

Kneat



Kneat Gx

Easier, Faster, Smarter Validation



Kneat is at the top of the line as far as paperless validation, DMS system, document storage, archiving... I saw what it can do, how configurable it was, that it allowed us to implement what we wanted from the beginning versus trying to build a system around something that was already existing... we chose it because it was the most innovative product out there.





Director, Quality Assurance Validation at ElevateBio, Matt Ostrowski

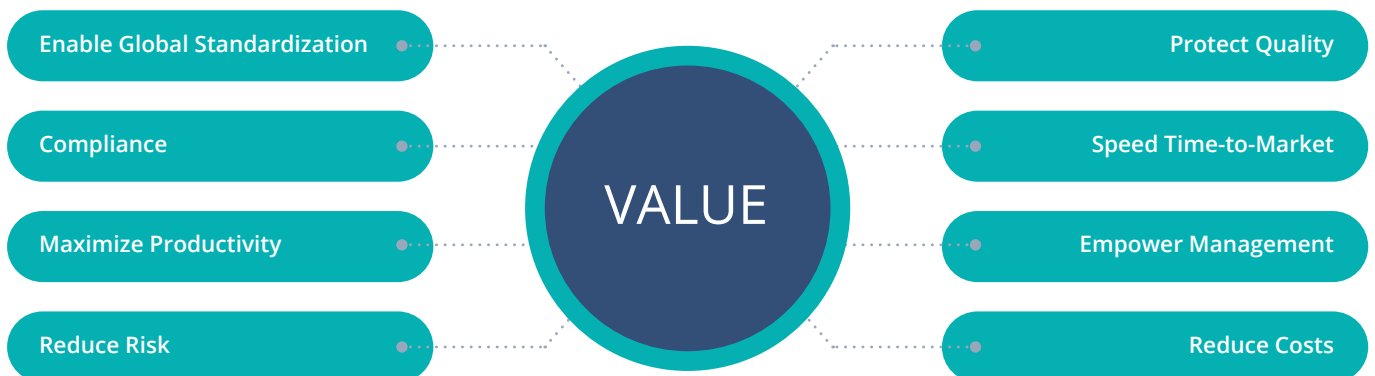
Kneat Gx, the Leading Digital Validation Platform

Kneat Gx is the leading digital validation platform for the implementation of paperless, data compliant, validation. It is trusted by the leaders in Life Sciences, including eight of the top 10 life sciences companies, whose regulations demand that the development and manufacture of medical and healthcare products must have their equipment, computer systems, and processes validated to ensure product quality and patient safety.

Our in-house team has designed and built Kneat Gx using the latest technology to provide the most effective, secure, and easy to use platform on the market.

Quality, Compliance and Patient Safety

	Quality Compliance & Audit Readiness	Digital Validation processes, configured on Kneat Gx, are streamlined, repeatable best practice. They have enhanced Data Integrity with real-time global visibility.
	Cost	Kneat Gx reduces validation labor hours and cycle times by 50% or more, leading to lower cost and faster time to market.
	Sustainability	End-to-end digitization removes paper completely, supporting environmental initiatives. Kneat Gx is delivered on an AWS multitenant scalable elastic infrastructure which delivers high energy efficiency. AWS is targeting to be powered with 100% renewable energy by 2025.
	Scalability	Kneat Gx scales easily across all your global sites and can be used for multiple processes where the goal is to prove compliance with regulations.



Kneat Gx At-a-Glance

✓	Data Integrity	Enables 21 CFR Part 11/ Annex 11 compliance: secure access control; full audit trails and version management complete with electronic signatures.
✓	Ease of Use	The intuitive user interface results in fast deployment and user adoption; Easy configurability means you map your process on the Kneat platform.
✓	Smart Validation	User defined templates automate the development of validation documentation packs and Requirements Traceability Matrix (RTM).
✓	Review & Approval	Collaborative real-time review or approval in parallel or in sequence.
✓	Online Test Execution	Execute testing digitally on your device, complete with integrated deviation lifecycle management and all test evidence.
✓	Drawing Management	Engineering drawings, including live walkdown markups, may be stored, controlled, reviewed, and approved within Kneat Gx.
✓	Document Management	All your document files such as Word, PDF, Excel, images, and more and may be stored, controlled, reviewed, and approved within Kneat Gx.
✓	Electronic Logbooks	Used for compliant data capture in your laboratories or on your manufacturing floor.
✓	Integration APIs	Kneat Gx APIs enable integration with all your key software systems e.g., import/export documents/ drawings/data.
✓	Dashboard Reporting	Run status reports or create progress reports using detailed filters. Gain real-time visibility at macro and micro levels.
✓	SaaS	Software-as-a-service delivered on a secure multitenant AWS cloud infrastructure, complete with elastic scalability, high availability and zero downtime.
✓	Innovation	Kneat Gx continuously improves to grow with our customer needs.





Kneat Gx for All Validation Needs

As a complete end-to-end validation solution, Kneat scales to meet any validation need across all facilities globally, including:

- ▶ Commissioning, Qualification and Validation (CQV)
- ▶ Computer System Validation (CSV)
- ▶ Process Validation
- ▶ Analytical Instrument Validation
- ▶ Method Validation
- ▶ Cleaning Validation
- ▶ Cold Chain Validation
- ▶ Electronic Logbooks
- ▶ Drawing Management
- ▶ Document Management

Kneat Gx is a Mature Proven Solution

Our clients are experiencing a 50% reduction in validation work hours and a 50% reduction in cycle times. Access a full set of customer case studies, online at kneat.com/client-stories.

	Reduces equipment changeover time by as much as 85%* *Found in an independent customer benchmarking study. Used Kneat for: Commissioning & Qualification, Equipment Validation		Reduces validation life cycle time by over 50%* *As found by multiple independent customer benchmarking studies. Used Kneat for: Commissioning & Qualification	-65% Fewer validation labor hours
	Reduces labor hours and cost by 50-65% *Found in an independent partner benchmarking study. Used Kneat for: Commissioning & Qualification, Equipment		Saved \$810,000 USD in ERP deployment* *Found in an independent partner benchmarking study. Used Kneat for: Computer System Validation	-46% Fewer process steps

+40%
More efficient than leading competitor

Experience Kneat for Yourself

If you're looking for a digital validation solution for your company, Kneat Gx may be your answer. Contact us to book a personalized demonstration and see if Kneat is right for you.

[BOOK DEMO](#)

About Kneat

Helping Life Sciences develop, manufacture, and deliver therapies to their patients to the highest safety standard.

At a Glance

- ▶ Public company, listed on the Toronto Stock Exchange (TSX), held to high governance standards
- ▶ 280+ employees, 140 in Product Development & 50 in Professional Services
- ▶ Corporate validation platform to eight of the top 10 life sciences companies & three of four COVID-19 vaccine manufacturers
- ▶ 80+ customers in North America, Europe, & Asia
- ▶ 40,000+ users in the Kneat SaaS platform
- ▶ 150+ site global deployments
- ▶ 40+ certified global partners
- ▶ Operations in Ireland, France, Germany, Switzerland, Denmark, Canada and the USA.
- ▶ All in-house development, no outsourcing for Quality reasons
- ▶ ISO 9001:2015, ISO 27001 certified

Our Compliance

We're compliant to the world's leading quality standards, to provide the highest level of assurance. As a quality first organization, quality leads the way in everything we do. From board governance to management decision making and team execution, we're dedicated to the continuous improvement of standards across all areas of our business. Each of our certifications are tied to leading global quality standards and are accredited to us by reputable independent authorities following rigorous audit. We are committed to ensuring full transparency of the standards of our work.

Our ISO Certifications

ISO 9001: 2015 | Quality Management Systems

Kneat is independently certified to ISO 9001: 2015 by the National Standards Association of Ireland (NSAI), encompassing design, development, maintenance, support, & hosting of Software for Data & Document Management within Regulated Environments.

ISO/IEC 27001: 2017 | Information Security

ISO/IEC 27001: 2017 certifies Kneat to securely manage the security of information assets such as customer information & data, financial information, intellectual property, employee details, & other information entrusted by third parties. Under this leading standard, Kneat is also certified to correctly manage the treatment of information security risks, tailored to the needs of the organization.





By 2022, the entire validation and qualification space will be in Kneat, end to end, at all sites. Kneat has become one of the foundational systems in QMS and beyond.

Global Executive Director, QMS Technology Transfer & Commercialization, MSD

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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 kneat.com