

eValidation, the future is now: compliance, efficiency, and integrity



In the ever-evolving landscape of digital technologies, numerous innovations have emerged – data analytics, digital twins, virtual or augmented reality, artificial intelligence, and more. While some have come and gone, one technology is proving indispensable: eValidation, also known as paperless validation or digital validation. This article delves into what eValidation entails and how it enhances compliance, efficiency, and data integrity in the pharmaceutical industry.

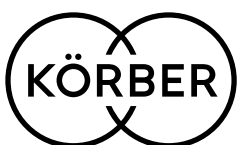
Replacing manual operations

The European Union's Good Manufacturing Practice (GMP) Annex 11 states:

“Where a computerized system replaces a manual operation, there should be no resultant decrease in product quality, process control or quality assurance. There should be no increase in the overall risk of the process.”

While this guidance focuses on computerized systems used in GMP operations, it generally applies to software applications related to validation activities for these systems. As validation requirements grow increasingly complex, the need for efficient and innovative solutions becomes paramount.

Traditional paper-based validation methods may no longer suffice to meet current and future challenges. eValidation is not merely a technological upgrade; it's a transformative approach that maintains compliance, boosts operational efficiency, and upholds the highest standards of data integrity.



eValidation in a nutshell

eValidation involves managing validation activities through electronic systems rather than paper-based documentation. This transformation encompasses all aspects of the validation process from specification to verification, including test execution, approvals, audit trails, traceability, and regulatory reporting. By digitalizing these processes, companies can accelerate validation timelines, and reduce errors.

Key benefits:

Why eValidation is a game changer

The 2025 State of Validation report found that 66% of validation professionals in highly regulated industries experienced increased workloads due to new products, process changes, and evolving regulatory demands. Traditional validation methods often involve time-consuming manual tasks, lengthy approval cycles, and compliance risks stemming from human error. eValidation offers an automated, scalable solution that aligns with regulatory expectations while enhancing productivity.

1. Ensuring data integrity

Data integrity is a cornerstone of global regulations and is addressed by best practices like ISPE's GAMP® 5 and the Record and Data Integrity Guide. Robust eValidation systems uphold ALCOA++ principles, ensuring that data is:

- **Attributable:** Each action is linked to a specific user via secure logins and digital signatures.
- **Legible:** Eliminates errors and misinterpretations associated with handwritten notes.
- **Contemporaneous:** Actions are time-stamped, ensuring real-time accuracy.
- **Original:** Data is captured directly in digital format, eliminating transcription errors.
- **Accurate:** Built-in validation checks reduce errors and ensure compliance.
- **Complete:** Automated workflows ensure all required data is captured, preventing omissions.
- **Consistent:** Standardized templates and workflows maintain uniform data entry.

- **Available:** Cloud-based access enables authorized users to retrieve records instantly from any location.
- **Traceable:** Comprehensive audit trails log all actions, ensuring transparency, accountability and you get a Traceability Matrix on top.

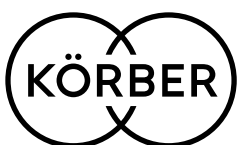
By adhering to these principles, eValidation provides a secure, traceable, and audit-ready system that mitigates compliance risks.



2. Improving efficiency across the validation lifecycle

Validation processes encompass multiple steps, including document authoring, review and approval, test execution, and archiving. eValidation systems significantly reduce the time spent on each stage by enabling:

- **Automated document creation and approval workflows:** Streamlines the generation and authorization of validation documents.
- **Online test execution:** Allows for real-time recording of test results, enhancing accuracy and increased transparency.
- **Instant digital signatures:** Eliminates the need for physical sign-offs, expediting the approval process.
- **Real-time collaboration:** Facilitates seamless interaction across departments and locations.
- **Automated audit trails:** Reduces preparation time for inspections by maintaining comprehensive records.



3. Harmonizing validation across multiple sites

Global pharmaceutical companies often face inconsistencies in validation practices across different sites. eValidation fosters a standardized process that ensures:

- **Consistent validation procedures:** Uniform practices across all locations enhance compliance and quality.
- **Simplified compliance monitoring:** Centralized systems make it easier to oversee adherence to regulations.
- **Automated traceability matrices:** Facilitates seamless documentation tracking and retrieval.
- **A centralized eValidation system breaks down silos, improving coordination between departments and regulatory teams.**

4. Reducing deviations and improving right-first-time outcomes

Manual validation processes are prone to deviations due to documentation errors, missing approvals, or inconsistent testing methods. eValidation minimizes these risks by:

- **Providing real-time access to the latest protocols and documents:** Ensures all team members are working with current information.
- **Automating deviation tracking and resolution workflows:** Streamlines the identification and correction of issues.

By reducing the likelihood of deviations, eValidation supports a right-first-time approach, cutting down on costly rework and delays.

Implementing eValidation successfully with Körber

Transitioning from paper-based to eValidation requires careful planning. Companies should:

- **Assess current processes:** Identify bottlenecks and inefficiencies in the existing validation workflow.

- **Choose the right eValidation solution:** Look for a platform that meets regulatory requirements, offers configurable workflows, is scalable, and provides real-time data access.

- **Train teams for adoption:** Provide comprehensive training to ensure seamless transition and adoption of eValidation systems.
- **Monitor and optimize:** Use data analytics to continuously refine validation processes and improve efficiency.

Körber helps customers to successfully implement an eValidation solution. Whether starting from scratch or transforming an analog process, Körber has the know-how and the tools to get you fully digital for all your validation and qualification activities. Starting with an assessment of your capabilities and needs, we help you to set up and run your solution, provide the required templates and workflows for easy and efficient use, and configure your dashboards and reports to maximize benefits. Add training on top and you're ready to go!

Körber and Kneat: A stronger validation ecosystem

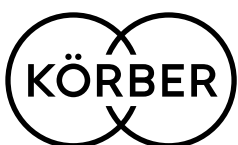
Körber and Kneat are committed to driving innovation in validation by enabling seamless, efficient, and compliant eValidation processes for pharmaceutical companies.

Körber was a proud supporter of Kneat's 2025 State of Validation Survey. We invite experts in the pharmaceutical validation to participate in the next survey, aimed aimed at evaluating the current state of validation practices within the industry.

Through this partnership, we are enhancing capabilities by leveraging Kneat Gx with Körber's manufacturing and validation expertise. This collaboration empowers organizations to adopt smarter, data-driven validation strategies that improve product quality, streamline compliance, and reduce time to market.

As a Kneat-certified Strategic Partner, we are equipped to address your unique eValidation requirements, all tailored to suit your budget.

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