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EBOOK

The Business Case for Modernizing Validation Management

A Guide for Validation Leaders

Shifting to digital, data-centric validation management enables significant ROI.

This guide provides a framework for communicating the value of unified digital validation management to executives and stakeholders.

Validation of processes, equipment, and software systems became standard industry practice in the **1980s**[1]. Four decades later, **Validation 4.0**[2] emphasizes the need for digital, lifecycle-based practices, yet the industry still depends on manual processes, paper, and siloed systems.

These traditional practices limit data access and visibility, forcing validation teams to manage and evaluate records manually. This time-consuming process often introduces delays and limits teams' ability to track progress. It also increases the risk of errors, process inconsistency, and data integrity issues, which hinders readiness for inspections and audits. The result is significant compliance risks, which, between 2010 and 2020, accounted for **26% of all FDA cGMP Warning Letters**[3].

Connecting validation to quality

Validation leaders have already seen benefits by moving from paper-based approaches to paper-on-glass approaches used in point solutions. Now, modern digital validation management solutions can achieve better results by connecting validation to quality management systems (QMS) and quality content management (DMS), improving speed, compliance, and data visibility. Unifying validation and quality processes and optimizing validation management with industry best practices reduces the validation lifecycle by 50-80%. This results in a better user experience and accelerates change management, product release, and implementation timelines.

Unified digital validation solutions, which connect validation to quality management, enable better reporting, trending, and KPI tracking so that validation teams can monitor critical activities — requirements approval, deviation status, trends, and IT or GxP change controls that may require revalidation.

Designed to scale quickly, unified digital validation solutions can be easily integrated with existing systems to improve overall performance in four crucial areas, as shown in **Table 1**:

50–80%
reduction in validation lifecycle time

Unified digital validation solutions connect validation to quality management, enable better reporting, trending, and KPI tracking.

Efficiency	Compliance and security	Visibility and traceability	Reporting

In addition, by making data accessible in a central location and leveraging application over procedural controls, unified digital validation solutions automatically ensure that validation meets validation meets regulatory data integrity standards. Companies that have adopted this approach have also improved reliability, data integrity, and audit readiness.

TABLE 1.

The Business Value of Modern, Unified Validation Management

QUALITY OUTCOMES	PERFORMANCE METRICS	BUSINESS VALUE (ROI)
Efficiency	• End-to-end validation lifecycle times • Enhanced review and approval process • Change management process • Accelerated release process	• Save resources • Reduce cycle time • Decrease change management cycle times • Shorten project timelines
Compliance and security	• Use of application controls vs. procedural controls • Enforcement of ALCOA+ principles • Audit readiness with a single source of truth	• Diminish regulatory risk • Improve inspection/audit readiness
Visibility and traceability	• Automated traceability matrix • Real-time validation status • Tasked deliverables with due dates • Related processes linked (e.g., bottle washer with associated cleaning process)	• Save resources • Decrease manual data transfer • Reduce cycle time
Reporting	• KPI tracking across operations • Enhanced periodic review • Track phase times (e.g., time from test discrepancy creation to closure)	• Save resources • Increase productivity

Emphasize ROI and the need for change

Support from senior leaders across business and IT is critical to successfully modernize validation management practices. Obtaining their buy-in requires evidence of ROI and business value to justify investment.

Identifying the relevant business owners and key influencers who can serve as change agents is an important step. Then, it is effective to tailor messages to each stakeholder based on their primary objectives, using the main drivers of ROI below to communicate the benefits of change. For example, senior IT leaders prioritize updates and change management, security, and cost, while quality leaders emphasize compliance, reduced human error, and efficiency.

50–80% reduction in validation lifecycle time

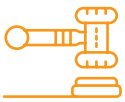
A significant reduction in lifecycle time translates into reduced project costs, timelines, and time to market, freeing validation team members to take on and complete more projects in less time.

Improved updates and change management

Streamlining and reducing the validation lifecycle time enables organizations to adopt new features and manage change requests more efficiently. For one company, it doubled the number of change controls they could close out year over year.

Error reduction via application controls and audit trails

Application controls streamline the validation approach across the organization and reduce human error.



Reduced compliance risk

Audit trails, electronic collaboration, and e-signatures improve compliance and accuracy, reducing inspection cycle times and enabling a review-by-exception approach.

To measure the ROI and communicate the benefits of change, align with stakeholders on the baseline by assessing the maturity of existing practices.

Assess the maturity of existing practices

Determine the current state of your organization's validation management practices. **Figure 1** groups current practices into three successive stages. Many companies are at Stage 1 or 2, in which validation processes are managed either on paper or PDFs in paper-on-glass approaches, which may not offer the flexibility and efficiency needed to keep pace with evolving demands and scale.

Assess your current stage by reviewing how your teams manage validation processes daily. Are they spending significant amounts of time managing documentation? If so, you are likely at the paper-on-glass phase of Stage 1. If documentation management time seems reasonable, are audit trails preserving all user actions, tasks, and signatures in one location? Can you track projects across all sites or obtain critical metrics for those projects? If not, you may be at Stage 2.

Consider the disconnects between validation and related quality processes. For example, does your organization include IT or GxP change controls or deviations in its validation practices? If the validation team finds a discrepancy, how easily can they track the escalation into a quality deviation? Can they zero in on validation data and metrics to improve results? If you can't answer 'yes' to these questions, your organization's baseline is not yet at Stage 3.

Assess your current stage by reviewing how your teams manage validation processes daily.

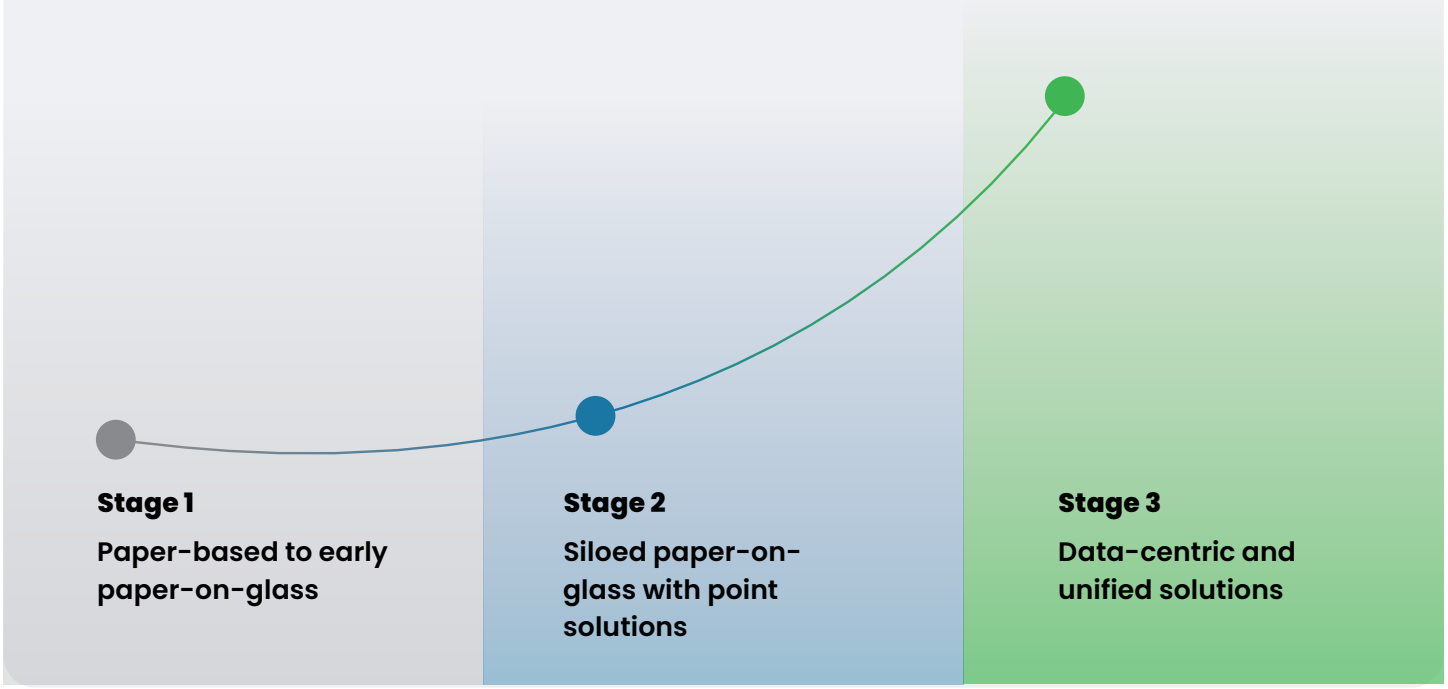
Consider the disconnects between validation and related quality processes.

Stage 1 Teams collaboratively author, review, and approve all documentation, including the validation master plan, requirements specifications, test scripts, and summary report, on paper or PDFs in SharePoint, the company's DMS, or via email. They manage documentation manually, although e-signature tools like DocuSign may be bolted on.

Stage 2 Teams use paper-on-glass approaches with point solutions (e.g., for change control) that are disconnected from other quality data associated with this process. The result: validation teams transfer data manually or add attachments for GxP or IT change controls, discrepancies, and deviations, with little end-to-end visibility into or control of the process.

Stage 3 Integrating validation management with QMS and document management results in end-to-end validation and quality processes so that teams create an ecosystem of shared data, documents, and workflows. They can readily access links to supplier information, associated quality events, and other documents.

FIGURE 1.
The Three Stages of Validation Management Maturity



Articulate the need for change

Continue mapping processes to identify the top drivers for improvement. Based on the **template** we provided, **Table 2** provides a simplified process mapping framework featuring questions along with typical answers for Stage 1 and 2 maturity levels. Review the **template** and record your answers to the key questions.

TABLE 2.
Process Mapping Examples

	PROCESSES AND KEY ELEMENTS	KEY QUESTION	ANSWER EXAMPLES
NEW PROJECTS	**Change controls**	• Where are they captured? • How do we track related validation activities?	• IT change requests are communicated by email.
	New system release	• How do we track?	• The release schedule is tracked in MS Excel.
OVERSIGHT	**System inventory**	• How are these managed?	• Tracked in MS Excel.
	Resource planning	• How are these managed?	• 20 GxP systems on five release schedules.
PLANNING	**Validation team**	• Do we have a dedicated team? • Do we use consultants, and if so, what is the cost?	• Small validation team and no consultants. Business owners help with input and execution.
	Validation deliverables	• What is the timeline for a validation project?	• Four weeks (average).
REQUIREMENTS	**User, functional, design risk assessment**	• Who captures and how?	• The team collaborates in eDMS, using FMEA.
TESTING	**Scripted or unscripted?**	• How do we execute tests? • How often do errors occur? • How long does testing take?	• We use a paper-based approach, scanning files into SharePoint. GDP errors occur frequently.
CLOSURE AND REPORTING	**Traceability matrix**	• How do we do this, and who is involved?	• The validation lead transcribes manually.
	Validation Summary Report	• How is this done?	• Validation data is captured and manually added to a document — taking a few days per project.

Create a vision and set priorities

Once you've mapped your validation processes and workflows as they are today, consider a future state where your end-to-end validation processes were further digitalized and unified with quality. What steps could be eliminated? What errors or risks would you avoid? Reflect on the following:

- Could maintaining the status quo put mission-critical projects at risk? What would be the risk of being unable to keep up with releases and projects?
- How might unified digital management improve your team's handling of new releases and change management?
- What would a 50–80% reduction in validation lifecycles mean for new system adoption? Could it reduce time to market or the number of project team members, or enable more enhancements to be completed yearly?
- Are audit or inspection findings a risk due to GDP errors or mistakes? How much could you save by reducing or eliminating errors and leveraging a review-by-exception mindset and audit trails to improve inspection readiness and test script accuracy?

Prioritize effort based on potential savings and risk reduction in evolving each process and its workflows. Refer to **Table 3** to assess how workflow execution evolves with the introduction of unified digital capabilities.

TABLE 3.

Workflow Execution for Paper, Paper-on-Glass, and Unified Digital Validation

		PAPER-BASED	SILOED PAPER-TO-GLASS	DATA-CENTRIC & UNIFIED
INITIATION AND CONCEPT	SYSTEM ASSESSMENTS	• Print • Complete by Hand • Wet Approval • Scan	• Electronically Completed • Managed as Document	• **Electronically Completed** • **Managed as Checklist**
	PLANS	• Print • Wet Approval • Scan	• Electronically Completed • Managed as Document	• **Electronically Completed** • **Managed as Dynamic Document**
	CHANGE CONTROL	• Manual Reference	• Manual Reference	• **Linked to Change Control Record in Quality Ecosystem**
DESIGN AND BUILD	REQUIREMENTS	• Print • Wet Approval • Scan	• Electronically Completed • Managed as Document	• **Electronically Completed** • **Managed as Data**
	SPECIFICATIONS	• Print • Wet Approval • Scan	• Electronically Completed • Managed as Document	• **Electronically Completed** • **Managed as Data**
	RISK ASSESSEMENT	• Print • Wet Approval • Scan	• Managed Outside of System	• **Linked to Risk Record in Quality Ecosystem**
TEST AND RELEASE	TEST PROTOCOLS	• Print • Execute Pen & Paper • Wet Approval • Scan	• Electronically Completed • Managed as Document	• **Electronically Completed** • **Managed as Data**
	TEST REPORT	• Manually Draft • Print • Wet Approval • Scan	• Electronically Completed • Manual Data Summary	• **Electronically Completed** • **Automated Data Summary** • **Managed as Dynamic Document**
	TRACEBILITY MATRIX	• Print • Wet Approval • Scan	• Automated Report	• **Automated Dynamic Report**
	PROCEDURES	• Print • Wet Approval • Scan	• Managed Outside of System	• **Linked to Procedure Document or Record in Quality Ecosystem**

Align cross-functional stakeholders around the project's vision

Share the baseline mapping and future state vision with stakeholders, engaging them early and working toward alignment. Do all teams use consistent approaches to manage validation and determine risk? If not, get them together to agree on goals and methods. Utilize workshops or meetings to facilitate open discussion and ensure every user's voice is heard.

To ensure end-user support and alignment, log the project's IT, business, and system requirements, make this list accessible to cross-functional team members, and stack rank requirements based on must-haves vs. nice-to-haves.

Be realistic about the new solution's capabilities and limitations, the timeline for implementation, and the adoption curve. Plan for the must-haves at go-live and allow for incremental improvements over time to drive your vision.

Success depends on establishing teams around the project's goals, so that people are on board. Be flexible and adjust plans as needed to reinforce a shared vision.

Do all teams use consistent approaches to manage validation and determine risk? If not, get them together to agree on goals and methods.

Develop vendor requirements

As you explore solutions, evaluate the vendor requirements list below to ensure compliance with FDA, EMA, and other system requirements you've collected.

Review the following to validate solution reliability, accuracy, and compliance:

- Data security
- Validation documentation
- Quality management processes

Partner with IT to mitigate project risk

Ask the following questions to review support and maintenance, systems scalability and integration with existing systems.

Q: What is the vendor's validation strategy?

Each vendor will provide a certain level of testing services. Determine whether the services meet your organization's requirements.

Q: What is the vendor's standard release or upgrade cycle, and what's the impact on the customer?

Understand how you will need to handle configuration and production data during upgrades. Compare the vendor's processes to your needs and adjust if needed.

Q: Does the solution provide a comprehensive audit trail?

Audit trails help ensure the integrity, security, and reliability of electronic records and signatures. Determine whether these audit trails are intuitive and easy to access and export.

Q: What user and product support model(s) does the vendor offer?

Explore the vendor's training programs to understand how well the vendor will support training and how to troubleshoot if product or process issues arise.

Q: Will the vendor help with software integration?

Consider or ensure that your IT team considers issues such as compatibility, APIs, security, scalability, error handling, workflow alignment, and documentation.

Q: Will the solution permit flexibility during implementation?

Assess whether the solution includes built-in industry best practices and whether it allows for configuration to align specific business requirements during implementation.

Deliver value with a successful implementation

Start planning the implementation — particularly its timeline and rollout strategy — as early as possible, considering other planned projects and release dates.

Consider all factors to establish a realistic time frame for adoption.

Understand the cutoff for new projects.

- Are there any projects in flight that you'll have to continue using your old validation method?
- What is the cutoff period for new projects your team will manage in the new system?

Identify critical go-live dates for upcoming releases for any GxP systems you have already implemented.

Your timeline and complexity will depend on the size of your organization. Allocate time to execute the success strategies outlined in **Figure 2** as they are best practices for successful implementations. Ensure that business leaders agree on a timeline, budget, and available resources.

FIGURE 2.
Implementation and Change Management

Success strategies

1 **Vendor and Partner Selection**
Assess time required by your team and the need for a partner for successful implementation.

2 **Project Rollout**
Who will be on the project team? What is in scope for this project? What is the target go-live date? How much and what data do we migrate into the new system?

3 **Plan for System Updates**
Rolling out the system will identify changes/improvements that can be made. Incremental change is still change.

4 **User Training**
Plan to create collateral: videos, ppt., SOPs, of the new system. Plan for the user training to ensure a successful adoption.

5 **Company Rollout**
What other projects are in flight? Identify a cutoff period for new project on the roadmap and upcoming system releases.

6 **Host a Mock Inspection**
Host a mock inspection with your team to ensure they are comfortable pulling records in a new system.

Adopt change-management and training best practices

Remember that user adoption is the key to success with any new approach. Create user-friendly videos, presentations, SOPs, live training sessions, and vendor information to demonstrate the value of modernized approaches and ensure long-term end-user adoption.

Reduce risk with unified digital validation

Unified digital validation management is a modern approach that offers savings and reduces non-compliance risk. Designed with industry best practices, it optimizes validation processes and frees validation teams from documentation management. As a result, they can focus on identifying and addressing problems and planning and improving validation programs.

Download this Business Case template to map your organization's validation practices.

Explore the value of unified digital validation with Veeva's fast and cost-effective validation management solution.

References

[1] Anthony J. Margetts, Ph.D. Line Lundsberg-Nielsen, PhD, "The History and Future of Validation", ISPE, April 2021

[2] Chip Bennett, PMP Hans Heesakkers Stefan Horneborg Gilad Langer, PhD Line Lundsberg-Nielsen, PhD Anthony J. Margetts, Ph.D. Fritz Röder, "Industry Perspective: Validation 4.0 - Shifting Paradigms", ISPE, December 2020

[3] Anurag S. Rathore, Yuexia Li, Hemlata Chhabra, Akshat Lohiva, "FDA Warning Letters: A Retrospective Analysis of Letters Issues to Pharmaceutical Companies from 2010-2020", NIH

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