

Kneat



The Digital Process Validation Guide

Adopting a process-centric and data-driven
approach to process validation

Table of Contents

Traditional Process Validation	03
What Is Process Validation	03
Process Design	04
Process Qualification	05
Continued Process Verification	05
Process Validation: Challenges and Opportunities	06
Regulatory Differences	07
Complex and Contrasting Processes	08
Documentation and Data Analysis Inefficiencies	08
Effective Communication and Collaboration	09
Change Control	09
Adequate Resources	09
Digitalizing Process Validation	10
What Is Digital Process Validation	10
Largest Benefits of Digital Validation	10
Kneat Gx: Complete Digital Validation in a Single Platform	11
Kneat's Digital Process Validation Solution	11
Digital Validation Value	13
Process Validation Value	13
Audit Readiness	14
Dashboard Reporting	14
Document Management	15
Drawing Management	15
Dynamic Data and Documents	16
Online Test Execution	16



In today's rapidly evolving landscape of manufacturing and quality assurance, the need for efficient, accurate, and compliant process validation has never been more critical. As industries strive for higher standards, regulatory agencies demand greater rigor, and technologies continue to advance, traditional methods of process validation face increasing challenges. The solution to many of these challenges lies in embracing the digital transformation of process validation.

This guide will explore the evolution of process validation, the challenges and opportunities it presents, and the benefits of adopting a fully digital process-centric and data-driven approach. You will learn how to accelerate your program and drive good manufacturing practices to spur growth at your organization.

Traditional Process Validation

What Is Process Validation?

The U.S. Food and Drug Administration (FDA) defines process validation as “the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product.”¹ It involves demonstrating the process is robust, reliable, and capable of consistently delivering products that meet the desired quality, safety, and efficacy standards.

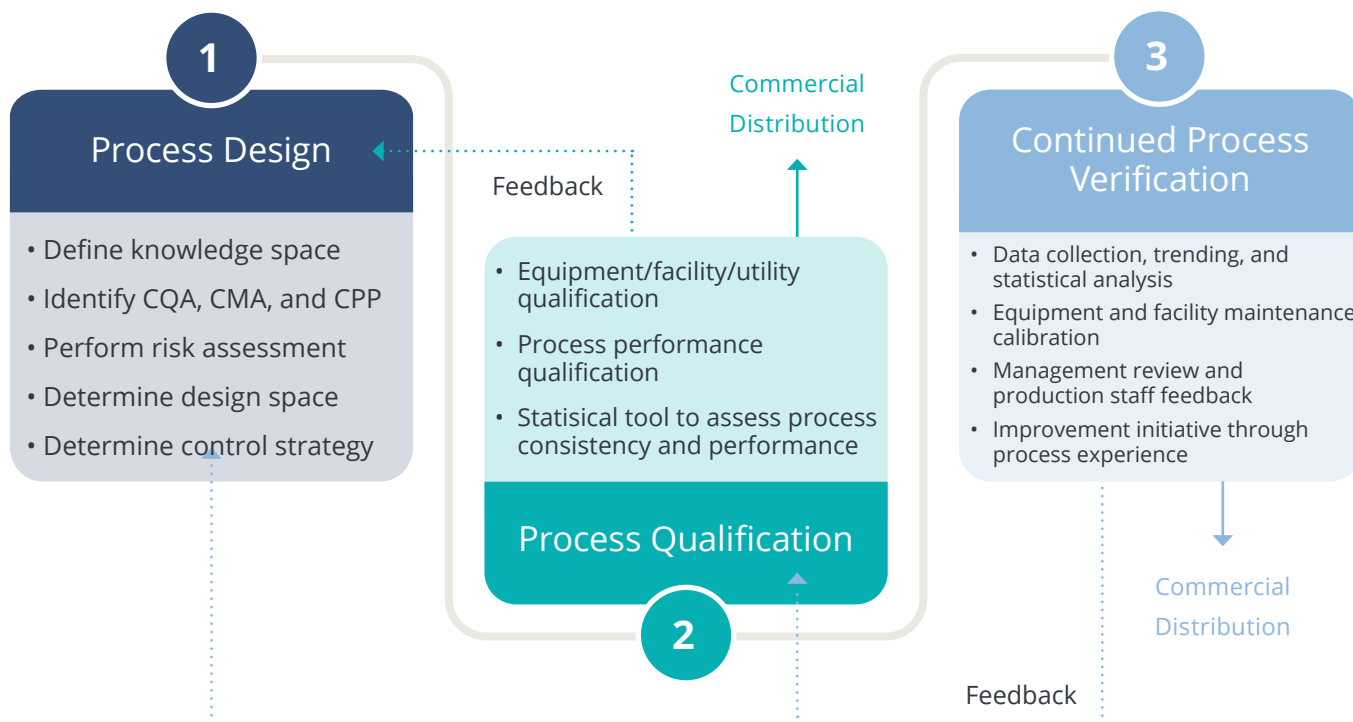
There are three stages of process validation:

Stage 1 – Process Design: The commercial process is defined during this stage based on knowledge gained through development and scale-up activities.

Stage 2 – Process Qualification: During this stage, the process design is confirmed as being capable of reproducible commercial manufacturing.

Stage 3 – Continued Process Verification: Ongoing assurance is gained during routine production that the process remains in a state of control.

¹ Food and Drug Administration. (2011). *Guidance for industry process validation: General principles and practices*. Retrieved from <https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf>



Process Design

Process validation begins with the initial phase, which is **process design**. In this stage, pharmaceutical manufacturers define and create a detailed plan for how a drug or biologic product will be manufactured. The objectives include:

- ▶ **Identifying critical quality attributes (CQAs):** These are the characteristics of a product that are essential to meet its desired quality standards. For example, the potency of an active pharmaceutical ingredient (API), product stability, and sterility are CQAs.
- ▶ **Defining critical process parameters (CPPs):** These are the variables in the manufacturing process that can affect the CQAs. Identifying and controlling CPPs is vital to ensuring product consistency and quality. For instance, temperature, pressure, and mixing duration might be critical process parameters in a tablet manufacturing process.
- ▶ **Developing a detailed process flow:** Manufacturers create a step-by-step blueprint of the manufacturing process, including equipment, materials, and operating procedures which will be encompassed in a Master Batch Record (MBR).
- ▶ **Drafting a validation master plan:** This document outlines the overall strategy for process validation, including the scope, resources, responsibilities, and timelines.

Process Qualification

The second stage of the process validation life cycle is **process qualification**. It involves executing the validated process as per the design and ensuring that it consistently delivers products meeting the predefined quality attributes and process parameters. Key components of process qualification may include:

- ▶ **Installation Qualification (IQ):** This verifies that equipment and systems are correctly installed, ensuring they meet specifications.
- ▶ **Operational Qualification (OQ):** This confirms equipment operates according to predetermined specifications and settings, and it can produce the desired results.
- ▶ **Process Performance Qualification (PPQ):** In this step, the process is tested to ensure that it consistently produces products meeting the predefined quality attributes. This typically involves multiple runs to establish a track record of consistent performance.

Continued Process Verification

The third and final stage of the process validation life cycle is **continuous process verification** (CPV). Unlike the previous stages, CPV is an ongoing process that extends beyond the initial qualification. Its objectives include:

- ▶ **Continuous monitoring of the manufacturing process:** This involves real-time data collection and analysis to detect deviations and trends that may affect product quality.
- ▶ **Data-driven decision-making:** CPV relies on statistical tools and analysis to make informed decisions about process control and improvements.
- ▶ **Risk management:** By identifying and mitigating risks in real-time, CPV ensures the manufacturing process remains in a state of control.



Process Validation: Challenges and Opportunities

Process validation is not just a regulatory requirement; it is a fundamental quality assurance step that ensures products consistently meet the desired specifications. It plays a vital role in risk management, as the failure to validate processes can lead to variations in product quality, safety concerns, increased costs, and, in some cases, regulatory penalties.

The benefits of effective process validation extend far beyond regulatory compliance. A well-executed validation process contributes to:

- ▶ **Enhanced Product Quality:** Validated processes lead to reduced defects, higher quality products, and greater customer satisfaction.
- ▶ **Improved Safety:** Ensures safety, especially in sectors like pharmaceuticals and food, by preventing contamination or adverse effects on users.
- ▶ **Cost Reduction:** Identifying and rectifying issues early in the process minimizes costly rework and recalls.
- ▶ **Consistency:** Reduces process variability, leading to more consistent product output.
- ▶ **Enhanced Reputation:** A commitment to validation reflects a dedication to quality and safety, strengthening the reputation of the organization.



Some of the key challenges in process validation include:

- ▶ Regulatory Differences
- ▶ Complex and Contrasting Processes
- ▶ Documentation and Data Analysis Inefficiencies
- ▶ Effective Communication and Collaboration
- ▶ Change Control
- ▶ Adequate Resources





Regulatory Differences

Challenges in process validation often arise from the differences in regulatory requirements across industries and geographic regions. For example, the pharmaceutical industry follows guidelines from regulatory bodies like the FDA² or the European Medicines Agency (EMA),³ while other industries may adhere to standards set by organizations such as the International Conference on Harmonization (ICH)⁴ or the International Organization for Standardization (ISO).⁵

These regulatory differences can lead to confusion and complexity for organizations operating in multiple regions or industries, making it challenging to maintain a consistent approach to process validation.

In addition, regulatory standards are continually evolving, making it difficult to keep up with the latest requirements and ensuring compliance. For example, the FDA published draft advice in October 2023,⁶ outlining expectations for establishments taking part in a remote inspection, as well as outlining how the agency intends to seek and carry out voluntary remote interactive inspections of drug production sites and other facilities. These requirements include openness and collaboration, electronic or shared screen document delivery, and sufficient technology at participating sites.

Comprehensive documentation and standardized procedures are essential to ensure that the validation process is consistent and transparent. Clear guidelines and documentation help teams follow the process efficiently and adhere to regulatory requirements.

2 Food and Drug Administration. (2011). *Guidance for industry process validation: General principles and practices*. Retrieved from <https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf>

3 EMA. (2018, September 17). *Process validation for finished products – information and data to be provided in regulatory submissions - Scientific guideline*. European Medicines Agency. Retrieved from <https://www.ema.europa.eu/en/process-validation-finished-products-information-data-be-provided-regulatory-submissions-scientific>

4 ICH. (2020). ICH Official website: ICH. [ich.org](https://www.ich.org). Retrieved from <https://www.ich.org/page/quality-guidelines>

5 ISO. (2017, March 7). ISO 9000:2015. ISO. Retrieved from <https://www.iso.org/standard/45481.html>

6 Research, C. for D. E. and. (2023, October 25). *Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities*. www.fda.gov. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities>

Complex and Contrasting Processes

In many highly regulated industries, especially pharmaceuticals and biotechnology, processes are intricate and involve numerous variables. Managing and validating such complex processes can be overwhelming.

Implementing a risk-based approach to process validation can help prioritize efforts where they are most needed. Identifying critical process parameters and focusing validation efforts on them can simplify the process.

A comprehensive **Validation Master Plan** is developed that outlines the scope, objectives, and responsibilities that will take place during the validation process. This plan serves as a roadmap for the entire validation effort and a tool for process control.

Process validation is used to validate a wide variety of contrasting processes. With each individual process, preliminary studies must be performed, critical quality attributes and critical process parameters must be identified, and sampling plans must be determined for the Process Performance Qualification (PPQ) batches. Since each process is unique, the described items will be different and are dependent on the process.

A **team of knowledgeable members** must come together to determine each of these steps and the best approach to prove the manufacturing process is controlled and delivering quality products.

Documentation and Data Analysis Inefficiencies

Process validation generates a huge amount of data and documentation. Traditional validation methods rely heavily on paper-based records and manual data collection, making the management and retrieval of this information a cumbersome and time-consuming process. The extensive paperwork not only increases the risk of errors but also hinders timely decision-making and analysis. Furthermore, the long-term storage and accessibility of paper records pose logistical challenges and can lead to headaches like data loss or degradation over time.

Traditional methods of process validation often **involve manual data analysis, which can be both time-consuming and prone to human errors.** This approach may result in missed opportunities for process improvement or early detection of deviations. Moreover, the reactive nature of traditional validation processes can lead to inefficiencies and the allocation of resources to resolving issues after they have occurred, rather than preventing them in the first place. **Implementing advanced document and data management and analytics tools** can streamline the process of collecting and analyzing validation data. These tools can help identify trends, outliers, and potential issues more efficiently. **Implement automation** wherever possible in the validation process. Automation can significantly reduce the potential for human error and expedite data collection and analysis.

Effective Communication and Collaboration

Process Validation often requires close **collaboration between different departments**, and this can be challenging due to differences in priorities and communication barriers. Encouraging **effective communication and collaboration among different departments** is essential.

Establishing cross-functional teams that meet regularly to discuss validation progress and challenges can bridge the communication gap. In industries that rely on a supply chain, **collaborating with suppliers** can be beneficial. Ensuring that suppliers meet specific quality standards and validate their processes can reduce the risks associated with raw materials.

Post validation, it's crucial to continuously monitor the process to ensure it remains in a state of control. **Periodic reviews and audits** help identify deviations and initiate corrective actions promptly.

Change Control

Process Validation is an **ongoing operation**. If a process has been validated and there is a change required to be made, the process in its entirety must be assessed and a path forward will be determined on how to incorporate the change via change control.

If the change is critical to the process, additional validation activities may be required such as an addendum Process Performance Qualification (PPQ) batch, equipment qualifications, etc. Changes may be inevitable, but **potential future changes must be analyzed** along with the time and monetary commitment.

Adequate Resources

Adequate resources, both in terms of human resources and budget, are often required for successful process validation. Many organizations may face limitations in this regard. Investing in **training and development** for staff members is crucial. This includes staying up to date with changing regulations and standards and enhancing data analysis and validation techniques skills.

Use specialized **validation software solutions** to streamline validation, document management, and facilitate compliance with industry standards.



Expert Tip

Go digital. Removing paper from validation processes makes documents dramatically more accessible, lowers overhead, reduces cycle times, and improves accuracy and efficiency.

Learn more about Digital Validation — including identifying the right method for your company — in our Digital Validation Handbook.

[Download Handbook >](#)

Digitalizing Process Validation

What Is Digital Process Validation?

Digital process validation is the modern approach to process validation that leverages digital technologies and automation to enhance the entire process. It involves the integration of data collection, analysis, and documentation into a unified digital framework.

Largest Benefits of Digital Validation

When looking for a digital process validation solution you should balance cost, utility, and fit. For example, some solutions are more document management systems (DMS), which can scan existing paper documents, but don't offer online test execution or support a process-centric or data-centric approach.

When digitalizing process validation, companies typically see a greater return on investment (ROI) the more the solution is used. Look for a provider that can accommodate a number of disciplines, sites, and processes in order to maximize your ROI.

You should expect a digital validation solution to:

- ▶ **Standardize for efficiency:** A good digital validation solution can seamlessly scale across an organization, making standardization easier to deploy in global workplaces.
- ▶ **Leverage existing data and documents to accelerate production:** Digital validation enables companies to leverage data points as tools themselves rather than specific answers to single questions.
- ▶ **Make data more accessible to reduce wait times:** An obvious benefit of digital process validation is the removal of paper from the process. There's no need for manual storage or compiling of binders, no wait time for retrieval of documents, reduced need for travel and physical mailing, and flexibility to draft, execute, and sign off from anywhere.
- ▶ **Generate audit trails to be audit ready at any time:** An organization must be audit ready at any time. With digital validation you can be. Features such as version histories, version controls, password protected e-signatures, and traceability matrices make it far easier to demonstrate compliance and adherence with the highest quality standards.
- ▶ **Automate workflows to get started faster:** Generate template documents, project maps, and processes to give process validation a head start at kickoff. Whether set at a global or site level, preloaded templates can leverage automation to cut cycle times in half.
- ▶ **Execute tests in real time:** Record results directly in your digital validation platform as they come in. Real time test execution reduces cycle times, enhances accuracy, and aligns with ALCOA+ principles of timely documentation. Tests are sent for review and approval and recorded results are accessible at any time.

Kneat Gx: Complete Digital Validation in a Single Platform

Kneat Gx is the industry-leading digital validation solution providing end-to-end validation life cycle management across all validation disciplines. Today, Kneat is trusted by eight of the Top 10 life sciences companies to digitalize:

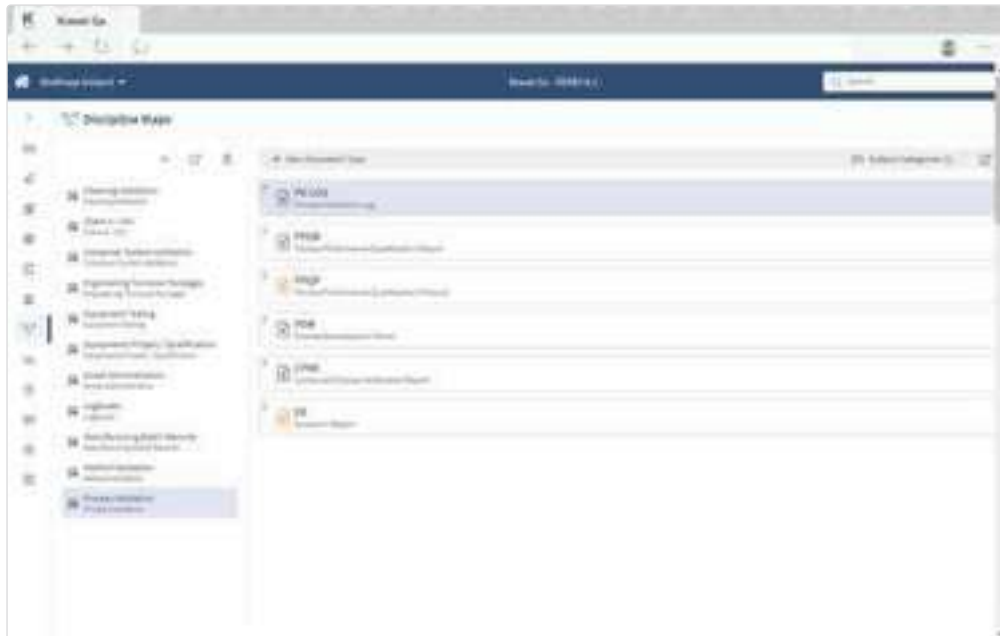
- ▶ Analytical Instrument Validation
- ▶ Cleaning Validation
- ▶ Cold Chain Validation
- ▶ Commissioning and Qualification
- ▶ Computer System Validation/Computer Software Assurance
- ▶ Electronic Logbook Management
- ▶ Equipment Validation
- ▶ Method Validation
- ▶ Process Validation
- ▶ Utility and Facility Validation
- ▶ Document Management
- ▶ Drawing Management

Kneat's Digital Process Validation Solution

All the benefits — and then some — of digital process validation are realized through Kneat Gx. Its all-in-one design, purpose-built for highly regulated companies, delivers greater return on investment the more it's leveraged.

Kneat Gx allows you to manage all your products' life cycle starting with **Critical Quality Attributes** and **Critical Process Parameters** through to **Validation Final Reports** in one easy-to-use application. The platform's built-in validated features and functions support all types of process validation documentation, including:

- ▶ Design Documents (Process Control Strategy)
- ▶ Decommissioning
- ▶ Operational Forms
- ▶ Risk Assessment
- ▶ Test Protocols
- ▶ Validation Final Report
- ▶ Validation Master Plan
- ▶ Validation Summary Report



Process Validation Discipline Map in Kneat Gx



MSD chose Kneat to digitalize seven validation work processes, including process validation, at 27 sites worldwide. As a result, MSD achieved a “more than 50% cycle time reduction for test execution”, simplified process steps from 15 to just eight on average, and eliminated reliance on three different quality management systems, generating “very significant value in dollars” for the organization.

[Download Case Study >](#)



Digital Validation Value

Many features of Kneat Gx within the platform provide significant value regardless of validation discipline including:

Automation	User defined templates automate the development of validation documentation packs. Pre-load template packs into your Kneat Gx to automate workflows and increase efficiency by removing as much as 80% of the upfront work.
Configurability	An intuitive user interface can result in fast deployment and user adoption. Easy configurability means you map your process on the digital validation platform.
Data Accessibility	All documents used in Kneat Gx are stored on customer-exclusive databases, available instantly to all who have permissions. Advanced search features (and the robust RTM) make finding documents quick and easy.
Data Integrity	Enables 21 CFR Part 11/Annex 11 compliance with ALCOA+ principles
Data Security	Robust cybersecurity protects sensitive data, ensuring compliance with regulatory standards.
Electronic Logbooks	Used for compliant data capture in laboratories or on the manufacturing floor.
Enhanced Efficiency	Digital tools reduce manual paperwork, streamline communication, and improve the overall efficiency of the validation process.
Integration APIs	Integration with other key software systems such as PAT, to capture and support data.
Remote Review and Approval	Secure cloud-based technology enables globally remote review and approval, in parallel or in sequence, so you can work from anywhere online.
SaaS	Software-as-a-service delivered on a secure AWS cloud infrastructure, complete with elastic scalability, high availability, and zero downtime.
Standardized Validation	Use a Kneat partner to make process mapping quick and easy, ensuring alignment across teams and sites for faster, more accurate validation.



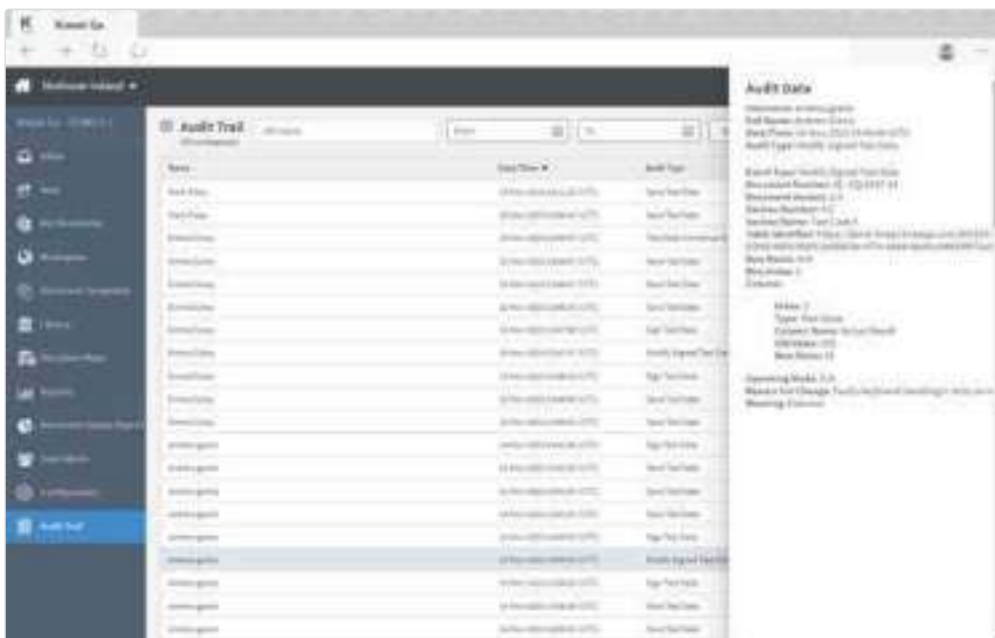
Process Validation Value

Other key components of Kneat Gx for digital process validation include:

- ▶ Audit Readiness
- ▶ Dashboard Reporting
- ▶ Document Management
- ▶ Drawing Management
- ▶ Dynamic Data and Documents
- ▶ Online Test Execution

Audit Readiness

Digital validation platforms enhance audit readiness by providing real-time data access, traceability, and automated compliance checks, streamlining record-keeping, and ensuring regulatory compliance for a seamless audit process. Process validation actions can be taken directly within Kneat, which automatically logs them to prepare a ready-made audit trail.



System Audit Trail in Kneat Gx

Dashboard Reporting

Run status reports or create progress reports using detailed filters. Digitalization enables real-time visibility, providing instant insights into the status of the manufacturing process at macro and micro levels. This allows for immediate corrective actions when deviations are detected.



Dashboard Reporting in Kneat Gx

Document Management

All your document files such as MS Word, Excel, PDF, images, and more, may be stored, controlled, reviewed, and approved within Kneat Gx.



Document Management in Kneat Gx

Drawing Management

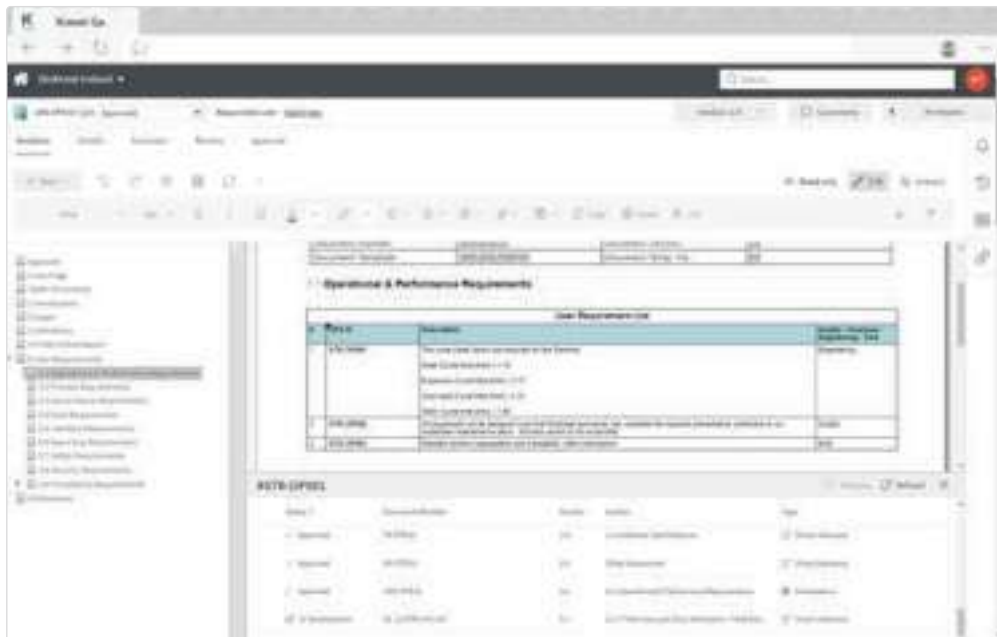
Kneat Gx allows for real-time validation in walkdowns with its Drawings module. Engineering drawings, including live walkdown markups, may be stored, controlled, reviewed, and approved.



Drawing Management in Kneat Gx

Dynamic Data and Documents

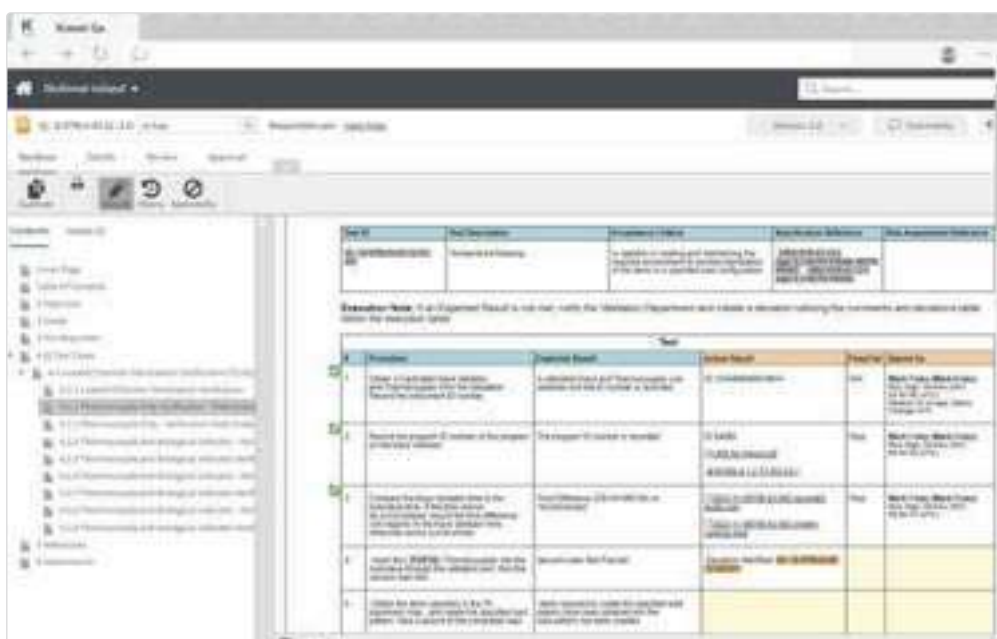
Remove redundant steps by using data and documents throughout processes. Kneat Gx auto-populates relevant data in templates and allows referencing to documents, by automatically populating a range of unique IDs across document packs, to streamline validation.



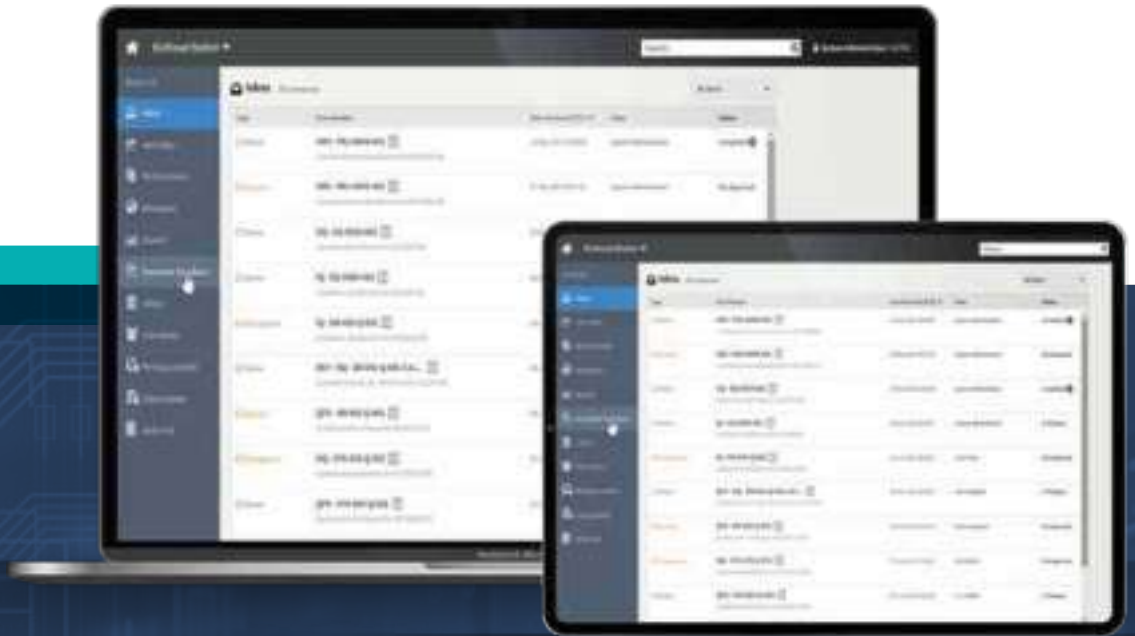
User Requirement Dynamic Data in Kneat Gx

Online Test Execution

Execute testing digitally on your device, complete with integrated deviation life cycle management and all test evidence. Record test results as they happen to improve data integrity and accelerate production.



Online Test Execution in Kneat Gx



Is Kneat Gx Right for You?

Kneat Gx is purpose-built for highly regulated companies, bringing efficiency and transparency to validation with a focus on 21 CFR 11 compliance. Digital validation is about more than removing paper from the process, it's a move towards Pharma 4.0, leveraging data, connecting sites, machines, and professionals to enhance product quality.

The best way to know if Kneat Gx is right for you is to book a demo. You'll receive a one-on-one demonstration of Kneat Gx, and an expert will be on hand to answer all your questions.

Book your no-obligation demo today!

[Book My Demo >](#)

Kneat

Talk to Us

Find out how Kneat can make your validation easier, faster, and smarter.
Start your validation revolution by speaking to our experts.

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