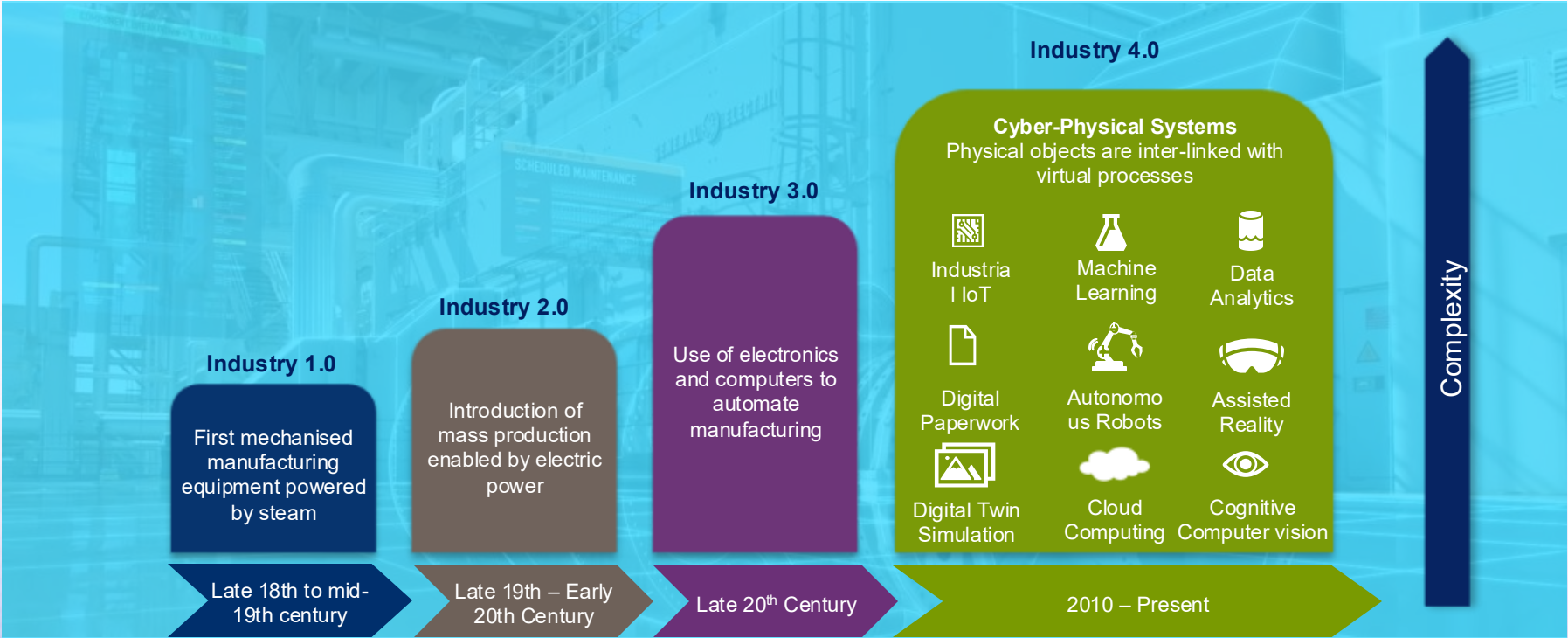


MSc Commissioning, Qualification and Validation for Biologics Manufacturing (CQV)
2 Years

In-Progress

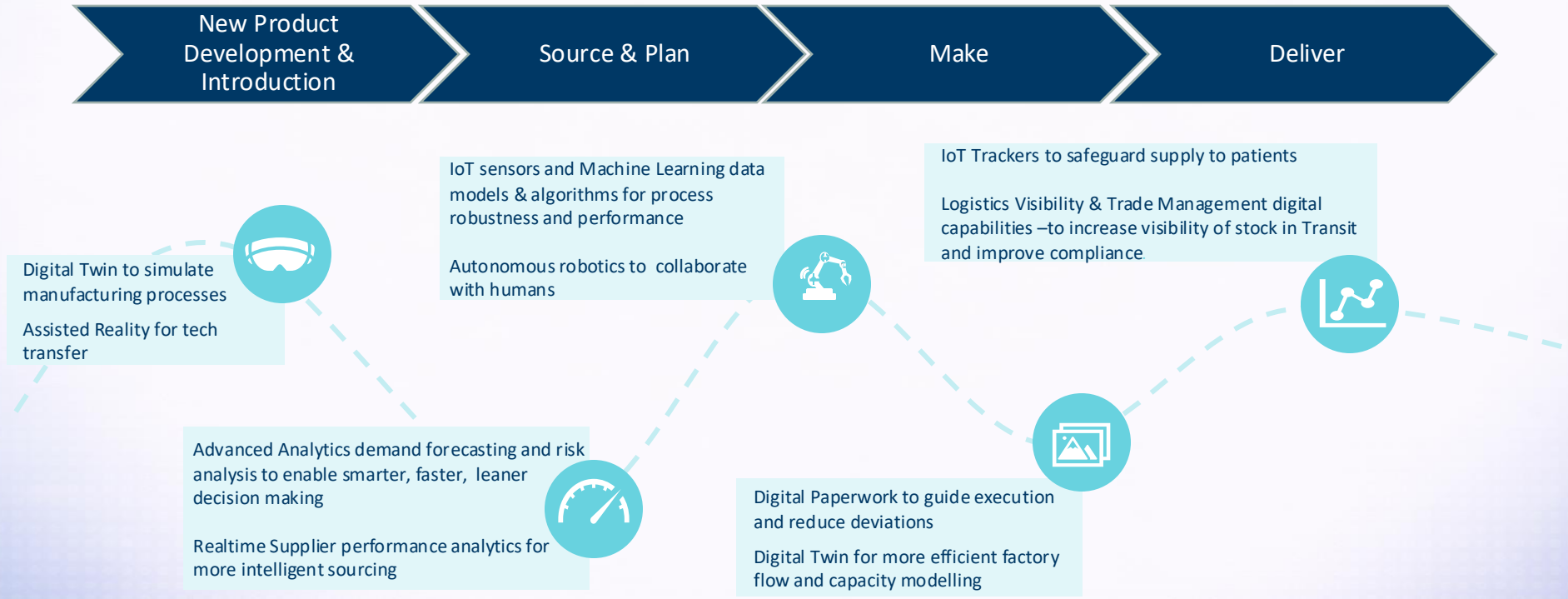


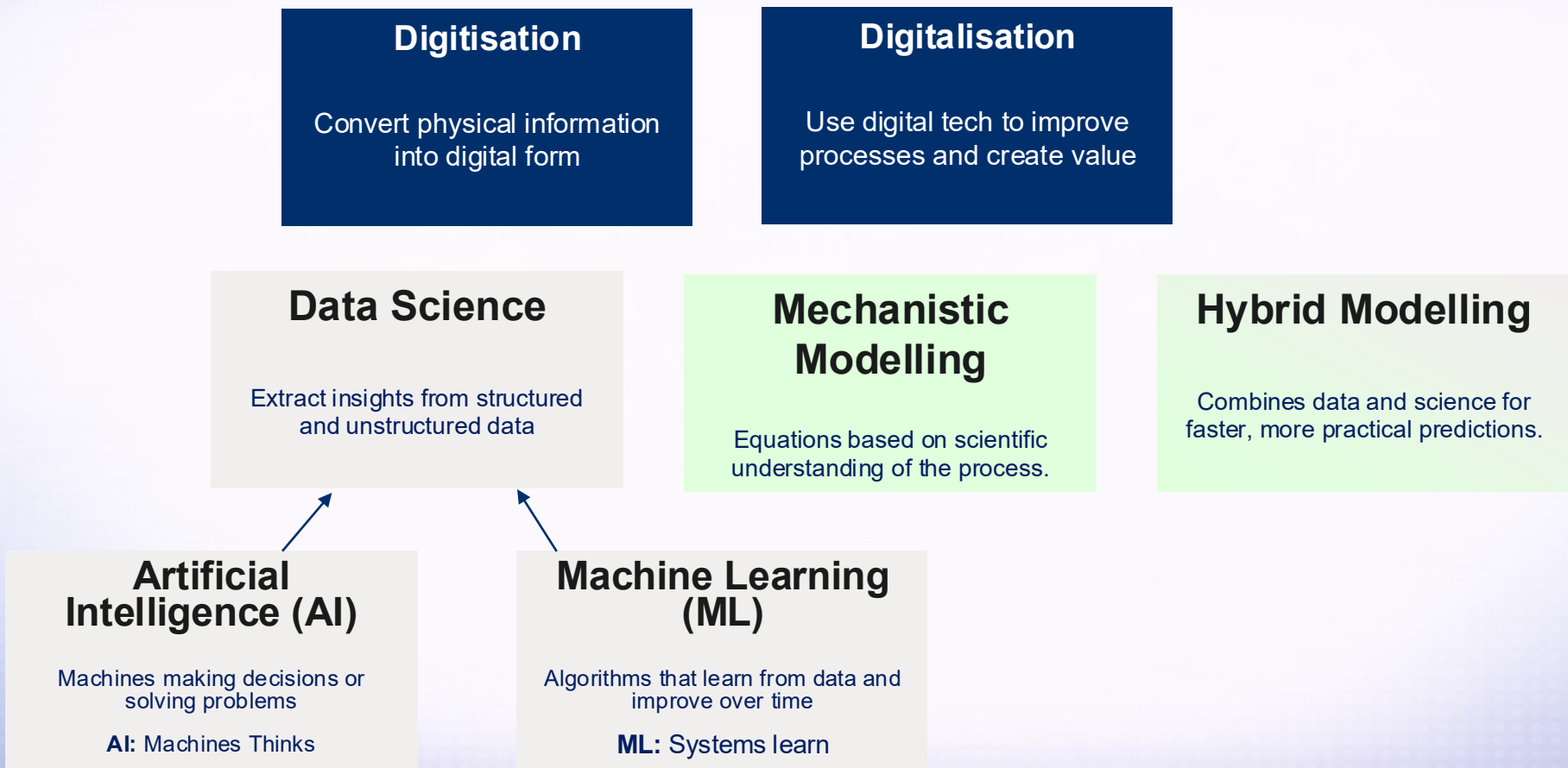
THE FOURTH INDUSTRIAL REVOLUTION





TECHNOLOGY IS DISRUPTING EVERYTHING





BUILDING THE SMART FACTORY: KEY DIGITAL CAPABILITIES FOR THE FUTURE

8 |



AI powered product development



Digital Twin & Autonomous Supply Networks



IoT connected autonomous manufacturing



Extended reality augmented workforce



Why Smart Factories Are Hard to Deliver in Pharma?



Fragmented systems
and data silos



Validation driven by
documents, not data



Validation & Quality
Come in too late



Technology exists - delivery is the challenge

THE SMART FACTORY VISION: FROM DATA TO VALUE

10 |

Smart Factories are process-centric, standardised and patient-focused
Real-time visibility, Reduced variability and Less waste.

Enabled
by.

- **End-to-End Data Visibility** - Faster decisions, less variability
- **Advanced Analytics** - Predict outcomes, prevent disruption
- **Augmented Workforce** - Automation + intelligence driving performance



... to develop advanced, intelligent and data enabled
Smart Factories.

Augmented Training

using Augmented and Virtual Reality to reduce lead-time to train new operators, increase understanding and improve safety and efficiency

Cognitive Vision

using AI and vision to monitor processes, inspect products and alert in real-time

Advanced CPV, Yield and Settings Optimisation

Using Advanced & Predictive Process Analytics to improve product robustness & performance through



Factory Dashboard

using Analytics and Visualisations to enable rapid decisions based on real-time data insights

Digital Paperwork

using digital work instructions and workflows to improve right first time & improve efficiency

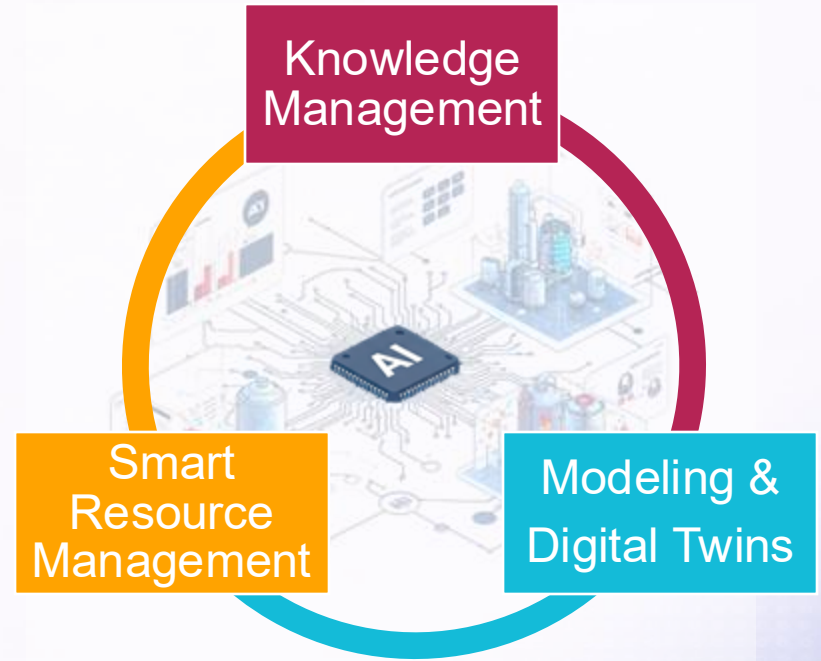
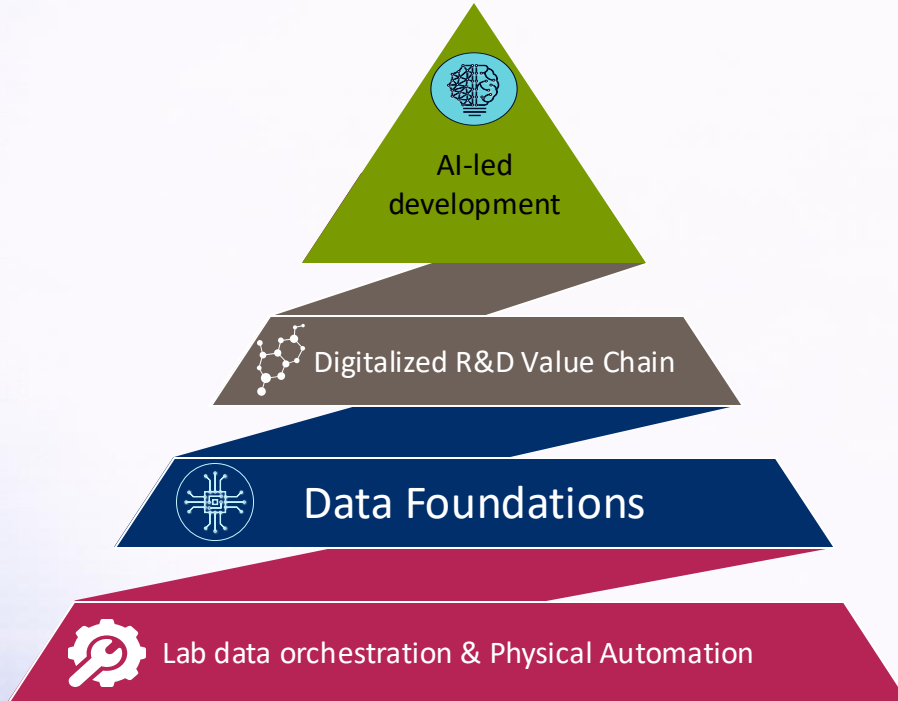
Dynamic Work Scheduling

using AI to optimise and synchronise process flows through laboratories and factory floors, and warehouses

Monitor → Understand → Decide →
Execute → Optimise

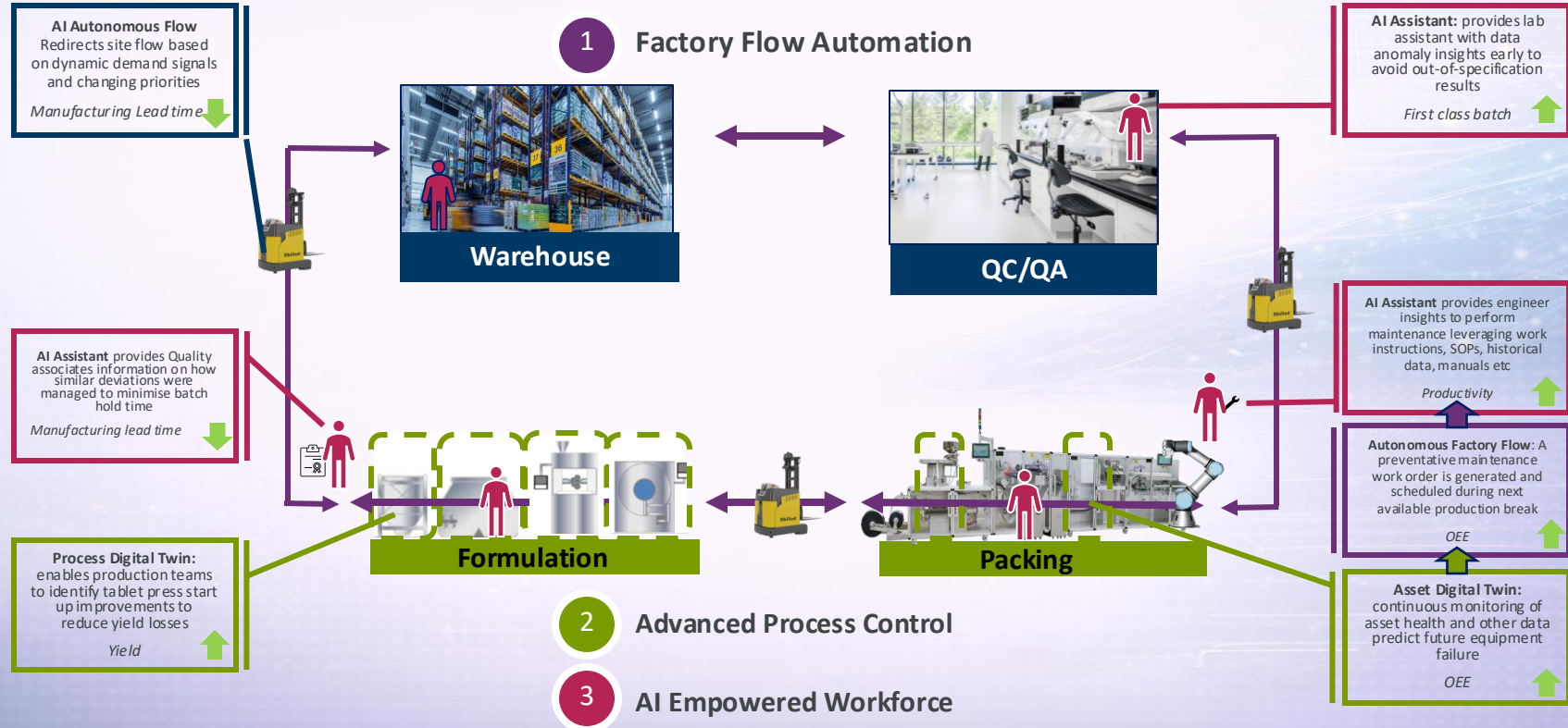
CORE CONCEPTS UNDERPINNING SMART MANUFACTURING

12 |



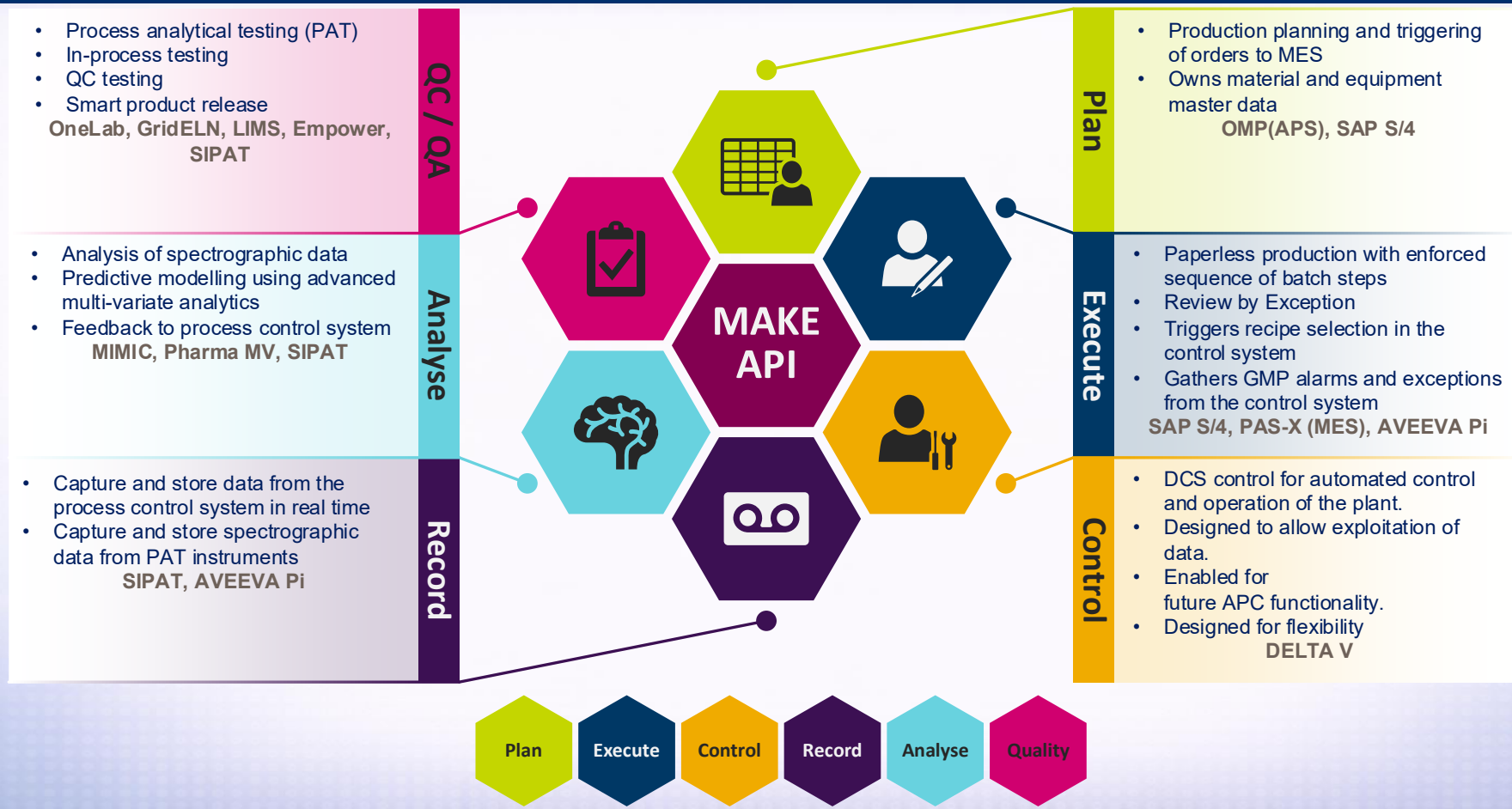
AUTONOMOUS MANUFACTURING: END-TO-END PROCESS INTEGRATION

13 |



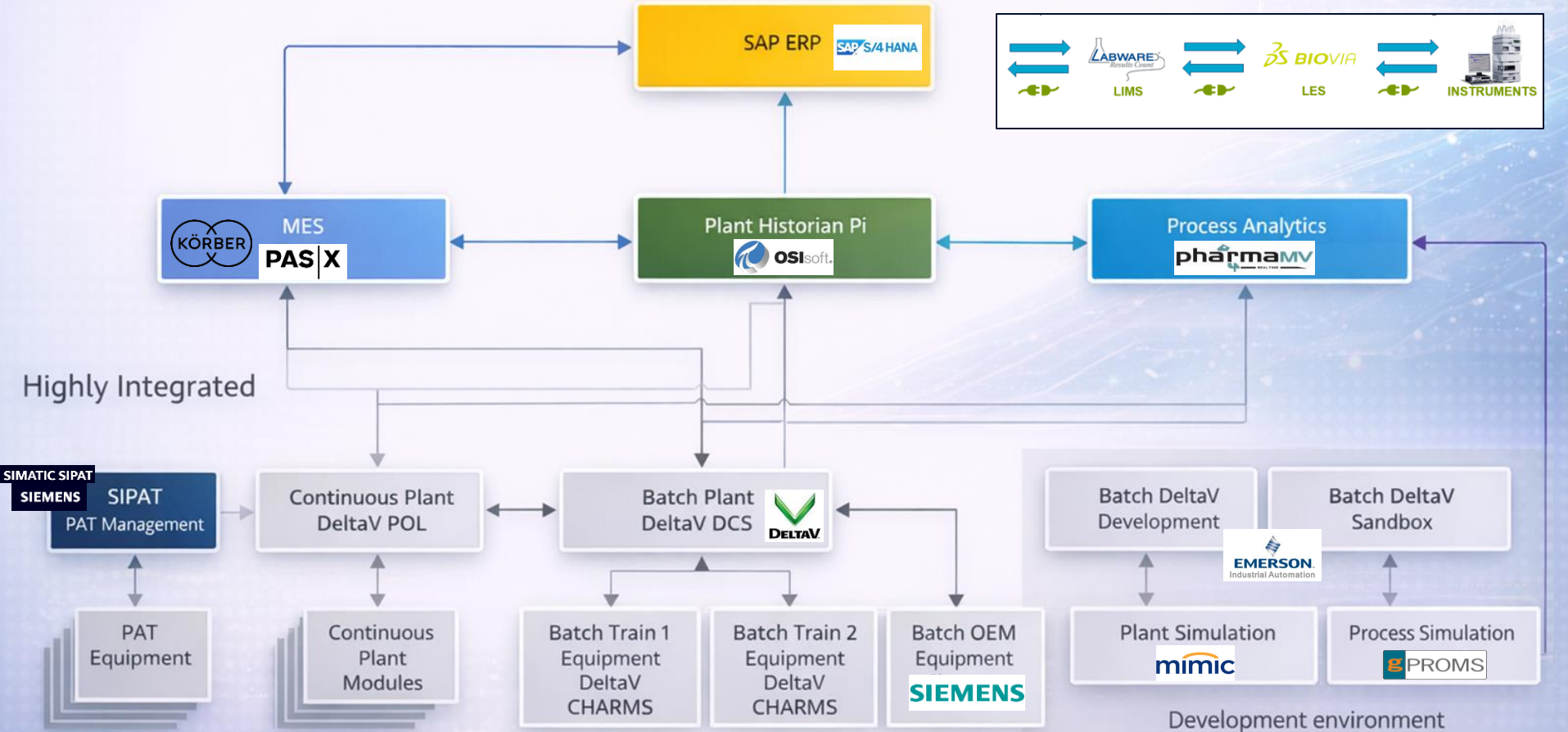
THE DIGITAL ARCHITECTURE SUPPORTING OUR SMART FACTORIES

14 |



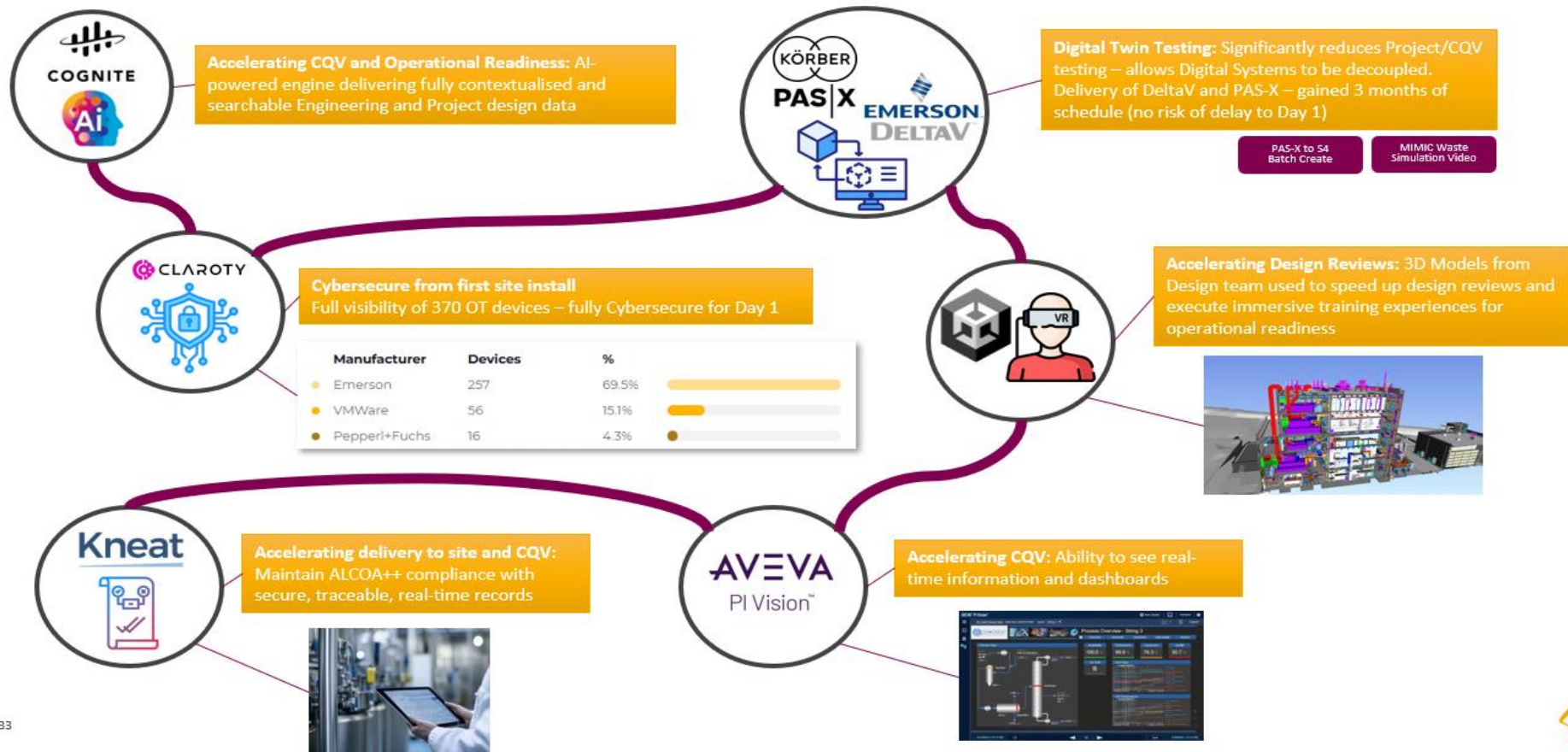
AUTONOMOUS MANUFACTURING: END-TO-END PROCESS INTEGRATION

15 |



INTEGRATED DIGITAL ECOSYSTEM ENABLING SMART MANUFACTURING

16 |



THIS IS WHERE SMART COMMISSIONING CHANGES THE GAME

1. Integrated by Design

- Commissioning, CQV & CSV connected
- Single data flow across lifecycle

2. Data-Led Verification

- Moves from documents → data
- Uses live system data (DeltaV / AMS / PI)

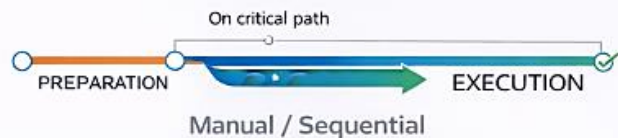
3. Early & Risk-Based Testing

- Digital twins enable early testing (MIMIC)
- CSA delivered through risk-based approach

From reactive validation → proactive, data-led assurance

Smart Commissioning shifts validation from sequential execution to parallel, data-driven delivery.

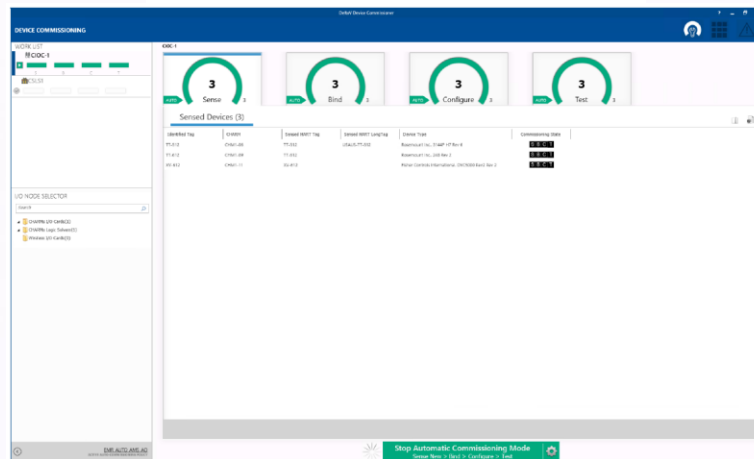
Traditional Commissioning



Smart Commissioning

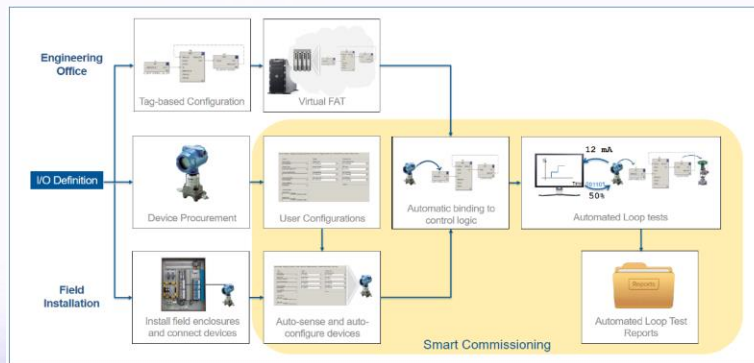


AMS Device Manager



SMART
COMMISSIONING
USING AMS &
DELTA V

FROM DEVICE
CONFIGURATION
TO AUTOMATED
LOOP
VERIFICATION



Document Revision

Test	Actual Result	Pass / Fail	Signature
1°C		Pass	System Administrator (Administrator) Mon Sep, 19 at 20:19 19.09.2017
2 mg		Pass	System Administrator (Administrator) Mon Sep, 19 at 20:19 19.09.2017
10°C			

Revisions

- 1. 1°C Temperature Reading Error (19.09.2017)
- 2. 2 mg Weight Error (19.09.2017)
- 3. 10°C Temperature Reading Error (19.09.2017)

Kneat

**Upload
Electronically –
AMS Software
Automated
Loop Check
Summary
Report**

Generated on 10/16/2025 12:45:38

Summary

Node Name

Node Description

HART Devices Passed

HART Devices Failed

HART Devices Not Tested

HART Devices Eligible for Testing

Test Completion Percentage

IEDNB3030PCIO19

Remote IO Panel RIO-309119-30

5

5

100.00% (5 of 5)

HART Devices

Deviation Signal Tag	Manufacturer Device Type Revision	Module	Module Description	Test Status	Test Steps Taken			Last Test Date	Last Test	
					Step	Test	Expected			Actual
PT_240122_188	Endress+Hauser PTE0902 2	PT-301222-190	Cookson Glycol Supply Pipe	Passed	1	40%	0.01 (0.1 ± 1%)	-0.011 0.1	10/16/2023 12:44:43	BERNARDSON L1AYAZ.LOZ QL372
					2	25%	10.01 (0.1 ± 1%)	10.007 0.1		
					3	50%	50.01 (0.1 ± 1%)	49.999 0.1		
					4	75%	70.01 (0.1 ± 1%)	74.973 0.1		
					5	100%	100.01 0.1 ± 1 %	99.976 0.1		
L.T_240122_186	Endress+Hauser Membrane Tech 7401 07 1	LT-301222-406	Reactor Level	Passed	1	40%	0.01 (0.1 ± 1%)	-0.006 0.1	10/16/2023 12:44:49	BERNARDSON L1AYAZ.LOZ QL372
					2	25%	10.01 (0.1 ± 1%)	10.008 0.1		
					3	50%	50.01 (0.1 ± 1%)	49.994 0.1		
					4	75%	70.01 (0.1 ± 1%)	74.978 0.1		
					5	100%	100.01 0.1 ± 1 %	99.981 0.1		
PT_240122_182	Endress+Hauser Coulter Tech 7401 07 2	PC-301222-402	Reactor Phases Cast (GAP)	Passed	1	40%	0.01 (0.1 ± 1%)	-0.006 0.1	10/16/2023 12:44:46	BERNARDSON L1AYAZ.LOZ QL372
					2	25%	10.01 (0.1 ± 1%)	10.009 0.1		
					3	50%	50.01 (0.1 ± 1%)	49.991 0.1		
					4	75%	70.01 (0.1 ± 1%)	74.976 0.1		
					5	100%	100.01 0.1 ± 1 %	99.995 0.1		
PT_240122_180	Endress+Hauser Coulter Tech 7401 07 3	PC-301222-403	Reactor Phases Cast (GAP)	Passed	1	40%	0.01 (0.1 ± 1%)	-0.006 0.1	10/16/2023 12:44:47	BERNARDSON L1AYAZ.LOZ QL372
					2	25%	10.01 (0.1 ± 1%)	10.009 0.1		
					3	50%	50.01 (0.1 ± 1%)	49.996 0.1		
					4	75%	70.01 (0.1 ± 1%)	74.982 0.1		
					5	100%	100.01 0.1 ± 1 %	99.996 0.1		
PT_240122_182	Endress+Hauser Coulter Tech 7401 07 3	PC-301222-191	Cookson Gly Supply Temp.	Passed	1	40%	0.01 (0.1 ± 1%)	-0.002 0.1	10/16/2023 12:44:48	BERNARDSON L1AYAZ.LOZ QL372
					2	25%	10.01 (0.1 ± 1%)	10.005 0.1		
					3	50%	50.01 (0.1 ± 1%)	49.991 0.1		
					4	75%	70.01 (0.1 ± 1%)	74.978 0.1		
					5	100%	100.01 0.1 ± 1 %	99.990 0.1		

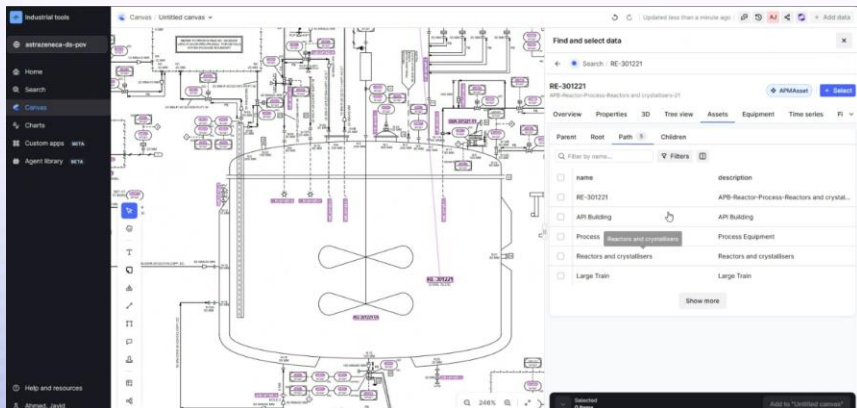
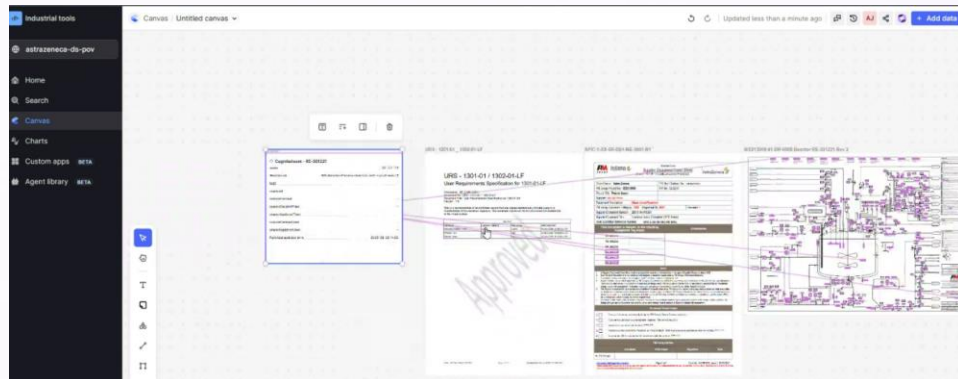
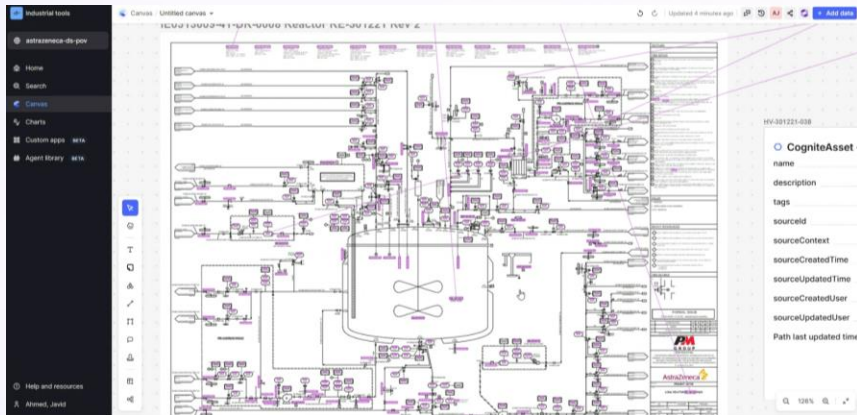
Approvals

20 |



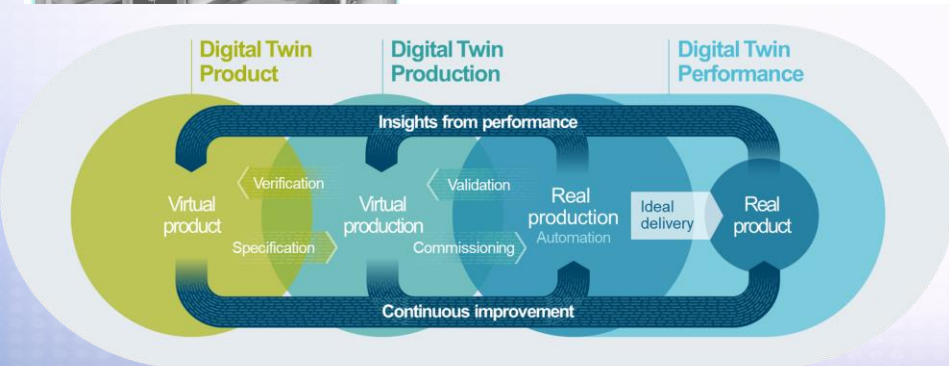
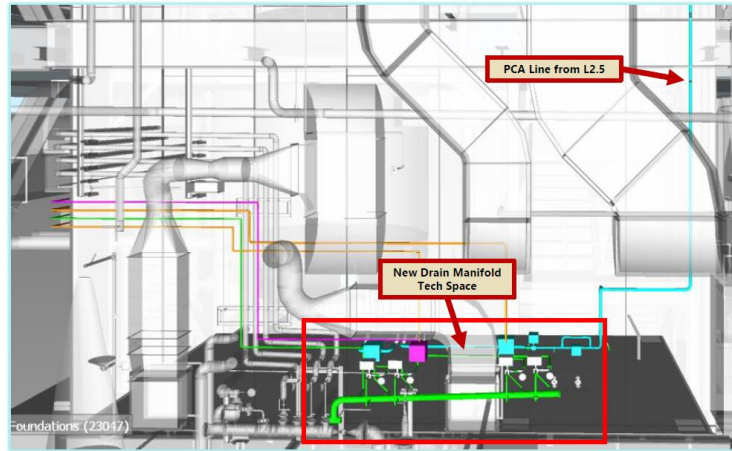
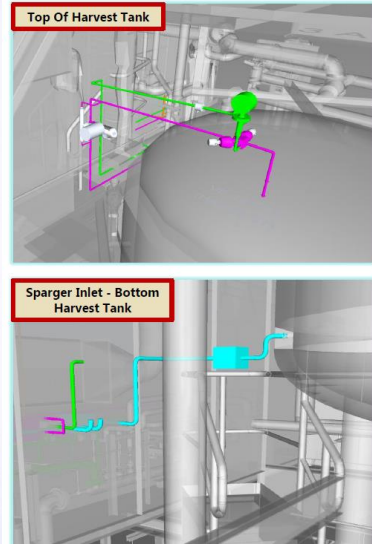
DATA CONTEXTUALISATION - COGNITE AS THE SMART FACTORY DATA LAYER

21 |



DIGITAL TWINS

22 |



Smart Commissioning Ecosystem

- Transform CQV, CSV and Technical Transfer from document-centric compliance into a data-driven, risk-based Smart Factory capability.
- Embed Computer Software Assurance (CSA), Smart Commissioning and digital lifecycle verification.
- Preserve and transfer process knowledge digitally, reducing transfer risk, timelines, and post-go-live issues.



Smart, Data-Led CQV, CSV & Technical Transfer

Core Platforms:

- Emerson DeltaV & MIMIC – automation and control emulation.
- Kneat – digital CQV execution and system of record.
- Cognite – data contextualisation and Smart Factory backbone.
- ellab ValSuite – thermal mapping and environmental qualification.
- PI Historian – operational data trending and verification.



TRADITIONAL NPI MODEL (CSV) VS. FUTURE SC-NPI MODEL (CSA)

25 |

Traditional NPI Model



Future State SC-NPI Model (CSA)

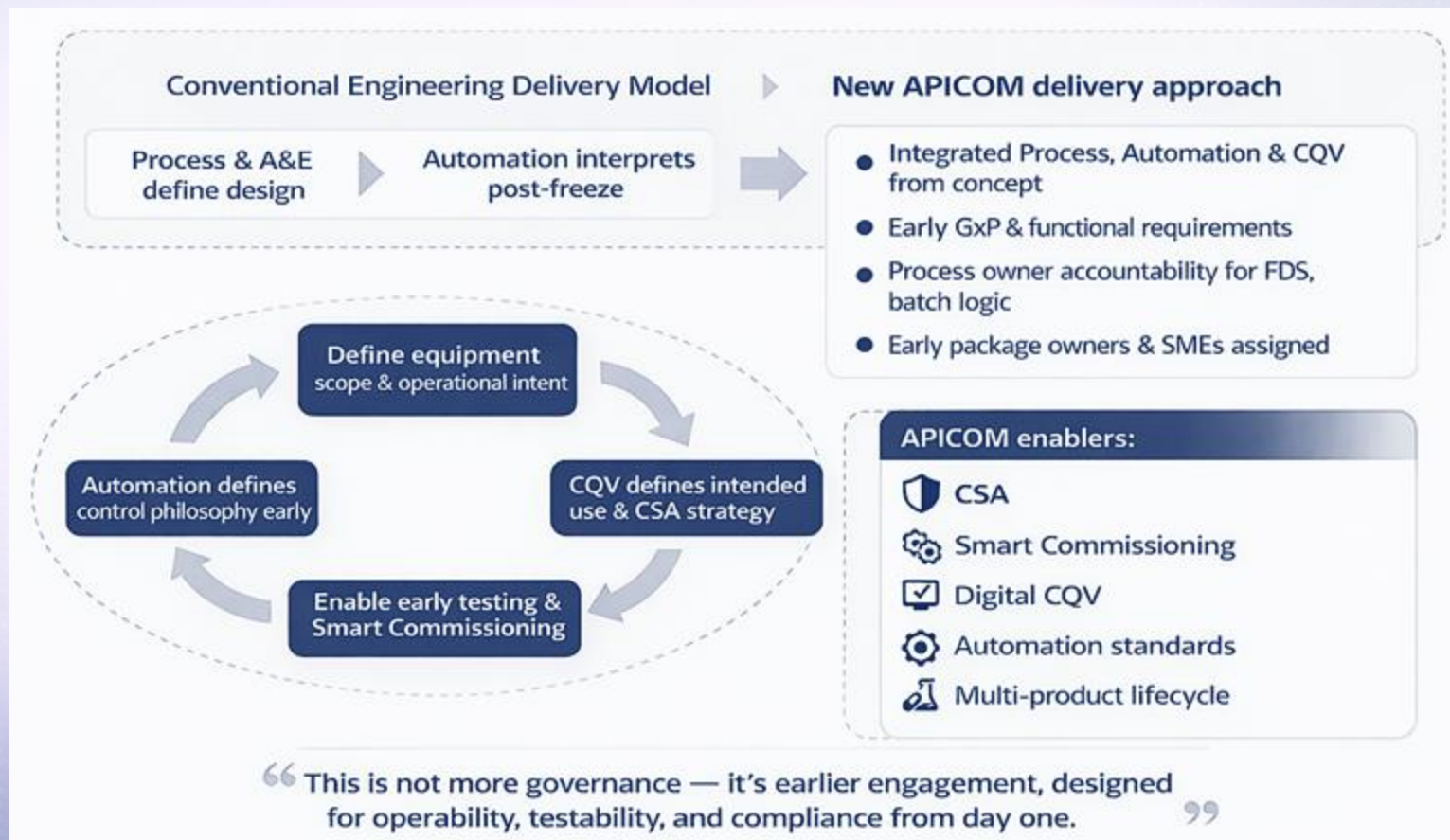


CSV never arrives
late its always
present



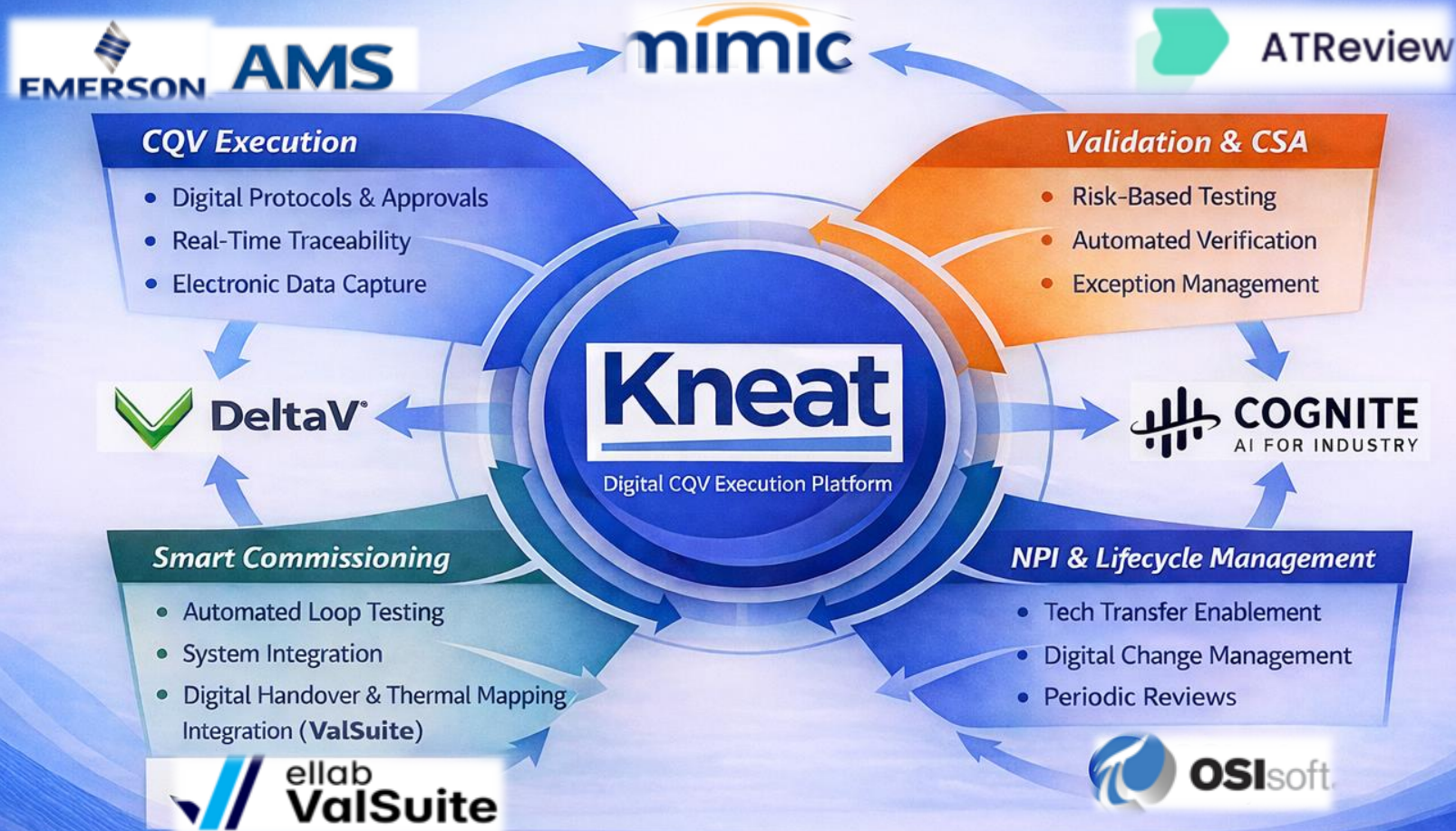
CSA Testing Model

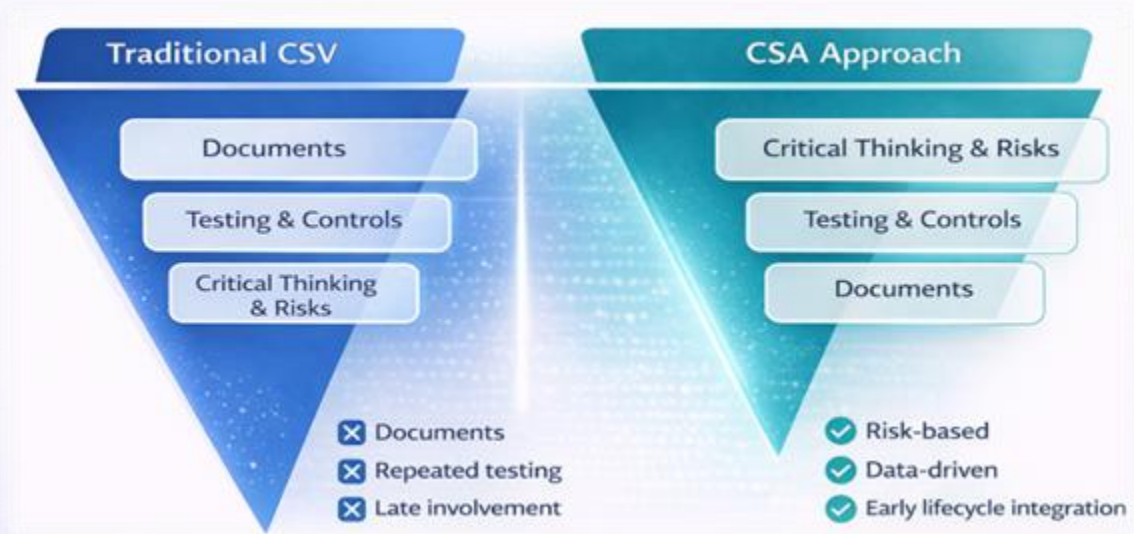
Type of Assurance Activity	Sub-Type
Unscripted Testing	Ad-Hoc Testing
	Error-Guessing
	Exploratory Testing
Scripted Testing	Robust Scripted Testing
	Limited Scripted Testing



CONNECTING CQV, CSA AND LIFECYCLE VALIDATION IN A SMART FACTORY

27 |





- Risk-based testing aligned to criticality
- Leverage vendor testing and automation data
- Focus on what matters (patient safety & product quality)

CSA enables us to test once, leverage data and avoid duplication across the lifecycle.

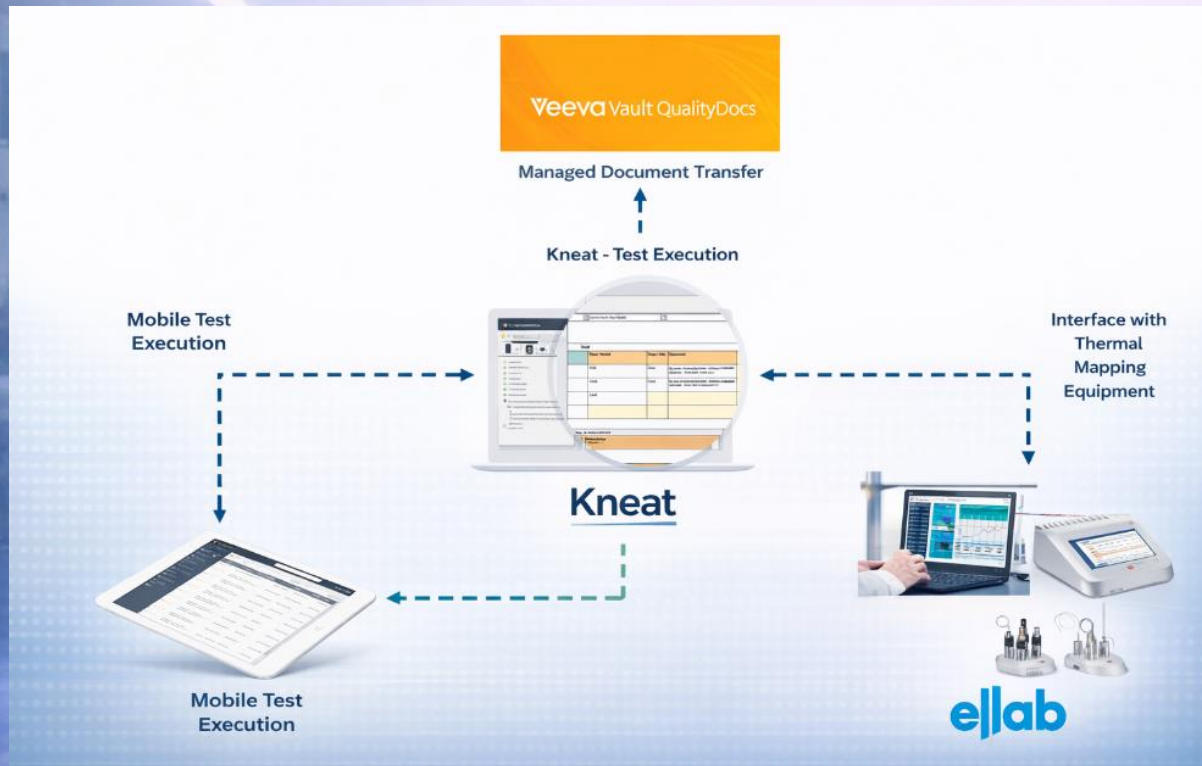
One Data Flow Across the Life Cycle



Create Data once, Verify Once, Reuse across the lifecycle.

Eliminating Duplication and Enabling Continuous Assurance.

INTEGRATION OF QUALITY MANAGEMENT SYSTEM



CONTINUOUS PROCESS VERIFICATION (CPV)



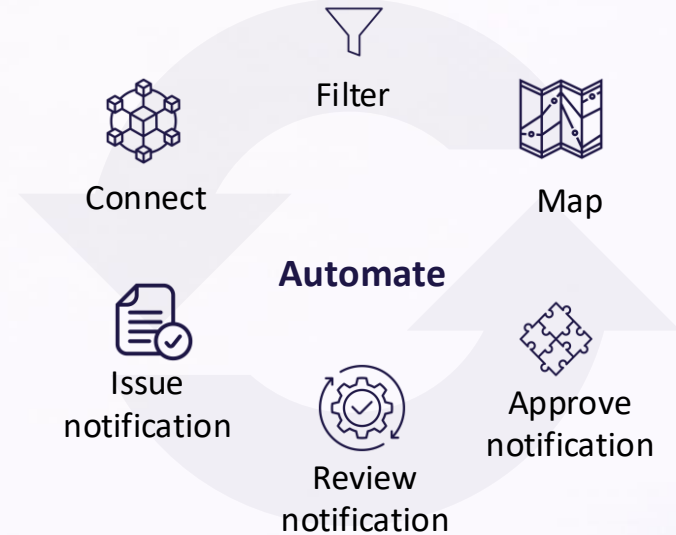
FROM WEEKS OF MANUAL REVIEW TO REAL-TIME AUTOMATION

31 |

Traditional Approach



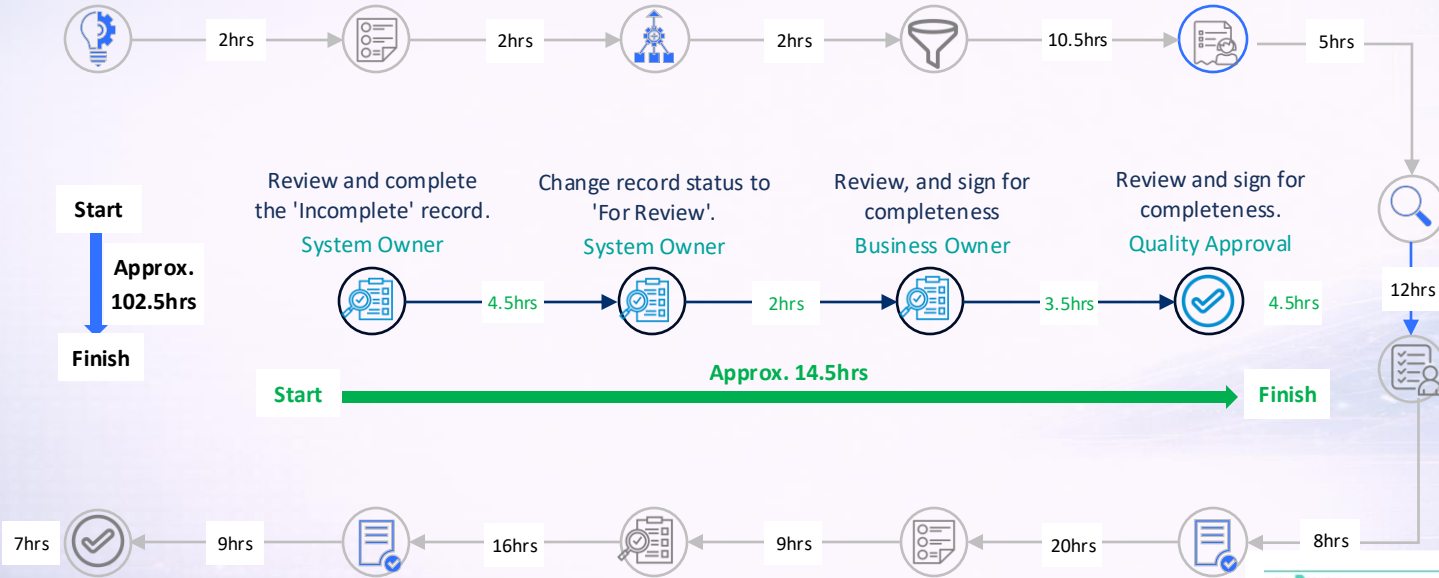
New Approach



AUDIT TRAIL REVIEW SOFTWARE: Orise ATReview

32 |

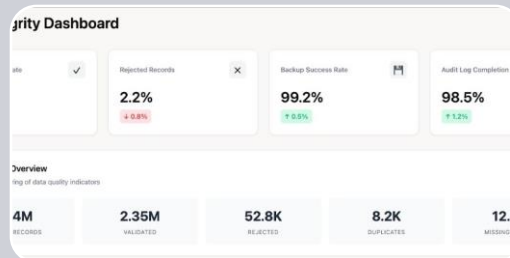
Digital Automated Audit Trail Reviews



ID	Status	Attributable User	Date & Time Stamp	System	Change	Reason
ATC-000-017	Complete	user@company.com	31-Jun-2022 17:04:26	Hot Heat Exchanger	speed 1 = 44	Updated reason
ATC-000-018	For Review	user@company.com	31-Jun-2022 17:04:26	Hot Heat Exchanger	speed 1 = 44	Updated reason
ATC-000-019	Reviewed	user@company.com	31-Jun-2022 17:04:26	system Name	speed 1 = 44	Updated reason
ATC-000-020	Reviewed	user@company.com	31-Jun-2022 17:04:26	Hot Heat Exchanger	speed 1 = 44	Updated reason
ATC-000-021	For Review	user@company.com	31-Jun-2022 17:04:26	system Name	speed 1 = 44	Updated reason
ATC-000-022	Incomplete	user@company.com	31-Jun-2022 16:05:02	system Name	number unknown = 12	Not unknowns
ATC-000-023	Incomplete	user@company.com	31-Jun-2022 16:05:02	Hot Heat Exchanger	unknown = 12	Not unknowns
ATC-000-024	Incomplete	user@company.com	31-Jun-2022 16:05:02	Hot Heat Exchanger	number unknown = 12	Not unknowns

WHAT SMART COMMISSIONING ENABLES

33 |



⚡ SPEED

- Faster commissioning
- Reduced NPI timelines
- Earlier system readiness

↓ 30–40% Faster Commissioning

🛡️ QUALITY

- End-to-end traceability
- Improved data integrity
- Inspection-ready by design

↓ Reduced Deviations & Rework

⚙️ EFFICIENCY

- Reduced manual effort
- Elimination of duplication
- Reuse of data across lifecycle

↑ Right-First-Time Execution

Regulatory and Compliance Requirements



Importance of Compliance

Compliance with regulations ensures safety and efficacy in pharmaceutical products, protecting public health.

Navigating Regulations

Commissioning teams must be well-versed in navigating complex regulations to complete projects successfully.

Successful Project Completion

Adherence to compliance requirements is vital for the timely and successful completion of pharmaceutical projects.

Typical Commissioning Bottlenecks



Delays in Projects Handover

Delays in project can significantly hinder the commissioning timeline, causing setbacks in project delivery.



Data Silos and Fragmented Systems

Data is often stored across disconnected systems, limiting visibility and traceability.

This fragmentation creates inefficiencies, delays decision-making, and increases the risk of errors during commissioning and qualification.



Control System Integration Issues

Integration issues with control systems can create significant challenges during commissioning, affecting overall project success.



Lack of Team Collaboration

A lack of collaboration among teams can lead to misunderstandings and inefficiencies, complicating the commissioning process.

Effective collaboration between CQV CSV and IT teams is crucial for project success, ensuring that both teams align their goals and objectives.

Leveraging Data for Ongoing Optimisation



Continuous Optimisation

Collecting and analysing data allows businesses to continuously improve their processes through informed decision-making.

Adaptation Over Time

Data-driven insights enable companies to adapt their strategies and processes as conditions and market demands evolve.

Improvement Strategies

Utilising data effectively leads to the development of better strategies for process improvement and operational efficiency.

KEY TAKEAWAYS

36 |



Smart Commissioning is a foundation for the Smart Factory



Digital CQV enables CSA in practice



Integration matters more than tools



What We'd Do Differently Next Time



Define data
strategy earlier



Standardise
integration patterns



Align CSA
upfront

QUESTIONS?

38 |



Partner Technologies

Kneat



Session 10.2

Digital Validation Mastery: Enabling Validation 4.0





VALIDATE 2026

APRIL 29-30, 2026
THE MARKER HOTEL, DUBLIN

SAVE THE DATE

 validateconference.com



Good Practice Guide: Digital Validation

- The transition from traditional, paper-based validation to a digitally integrated framework remains a complex challenge.
- This Good Practice Guide considers how increased adoption of Digital Validation Tools (DVTs) in the life sciences industry can support a growing commitment to data integrity, operational efficiency, and regulatory compliance.
- Developed by a global team of experts in validation, regulatory compliance, quality assurance, and digital transformation, this Guide presents real-world insights, case studies, and structured methodologies to facilitate the successful integration of digital validation into business operations.

Concept Paper: Digital Validation – Future Advances

- Exploring the need for easily accessible data, the role of AI, LLMs, ML, predictive analytics, and pivoting to a more data-centric digital validation mindset.



GOOD PRACTICE GUIDE:

Digital Validation



Digital Validation Mastery: Enabling Validation 4.0

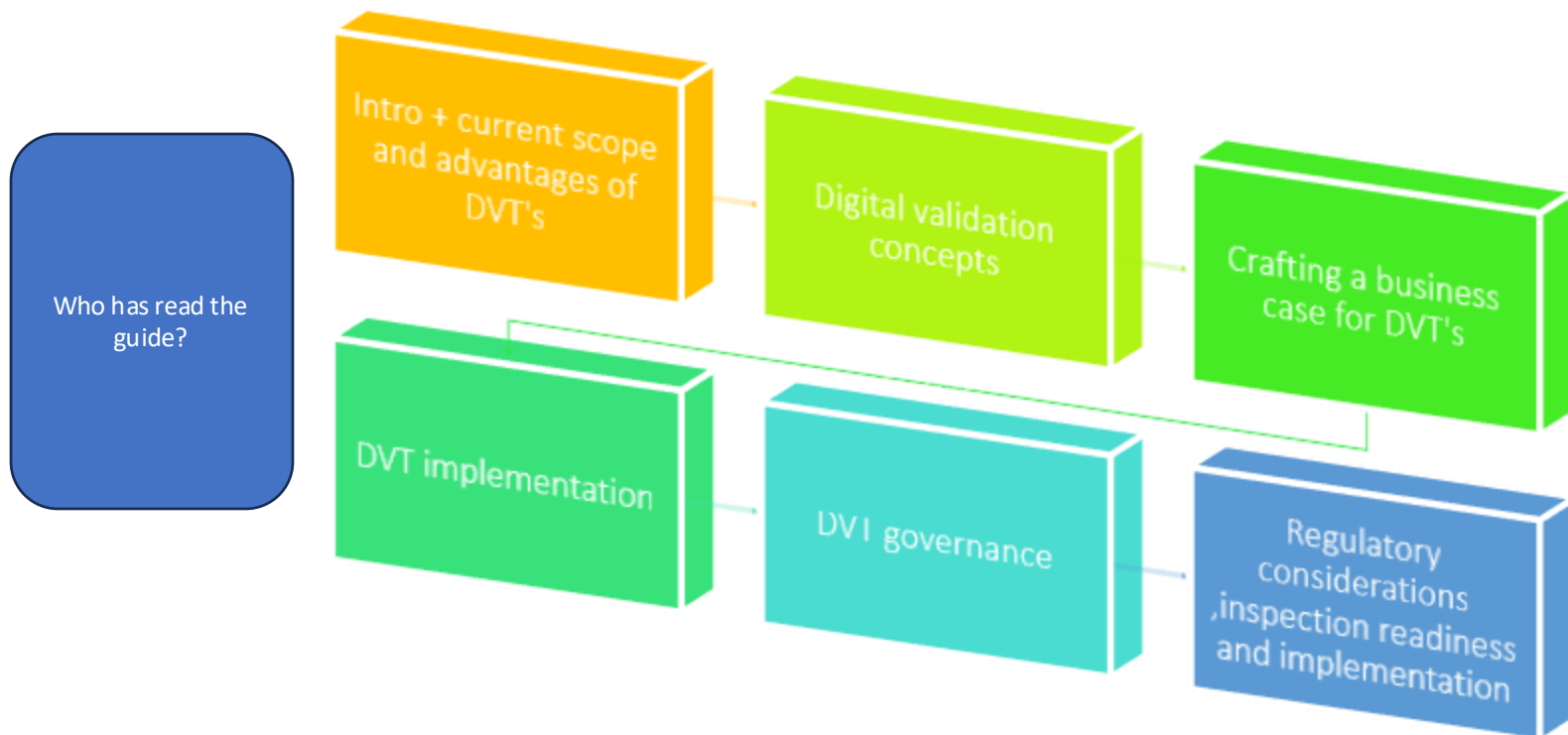
Dori Gonzalez-Acevedo , USA
Phillip Jarvis, No deviation , Ireland
Dave O'Connor, No deviation, Ireland

PROCELLARX



No deviation
by Efor

Good Practice Guide: Content



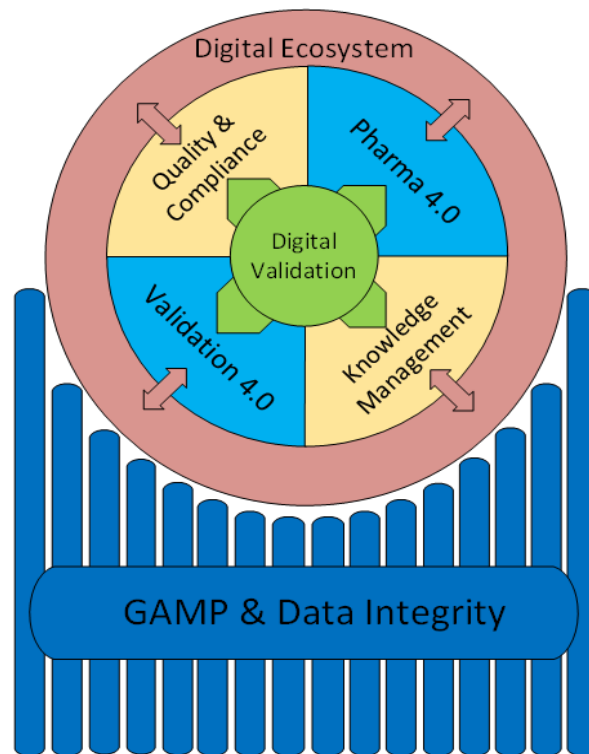
DVT: Current State

- DVTs have been widely adopted over the past 10 years
- In a sustaining and continuous improvement phase
- Mindsets have recentered to a more digital outlook
- Focus on validation 4.0
- Full potential of DVTs not yet realized



DVT: Key Digital Validation Concepts

- A DVT, What is it?
- Intended Use
- Culture Change, Organizational Change Management, and Knowledge Management
- Data Accessibility
- Integration



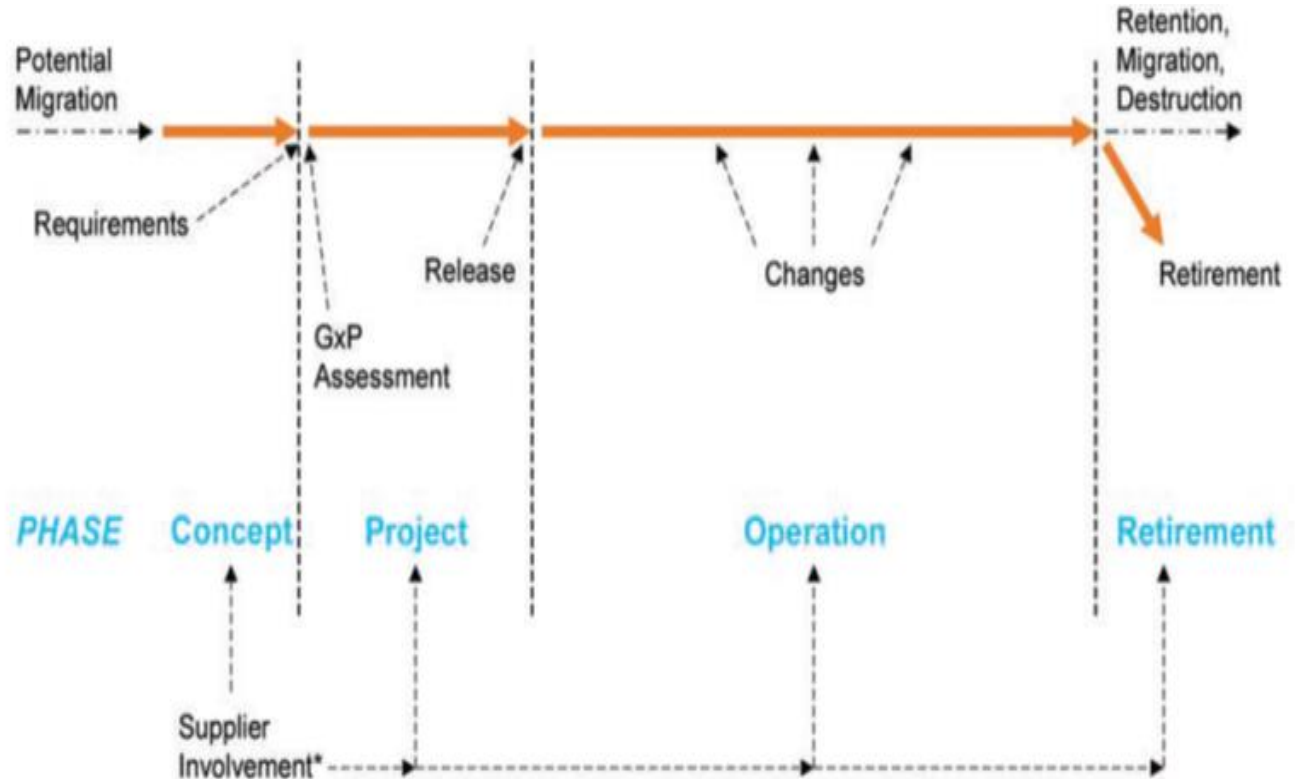
DVT: The Business Case

- Automatic Data Integrity/ALCOA++ compliance
- Review, Approval and execution efficiency
- Remote Working
- Paper reduction/Sustainability
- Audit Readiness



DVT: Implementation

- Define what the owner/user wants (URS)
- Creating a Culture for Digitalization and a digital mindset
- Maturity Assessment of organization
- Implementation
- Sustaining
- Opportunities
- Retirement, migration
- Creation of right “culture” for DVT adoption



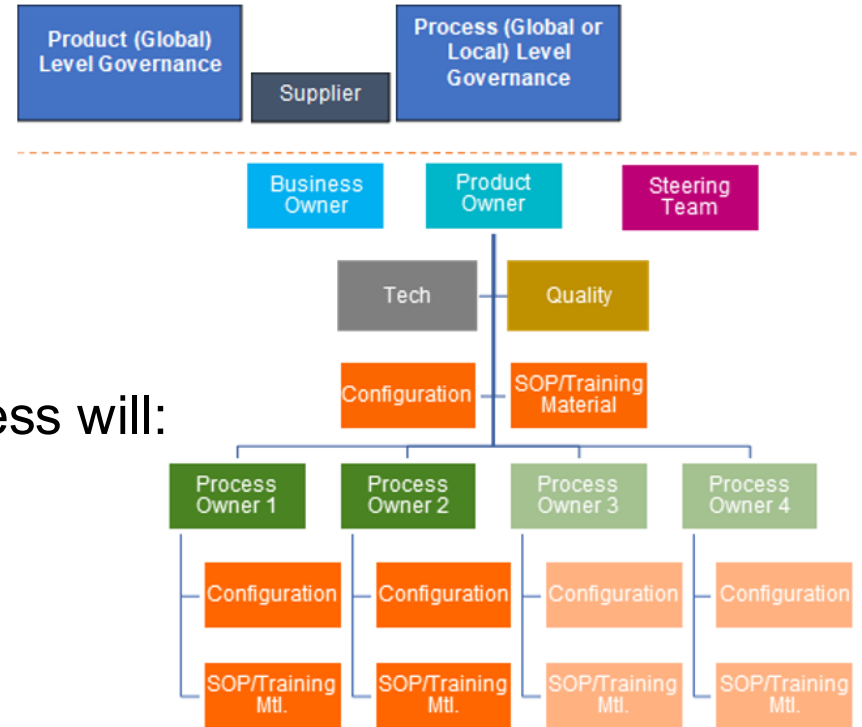
DVT: Governance

Governance Team will:

- Manage Change
- Procedures
- Training
- Performance Monitoring/Feedback

A visible and strong governance process will:

- Speed up deployment
- Simplify
- Reduce variability
- Achieve standard work



DVT: Key Regulatory Considerations

- Current Regulatory Landscape
- Audit Strategy and Readiness
- Remote/In Person Audits
- Case Study Success
- Unexpected Challenges



Convergence of Guidance and Technology



Recent guidance published on AI allows us to see a future where DVT's and AI could enable a Validation 4.0 paradigm

VALIDATE 2026

Val 4.0 - The Whole Plant View

Slide courtesy from
Validation 4.0 GPG

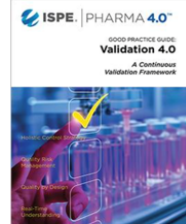
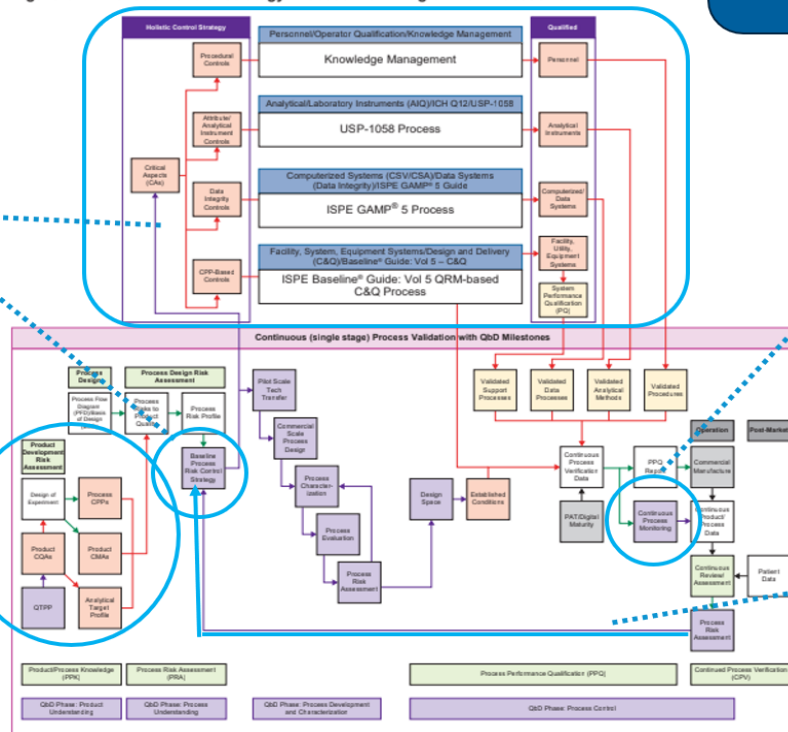


Figure 12.1: Holistic Control Strategy Process Flow Diagram for Process Validation



Process control strategy is the heart that feeds the requirements for all other parts of the plant.

Evidence of effectiveness supports continuous validation

*QbD is the foundational basis

Feedback loop enables real-time and continuous validation

*QbD= quality by Design

VALIDATE 2026



Enablement of Validation 4.0 (case study for QbD /control strategy)

- Capturing key process knowledge in phase 1 of process validation digitally enables efficiencies for process validation / *CQV /tech transfer + Enables Validation 4.0

Risk:

Intermediate or Final Attributes	Effect on Attribute	Impact/Severity	Criticality
☐ Dissolved O2 IQA-55 Critical • Production Culture		9. Very High	9 Critical
Justification: Reduced dissolved oxygen (DO): Lower impeller speed results in decreased gas-liquid mass transfer, leading to insufficient oxygen supply for cell growth and metabolism. This can cause reduced cell viability and productivity. High impeller speed significantly increases dissolved oxygen (DO) levels in a production culture. The increased agitation enhances gas-liquid mass transfer, allowing more oxygen to dissolve into the culture medium.			



Process parameters linked via process knowledge to risks and classification of CQA 's (Critical Quality Attributes)/ CPP's (Critical Process Parameters)

All captured digitally , so can feed into DVT (Digital Validation Tool)

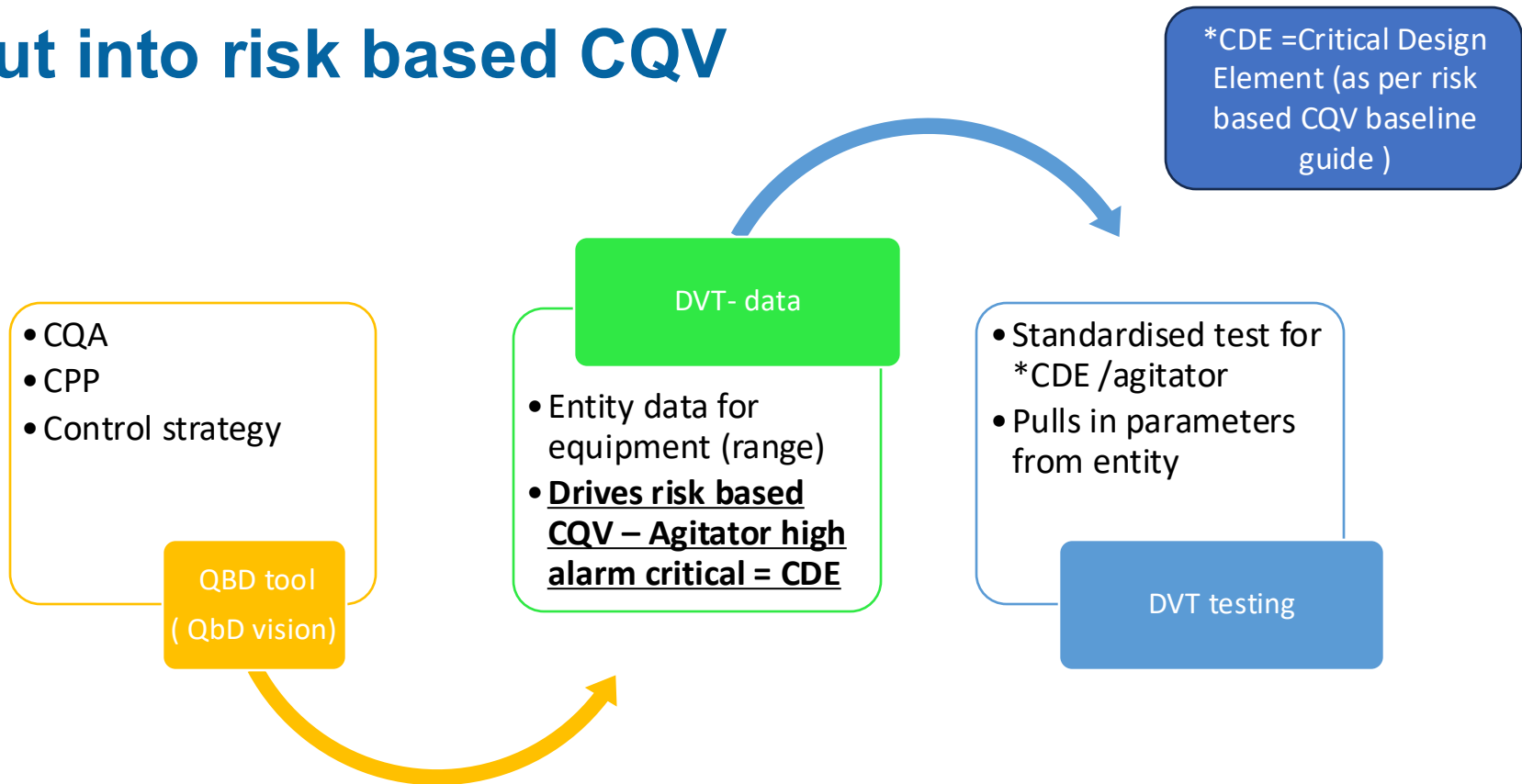
** case study from Validation 4.0 guide using QbD vision, for A-mab process

*CQV = commissioning ,Qualification / Validation

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Input into risk based CQV



VALIDATE 2026

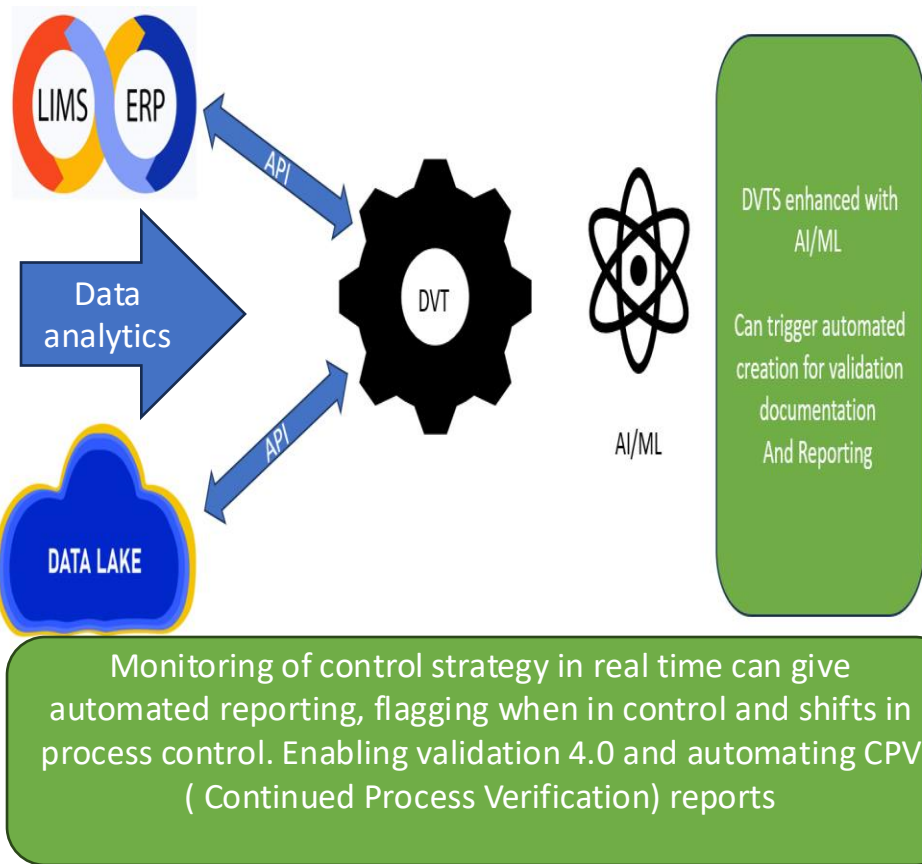
Monitoring Control Strategy

Figure 6.16: Process Analytics/Batch Data for Aggregation

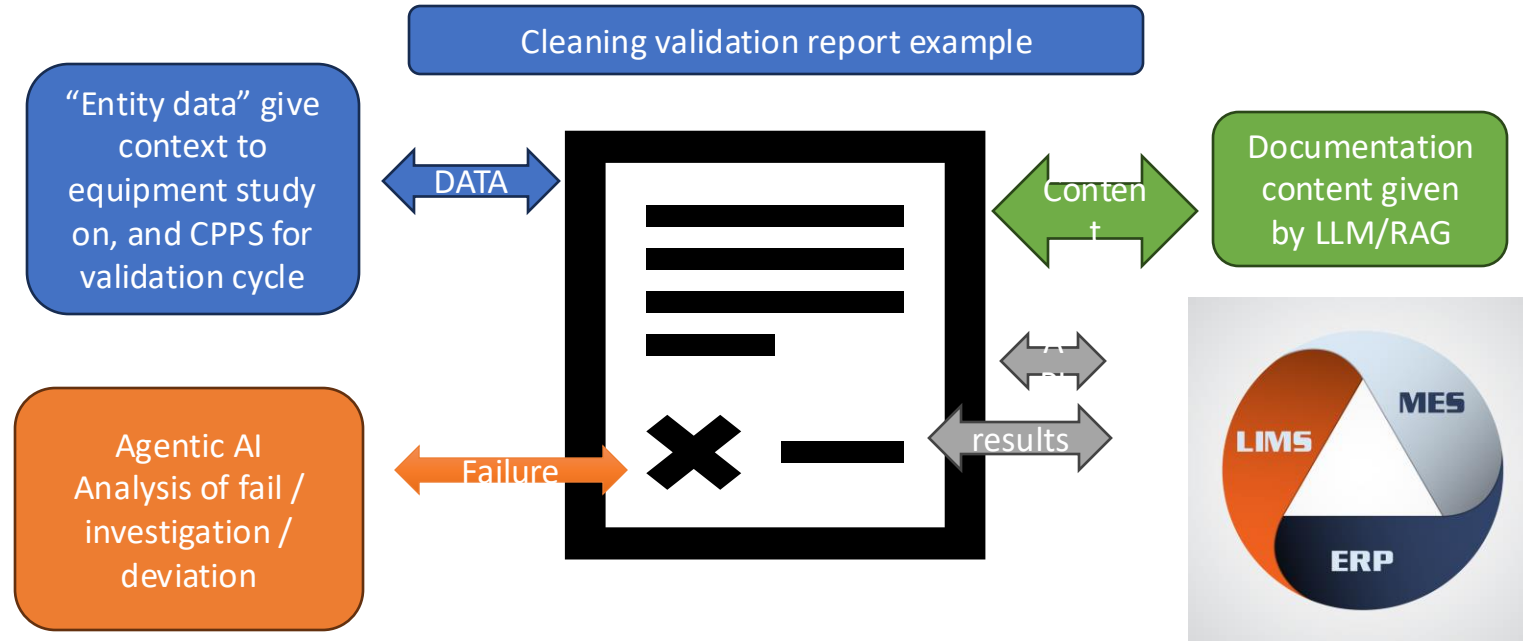
Section Break (Next Page)



*** figure reference from Validation 4.0 GPG



What could a mindset shift from Paper on Glass to Data-centric look like?



VALIDATE 2026

Session 11.1

The State of Validation 2026:

Accelerating Digital
Maturity in the Age of AI



Agenda

- Introductions
- About the State of Validation
- Pressure & Practice
- Digital Maturity
- AI — Arrival & Accountability
- The State of Validation 2026 Report Launch
- Audience Q&A



Introductions

- The 2026 State of Validation report is authored by validation industry expert **Donncadh Nagle**, senior CQV consultant at Jacobs Engineering and lecturer at Technological University Dublin.
- With oversight from **validation subject matter experts** at Kneat, IPS-Integrated Project Services, PM Group, and Telstar (A Syntegon Company).



Session Panelist

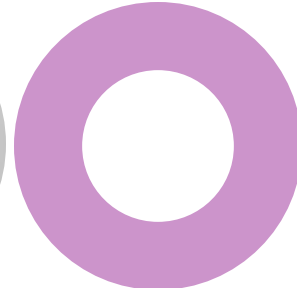


Donncadh Nagle

Moderator, Jacobs / TU Dublin



Session Panelists



Michael Sweeney

CQV Electronic Validation
Lead, PM Group



Durward Sutherland

Validation & Compliance
Manager, IPS EMEA



Ruairi McGarry

Senior Product Manager,
Kneat Solutions



About State of Validation



Background & Purpose

- Fifth year with **87% survey response growth** from 2025.
- Initiated in 2022 by Kneat, an annual global validation industry study — **the first of its kind in the validation industry.**
- State of Validation 2026 includes **qualitative research insights and showcases trends** to illustrate the evolving dynamics in the validation industry.
- The **only available and actionable industry dataset** that enables regulated companies to reference, benchmark, and enhance their validation programs, teams, and technologies.
- Enables a **deeper longitudinal analysis** of broader trends impacting the validation industry.

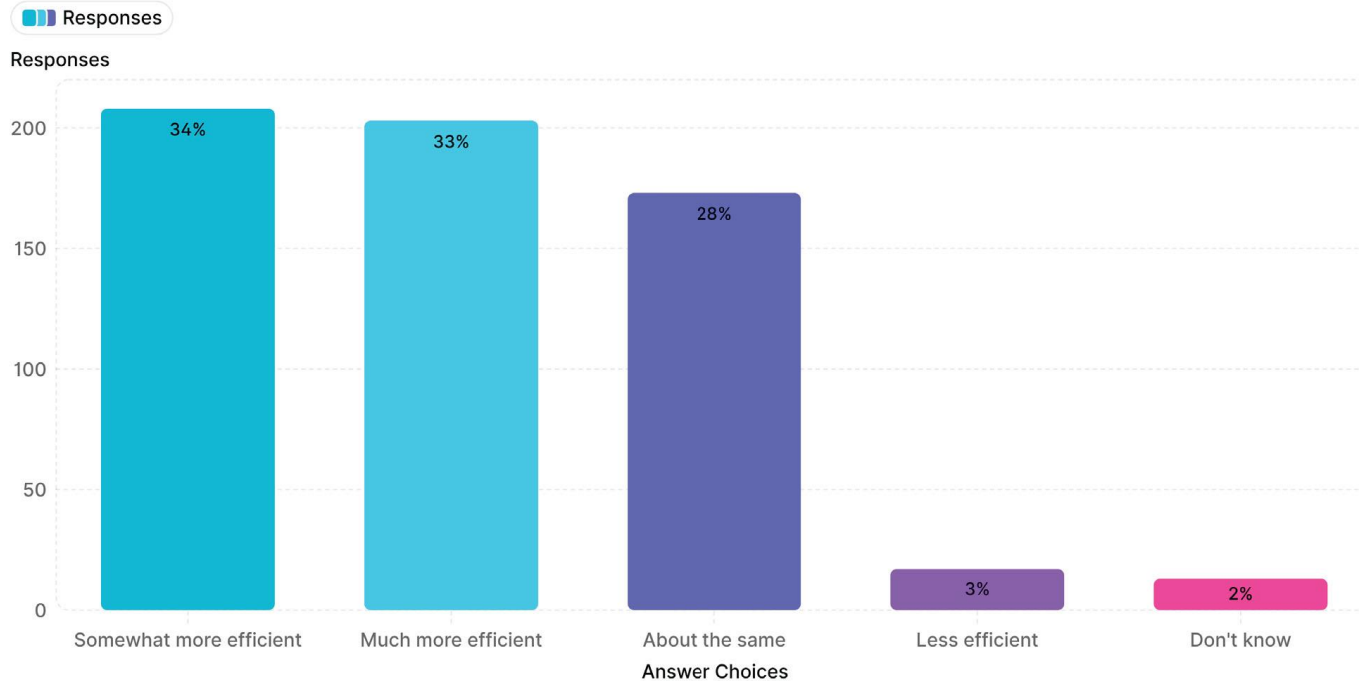
Pressure & Practice

WORKLOAD | CHALLENGES | EFFICIENCY PARADOX



Workload at a Five-Year High

- 80% report increased workload in 2026.
- 45% say workload increased significantly — the highest in 5 years of the study.



Challenge + Efficiency Paradox

- Top 3 challenges — 3rd consecutive year.
- 67% report greater efficiency than a year ago:
 - 33% much more efficient
 - 34% somewhat more efficient
 - 3% less efficient

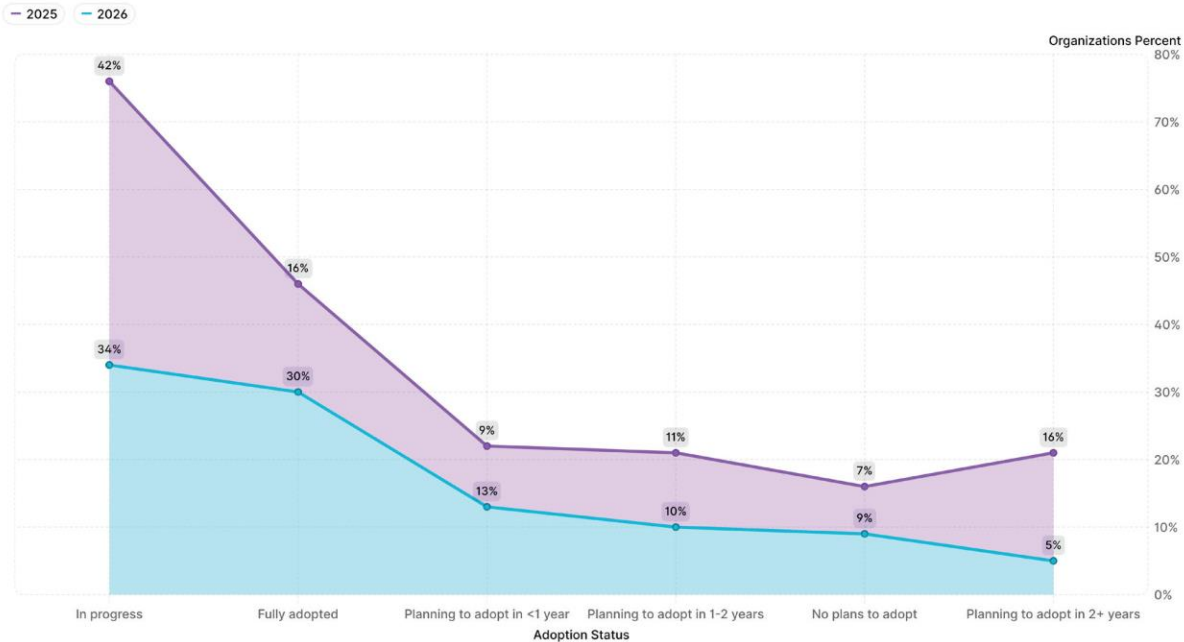
Rank	2026	2025	2024	2023	2022
#1	Audit readiness	Audit readiness	Compliance burden	Shortage of human resources	Shortage of human resources
#2	Compliance burden	Compliance burden	Audit readiness	Efficiency	Efficiency
#3	Data integrity	Data integrity	Data integrity	Lack of tech resources	Lack of tech resources

Digital Maturity

DIGITAL VALIDATION ADOPTION | THE PAPER GAP



Digital Tool Adoption — The Tipping Point



- **64% using or implementing a digital validation tool:**
 - **30% fully adopted**
 - **34% in progress**
 - **Full adoption nearly doubled year-over-year (16% to 30%)**

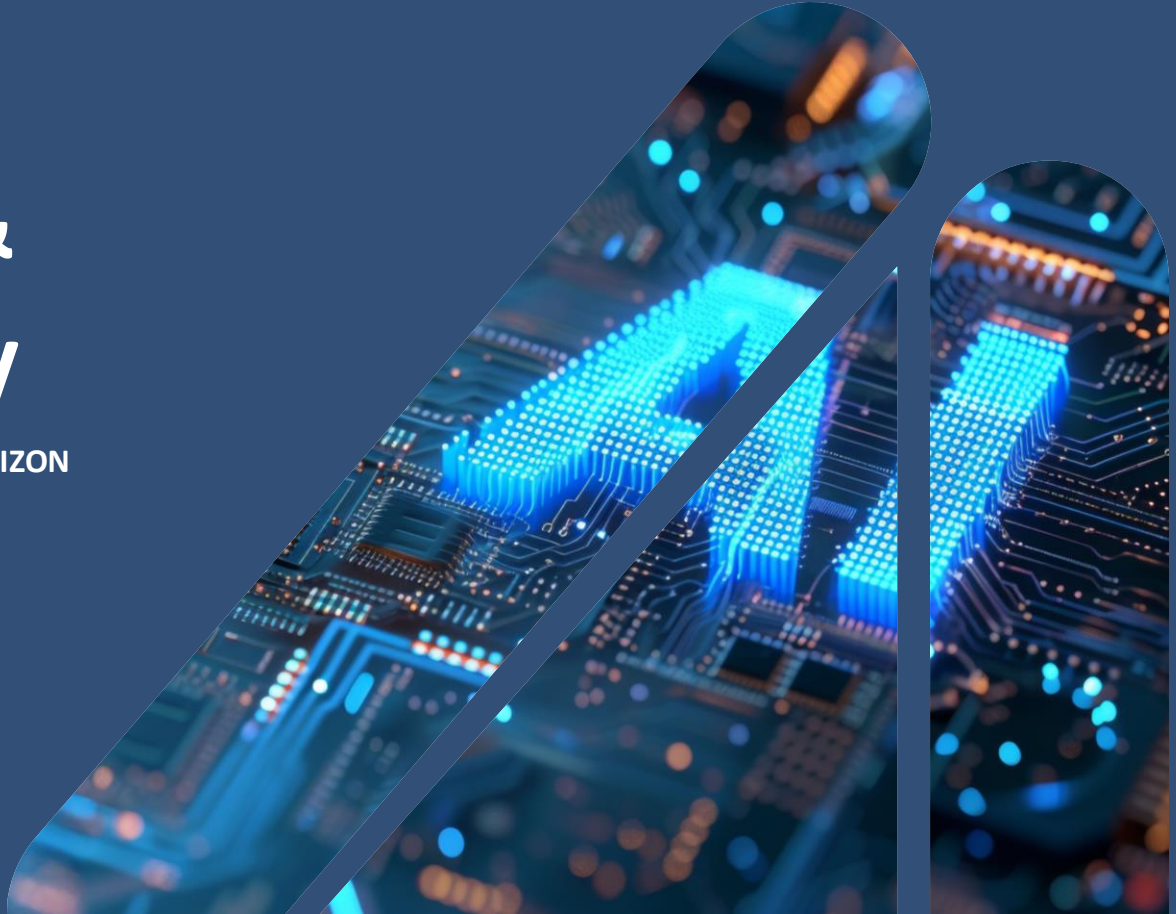
Digital Maturity & The Paper Gap

- Only 13% fully digital across all record types.
- Hybrid environment are the norm — even in digitally progressed organizations.
- Most paper-persistent records: logbooks (41%), batch records (35%), validation protocols (33%).

Maturity Level	2026 (n = 614)
Level 3 - Maturing (hybrid paper-digital model)	25%
Level 4 - Optimizing (predominantly digital)	23%
Level 2 - Defined (early adoption, predominantly paper-based)	21%
Level 1 - Initial (primarily paper-based)	17%
Level 5 - Transformed (fully digital and automated)	12%
Don't know	2%

AI — Arrival & Accountability

USE CASES | CONCERNS | THE 2030 HORIZON



AI Has Arrived in GxP Validation

- **The turning point:** for the first time more respondents are actively using AI in GxP (22%) than have no AI strategy at all.
- **"Not considering AI"** collapsed from 46% to 19% in a single year.
- **Active use cases:** protocol drafting, data review, traceability, deviation narratives, test case generation.

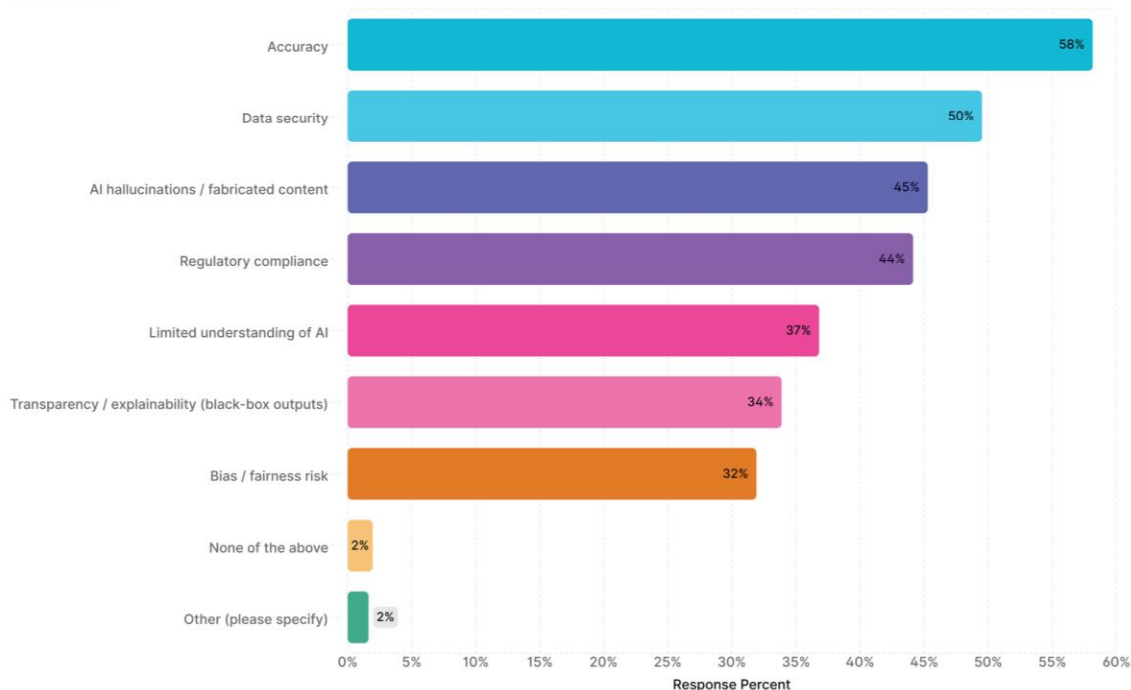
AI Status	2026	2025
Yes - planning to implement AI in validation / quality (GxP)	24%	28%
Yes - currently using AI in validation / quality (GxP)	22%	16%
No - not currently considering AI in any area	19%	46%
No - but using AI in other (non-GxP) areas	18%	10%
Yes - piloting / evaluating AI for validation / quality (GxP)	17%	-

Note: 2026 response options were expanded to include a separate "piloting/evaluating" category not present in 2025.

AI Concerns — What the Industry Is Worried About

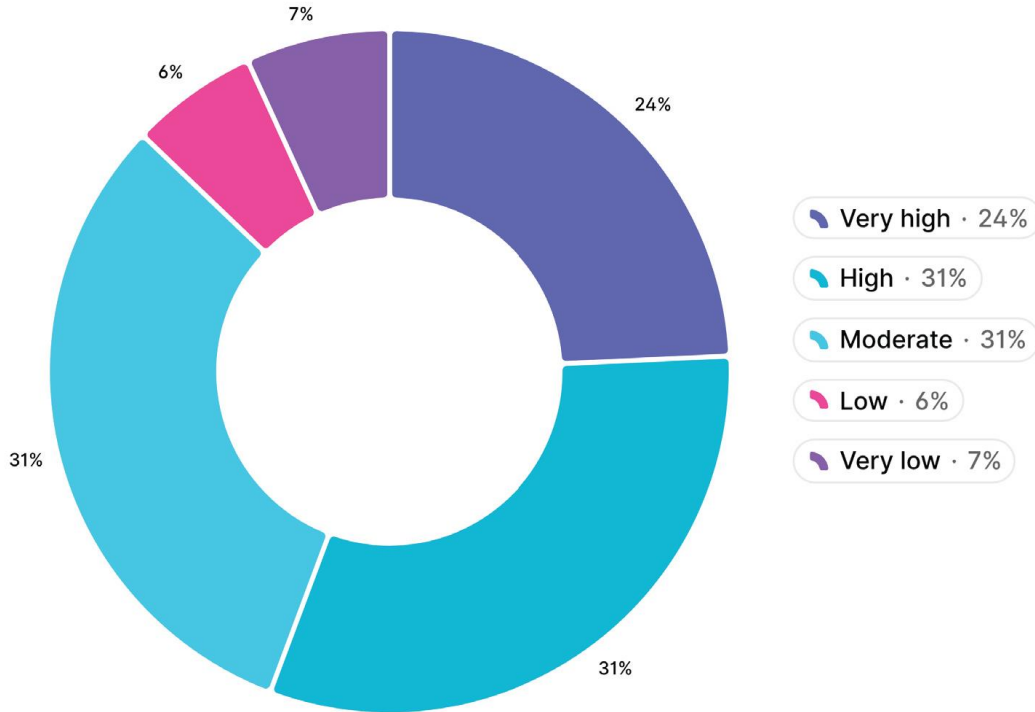
Response Percent

Answer Choices



- **Key signals:**
 - 58% accuracy (core GxP risk)
 - 50% data security
 - 45% hallucinations (new 2026 category)
 - 2% "none of the above" (concern is near-universal)

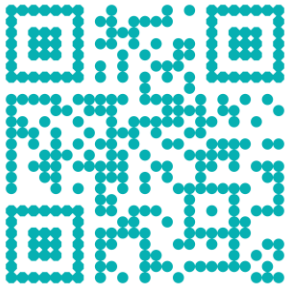
Risk-Aware. Committed. The 2030 Horizon.



- 78% very or somewhat confident AI will be standard in validation by 2030.
- The industry is not blind to the risks — it simply believes AI integration is coming, and the work is building the frameworks.

Launching Now: The 2026 State of Validation Report

Thank you to all **contributors, survey respondents, and interviewees** whose insights contributed to the report.



Be among the first to access the **2026 report** — scan the QR code to download your copy now or visit stateofvalidation.com



Session 12

Resilience is a Validation Activity: We Rebuild, We Validate, We Protect

Elba Madouar | Digital
Transformation Leader



RESILIENCE IS A VALIDATION ACTIVITY

We Rebuild. We Validate. We Protect.

Elba Madouar • Closing Keynote



Five seconds.



Lonza

SANOFI PASTEUR



ThermoFisher
SCIENTIFIC

18 years.



February 2024.

Sat 23:00

Lyon ER. Released 3am.

Sun 03:00

5 hrs driving back to Switzerland. Alone.

Sun 11:00

Zug Emergency Room. Sent home.

Tue 12:00

Zug Emergency Room again. Sent home. With throat lozenges.

Thu 13:30

Ambulance.

5 days. Alone.



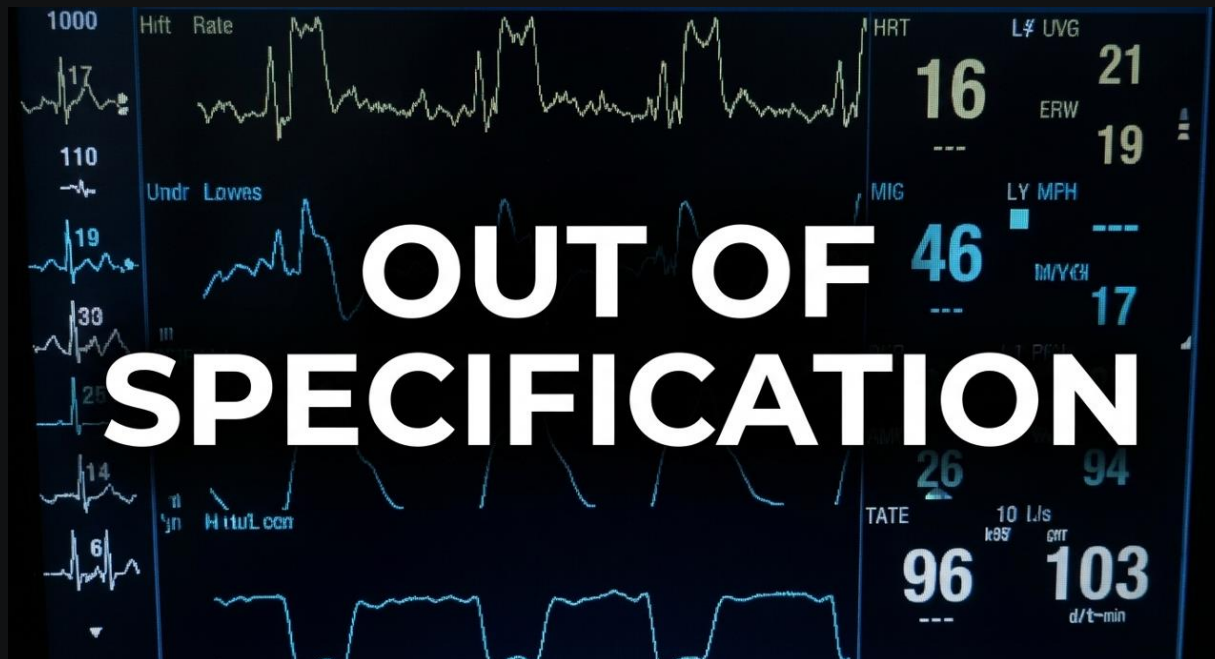
Day 5.

Hi Asma, Shane here from PDP I'm reaching out as we have tried to contact Elba following her incident we want to make sure all is okay but haven't gotten any responses from her. Can you give an update ? As we are worried and the client is looking to understand how long she will be on leave for.

12:58

Mechanical ventilation - Deep sedation - 7 surgeries - 18 days.

Day 8. Transferred to another hospital.



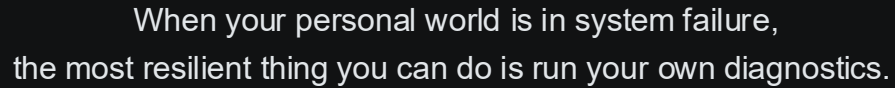
Don't silence the alarm because it's inconvenient. Don't silence it because someone with more authority says it's fine.

Trust Your Signal

Four Lessons

What a near-fatal system failure taught a validation professional
about the human system.

Run Your Own Diagnostics



Lesson 2

You Can't Copy-Paste a Legacy Identity

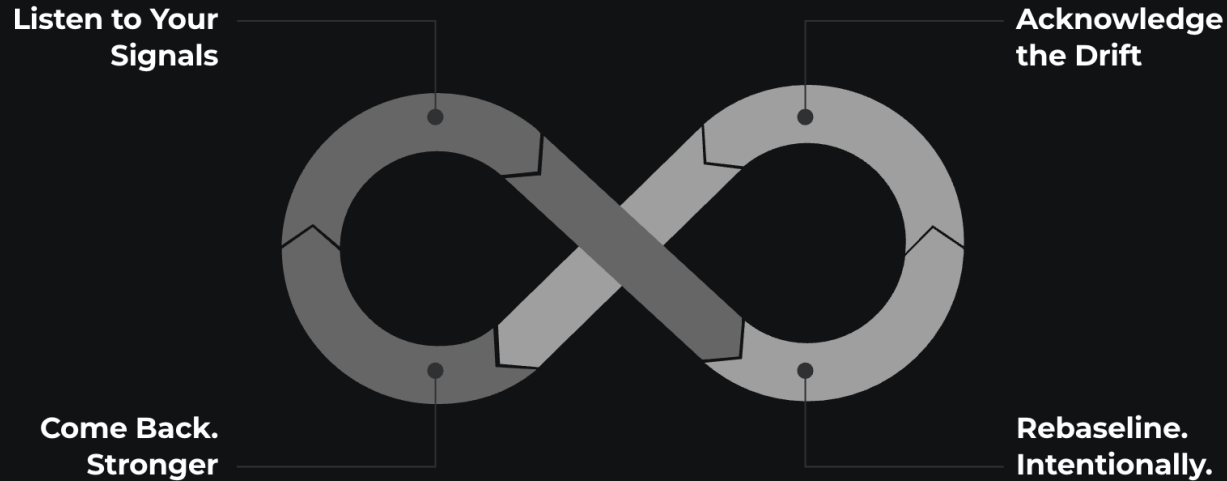


In every transformation, if you don't consider the environment, the project will fail.

Lesson 3

The Human Validation Loop.

Even the most validated system can drift.



Have the courage to pause before the system forces a shutdown on you.

Lesson 4

New Baseline. Same Purpose.



Your value is not defined by your temporary fragility.

Your Signature Is a Promise

A close-up, slightly blurred photograph of a person's hand typing on a laptop keyboard. The hand is positioned in the lower right quadrant of the frame. In the background, a laptop screen displays a document with text, which is also out of focus. The overall lighting is dim, with a dark blue and purple gradient overlay on the left side of the image.

I have checked.

I have traced.

I have verified.

This system will not fail the person who needs it.

Resilience Is a Validation Activity

*Our work is a line of defence.
For the next patient. For someone like me.*

We Rebuild. We Validate. We Protect.

YOU ARE THE VALIDATORS OF RESILIENCE.