DASSAULT SYSTEMES

BIOVIA

IMPLEMENTING A TOTAL QUALITY CULTURE IN CLINICAL TESTING

hVIVO IMPROVES GCP-CONTROLLED DOCUMENT & PROCESS MANAGEMENT

CUSTOMER STORY

CUSTOMER: A SPECIALTY BIOPHARMA COMPANY WITH CLINICAL TESTING CAPABILITIES

hVIVO is a UK-based specialty biopharma with clinical testing capabilities focused on respiratory and infectious diseases. Building on the insights acquired from clinical trial samples, they are also increasingly engaged in discovery research with three clinical stage products currently in development and a growing pre-clinical pipeline. hVIVO puts humans at the heart of disease modelling. Through its challenge study-based early clinical development studies and the hVIVO platform, hVIVO puts humans at the heart of disease modelling. Their human disease models in flu, RSV and asthma exacerbation enable hVIVO to capture "disease in motion" - illuminating the entire disease life-cycle from healthy to sick and back to health. The company's "human in a lab" approach advances the rational selection of drug targets and biomarkers, while also providing a revolutionary methodology for testing product safety and efficacy.

CHALLENGE: MANAGING QUALITY DOCUMENTS AND PROCESSES IN A PERIOD OF RAPID GROWTH

Experiencing a period of rapid site expansion followed by consolidation—and with limited experience in the use of computer systems—hVIVO was looking for a more efficient and effective way to manage approximately 700 standard operating procedures (SOPs), policies, work instructions, forms and templates, as well as corrective and preventive action (CAPA) documents and QA audit reports. All of these critical documents used traditional paper media and were stored in various locations—one in each lab, one in the clinic, one in the quarantine area and three in offices. Upon initial release and revision, they all required wet-ink signoffs for peer review and department head approvals. They were all managed using labor-intensive Excel spreadsheets. hVIVO management knew that rapidly multiplying paper files, inefficient manual processes and cumbersome approval cycles would not be sustainable in the long term as they opened new sites in the UK while simultaneously hiring new employees, reorganizing departments and collaborating with big pharma on new products requiring compliance with Good Clinical Practice (GCP).

"DocCompliance and ProcessCompliance are driving a GCP-compliant, Total Quality culture at hVIVO. Good communication with our BIOVIA project team helped us implement new document, CAPA and quality management workflows in a phased implementation that did not disrupt ongoing operations."

— Sarah Howard,
Head of Regulatory and Quality Governance, hVIVO

Challenge:

Improve GCP-controlled document and process management in a time of rapid growth and change without jeopardizing ongoing clinical testing operations

Solution:

Dassault Systèmes DocCompliance and ProcessCompliance

Results:

- **Total Quality Culture:** One-stop-shop for procedural documents harmonizes document, process and quality governance
- **Enhanced Compliance:** Accurately identify all documents linked to an activity while supporting continuous improvement
- **Better Performance Tracking:** Reporting tools generate dashboards and KPIs related to controlled documents
- **Effective Collaboration:** Easier sharing of data in an integrated system
- **Simplified Training:** Self-service, online training videos can be extended to other sites/functions across the business

SOLUTION: A PHASED APPROACH TO HARMONIZING DOCUMENT AND PROCESS COMPLIANCE IN A CLINICAL ENVIRONMENT

hVIVO implemented Dassault Systèmes DocCompliance to manage their SOPs and Dassault Systèmes ProcessCompliance for CAPAs and QA audits. Both systems utilize a user-friendly interface which provides access to all regulatory, quality and compliance tasks in a single view. Using a phased deployment, hVIVO implemented DocCompliance together with the user interface in Phase 1. This permitted employees to get trained on and comfortable with the SOP management processes before deploying ProcessCompliance for CAPAs in Phase 2 and QA audits in Phase 3. Adoption of the SOP system required only minor adjustments to map hVIVO's legacy, paper-based Excel system to the DocCompliance document approval, distribution and archiving workflows. Moving from hVIVO's legacy 6-step CAPA process to DocCompliance's 10-step process required more of an effort, but CAPA implementation in Phase 2 eased this transition as employees were by then familiar with the new approach. "In terms of lessons learned, we definitely recommend the phased approach because by going first with DocCompliance, it wasn't such a big leap for people."[1]

Approximately 90% of hVIVO employees only logon to the system to search for documents, print items of interest or complete their Read & Understand (R&U) requirements. For this reason, training is a simple task that can be carried out as part of onboarding or routine instruction. More extensive training for employees actively involved in SOP, CAPA or Quality management activities is provided using demo videos that are always available online.

RESULTS: INTEGRATED DOCUMENT, REGULATORY AND QUALITY GOVERNANCE

With DocCompliance and ProcessCompliance, hVIVO has deployed a fully integrated, closed-loop document management system that also addresses the compliance and quality requirements of regulatory bodies such as the UK Medicine and Healthcare Products Regulatory Agency (MHRA). The solution drives enterprise-wide control, consistency, and compliance throughout the document lifecycle of creating, reviewing, editing, approving, releasing and distributing SOPs, CAPAs and Quality documents. By accurately identifying all documents linked to an activity, the system helps drive continuous improvement with rationalized and harmonized content.

Today hVIVO scientists are sharing information and collaborating more effectively, while leveraging comprehensive reporting tools to generate 'dashboard' management information displays and key performance indicators (KPIs). By making it easier to track and report on controlled documents and processes, R&U compliance, overdue CAPA actions and Quality KPIs, the Dassault Systèmes solution is helping to drive a Total Quality culture at hVIVO.

[1] hVIVO presentation at European BIOVIA Forum 2017

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