

Client Story: A Risk-Focused Global Biotech

Transforming Traceability: Prohibitive to Productive Risk Mitigation

Applications:

Commissioning and qualification (C&Q), Equipment Validation

Introduction & Background

A rapidly expanding global biotech

After maximising the productivity of its paper-based Commissioning and Qualification (C&Q) processes through ISPE Baseline® Guide Volume 5 Commissioning and Qualification, the customer's Global C&Q organization sought a paperless validation system to deliver greater efficiencies for C&Q operations and capital expenditure projects, whilst maintaining the highest commitment to risk-mitigation.

The customer, a rapidly expanding biotechnology company with over 45,000 employees globally and manufacturing facilities in the U.S., Latin America, Europe, and Asia, develops products in 8 different therapeutic areas. Deploying Kneat more than halved the customer's site acceptance testing (SAT) time and resulted in an 88% reduction in User-Requirements-Specification (URS) approval cycle time - from 60 days to just 7.



Business Challenges

‘Painful’, ‘onerous’ manual risk-tracing

Increasing regulatory stringency on patient and product risk motivated the customer to implement risk-based C&Q processes based on ISPE Baseline® Guide Volume 5 Commissioning and Qualification, giving particular attention to ensuring quality by design in their Equipment C&Q processes.

Performing the Guide 5 C&Q approach on paper had been ‘painful’ according to the customer’s Director, Global Systems and Standards commenting, “as much as we like to think that a risk-based approach gives us more efficiency, without a paperless system...it is still labour intensive. The focus of a risk-based approach is risk-assessments, tracing and how you mitigate the risks identified - despite successfully applying a risk-based approach manually, having to do this manually has been painful.”

A combination of paper steps and the ongoing management of an excel file was required to ensure the risks were identified, incorporated into equipment design, tested and traced in order to stand up to the scrutiny of Qualification.

“It ended up being onerous when it came to the whole book-keeping exercise - to have a product that can ease some of that burden and ensure we were accurate was important. For instance, if for any reason the requirements changed, where initially there was a person keeping track of that, now the system could flag anywhere that those requirements have changed”, said the customer’s Associate Director, Commissioning and Qualification.

“Electronic execution does bring in all of the other efficiencies – [like] GDP errors, the fact that you can execute remotely, or a vendor can execute - all of those are definitely important and do bring value to the table but, the compliance piece of making sure that we’ve traced everything accurately is very important to us.”

Traceability, Data Integrity and Usability

Senior leaders of the customer's Global C&Q organization had been evaluating Paperless Validation Solutions for over two years, including a competitor pilot, before deploying Kneat. Establishing a scorecard to evaluate its business requirements against a group of paperless validation solutions (which did not include Kneat), the Global C&Q organization initially selected and implemented a pilot project with Kneat's competitor.

The customer's Associate Director, Commissioning and Qualification said, "using the scorecard we narrowed down to a particular vendor and implemented a pilot project with them, later our team attended a conference where Kneat was demonstrating their latest release and we decided to hold a comparison of the pilot vendor and Kneat."

"From the initial pilot we knew what efficiencies paperless would bring, when compared with paper. Comparing the two paperless solutions, the risk-based requirements that we were looking for really came through in the assessment of Kneat."

In the assessment, the customer prioritized risk-based features including, risk-assessment tracing, critical element tracing, testing tracing and automated data integrity to maintain their ISPE Baseline® Guide Volume 5 Commissioning and Qualification processes, whilst driving productivity.



“ We surveyed ten other vendors and were looking for not only a solution that could perform the tasks, but which solution was easiest to use. Deploying into all of our plants, that buy-in was very important, and we knew ease-of-use would be key to getting that buy-in.

- Director, Global Systems and Standards



On the comparison, the organization’s Global Commissioning and Qualification Lead for EU commented:

“With version 8.2, Kneat made a big leap and we saw that... when we conducted a side-by-side comparison with Kneat and the other vendor, we found Kneat to be 40% more efficient for C&Q.

- European Lead, Commissioning and Qualification



“One of the winning pieces of functionality for Kneat was the reporting, especially the automated-requirements-traceability-matrix which is really essential to a risk-based C&Q approach. That would have been one of the clinching features we wanted that Kneat provided. That was the sort of functionality that was very inefficient in some of the competitors’ products”, said the customer’s Global Commissioning and Qualification Lead for EU.

Usability was also critical for the customer, reflecting on the requirement the customer’s Director, Global Systems and Standards said “user friendliness was also key to us - the actual number of clicks it takes to get the job done....You can get people up to speed quicker, they don’t have to worry about where the latest template was. We surveyed ten other vendors and were looking for not only a solution that could perform the tasks, but which solution was easiest to use. Deploying into all of our plants, that buy-in was very important, and we knew ease-of-use would be key to getting that buy-in.”

Figure 1. Customer Observations: Risk-Based C&Q Functionality - Kneat vs Competitor

Requirement	Kneat
Efficient traceability functionality	Less clicks to set-up and use traceability than competitor
Review documents via traceability matrix	Easier to review documents linked to the traceability matrix than competitor
Efficient testing tracing & critical element tracing	Less documentation required to link system-risk-assessment (SRA) with testing than competitor

A 'Snowball' Approach

Commencing a four-year plan to deploy Kneat's SaaS platform worldwide to 30 of its company and sister-company sites, the customer's Global C&Q organization leadership initiated the roll-out of Kneat at its manufacturing site in Cork, Ireland.

The customer presented Kneat's Professional Services team with their process in a highly visual format, clearly demonstrating the flow of its C&Q processes. Kneat's Lead Process Engineer and lead technical contact for the customer said, "the visuals gave us a solid foundation to kick-off process mapping from the out-set, cutting weeks off the iterative process-mapping stage. From there it was a simple case of bringing in the Guide 5 Pilot site templates and going through finer details during the second and third iterations."

On process-mapping, the customer's European Lead, Commissioning and Qualification, who led the customer-side process system configuration team, said "we didn't have many established global templates in our C&Q process...but by not having those templates in place we were freer to implement a process which allowed the best approach to digitalizing those processes rather than just copying paper onto glass."

Following the process-mapping stage, once the instance was live, the customer could continue iterating the process further if they required, simply by updating the templates using Kneat's document editor and template creation functionality. "What we're seeing now is a process we are very happy with and seems to be quite optimal efficiency-wise" said the customer's European Lead, Commissioning and Qualification.

As standard, all Kneat Gx instances include validation reporting features, including the version deployed to the customer's Cork site. The customer's European Lead, Commissioning and Qualification said, "the non-custom reporting... showing how many protocols are in review, being executed etc. is really valuable from the point of KPIs, because at the moment any validation KPIs are very hard to track, so I think this gives us huge amounts of visibility."

“The team has been exceptional, the training has been exceptional.”

- European Lead, Commissioning and Qualification

During the deployment, the customer also opted to implement Kneat's add-on custom-reports product, with the aim of populating Kneat validation data into the customer's existing qualification reports in a separate system. "The first couple of iterations showed how we could use custom reports, such as the issues and deviations report, to populate some of our existing qualification reports in an efficient manner – Kneat's reports are really key to strategic efficiencies."

Following completion of the initial deployment in Cork, Ireland, the customer is currently scaling Kneat to 30 other company and sister-company sites. "What we are trying to create is a snowball approach. As we publish more of the C&Q efficiencies to our validation centre of excellence group, more sites are becoming aware and want Kneat", said the customer's European Lead, Commissioning and Qualification.

Three subsidiary-company sites will be early-adopters, followed by flagship sites in Asia, Latin America, and Western Europe.



Results and Customer Experience

From prohibitive to productive risk mitigation

Following the initial deployment in Cork, the customer's Global Systems and Standards leadership team conducted a benchmarking study, analysing Kneat's C&Q productivity impact against a paper baseline (*Figure 2*).

Reflecting on the project to date, the customer's Global Systems and Standards leadership team described their experience and working relationship with Kneat.

"The team has been exceptional, the training has been exceptional... one of the highlights I would say has been the process mapping and the iterative process that they go through with you, and the collaborative nature of it. That was a really good experience for us", said the customer's European Lead, Commissioning and Qualification.

"People got up to speed with the training very quickly...we have an intern Engineer, he doesn't have much Engineering experience, just with two to three days training he was able to create documents for a key piece of equipment by himself."

Figure 2. Post-Deployment Paperless C&Q Time and Cost Savings

Process	Before Deployment	After Deployment	Time Saving
User-Requirements-Specification (URS) Approval Cycle	60 Days (2 months)	7 days	88%
Site-Acceptance-Test (SAT) Execution	30 hours	14 Hours	53%
Creation of Site-Acceptance-Test (SAT)	30 Hours	20 Hours	33%

The customer's Associate Director, Commissioning and Qualification said "we had a dedicated contact and he was very responsive....it helped that we knew who to contact, rather than just a generic department like purchasing....we had a definite contact."

"I think it's very important that the team knows their product and knows the different ways a user requirement can be accomplished...the Kneat team is very knowledgeable about the capabilities of the product."

The customer also found that using Kneat was helping to gain Quality Assurance's 'trust in Engineering's documentation practices', as the customer's Director, Global Systems and Standards noted, "I think that's the value that the tool brings, our team have done a good job of bringing this tool to QA for their approval... because that is critical."

By deploying Kneat the customer transformed traceability achieving significant reductions in User-Requirements-Specification (URS) approval cycle time and site-acceptance-testing (SAT) time, whilst maintaining the highest commitment to risk-mitigation.

Authors

About the authors

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Phil Jarvis is an experienced team leader with over 20 years of experience in all areas of validation including; process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation. Through strategic thinking, he has success in steering and managing complex validation projects within the medical device / pharmaceutical / and biologics industries.

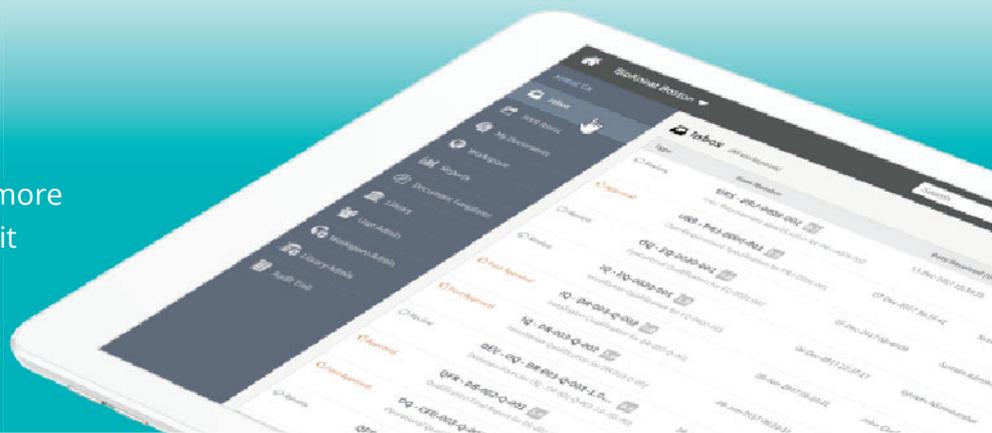
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What is Kneat?

Robust, Versatile E-Validation Software

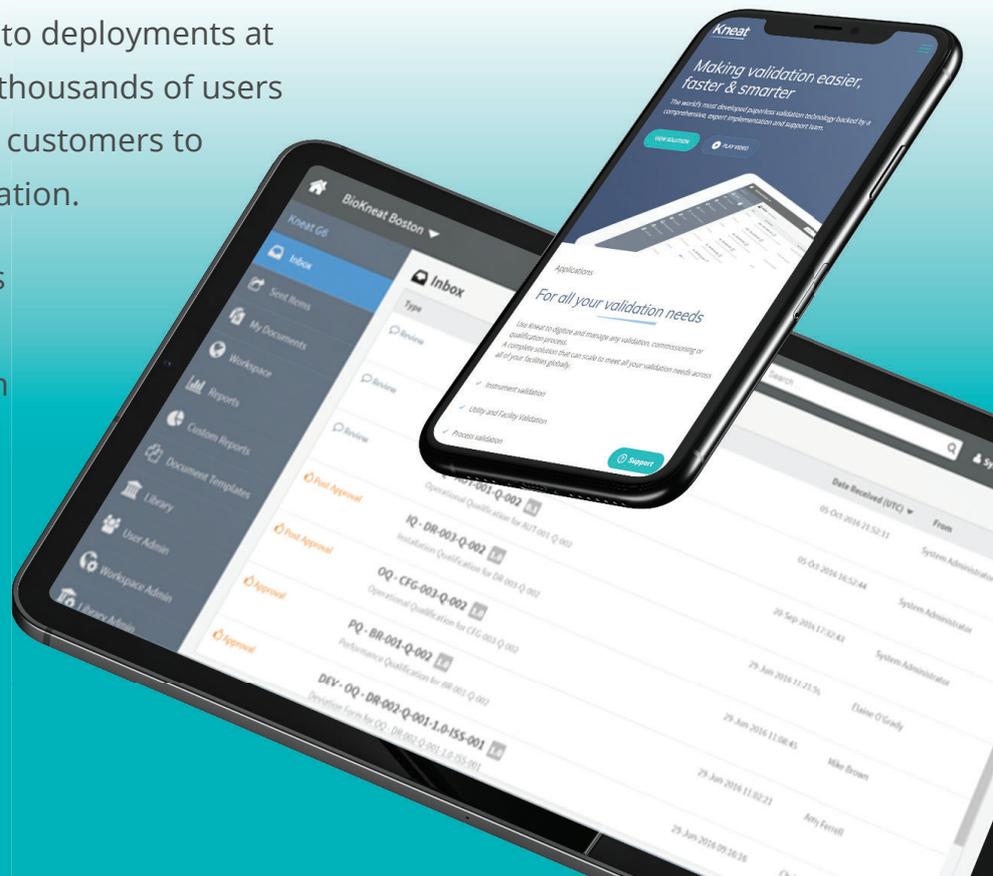
SCAN TO DISCOVER KNEAT



Kneat Solutions' e-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 over half of the world's Top 20 Life Sciences companies, discover how Kneat can transform validation for your organization.



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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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