CONTROLLED VALIDATION MANAGEMENT OF THE MYGCP APPLICATION

Innovating a regulatory intelligence learning solution

HIGHLIGHTS

- The project was completed on schedule and within the allocated budget.
- Validation activities and deliverables were successfully executed and delivered.
- Validation tooling has been implemented successfully to maintain the validated status and manage any future changes.

BACKGROUND

The client's **myGCP** platform delivers regulatory e-learning for clinical researchers in biotech, pharma, CROs, and hospitals. It covers essential topics like GCP, EU CTR, and MDR through a blend of interactive modules, exams, and certification, all managed via an integrated LMS and CMS. The platform supports continuous compliance training, allowing users to stay updated on clinical research regulations and practices.

APPROACH

The project approach ensured compliant, controlled implementation of myGCP's enhancements through the following steps:

1. **Requirement Gathering:** Collaborated with stakeholders to analyze new NFU and internal requirements.
2. **Verification Strategy Design:** Developed a strategy to meet regulatory standards, creating a validation plan with detailed steps and documentation needs.
3. **Validation Tool Setup:** Used Optimum Quality's MR4DevOps to manage version control, traceability, and testing, establishing test cases for verification.
4. **Testing and Validation:** Conducted rigorous testing, including user acceptance testing, to confirm feature functionality and compliance.
5. **Documentation:** Maintained thorough documentation to ensure traceability and compliance.
6. **Controlled Deployment:** Deployed new features with monitoring to ensure smooth integration and compliance.
7. **Knowledge Transfer:** Handed over tools and documentation to GCP Central for future system management.

OBJECTIVES

The objective was to ensure the platform met updated business and regulatory standards through a well-defined validation strategy that enhances workflow support and client-specific functionality.

Key enhancements focused on:

- Dependencies Management
- Meeting Scheduling
- Advanced Modules
- Continuous Learning Tracking

RESULTS

The project successfully met objectives within the set timeline and budget, resulting in meaningful enhancements to the myGCP system:

- **On-Time Completion:** Delivered on schedule, demonstrating strong project management and stakeholder collaboration.
- **Enhanced System Functionality:** Improvements streamlined user experience, enhanced training organization, and provided greater adaptability to meet specific client and regulatory needs.
- **Validation Tool Implementation:** The MR4DevOps tool enabled effective change management, detailed traceability, and version-controlled testing, ensuring thorough documentation and regulatory compliance.
- **Increased Compliance and Reliability:** The enhancements strengthened the system's ability to handle complex requirements, positioning myGCP as a reliable, compliant solution for evolving user and industry demands.

READ MORE

Read the full case study:
www.ionpharma.nl/mygcp

Want to know more about implementing future-proof validation tooling? Get in contact with us via *www.ionpharma.nl/contact*