Kneat

Client Story: Tier one biotech

Digitizing the validation lifecycle: a productivity leap

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

Introduction

The client, a US headquartered tier one biotech with multiple facilities in the US and the EU, achieved productivity improvements of 100% after digitizing validation on the Kneat platform.

Background & Challenge:

Rapid growth requiring increased productivity

The client introduces many new therapies every year, and with the addition of a new facility, the number of paper-based validation protocols required was forecast to grow rapidly from an already high average of 700 per year. Increasing regulatory expectations were also contributing to the validation challenge.

Need & Solution:

Validation enhancements across all facilities

The client needed to implement a digitized validation solution that would deliver productivity gains and support ongoing growth. To achieve this, the client sought to eliminate paper with a single platform, capable of managing and executing all records across the entire validation life cycle, automation of record storage, search & retrieval, real time visibility of all processes at site and global levels for managerial purposes, and robust data integrity.

Implementation & Result:

A productivity leap of over 100%

Following an assessment process, the Kneat platform was selected. Kneat's capability to remove paper from all stages of the validation lifecycle was cited as the deciding factor to implement, and the key to achieving their productivity goal.

"By going fully electronic, we reduced the number of manual and paper-based Validation process steps by 60%; productivity improvements of more than 100%, cycle time reductions of more than 60%, cross site alignment, Validation quality and Compliance assurance improvements.", Company QA Engineer.

- ✔ 85% resource and cycle time improvement for changeover processes
- ✔ 60% reduction in test protocol cycle time
- ✔ 48% reduction in pre-execution approval time
- ✔ 58% reduction in post-execution approval time

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.

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