Client Story: Digitalizing Validation Globally

MSD Global Digital Validation Rollout

Applications:
Computer System Validation, Facilities, Utilities and Equipment Validation, Process Validation, Cleaning Validation, Equipment Sterilization, Laboratory Equipment Validation, Supplier Qualification, Validation Master Planning

Kneat

Introduction and Background

Digitalizing Validation Globally

Executing on its visionary Global Quality Management Systems Strategy, industry leaders Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA (MSD) selected Kneat to digitalize seven validation work processes at 27 sites across two divisions (Manufacturing and Research).

As a result of this top-down corporate-led initiative, 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.

Continuous Improvement Opportunities

Accelerated Product Launch, Real-Time Regulatory Data, and Remote Work Amid COVID-19

Prior to deploying Kneat globally, MSD performed all validation documentation activities across a 'hybrid' mix of paper and off-the-shelf systems.

Comprising Microsoft Word templates, Microsoft SharePoint based tools, a paper-based test execution protocol, manually performed workflows, a mix of wet-ink and e-signatures; MSD's hybrid processes presented business opportunity challenges, including:

- numbering, generating, and approving documents across systems
- collecting review comments and approvals via multiple pathways
- manual workflow between author, reviewers, and approvers
- generating and maintaining binders of hard copy documentation

Seeing opportunity for continuous improvement of its processes, MSD sought to find and implement a digital validation system that could accelerate qualification and validation work, and further enable its commitment to providing real-time data to health authority agencies.

Further, the challenges of COVID-19 which emerged during MSD's adoption of an e-Validation solution, reinforced the need for a system that enabled remote work.

Solution Requirements and Purchase Decision

Digital Transformation, End-to-End, Worldwide

Led by a Global Executive Director, QMS Technology Transfer & Commercialization and a Director IT Compliance, Global Systems, MSD embarked on their digital transformation in early 2019, in a project later dubbed as “e-Val.”

Prior to initial digital validation vendor and solution research, MSD had clear goals and requirements: “the three main areas we wanted to see value in were efficiencies, integrated/ Automated Data Integrity controls, and acceleration,” said the QMS Executive Director.

“We wanted to get out of paper to build on a platform that facilitated inherent data integrity controls and enhance our knowledge management and data accessibility…the third area was acceleration, to move fast. When we launch new capital projects or products, we want to move fast and when you perform commissioning and qualification for a new site, there is a lot of commissioning and qualification work on paper. If you start from the beginning digitally, it is so much faster and efficient,” she said.

“We were trying to really transform our Quality Management Systems and move away from complicated paper-based processes…[and]…move to user-centric, simple, executable processes that are digitally enabled,” she continued.

At the project’s outset, MSD assembled a multi-functional team including key stakeholders across IT, Manufacturing Operations, Engineering, and Quality to collaborate in the assessment, selection, and later deployment of the preferred digital validation system.

"We established a multi-functional team comprised of site-level end-users and global process owners who head-up certain validation processes globally…IT was also on the team, as well as Digital Data Quality…we really ensured we had a very robust multi-functional team in place for this assessment," said the QMS Executive Director.

"When we started our vendor selection, our reference for comparison was the current state paper process. What we wanted to see is if [digital validation] is better than paper, comparable to paper, or worse…once we had final vendors selected, we also compared them," she said.

"With each vendor we went through a proof of value exercise, going through each discipline [including Process Validation, Cleaning Validation, Analytical Method Validation, Computer System Validation, and Equipment Qualification] using a very robust, quantitative assessment system including a questionnaire where we scored the systems based on many attributes including ease of use, robustness, and fit-for-purpose," she said.

"We did a lot of vendor homework before we started the relationship with Kneat. What really was the winning factor with Kneat, is ease of use and the seamlessness of use. I think users felt that Kneat was really, much more intuitive. We are also trying to look forward, to future users of the system - who will want to work with something that looks and feels modern and Kneat provided us with this in addition to all of the great capabilities," the QMS Executive Director continued.

"We took a very data driven and quantitative approach, because once we progressed and presented the solution to senior leadership, we needed a very robust business case in order to move forward… we documented everything, put together an initial proposal for a business case, went to our sponsors, and got the green light," she said.

"It was a very big sponsorship from Quality…but in addition to Quality, we absolutely needed Sponsorship from the users within the business, and Manufacturing Systems Design and Commercialization (MSDC) organization…senior leadership from both departments saw how robust our assessment was, that we spent several weeks assessing the systems, that we really looked into everything, that we had clear data to show them, and that we did our financial homework. We needed to deliver first results and proof of value, as quickly as we could," she said.

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> Global Executive Director, QMS TechnologyTransfer & Commercialization, MSD

Deployment and Scaling

Staged Deployment Iterating to Best Practice

Adopting best practice, MSD undertook a phased approach to deploying Kneat across all 27 of its manufacturing sites. The approach comprised three phases, including single site 'pilot' phase, seven site 'early adopters' phase, and finally, a 19 site 'global rollout' phase occurring in July 2021. The phased deployment strategy was also selected on the basis it would enable Kneat to be used for all commissioning activities in establishing the green-field pilot site, enabling analysis of the capital expenditure and speed-to-market impact of Kneat.

The Global Executive Director, QMS Technology Transfer & Commercialization said: "We always had the vision of a global solution – this was our true north. To get there we wanted first to hold a pilot, before deploying what we called 'early adopter' sites where we drew on the pilot's experience to scale Kneat up… we took what we learned in the Pilot, refined it, and applied it to six sites in the network. And then… we leveraged the learnings from the early adopter sites and pilot across the entire network."

"Typically, when we deploy an IT solution for QMS processes we go global right first time, usually you would develop, configure, and prepare before deploying globally to all sites over a period of a year and a half… with Kneat we actually took a different approach, which was fit for purpose for our goal as we had an urgency with first pilot site being operationally ready with Kneat. As we had our first pilot site volunteer and eager to go, we decided to take smaller steps first but quickly."

By taking a phased approach, MSD was able to draw on the results of each phase to iterate process design, optimizing design from initially site-specific processes to robust, globally standardized processes.

"Whatever we build in Quality, in QMS – it has to be standardized. We want to eliminate local standard procedures and have robust global procedures that are executable and standardized across all sites. Our initial pilot was customized more to that site's needs but then, once we started to scale up to additional sites, we made it clear that from then on we were standardizing… to ensure that it works for all of the sites, when we build the process, we have representatives from many sites on the team, with the final decision with the global process owner," said the QMS Executive Director.

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"You incorporate the best of all sites and make a decision based on the regulations, based on best practices – you build a standard process that probably will address 80% to 90% of the network, the rest will need to adjust…but we ensure that we enable the site with the right tools, with the right training on the process, and a lot of explanation about why we are building it this way… and what kind of efficiencies are behind it," she continued.

"It's not just the global team building a process, throwing it over the fence and saying, 'do this', but sites are partnering with us – we're listening to their input, we're listening to questions and addressing them…all of the sites are part of the design, and they know that their opinions are heard."

Continuing the quantitative analysis first applied during vendor selection, MSD analyzed each phase post-deployment to identify and demonstrate Kneat's value, gaining support and budget for subsequent phases.

"With the pilot site, as soon as possible we put together this return-on-investment presentation and presented this for different stakeholders to show value and return. Based on this we also built the business case for the next year's budget. That worked really well, because we weren't just showing case studies that Kneat showed us… now it's our own. The pilot site was very happy with this study, they were presenting this themselves, as voice of the user, together with global team," she continued.

"The commissioning space was more challenging for us to digitize because the commissioning space is mostly prior to GMP activities and requires a lot of collaboration between Quality and Engineering. We held a lot of change execution management work with relevant functions to bring them up the change adoption curve, because the true value of Kneat is when it's used from cradle to grave," she said.

In addition to business case benefits gained over time, MSD's phased approach allowed the multifunctional project team to strengthen its project management toolkit to better train, support, and communicate with site stakeholders.

"There were many questions that were repeated and many activities that were standard… with the early adopters, the first seven sites, we could manage it on an ad hoc basis…going global we saw that we needed to structure this standard work, so we put together a playbook including step by step instructions to implement Kneat," the QMS Executive Director continued.

Despite the outbreak and impact of the COVID-19 pandemic in late 2019 following the project's kick-off earlier that year, Kneat's capabilities as a SaaS based solution enabled MSD and Kneat to work together remotely to complete the global deployment to plan.

MSD's Director IT Compliance, Global Systems and senior leader in the MSD-Kneat project, commented: "the choice to go global was always the intent…the pilot site went live January of 2020, and then of course we had the stay-at-home order with COVID-19 on March 9, so what that meant was we were able to finish the work and testing remotely because Kneat gave us that chance. COVID-19, along with the testing getting completed faster was also a big driver for the company."

On the impact of COVID-19 on the deployment, the QMS Executive Director added: "when COVID-19 started, the pilot site was able to work remotely which was another push for us to show Kneat to the rest of the site network. They were able to complete a lot of their commissioning and qualification work remotely, which is under the circumstances another big plus for the value of the system."

Results and Customer Experience

Efficiency, Process Simplification, and Systems Consolidation

Following each phase of the deployment, MSD's Quality and Commercialization leadership recorded and analyzed Kneat's performance impact against a paper baseline.

Reflecting on Kneat's results, the Global Executive Director, QMS Technology Transfer & Commercialization commented: "once we had our first real data with the pilot site, we started to make financial assessments…after they [the pilot site] ran with the system for six months, they worked with finance to show the value and they generated very, very significant value in dollars."

"From [an] efficiency perspective as well, we were able to demonstrate more than 50% cycle time reduction during execution, which was huge for us. In addition to that, because the pilot site worked just in Kneat, we were able to demonstrate process simplification down from 15 steps to eight and we minimized the number of systems we used because of Kneat, from five to two," she said.

Commenting on this consolidation of systems, absorbed into the Kneat platform, the Global IT Director said: "there is an overall goal as part of our quality management system and process to use IT as an enabler…we put a lot of emphasis in IT being that electronic end-to-end enabler and we see Kneat as giving us that."

"What I really like about Kneat is the pre-approval and post-approval process – everything is within that same deliverable which is connected and finished together. A document can also be directly cross-referenced within another document eliminating duplication," she said.

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The QMS Executive Director added: “with Kneat you can do many things…for end-to-end technology transfer it can work great because you have this structure of protocol, execution, report – within that framework you can do so much. The big picture is that, especially now when we’re trying to digitize quality, we want to streamline the systems landscape for the user and leverage specific system scope of use as much as possible.

“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…we’re actually in a space where the site network wants to use Kneat for other needs…suddenly we started getting contacted by other process owners who wanted to use Kneat…So, what we’re trying to do if we’re already going to use Kneat for so many scope areas, let’s expand it even more – to utilize the potential beyond validation should be the goal because it’s a win-win. We already use the system, the system is great, it could be used for other areas – and then for the user it’s a one-stop-shop.”

The Director IT Compliance, Global Systems reflected on Kneat’s enhancement of MSD’s data integrity posture after transitioning from hybrid validation processes: “…the advantage of Kneat is it gives us that end-to-end without paper, things are contemporaneous, the reviews and approvals are concurrent…for us it gives us that data integrity advantage that we didn’t have before when some documents were in paper, some were electronic.”

Reflecting on the project, the QMS Executive Director noted MSD's working relationship with Kneat was also key to a successful outcome.

"Our partnership with Kneat was one of the critical factors for success. The minute we started our collaboration we felt so comfortable with each other…with Kneat it was very apparent. Based on our learnings from other systems deployments, we see how important it is, not just to have a robust relationship with the vendor – but also to have a robust vendor," she said.

"Kneat was proven to be an excellent partner, not just because of the technical support but because we felt as though we were part of the team. We were always together at relevant meetings, whether it was our internal governance meetings, community of practice meetings, Kneat partnered with us at the source, to solve all the potential challenges," she said.

"It always felt as though we were part of the team – we knew the goal and we were getting there together. It was never, this is the vendor – this is the team. It worked exceptionally well…to have such a relationship with any vendor, not only brings you to the finish line quicker, but if you have an open and transparent relationship you solve your issues quicker and from each one you learn for the next one how to do it better."

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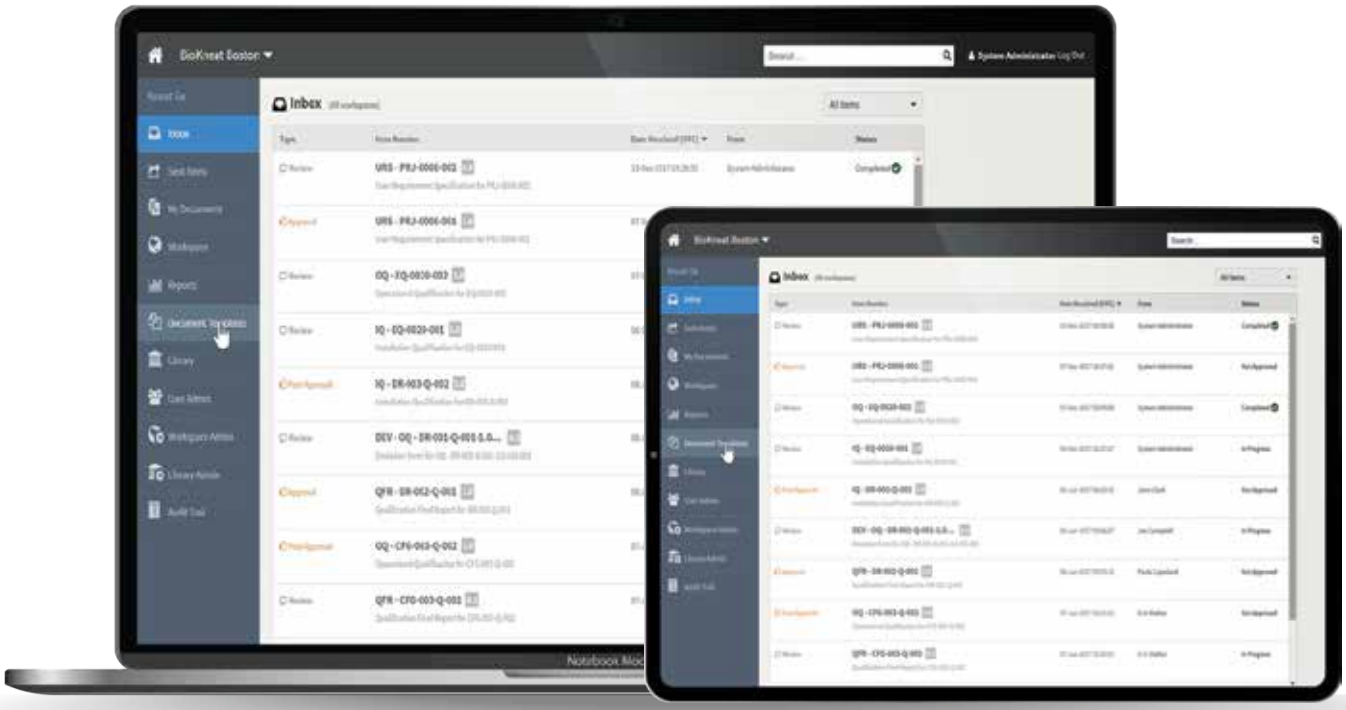
Robust, Versatile Digital Validation Software



Kneat Solutions' digital validation software, Kneat Gx, digitizes the entire validation life cycle, enabling users to author, review, approve, test-execute, manage exceptions, post approve, trace, and report in a 21 CFR Part 11 compliant web-based software, purpose built for Life Sciences.

From a single process at one site, to deployments at scale, covering multiple sites and thousands of users – our team works closely with our customers to plan and deliver digital transformation.

Trusted by eight of the world's Top 10 Life Sciences companies, discover how Kneat can transform validation for your organization.

Talk to Us

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

Kneat

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