Session 1.1

How Digital Validation Was a Key Enabler to MSD ONEQV

(Combing C&Q – CSV)

Kneat

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

Validate in Dublin

Apr 2026

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MSD

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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.

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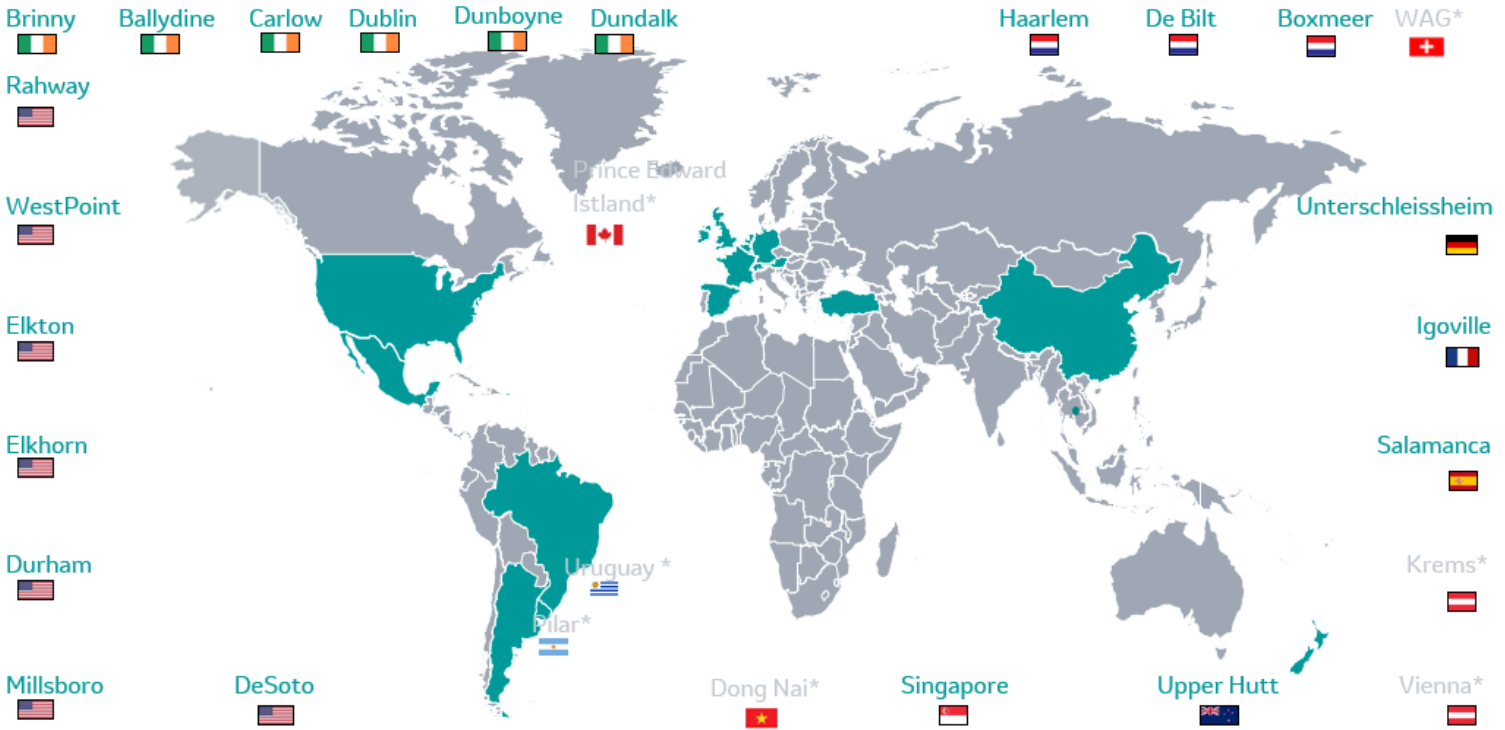
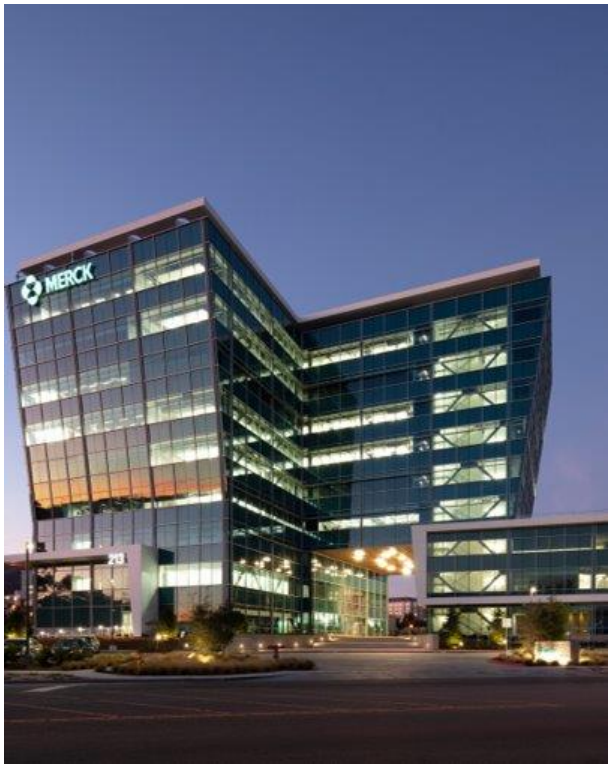
GES Around the World



*GES Consult only

MSD in Ireland

GES CQV Global Team



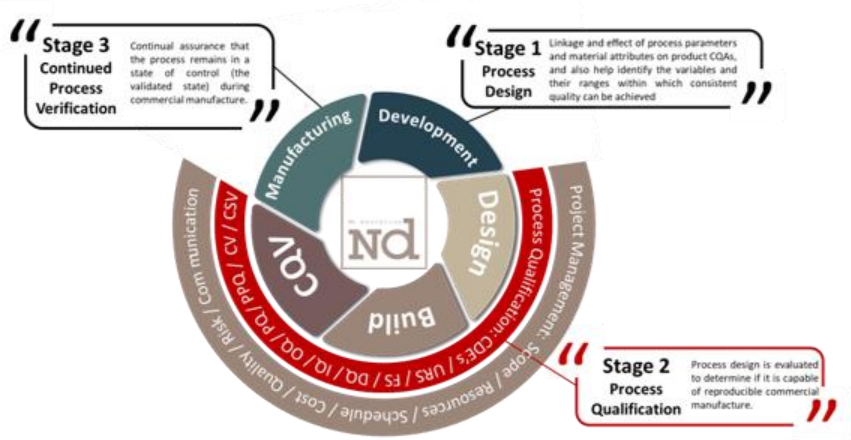
- Support C&Q strategy on our most strategic projects and implement new ways of working based on our experiences on previous projects.

- 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: Digitial 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.

MSD: CURRENT STATUS

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MSD : Early adoption and roll out

Phase 0 (Pilot Phase)

2Q2020

Phase 2 Global GES roll out

>July 2021

All Sites; newly initiated projects

Ongoing "in-flight projects" except where resources are a constraint (by exception)

Assess

Continuous Improvement

GES Live 1-July

eVal Live

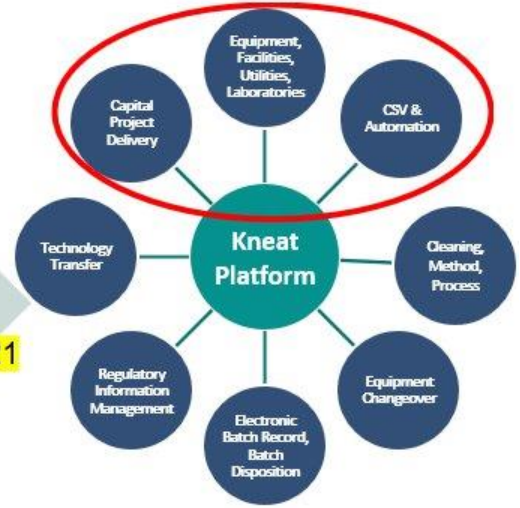
30-Sep-2021

Phase 1 Seven early adopter sites

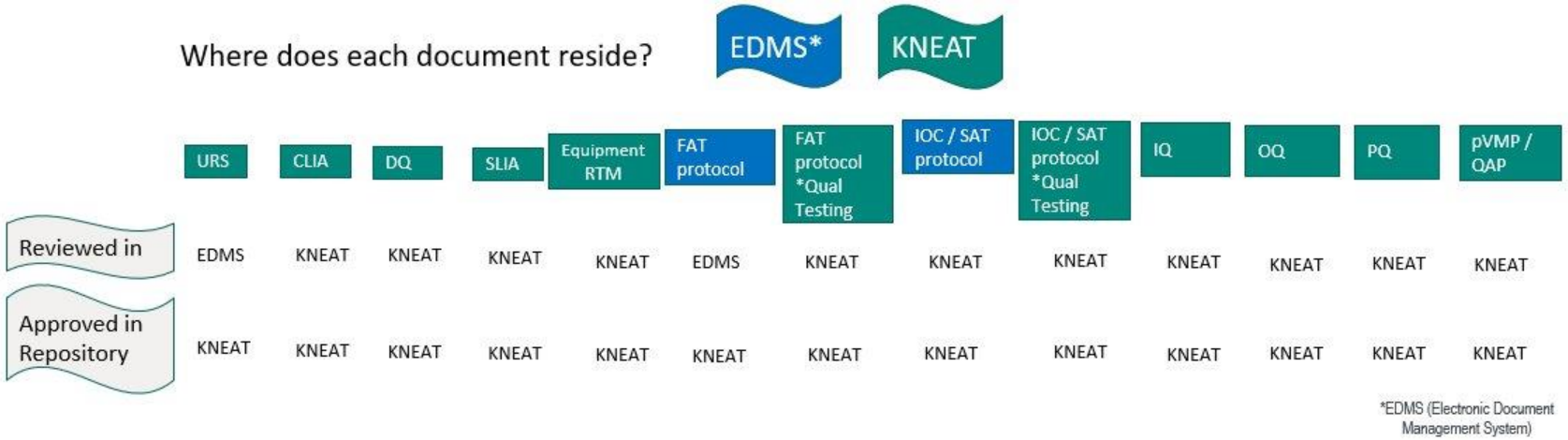
(Continue Pilots / GES Early Adopter Sites)

4Q2020 – July 2021

(Key **Business Critical** Projects **at key sites**)

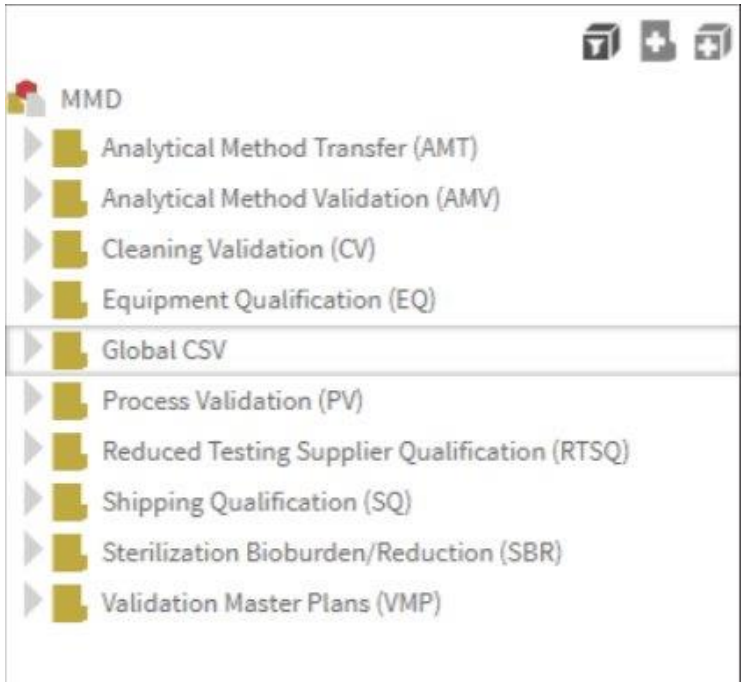


Digital Validation Roll Out



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

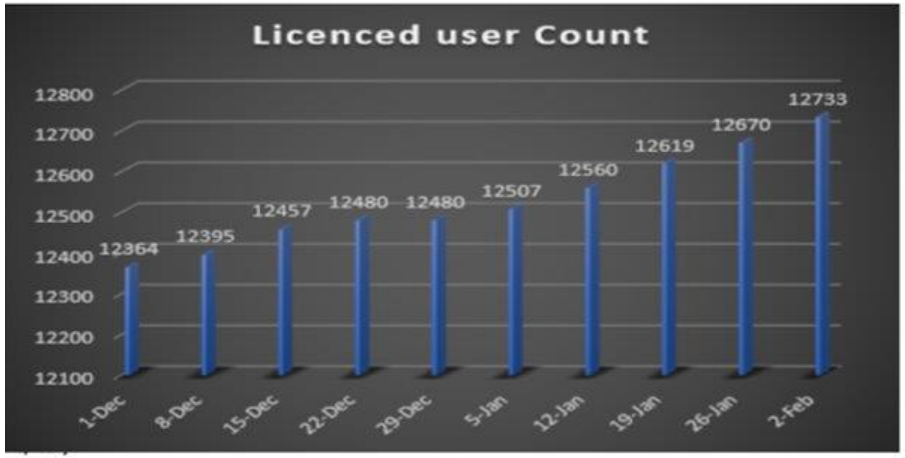
Roll out to other areas over the past 5 years



- 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

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INVENTING FOR LIFE

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ONECQV

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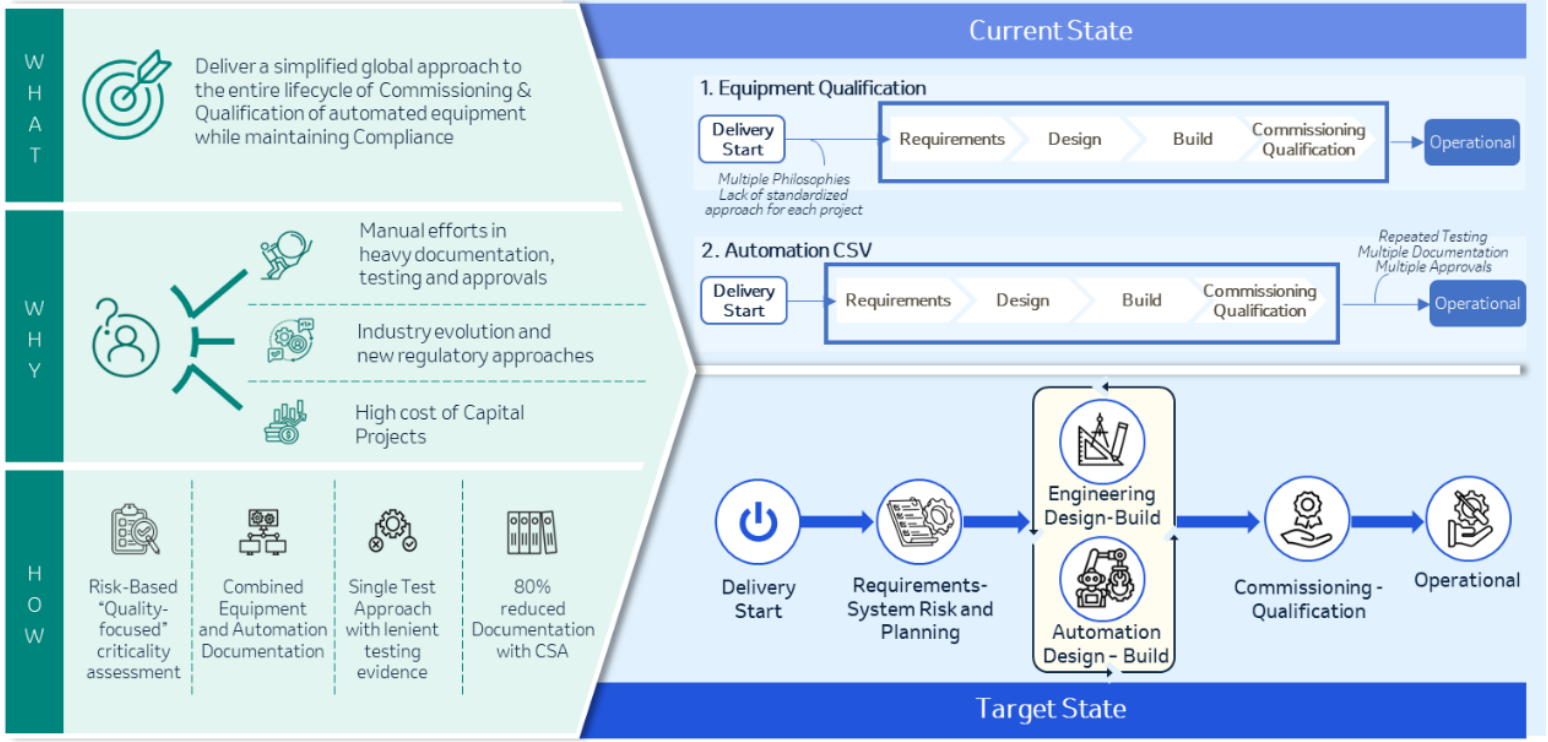
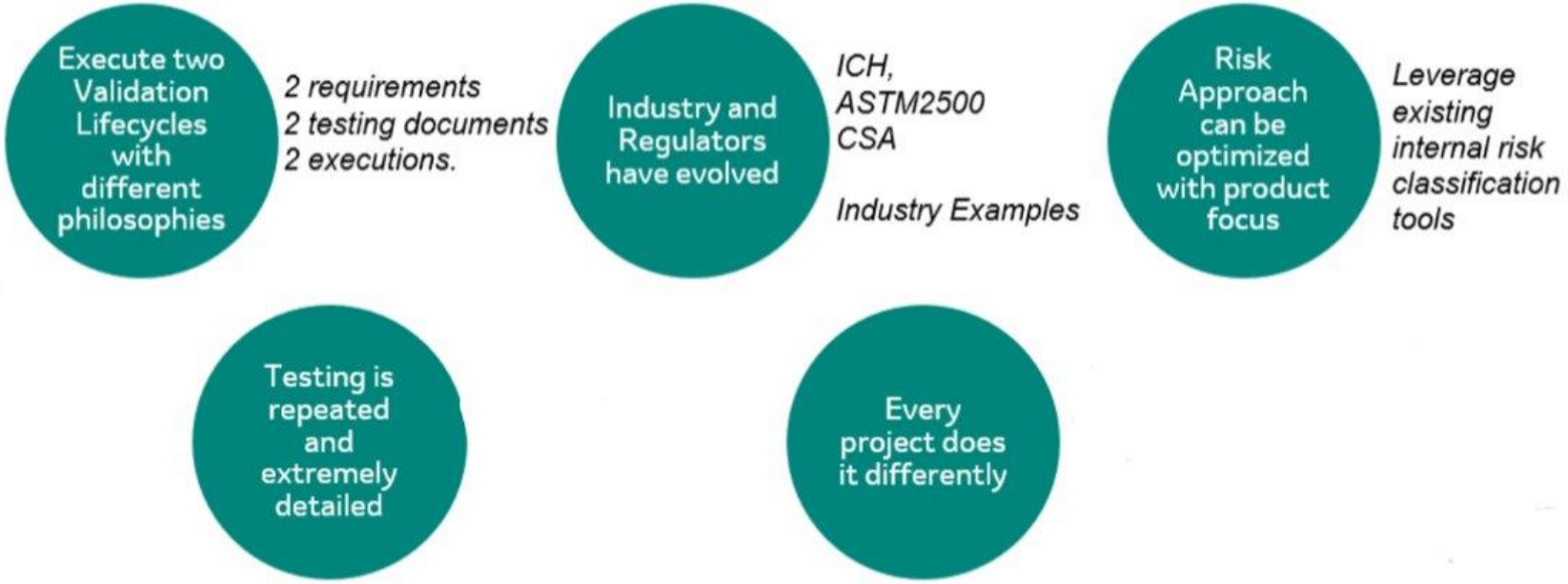
ONECQV : What, Why and How?



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

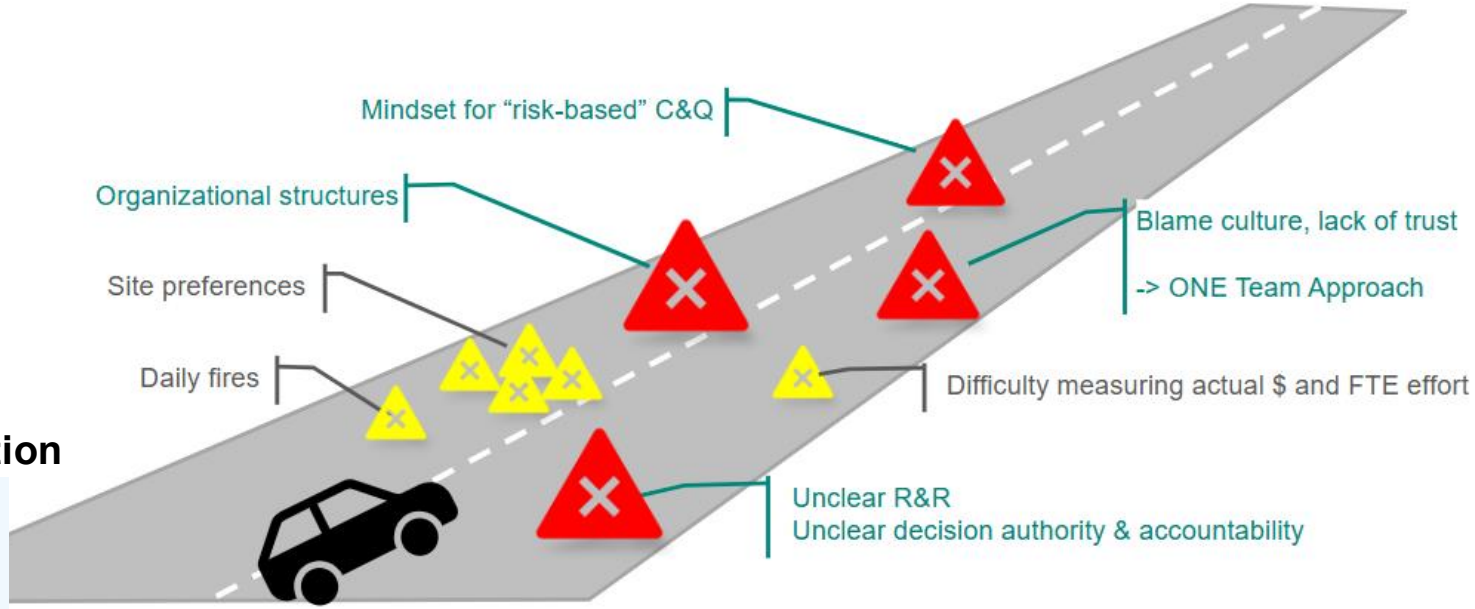
Mission:

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

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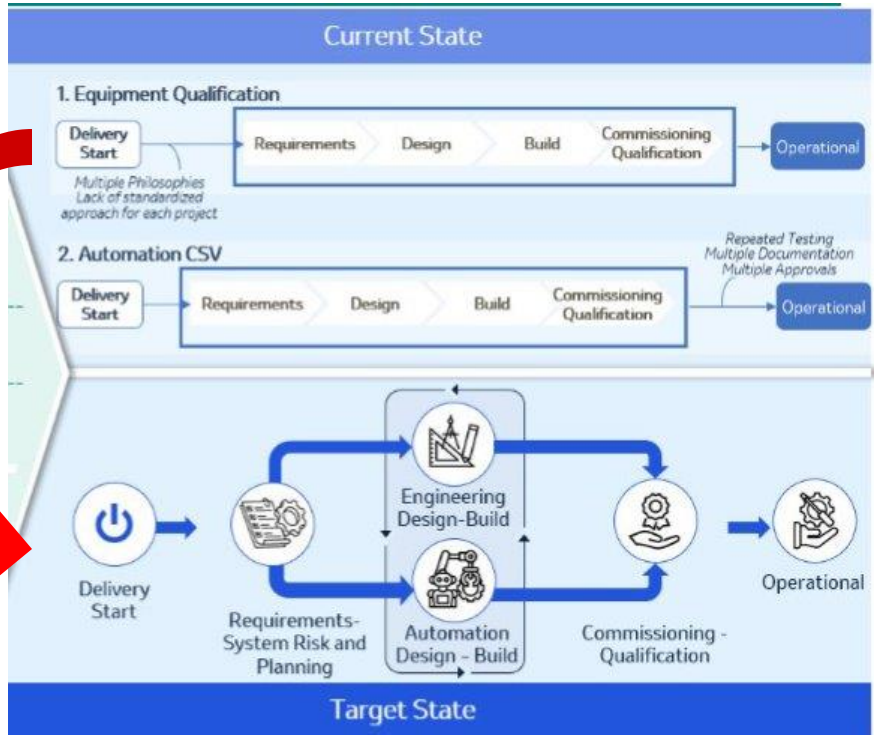
Digital Validation is a catalyst for OneCQV at MSD

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

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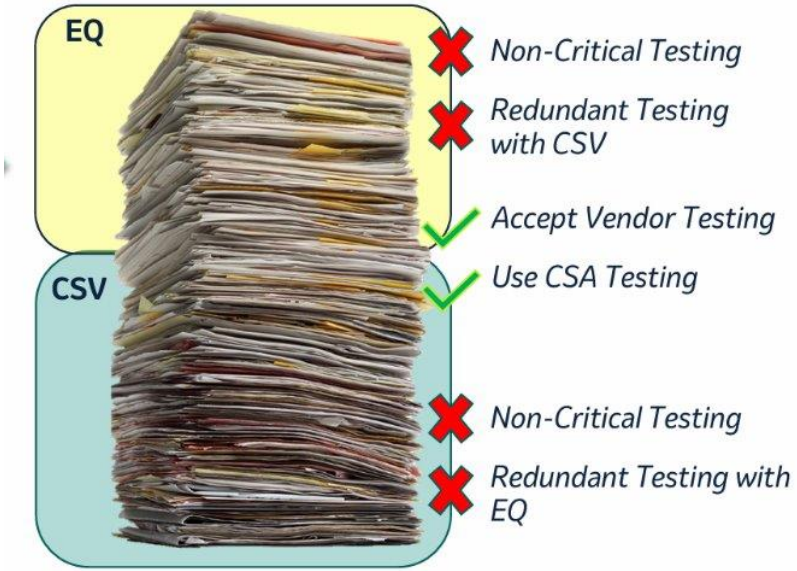
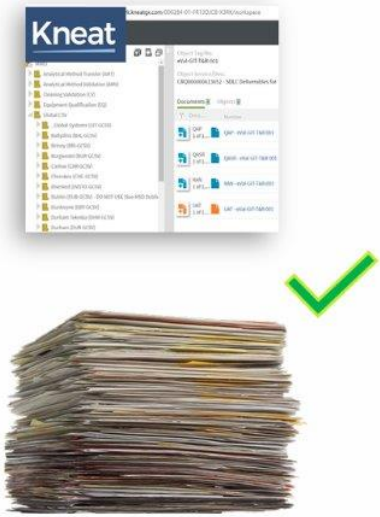
Advantages of OneCQV



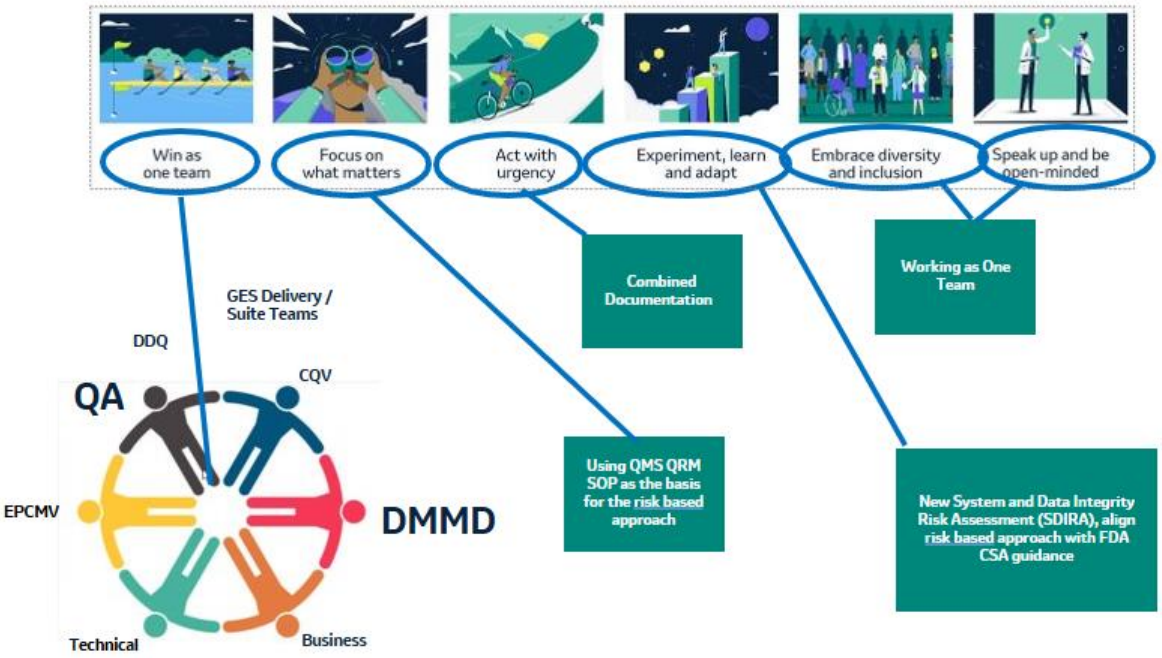


Reduce equipment and automation redundancies by linking them together in a single lifecycle

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

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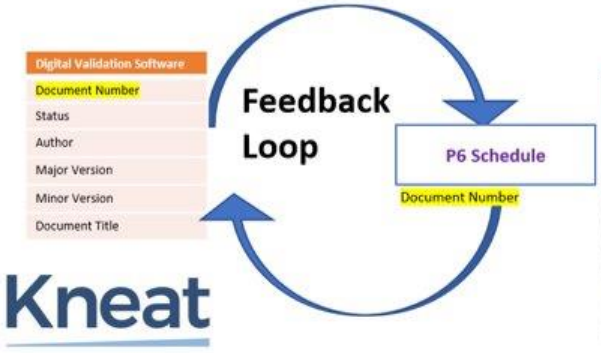
Digital Validation : Document Tracking Tool



Thank you

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