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CASE STUDY

‘Transforming traceability’

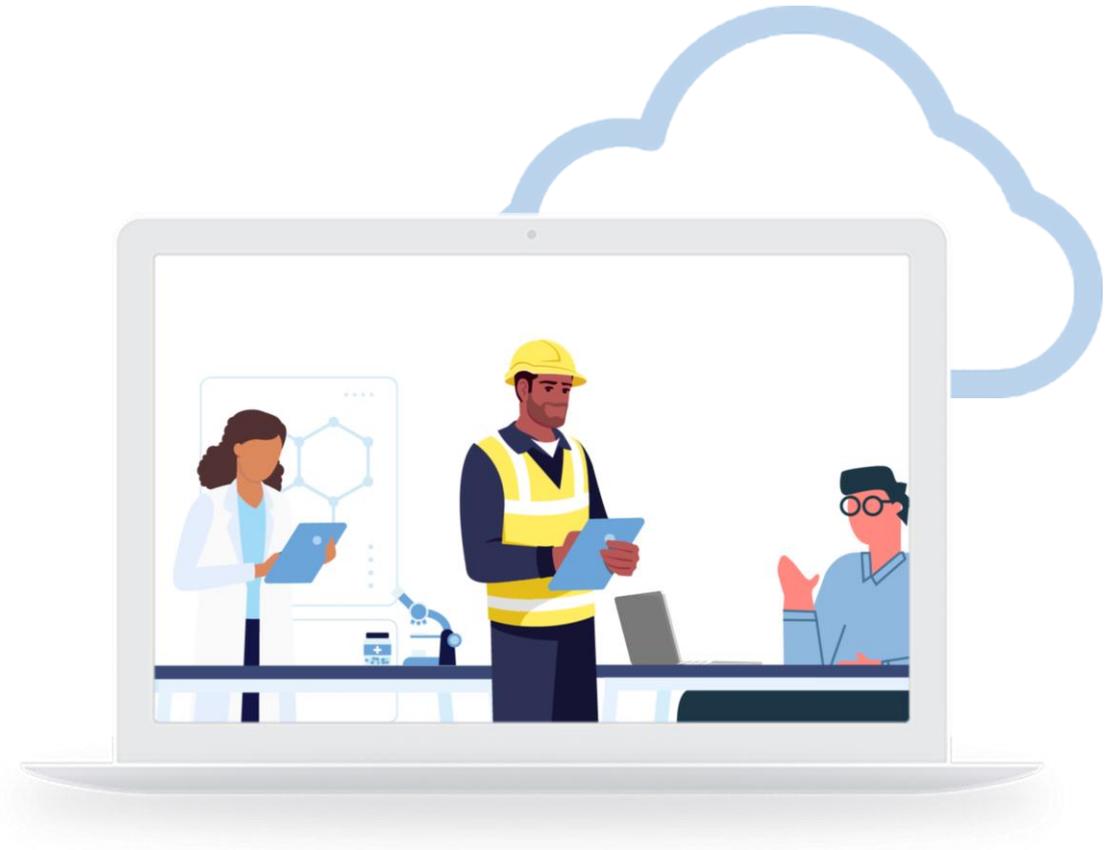
How Global Biotech Industry Leader Optimized Risk-Based Validation



Presented by | Jerry Quirke

Agenda

- Kneat Overview
- Why Digitize Validation?
- What is Kneat Gx?
- Case Study : Transforming Traceability
- Demonstration and Kneat Gx applications



Who is Kneat?

We help Life Sciences companies transition from cumbersome, paper-based validation processes to intelligent, data-centric, digital validation through our advanced e-validation software, **'Kneat Gx'**



What do we do?

Our mission is to help life sciences companies *unlock the chain of paper* to develop and deliver therapies to their patients as efficiently as possible...



Our international reach

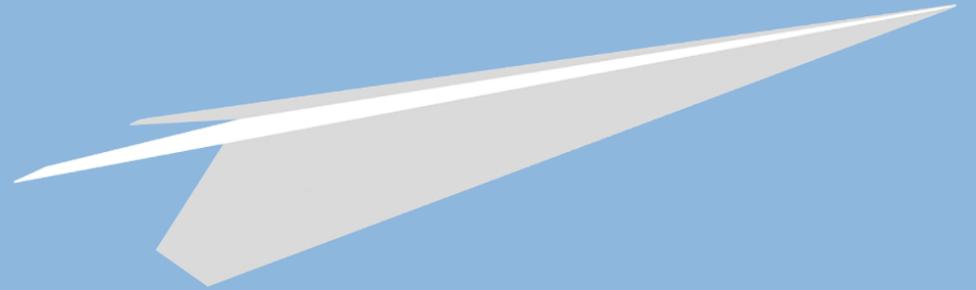
- Clients include 12 of top 20 global Pharma & Biotech
- Active customers in North America, Western Europe, Asia
- Located in Ireland, Switzerland, US and Canada
- Certified Partner Network extending service provision globally
- 100+ site deployments in US, Europe & Asia by 2022
- 3000+ users in Kneat Cloud platform





Why digitize validation?

- ✓ Reduce overall Touch points
- ✓ Eliminate Document Transportation
- ✓ Significantly Reduce Office Supplies Consumption and Storage
- ✓ Streamline Data Mining/Metrics
- ✓ Expedite Protocol Generation and Execution
- ✓ Real-Time Review
- ✓ Eliminate Scanning Archival



What is Kneat Gx?

A Purpose-Built, Enterprise Data Management Solution for Life Sciences that:

- ✓ **Improves Operational Efficiency**
- ✓ **Improves Compliance and Reduces Risk**
- ✓ **Improves Project Management and Collaboration**





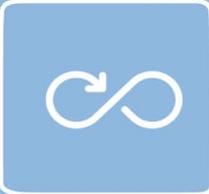
Productivity



Data Integrity



Cost Savings

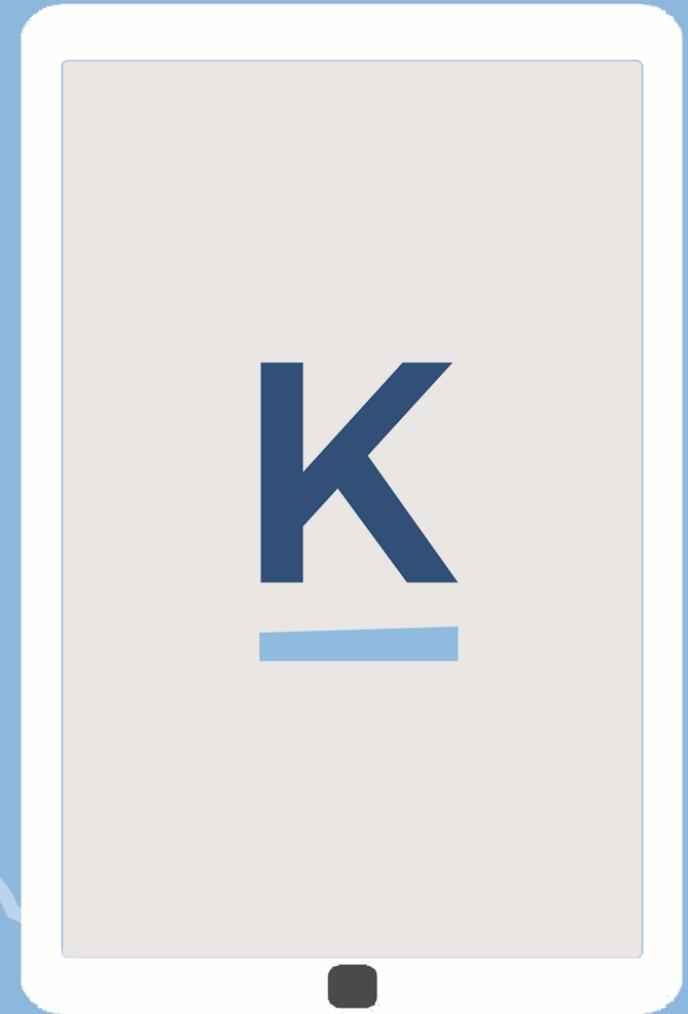


Cycle Time



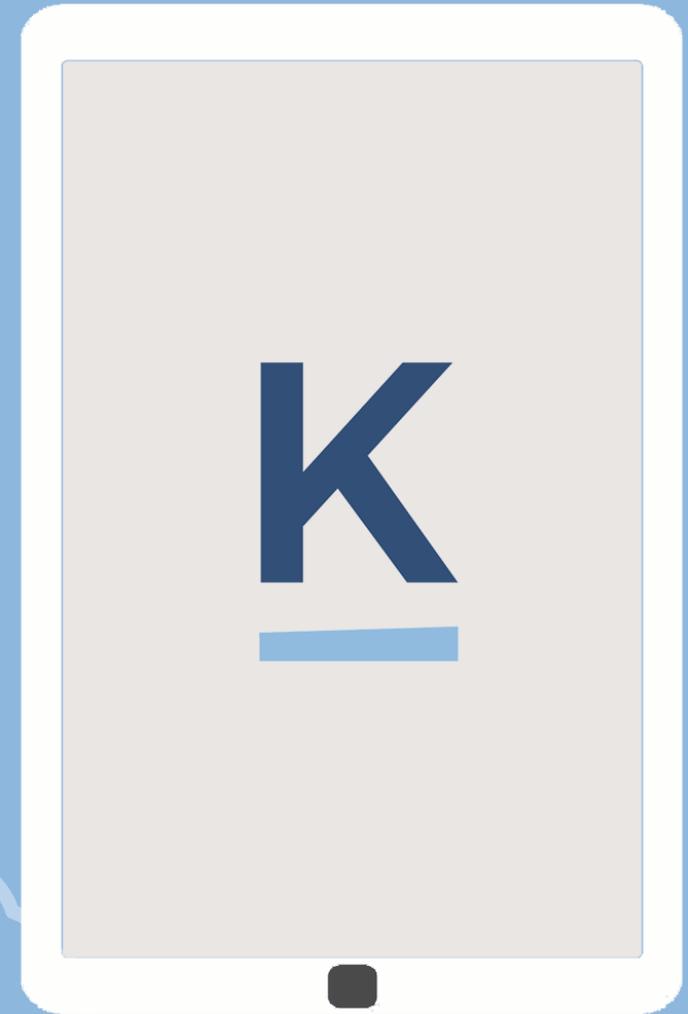
Why our customers use Kneat

- ✓ **Operational Efficiency.**
- ✓ Eliminates manual document handling, printing, routing, storage, retrieval and associated time-loss and costs.
- ✓ Author all validation documentation and templates in-application, without coding.
- ✓ Standardizes and locks-down validation records, protocols, and processes across an unlimited number of sites, globally.
- ✓ Significantly reduces cycle-time for any validation lifecycle.



Why our customers use Kneat

- ✓ Execute testing online;
- ✓ Provide Real-time validation status visibility and reporting.
- ✓ Be accessible, securely from anywhere online (**SaaS**)
- ✓ Role-based user access control;
- ✓ Direct-to-secure-database data capture (including attachments);
- ✓ **21CFR Part 11 compliant**, password-protected e-signatures;
- ✓ Comprehensive attributed time-stamped audit-trail.
- ✓ Integrated exceptions management.
- ✓ **Manage requirement and risk traceability with Automated Risk Traceability Matrix (RTM)**



CASE STUDY

'Transforming traceability'

How Global Biotech Industry Leader Optimized Risk-Based Validation



Presented by | Jerry Quirke

Introduction & Background

“A rapidly expanding global biotech”

“After using Kneat the customer reported and **88% reduction in the approval cycle of URS'**, from 60 days on paper to just 7 days in Kneat...”

Introduction & Background

“A rapidly expanding global biotech”

Introduction

- ✓ Global Biotech with over 45,000 employees
- ✓ Products in 8 different therapeutic areas
- ✓ Manufacturing facilities worldwide

Background

- ✓ Maximised Productivity of paper-based C&Q Process
- ✓ Where next to increase efficiency?
- ✓ Next Step: Paperless Validation System



Business Challenges & Solution Requirements

“Painful, onerous manual risk-tracing”

Business Challenges

- ! Increasing regulatory stringency on patient and product risk
- ! C&Q risk-based approach on paper ‘painful’
- ! Ongoing management, labor intensive, book-keeping exercise

Solution Requirements

- Risk Assessment Tracing
- Critical Element Tracing
- Testing Tracing
- Data Integrity

Assessment & Purchase Decision

Traceability, Data Integrity, Usability

Assessment

- ✓ Scorecard Evaluation & Comparison against Competitors
- ✓ Key Requirements assessed
 - Efficient traceability functionality
 - Review documents via traceability matrix
 - Efficient testing & critical element tracing

Purchase Decision

- ✓ Key 'Winning' Functionality
 - Reporting
 - Automated RTM
 - Usability

“ 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

- Associate Director, Commissioning and Qualification

”

“

user friendliness was also key to us - the actual number of clicks it takes to get the job done....,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

”

Deployment & Scaling

A “Snowball” Approach

Deployment

- ✓ Initial roll-out to a Manufacturing facility
- ✓ Collaborative process
- ✓ Template development with digitalizing in mind
- ✓ Best approach instead of “copying paper onto glass”

Scaling

- ✓ 4 Year planned rollout to 30 Sites
- ✓ Snowball approach
- ✓ Expansion of C&Q efficiencies

Results

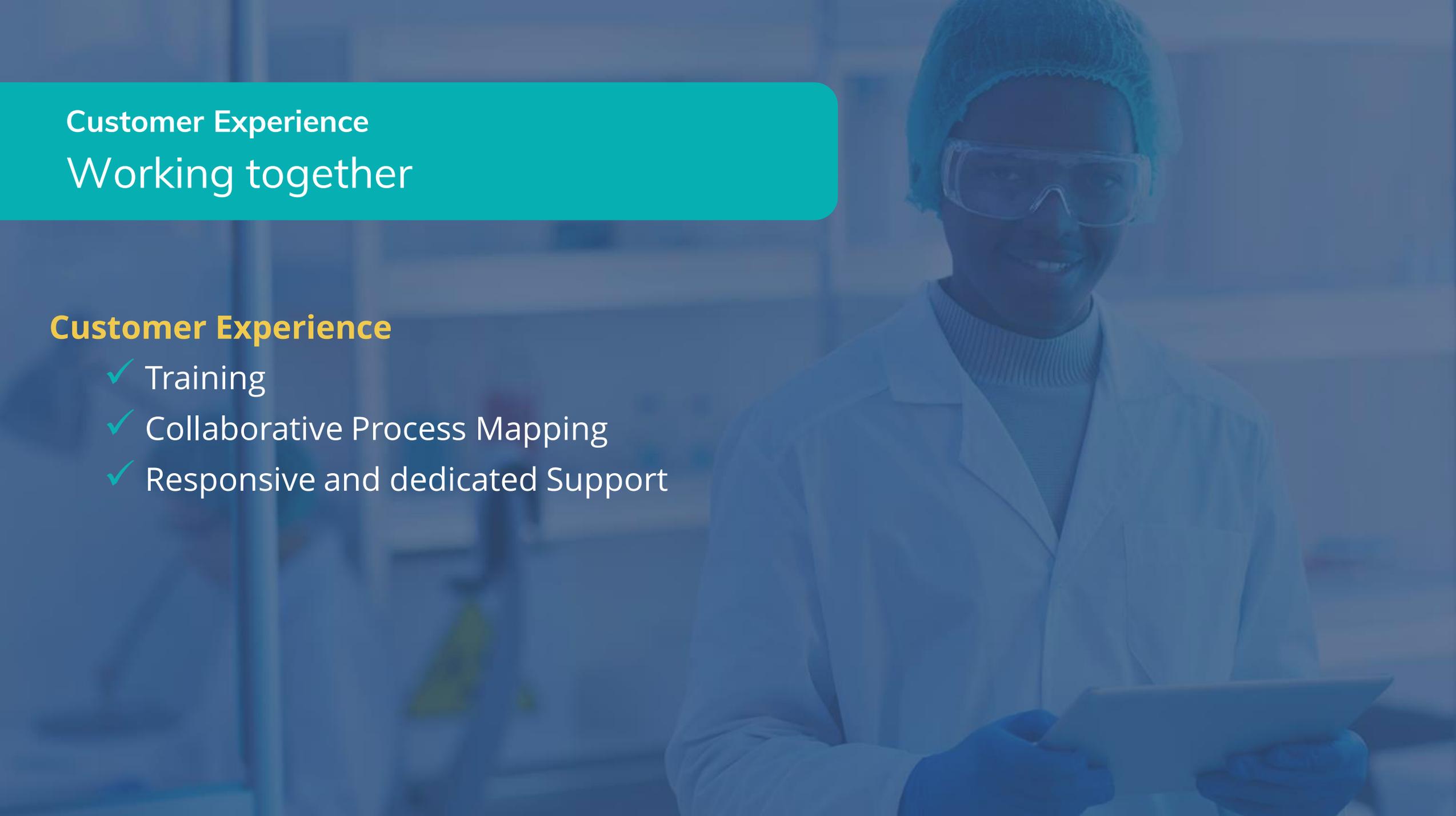
Productive risk mitigation

Results

- ✓ Benchmarking Study against paper baseline

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%



Customer Experience Working together

Customer Experience

- ✓ Training
- ✓ Collaborative Process Mapping
- ✓ Responsive and dedicated Support

“

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

”

- European Lead,
Commissioning and Qualification

“

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 - Associate Director, Commissioning and Qualification

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Thank you

Jerry Quirke, Lead Process Engineer

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