Session 10.2

Digital Validation Mastery: Enabling Validaiton 4.0

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VALIDATE 2026

APRIL 29-30, 2026
THE MARKER HOTEL, DUBLIN

SAVE THE DATE

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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.

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Digital Validation Mastery: Enabling Validation 4.0

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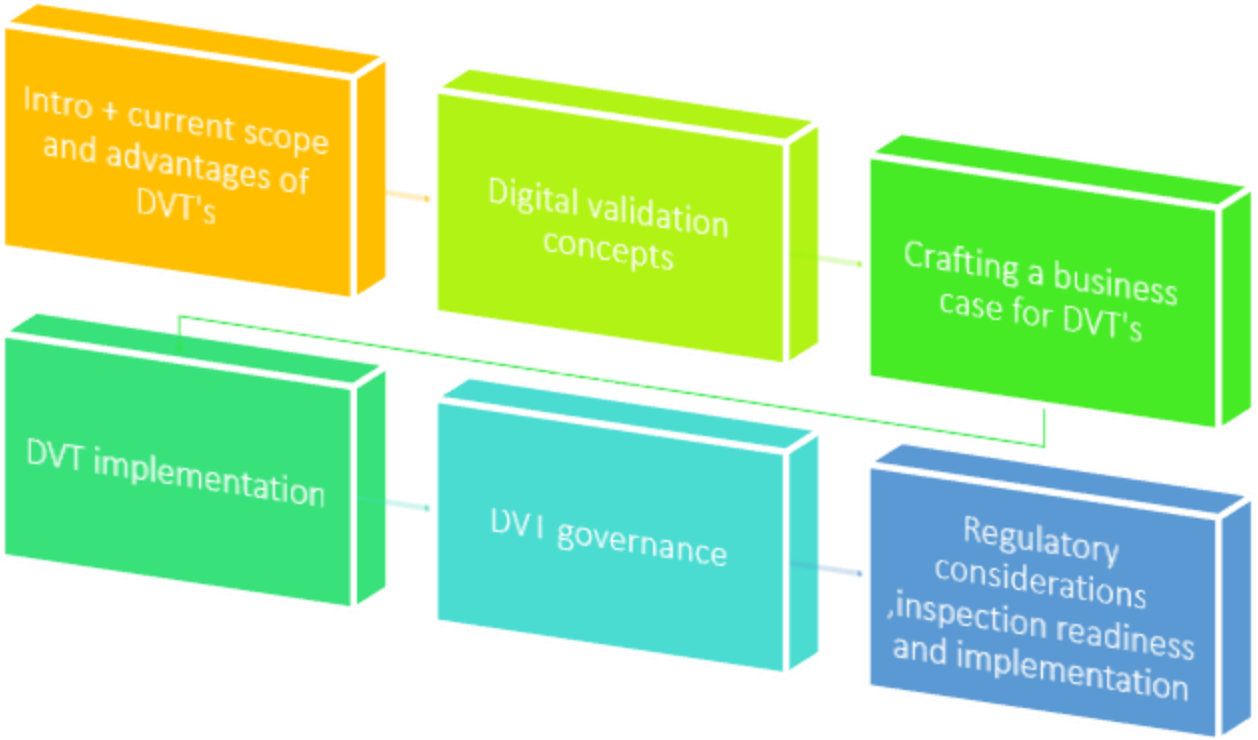
PROCELLARX

Good Practice Guide: Content

Who has read the guide?

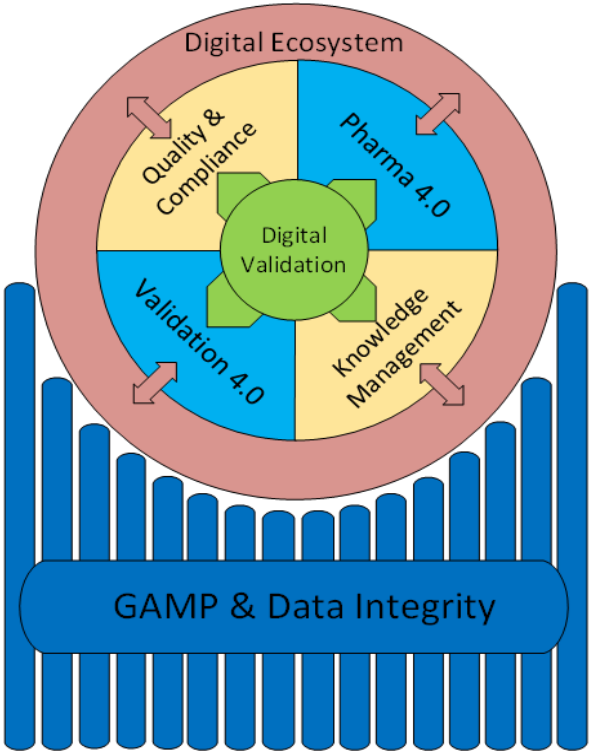


DVT: Current State

- 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

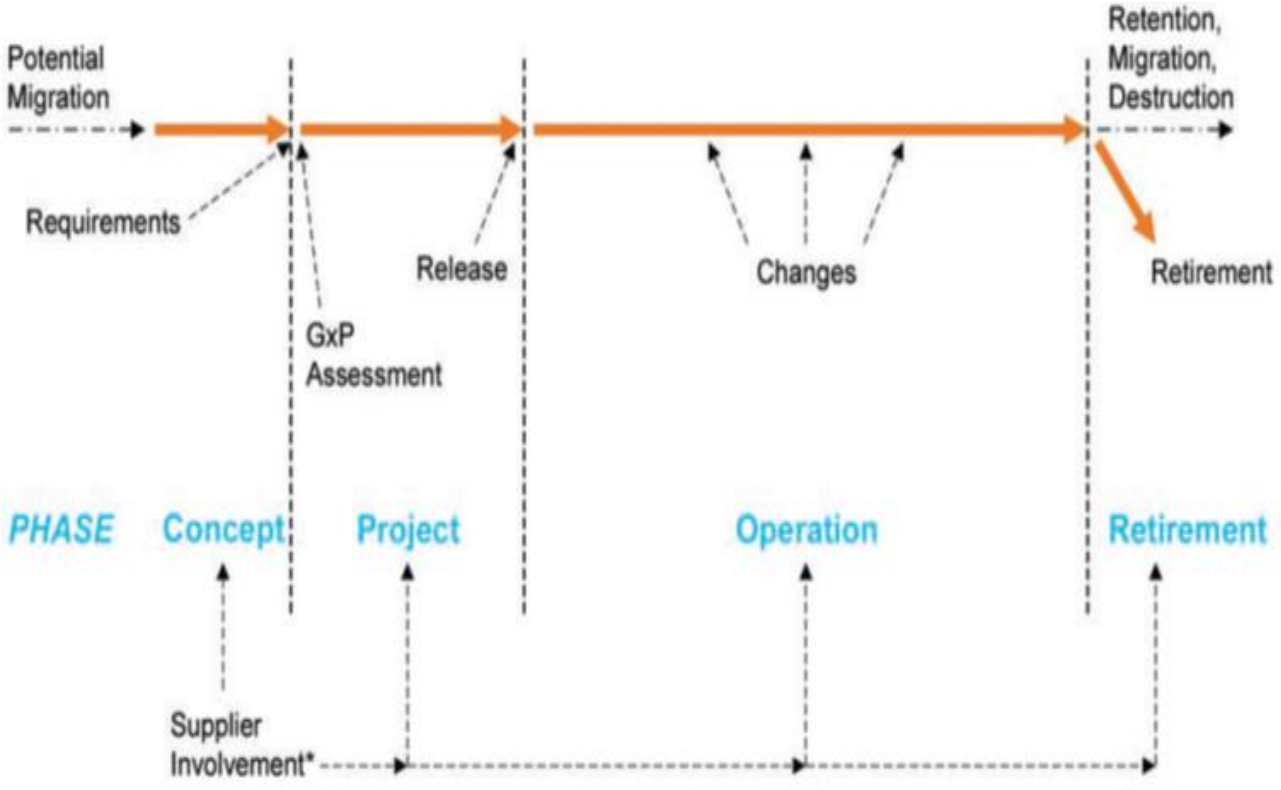


DVT: The Business Case

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

DVT: Implementation

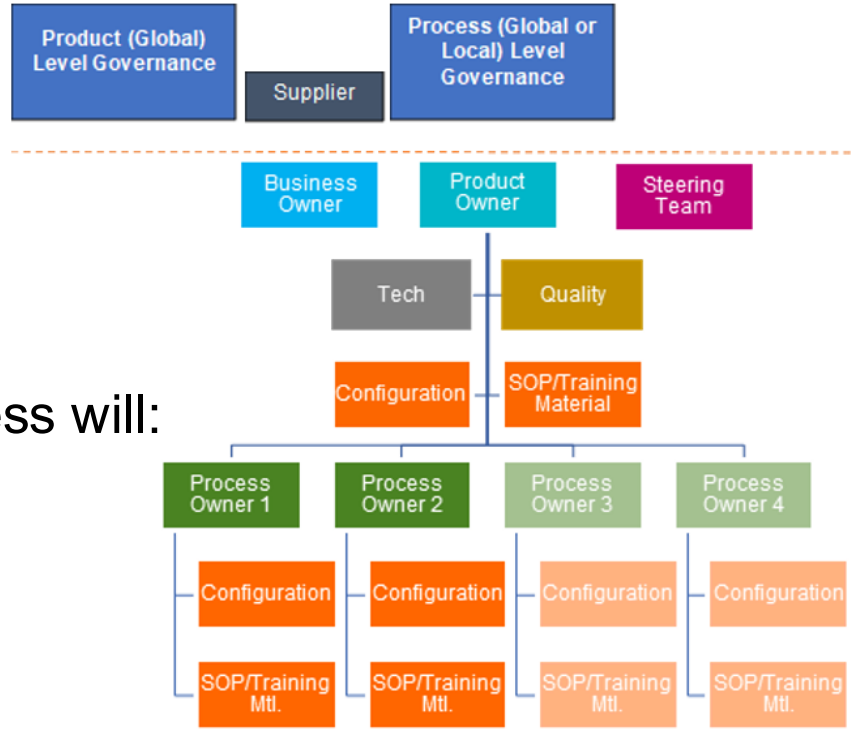
- Define what the owner/user wants (URS)
- Creating a Culture for Digitalization and a digital mindset
- Maturity Assessment of organization
- Implementation
- Sustaining
- Opportunities
- Retirement, migration
- Creation of right “culture” for DVT adoption



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

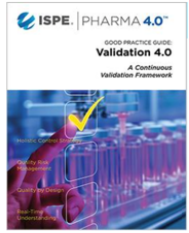
- Current Regulatory Landscape
- Audit Strategy and Readiness
- Remote/In Person Audits
- Case Study Success
- Unexpected Challenges

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

Val 4.0 - The Whole Plant View

Slide courtesy from Validation 4.0 GPG



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

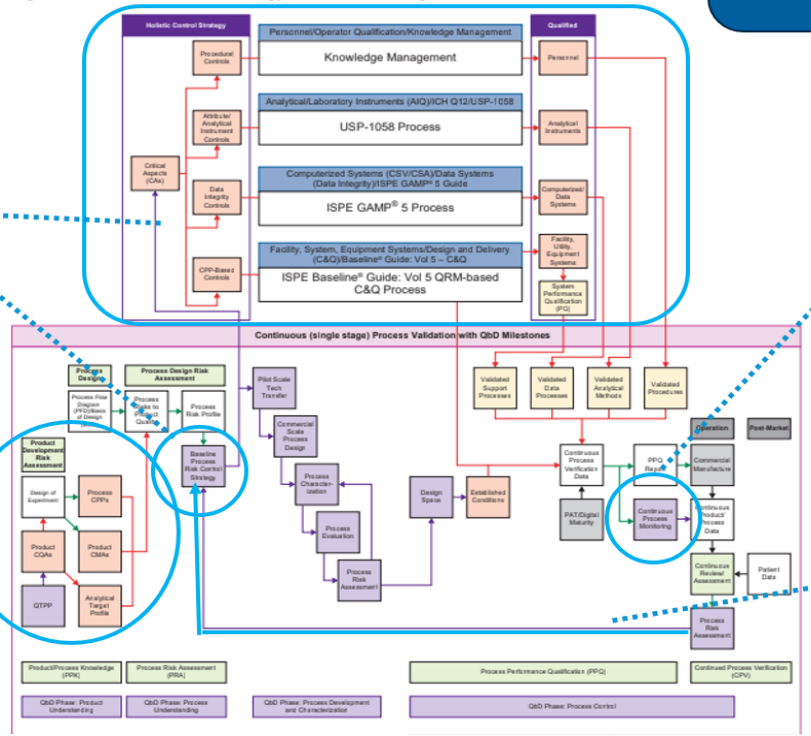
*QbD is the foundational basis

*QbD= quality by Design

Evidence of effectiveness supports continuous validation

Feedback loop enables real-time and continuous validation

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



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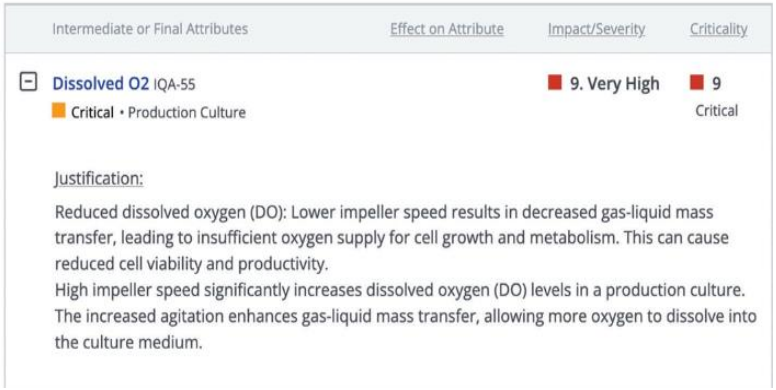
Enablement of Validation 4.0 (case study for QbD /control strategy)

- 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)

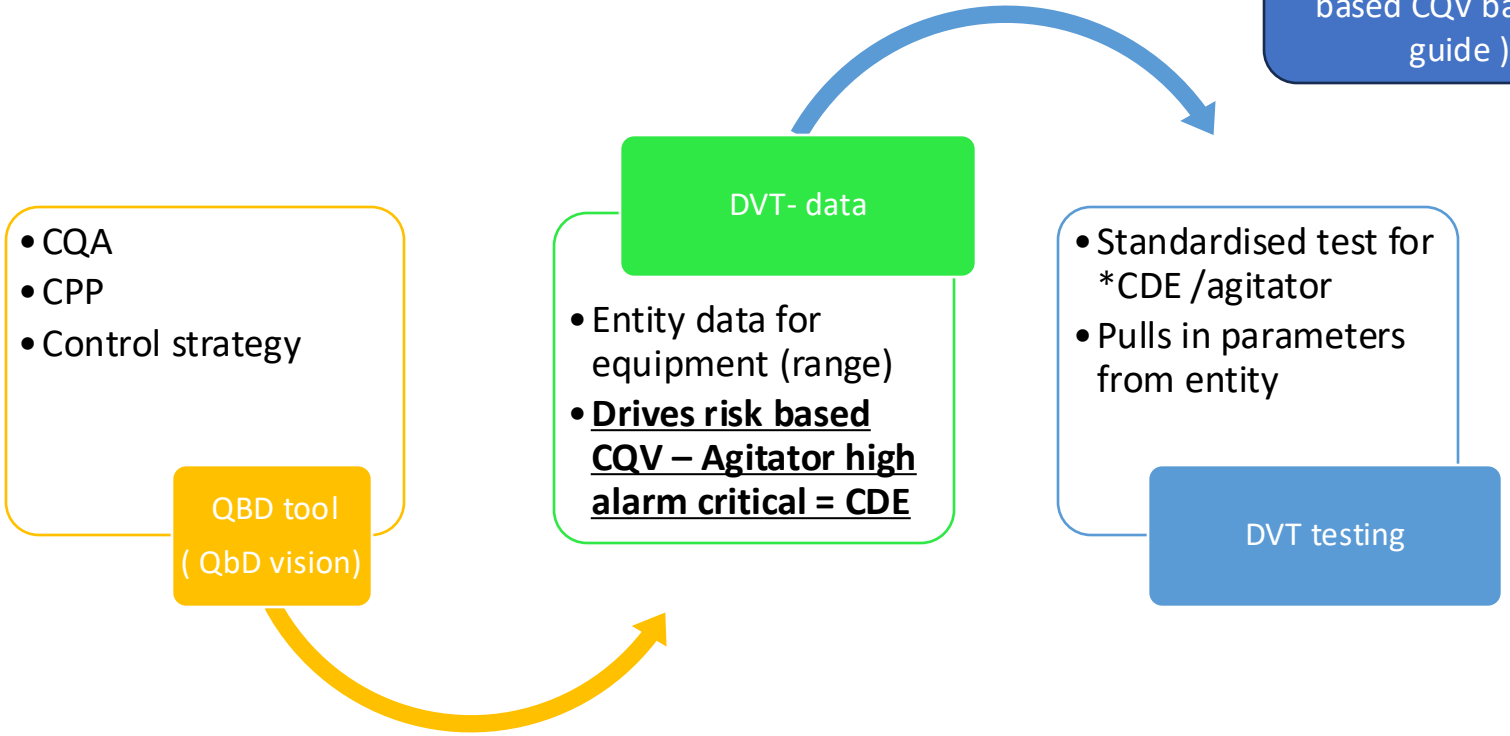
All captured digitally , so can feed into DVT (Digital Validation Tool)

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

*CQV = commissioning ,Qualification / Validation

Input into risk based CQV

*CDE =Critical Design Element (as per risk based CQV baseline guide)

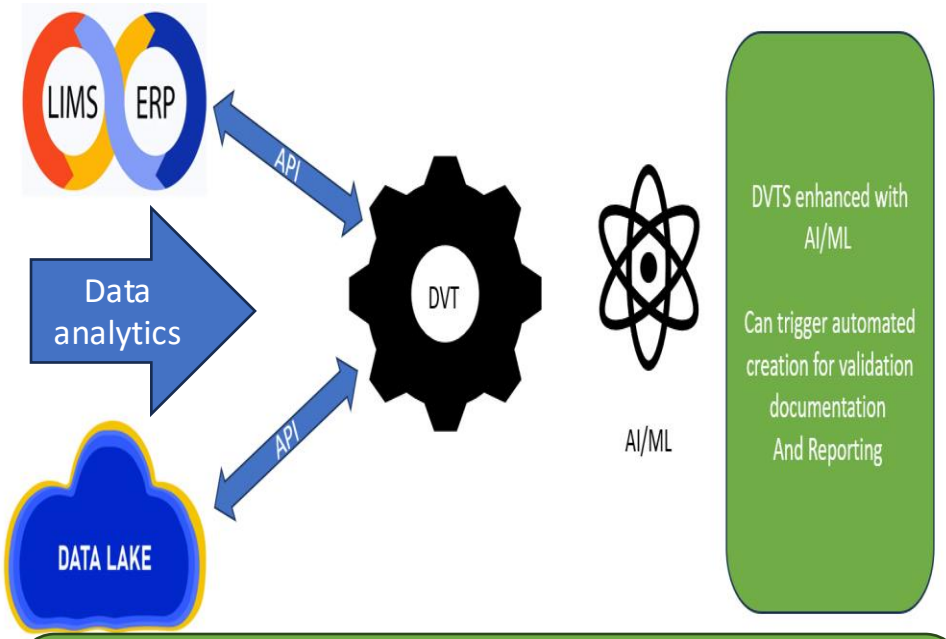


Monitoring Control Strategy

Figure·6.16:·Process·Analytics/Batch·Data·for·Aggregation¶

Section Break (Next Page)

*** figure reference from Validation 4.0 GPG



Monitoring of control strategy in real time can give automated reporting, flagging when in control and shifts in process control. Enabling validation 4.0 and automating CPV (Continued Process Verification) reports

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