

Client Story: A leading molecular diagnostics company

Meeting increased productivity and compliance demands

Applications: Computer system validation

Introduction

The client is a leading molecular diagnostic company dedicated to saving and improving lives by discovering and delivering tests across major diseases. They produce their own proprietary software which requires validation and FDA compliance and have been successfully using Kneat since 2014.

Background & Challenge:

Improve and fully digitize CSV

The client wished to move from a problematic, traditional, paper-based Computer System Validation approach to an electronic one while also improving their overall CSV process. In particular, they wanted to address GDP errors, eliminate the risk of record misplacement, streamline the review and approval process and address validation record management, filing, retrieval and archiving. During the CSV design phase, the team identified the opportunity to also configure their change management process on the Kneat platform.



Kneat has proven to be a highly adaptable software system that can be configured for use with multiple processes. The tools that are inherent to the application make it easy to implement and to deploy updates to an existing process.

– Keomony Kam, Software Validation Engineer, Myriad Genetics

Need & Solution:

End-to-end digitization

Following a solution assessment process and a subsequent vendor evaluation process, the Kneat platform was selected. Some key factors cited were: scope of functionality, ease of use, adaptability, the Windows-like interface (as it would “help with onboarding”) and Kneat’s capability to capture every step of the validation process, including test-execution, without ever going to paper.

Implementation & Result:

Greater productivity, shorter cycle times and a higher compliance standard

The Kneat platform was configured and validated within 8 weeks. The CSV and change management process was set up on the platform and user acceptance testing (UAT) completed within a further month. The complete solution was live within 3 months, including training and all support deliverables. The streamlined paperless CSV and Change Management processes have had a substantial impact on the business by enabling more right-first-time, greater productivity, shorter cycle times and a higher compliance standard.

- ✓ Simplified protocol generation, review and approval (including approvals while traveling)
- ✓ Simplified paperless protocol execution and discrepancy management
- ✓ Simplified protocol post execution review and approval
- ✓ Reduced deviations, greater right-first-time, greater GDP and data integrity assurance

Talk to Us

Kneat

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