

Client Story: A Validation Service Provider

Driving Temperature Profiling Productivity

Applications: Commissioning and qualification (C&Q),
Equipment Validation



Introduction & Background

Transforming validation productivity

Since 1996, Kneat's solution partner, Pharmaceutical Calibrations & Instrumentation LLC. (PCI) has provided the Life Science Industry with high-quality equipment and instrument services including Validation, Calibration (Process Equipment Services, Analytical Laboratory Instrument Services, Metrology Services) and Commissioning.

Temperature Profiling is a standard validation requirement for GMP chambers used to ensure a temperature-controlled environment for in-process materials, equipment, raw materials, and samples. Even though the temperature profiling work process is well established, documentation activities comprising the process are inefficient, costly and paper-based.

This case study describes the development and digitization of an innovative validation process by PCI for their customers, leveraging Kneat's paperless validation software to deliver a lean, end-to-end digital and compliant work process.



Challenge & Need

Improved efficiency for partner customers

Life Science Industry regulations require the Commissioning, Qualification, and Validation (CQV) of facilities and equipment involved in the manufacturing and processing of Life Sciences end-products and raw materials. Regulated equipment commonly includes temperature controlled chambers, such as sterilizers, ovens, incubators, freezers and storage rooms; for which a prominent CQV requirement is 'Temperature Profiling.'

Temperature Profiling assures that a temperature controlled environment is maintained to support the manufacturing process. Technology solutions for collecting temperature data, such as data loggers, provide an efficient means of monitoring and recording temperature data at key locations within chambers. However, the CQV documentation activities associated with temperature profiling (*including protocol/test process steps, capturing results, pre and post-review/approval and final summary report generation*)



Data Logger

are conducted manually on paper. In this paper-based environment, accessing and interpreting key validation data, such as validation status and test results, is inhibited by the need to physically store, retrieve and examine paper records - activities which resulted in high labor hours and subsequent cost for PCI and it's customers.

Business Goal

Reducing labor cost

PCI's goal was to minimize labor hours required to perform the CQV documentation activities required in temperature profiling, and as a result reduce cost - all while maintaining the same high level of service to it's customers.

A digitized, standardized lean work process

PCI set out to achieve their goal of reducing the labor hours involved in temperature profiling, in two key stages. The first, was to create a best practice, lean work process, before secondly embedding this process into a software system capable of standardizing the process across PCI's customer base. After developing a leaner, optimized temperature profiling work process, PCI were able to determine detailed requirements for validation software and begin evaluating software solutions. The PCI team reviewed several commercially available systems, before selecting Kneat for its ease of use, robustness, flexibility to accommodate any GxP process and scalability.

Following their newly developed work process, PCI was able to create standard approved document templates that are auto-populated with system metadata and shared document data, all within Kneat. This meant that documents could be created quickly and with a high degree of accuracy, which resulted in reduced review and approval and rework efforts.

What is Kneat?

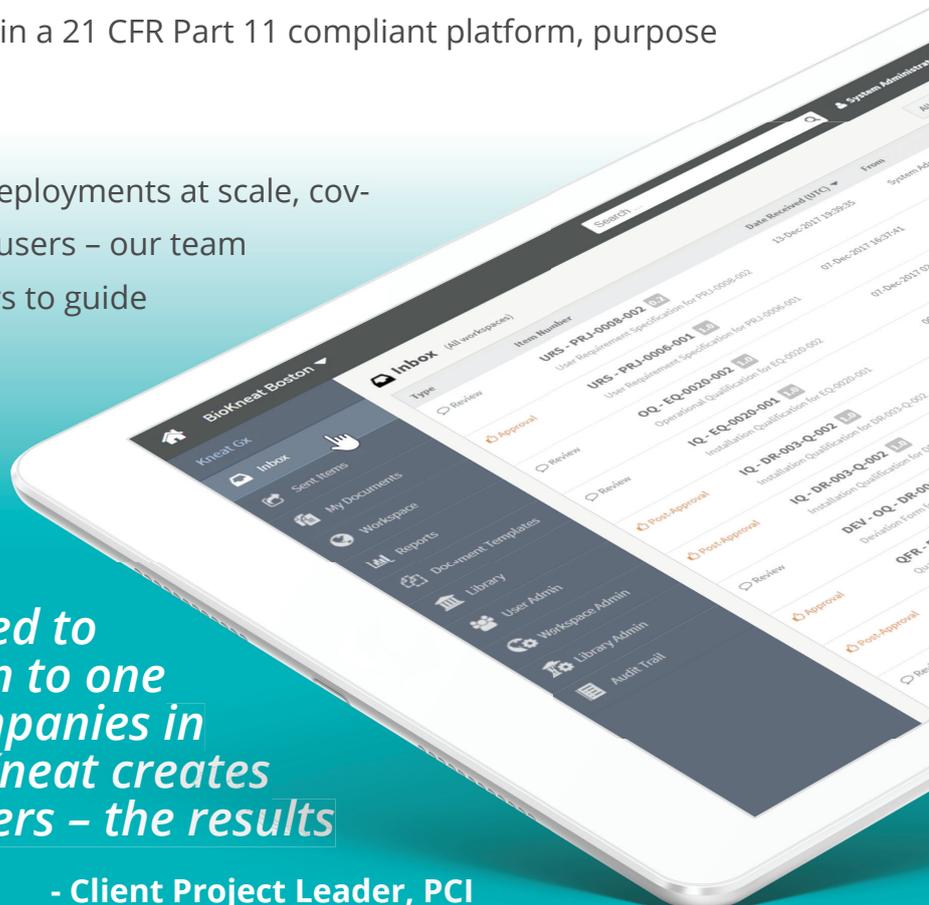
Robust, versatile paperless validation software

Kneat Solutions' paperless validation software, "Kneat Gx", digitizes the entire validation life-cycle, enabling users to author, review, approve, test-execute, manage exceptions and post-approve any process deliverable in a 21 CFR Part 11 compliant platform, 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 trusted partners to guide digital transformation.

Our partnership has helped to deliver digitized validation to one of the largest biotech companies in the world. Working with Kneat creates real value for our customers – the results speak for themselves.

- Client Project Leader, PCI



Paper-based versus digitized temperature profiling

The table below outlines the standard work process used by PCI and the differences between the paper-based and the digitized work process.

Business Process Steps	Deliverables	Paper-Based Process	Digitized Process
Temperature Profiling Plan for Chamber	Validation Master Plan	Create word documents from uncontrolled templates, manually populate with metadata, review, approve in document management system or wet signature.	Select data centric impact assessment checklist (for classification of validation category and metadata).
Create, review, approve design documents	Engineering Specifications Documents	Create word documents from uncontrolled templates, manually populate with metadata, review, approve in document management system or wet signature.	Central review process with document repository for leveraging common specs/ data and templates. Auto-generate "pack of documents" with "changes impact assessment." e-System supports efficient review, comment, approval process.
Create review, pre-approve test protocols	Pre-approved test protocols	Create documents from uncontrolled templates, manually populate with metadata, review, approve in document management system or via wet signature.	e-System supports efficient central creation, review, and approval process. Data sharing across documents reduces effort and errors.
Execute validation testing	Completed Validation records	Manual paper-based process: data handwritten into test protocol (data integrity, efficiency, and compliance concerns).	Enter required information directly into smart e-documents in GDP compliant process. Attach temp profile data from data loggers.
Deviation processing	Deviation forms post-approved and closed	Manual paper-based process: effort required to hand carry documents for wet signature or deviation tracking system.	Auto initiate deviation within system at point of observation and link to test step if required. Detail corrective process and route for pre-approval. Complete corrective action, attach evidence, route for post-approval, and close out.
Post review and approval	Post-approved validation records	Manual circulation for post review and approval. Approval using wet signature. Cumbersome and normal for many errors to be found during reviews, requiring back and forth corrections, etc.	Post execution instantly circulate the executed protocol complete with all supporting evidence for review. Use the review by exception aid to speed up the review. All review is completed online with instant access to all supporting information – attached evidence, deviations, validation summary report, etc.
Create validation summary report and approve	Approved final validation summary report.	Manual effort required to type test summaries, deviation summaries, etc. into the document. Then circulate it for review and approve manually or in DMS.	Auto generates validation summary report eliminating manual effort and GDP errors.
Validation records storage	Controlled storage and retrievable validation records	Manual effort required to scan, package, store, and maintain records. Storage offsite in the future. Records sometimes damaged or misplaced.	All records are created, modified, executed, reviewed, and approved centrally in the system. They are never checked out and remain centrally managed for their full lifecycle. Records are always quickly accessed in the system anytime in the future. Record handling and storage is eliminated.
System validation status/metrics.	Validation project status and quality metrics.	Manual spreadsheet efforts. Errors and delays in finding the true validation status of a system.	Any system validation status or project is instantly available and is based on actual work completed.

Results

A 65% reduction in labor hours per chamber

Prior to implementing the new digitized work process, PCI created and tested the concept for one of their customers to provide evidence of cost and labor savings.

The proof of concept showed an average savings of 15 labor hours per chamber, reducing the average labor hours per GMP chamber by 65%, from 26 hours to just 9 hours.

New Temperature Profiling Validation Process Benefits

- ✓ Simplify protocol generation
- ✓ Faster protocol review and pre-approval
- ✓ Leverage existing validation documentation
- ✓ Faster and compliant test execution
- ✓ Faster executed protocol review and post-approval
- ✓ Reduced overall validation cycle time
- ✓ No document manual handling
- ✓ Reduced errors - efficient & compliant deviations management
- ✓ Improved on-line status reporting and real time data/metrics access
- ✓ Improved audit preparedness
- ✓ Improved records storage management (no scanning/no PDF storage)
- ✓ Greater team collaboration and visibility

Old Process

- ✓ 1 person performing 6 chambers per month equating to approximately 26 labor hours per chamber

New e-Process

- ✓ 1.5 persons performing 26 chamber validations per month equating to 9 labor hours per chamber

Productivity Improvement

- ✓ Productivity improvements greater than 100%
- ✓ 26 labor hours per chamber reduced to 9 hours per chamber
- ✓ Faster Validation Cycle Times – Now performing 26 chamber validations per month with 1.5 full time resources versus 6 chambers with 1 full time resource before.





Authors

About the authors

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Justin is the Project Services Manager at PCI. He has an extensive background in equipment qualification, including temperature profiling studies. He and his team offer commissioning, qualification, validation, and consulting services to clients in the Life Sciences industry.

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Rick is the Operations Director at Kneat. Prior to joining Kneat he was the founder and President of Encova Consulting, a Division of PCI. He provides extensive technical engineering and validation consulting support to his customers.

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Lou is a Customer Success Director at Kneat. He has over 35 years of Life Sciences experience at Abbott, Genentech, and BioMarin.

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