

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

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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



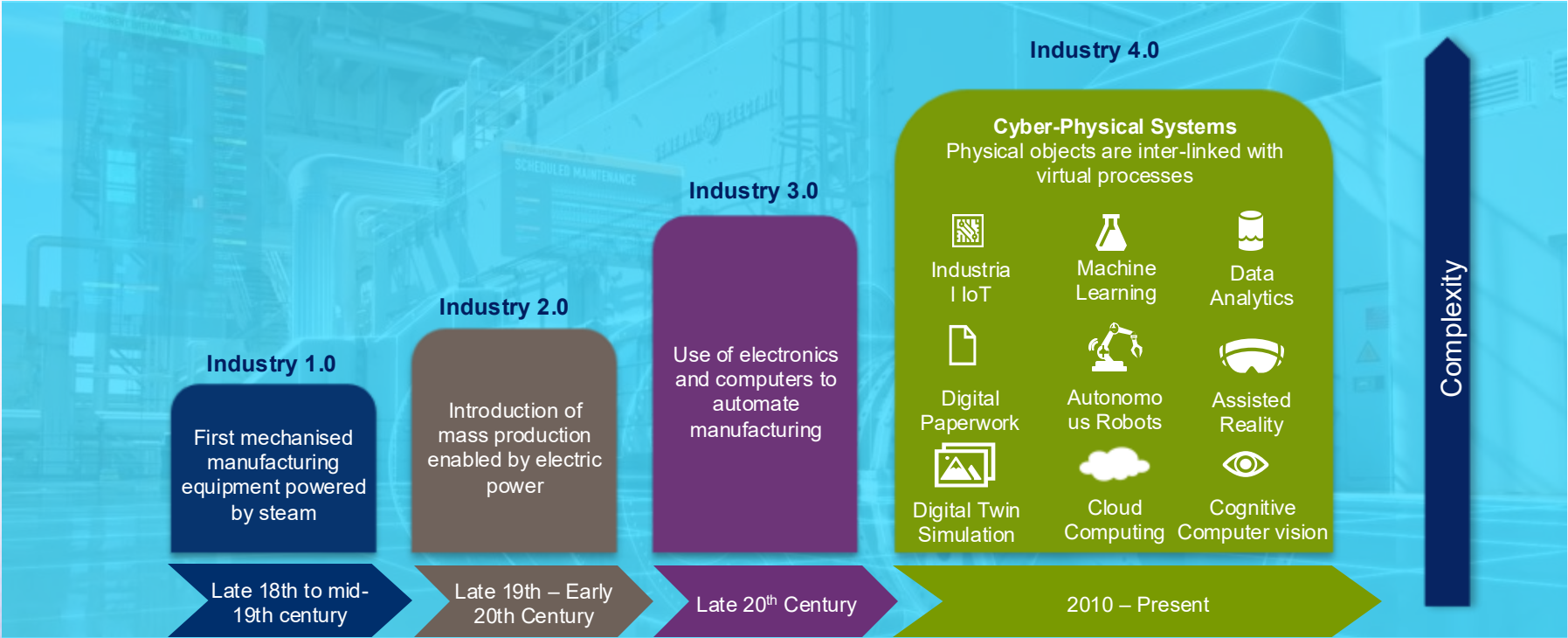
FdEng Manufacturing & Management Engineering
2 Years
BEng Honours Degree in Mechanical & Manufacturing Engineering
3 Years



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

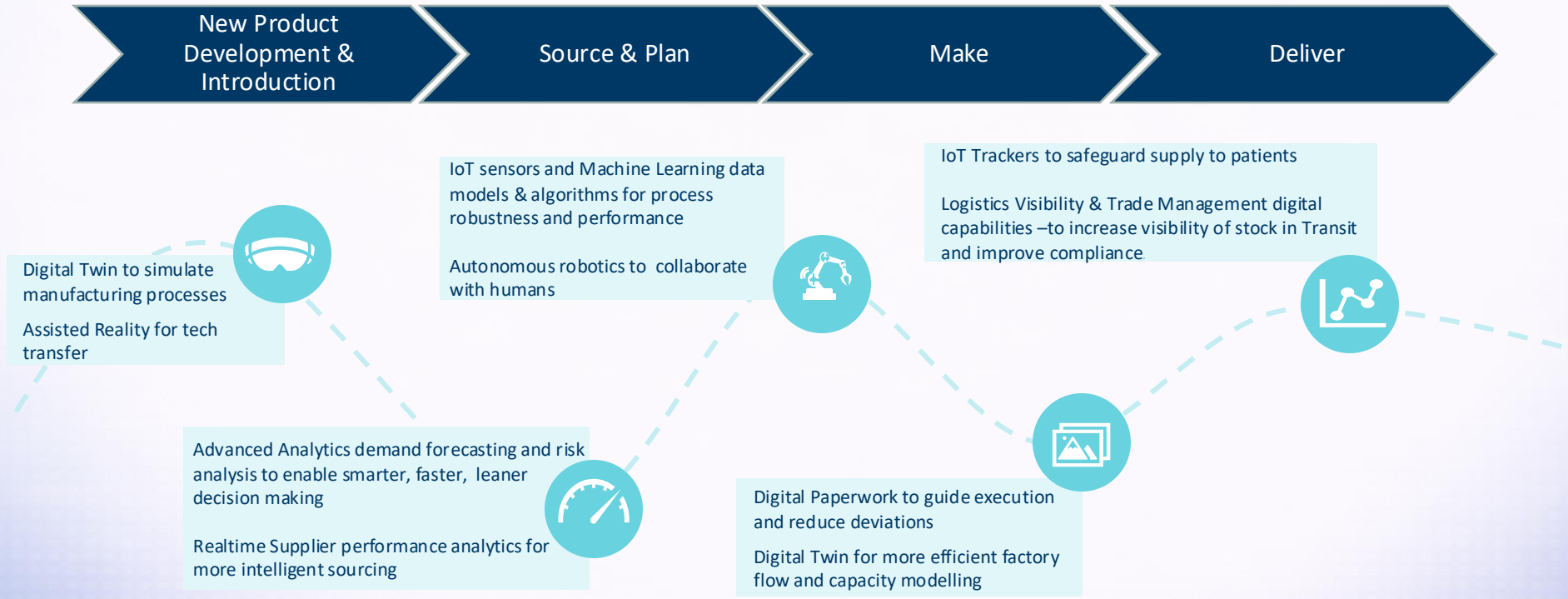


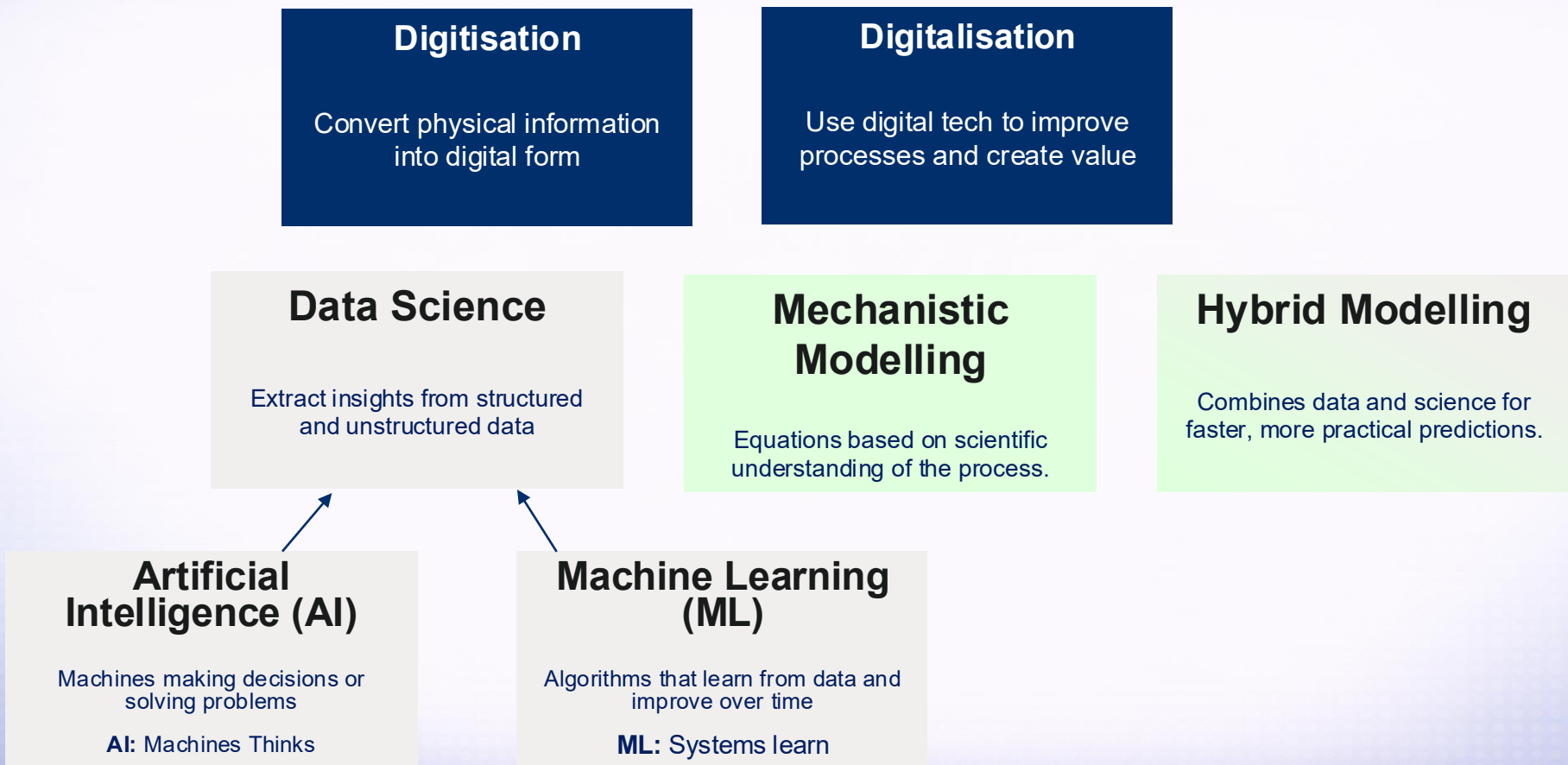
THE FOURTH INDUSTRIAL REVOLUTION





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

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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

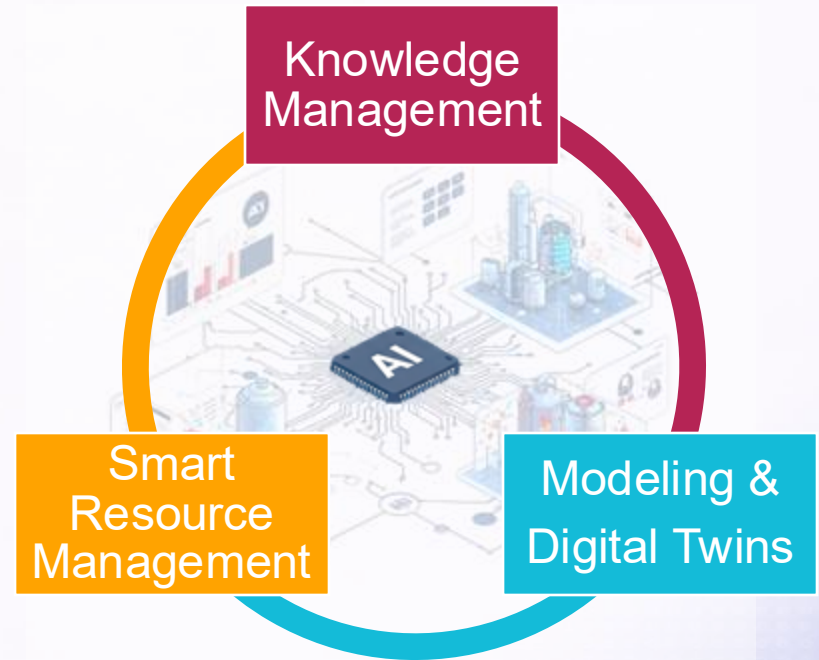
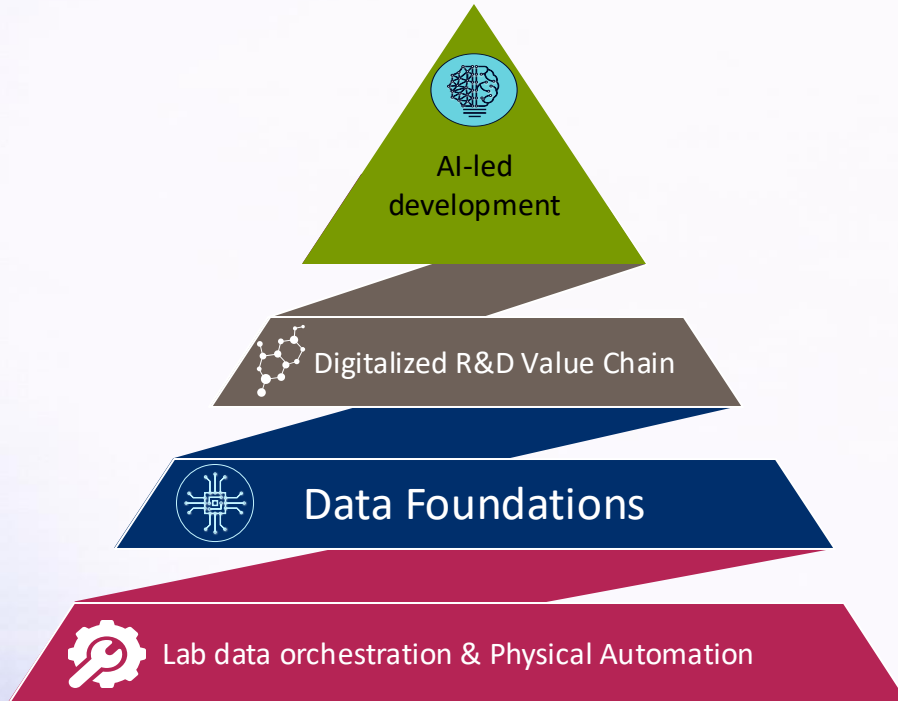
Dynamic Work Scheduling

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

Monitor → Understand → Decide →
Execute → Optimise

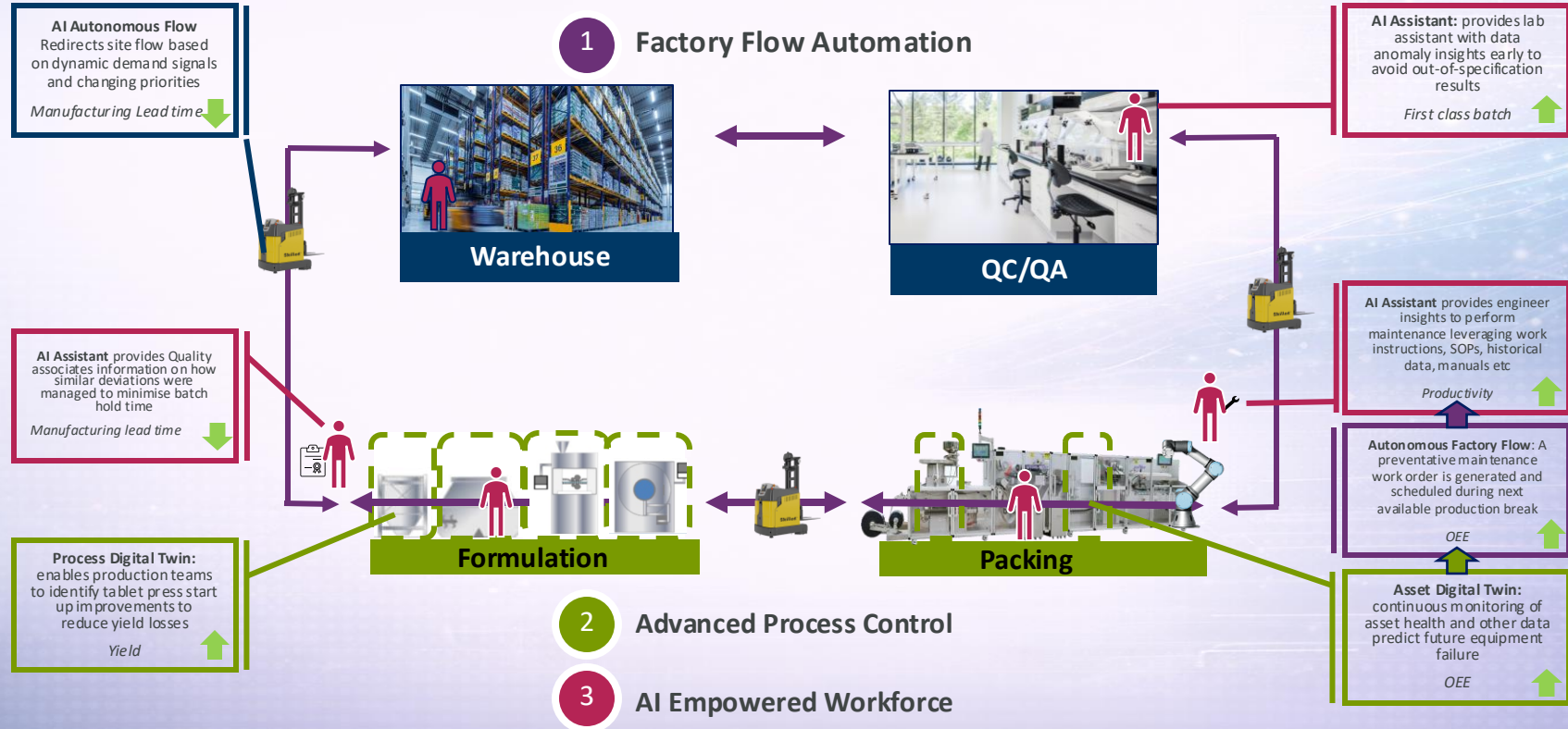
CORE CONCEPTS UNDERPINNING SMART MANUFACTURING

12 |



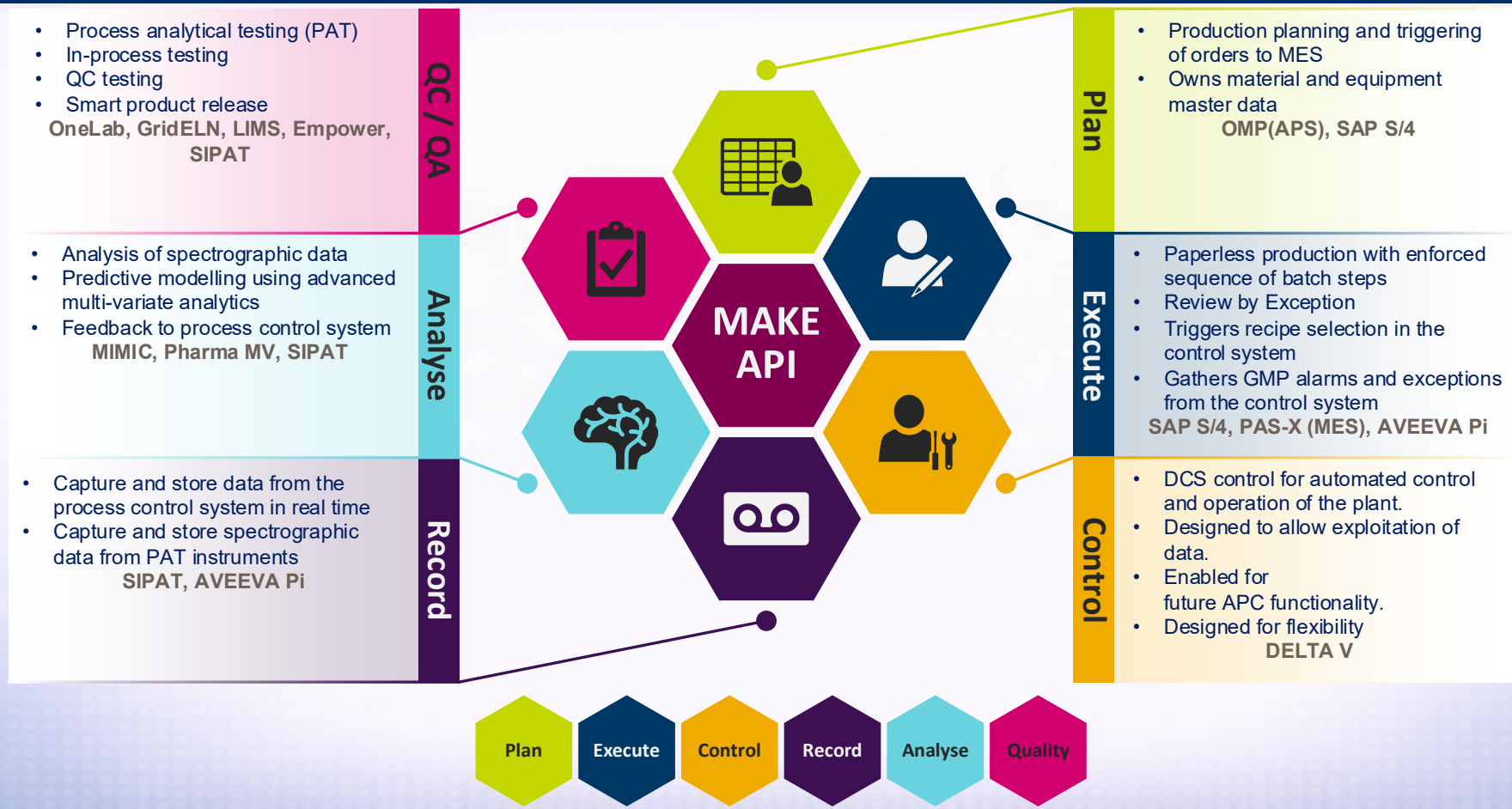
AUTONOMOUS MANUFACTURING: END-TO-END PROCESS INTEGRATION

13 |



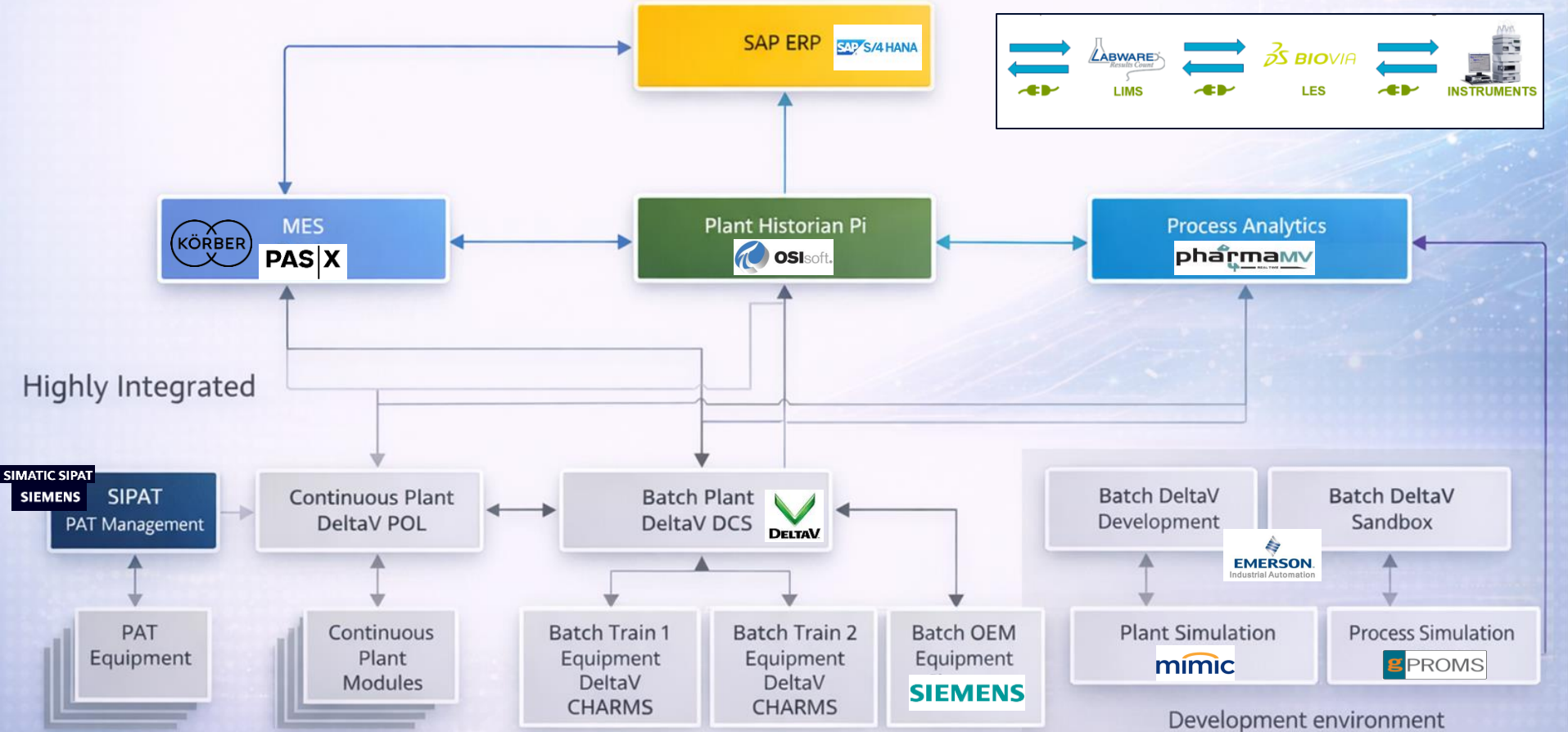
THE DIGITAL ARCHITECTURE SUPPORTING OUR SMART FACTORIES

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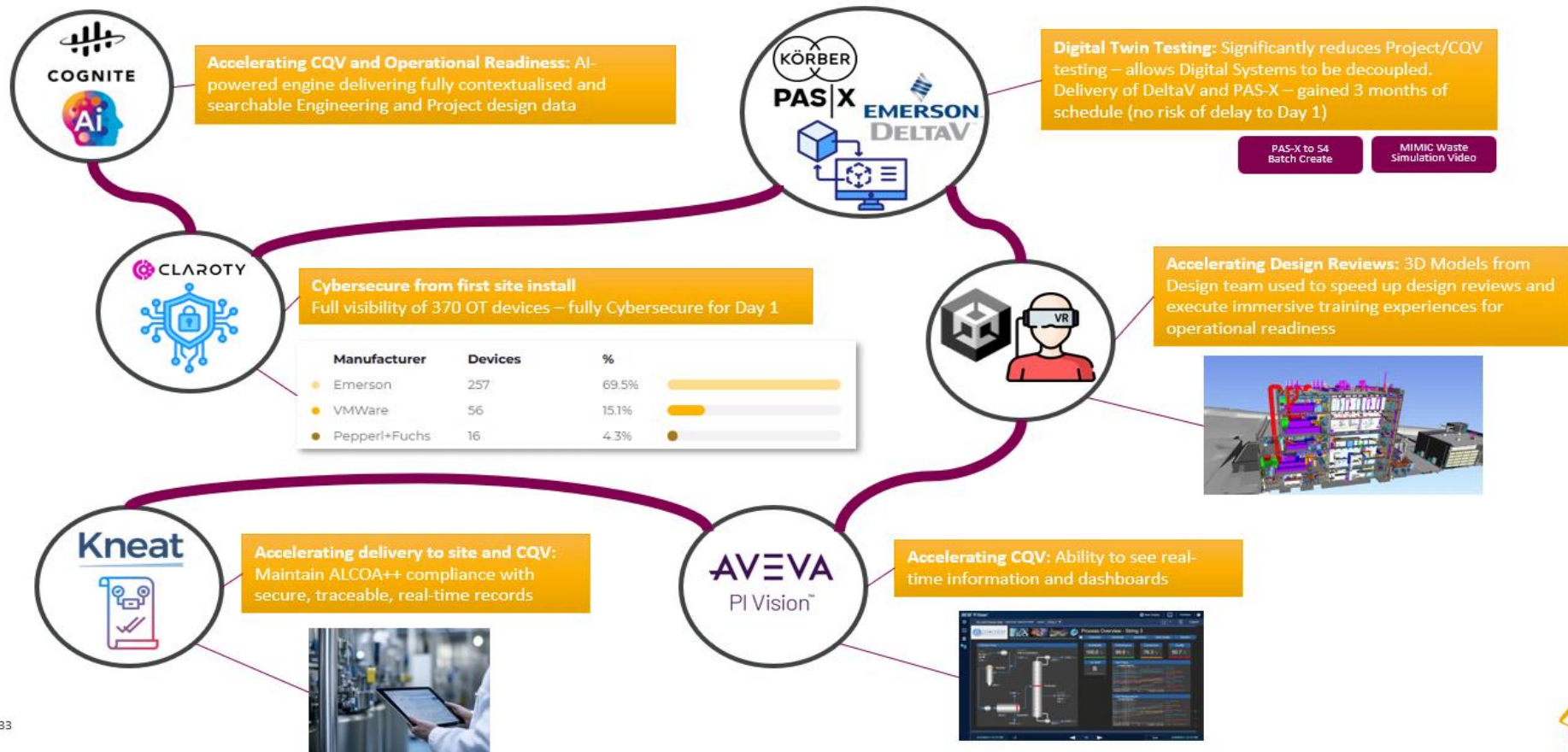
AUTONOMOUS MANUFACTURING: END-TO-END PROCESS INTEGRATION

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INTEGRATED DIGITAL ECOSYSTEM ENABLING SMART MANUFACTURING

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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)

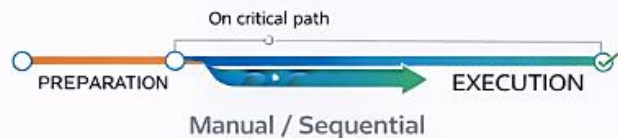
3. Early & Risk-Based Testing

- 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.

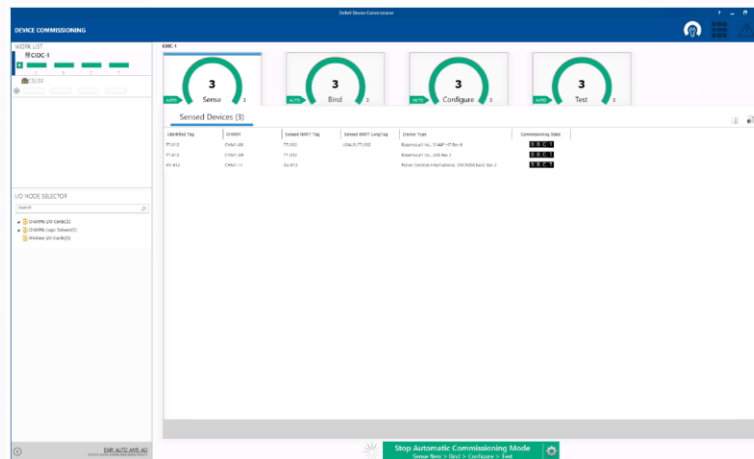
Traditional Commissioning



Smart Commissioning

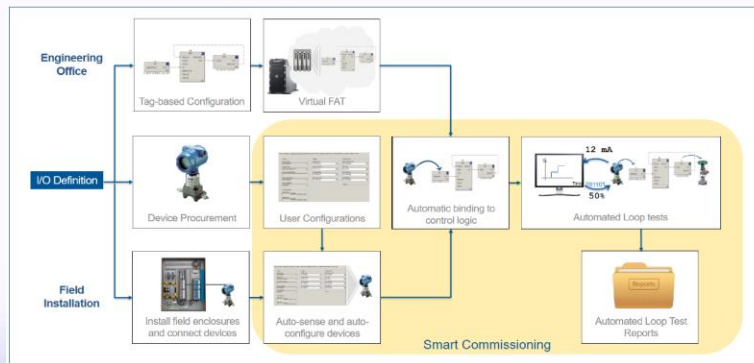


AMS Device Manager



SMART
COMMISSIONING
USING AMS &
DELTA V

FROM DEVICE
CONFIGURATION
TO AUTOMATED
LOOP
VERIFICATION



[illegible]

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

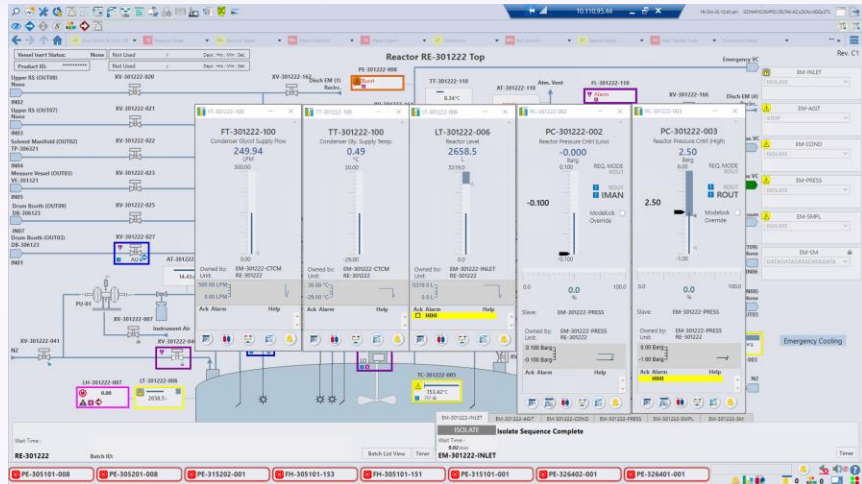
100.00% (5 of 5)

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	PT-301222-190	Cookson Glycol Supply Pipe	Passed	1	40%	0.01 (0.1 ± 1%)	-0.011 0.1	9/16/2023 12:44:43	BERNARDSON LTA/AZ/LCO QL722
					2	25%	10.00 (0.1 ± 1%)	10.002 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_486	Endress+Hauser Morphette 1619H107 1	LT-301222-496	Reactor Level	Passed	1	40%	0.01 (0.1 ± 1%)	-0.006 0.1	9/16/2023 12:44:49	BERNARDSON LTA/AZ/LCO QL722
					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_492	Endress+Hauser Cocobar 1617 T0107 2	PC-301222-492	Reactor Phases Cool (GWP)	Passed	1	40%	0.01 (0.1 ± 1%)	-0.006 0.1	9/16/2023 12:44:46	BERNARDSON LTA/AZ/LCO QL722
					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_493	Endress+Hauser Cocobar 1617 T0107 2	PC-301222-493	Reactor Phases Cool (GWP)	Passed	1	40%	0.01 (0.1 ± 1%)	-0.006 0.1	9/16/2023 12:44:47	BERNARDSON LTA/AZ/LCO QL722
					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_122	Endress+Hauser CICMP T0107C107 3	PT-301222-130	Cookson City Supply Temp.	Passed	1	40%	0.01 (0.1 ± 1%)	-0.002 0.1	9/16/2023 12:44:48	BERNARDSON LTA/AZ/LCO QL722
					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

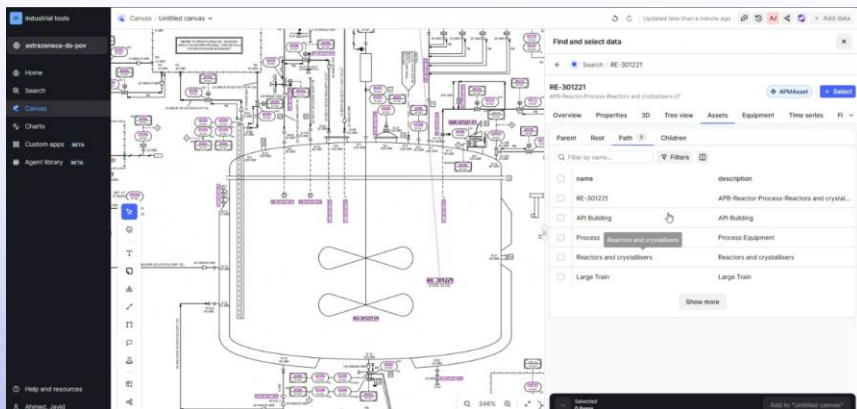
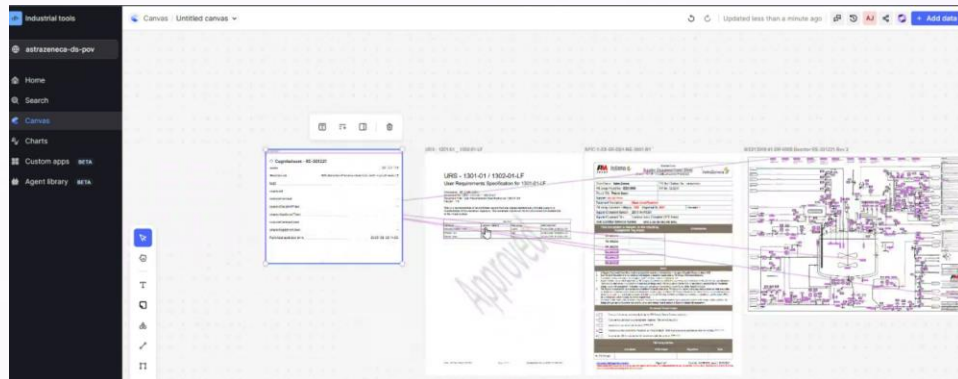
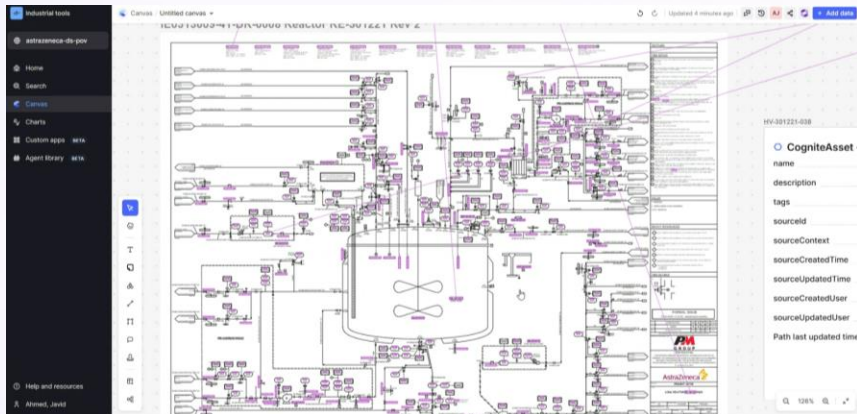
DELTA V AMS SOFTWARE SMART COMMISSIONING

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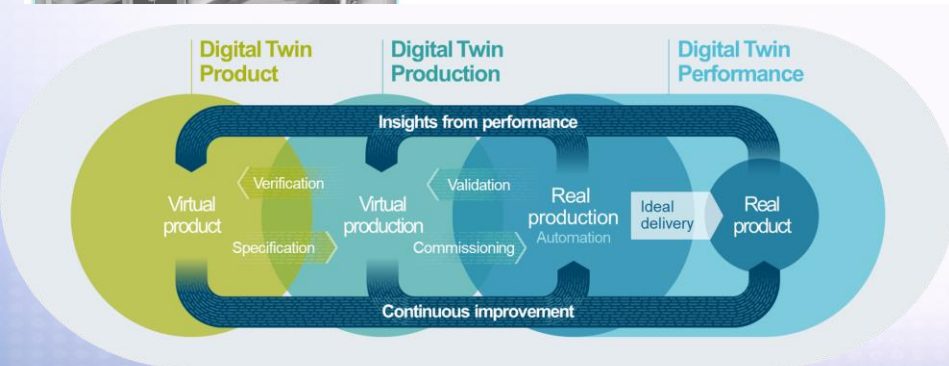
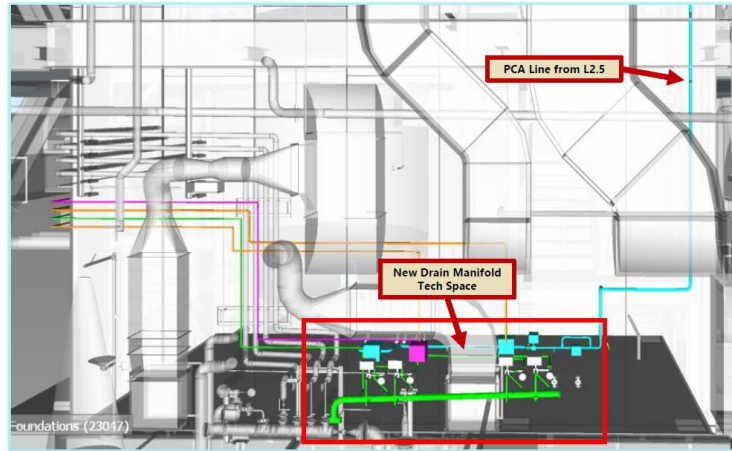
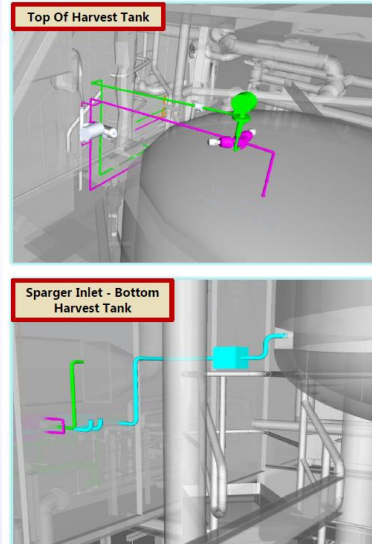
DATA CONTEXTUALISATION - COGNITE AS THE SMART FACTORY DATA LAYER

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DIGITAL TWINS

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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)

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Traditional NPI Model



Future State SC-NPI Model (CSA)

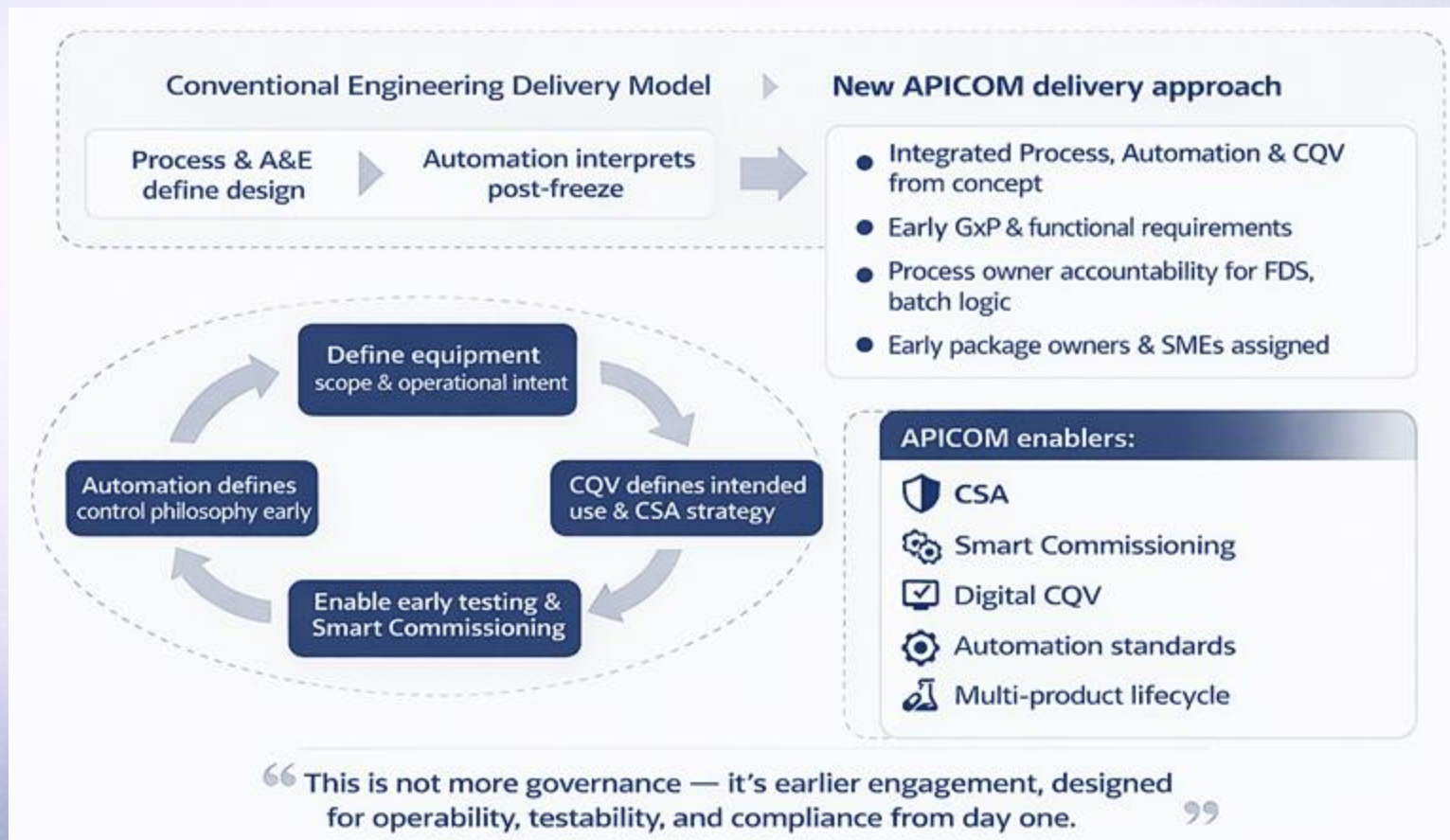


CSV never arrives
late its always
present



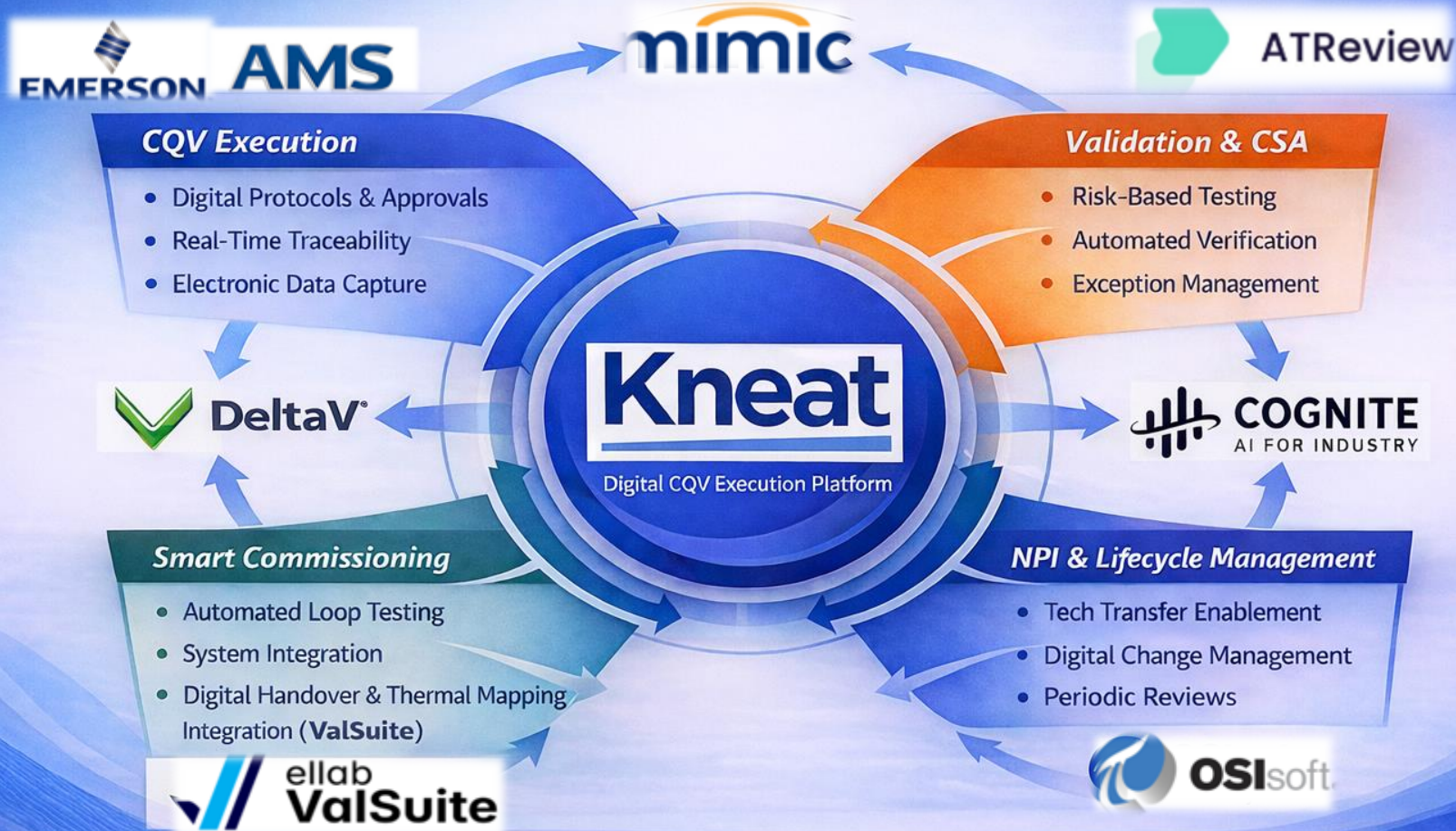
CSA Testing Model

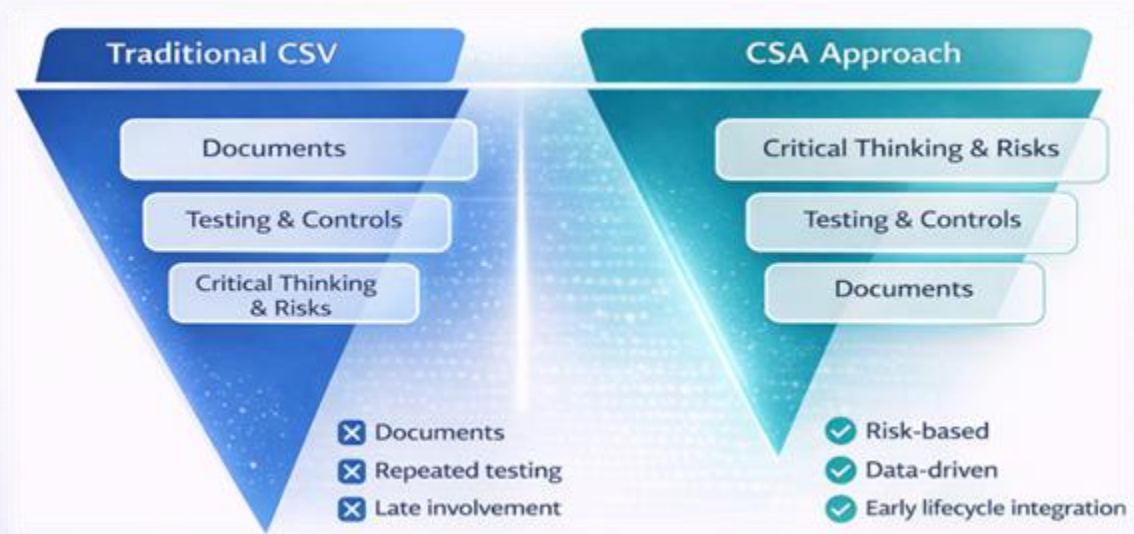
Type of Assurance Activity	Sub-Type
Unscripted Testing	Ad-Hoc Testing
	Error-Guessing
	Exploratory Testing
Scripted Testing	Robust Scripted Testing
	Limited Scripted Testing



CONNECTING CQV, CSA AND LIFECYCLE VALIDATION IN A SMART FACTORY

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- 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.

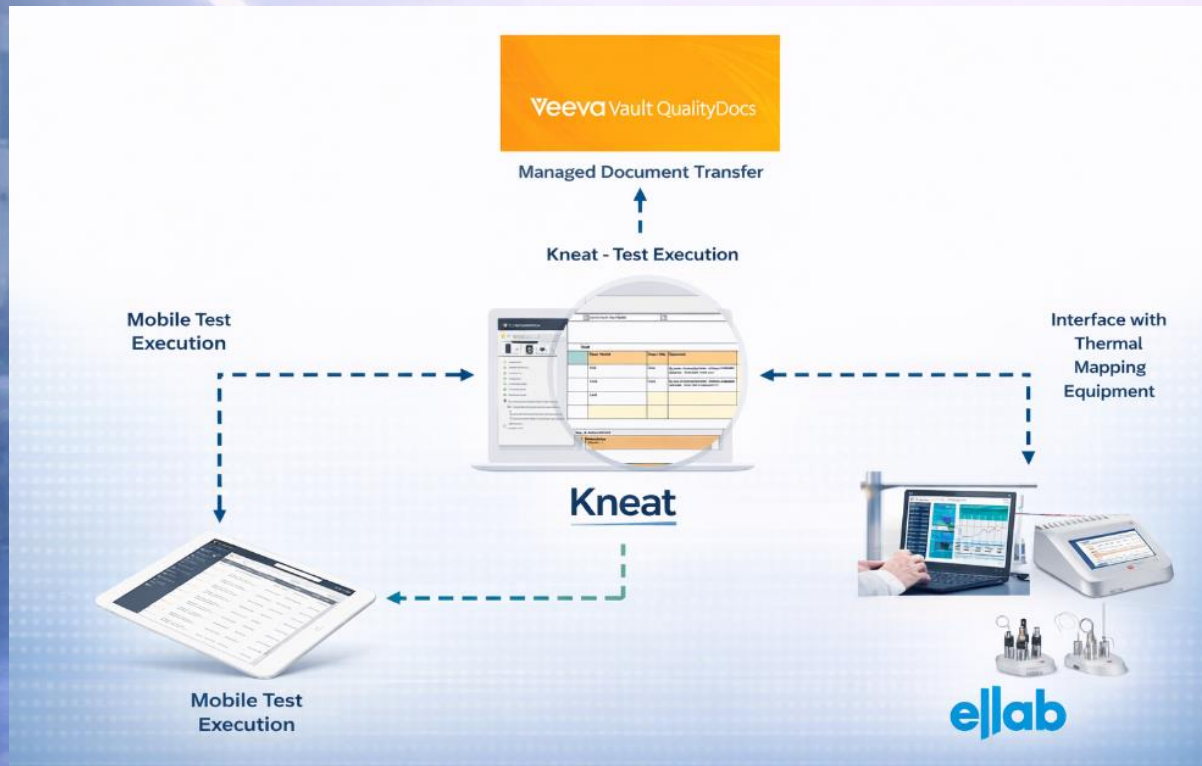
One Data Flow Across the Life Cycle



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

Eliminating Duplication and Enabling Continuous Assurance.

INTEGRATION OF QUALITY MANAGEMENT SYSTEM



CONTINUOUS PROCESS VERIFICATION (CPV)



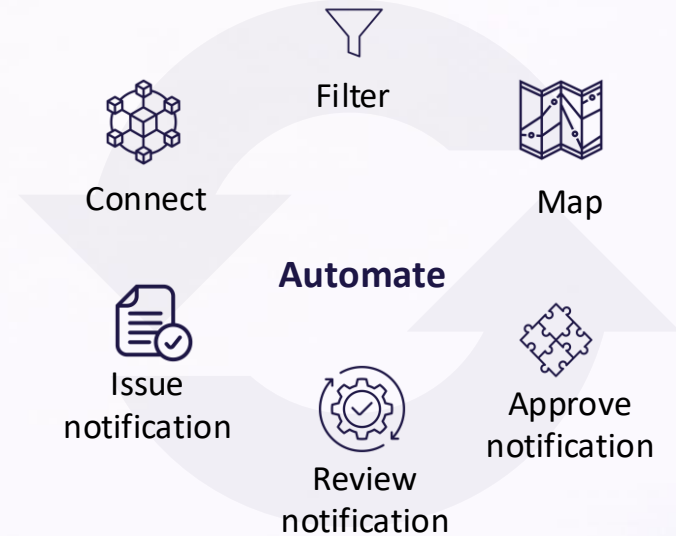
FROM WEEKS OF MANUAL REVIEW TO REAL-TIME AUTOMATION

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Traditional Approach



New Approach



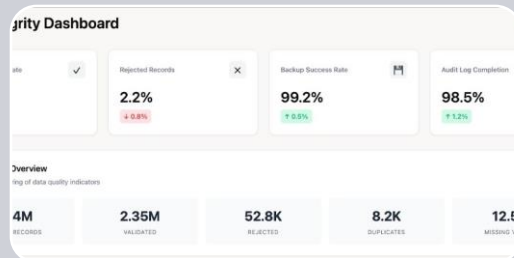
32 |

32 |

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WHAT SMART COMMISSIONING ENABLES

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⚡ 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

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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?

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Partner Technologies

Kneat

