PLC UPGRADE IN PHARMACEUTICAL MANUFACTURING: PERFORMANCE VALIDATION'S AGILE APPROACH IN API PRODUCTION ENHANCEMENT

Services Provided

- Project Management
- Automation Support
- Change Control
- Scheduling & Coordination
- Document Development
- Risk Assessments
- Verification and Testing
- Automation Execution
- Project Support
- Functional Spec Development
- System Reviews

AT A GLANCE

PV played a crucial role in collaborating with a major pharmaceutical manufacturer in Michigan to upgrade an obsolete Siemens Programmable Logic Controller (PLC) responsible for controlling the thermal oxidizer (TOX) used in the production of active pharmaceutical ingredients (APIs). The TOX system served as a mission-critical component, and its reliance on the outdated PLC posed a significant single point of failure risk. The project was initiated as part of the client's comprehensive automation strategy to tackle obsolescence issues and ensure the long-term reliability and efficiency of their operations. The upgrade delivered substantial benefits in terms of long-term maintenance, ensuring the client's system remains robust and dependable in the face of future challenges and advancements in technology.

PROACTIVE PROJECT MANAGEMENT ENSURES TIMELY DELIVERY OF CHANGE CONTROL

Initially, the client's operations team was tasked with owning and managing the change control project. As the project progressed, PV recognized the client’s need for additional support to keep the project progressing as planned. Through this collaborative effort, PV was able to help oversee the project’s progress, ensuring that all aspects were efficiently coordinated and executed to meet the required timelines.

EFFICIENT COLLABORATION AND TIMELINE OPTIMIZATION FOR FUNCTIONAL SPECIFICATIONS DEVELOPMENT

PV worked closely with the client's Subject Matter Experts (SMEs) to develop and rout their functional specifications. PV proactively kept all teams, including third-party teams, synchronized throughout the project.

To further enhance communication and collaboration, we leveraged Microsoft Teams, a powerful platform that brought together reviewers from various departments, including operations, quality, and the verification team. By having all stakeholders on a unified platform, we were able to efficiently work with instrumentation technicians and automation SMEs to review the documents in a segmented manner. This approach allowed for early feedback and facilitated swift revisions, ensuring a smooth and continuous development process.

Additionally, during the project's course, the client requested a shortened timeline, presenting a new challenge that demanded an innovative solution. In response, we implemented a strategy of reviewing the documents in pieces, rather than waiting until the end. This allowed us to maintain progress and promptly respond to any modifications, effectively meeting the client's earlier deadline.

Overall, PV's proactive project management, coupled with the effective utilization of Microsoft Teams and a segmented review process, proved instrumental in streamlining the functional specifications development, overcoming unforeseen obstacles, and ensuring the successful completion of the project within the client's revised timeframe.

Phase 1
Change Control & Timeline Generation

Phase 2
Document Development & Reviews/Pre-Approvals

Phase 3
Document Execution

Phase 4
Final Document Delivery to Client & Final Review/Post Approvals

CLIENT TESTIMONIAL

> *Thanks for your collective efforts that contributed to the accomplishment of the verification activities. Your assistance allowed the team to complete the tasks on schedule. The collaboration exhibited across the various disciplines was admirable.*

- Rodney Manning, Mgr. Project Management Verification

STREAMLINING DOCUMENTATION REVIEW PROCESS FOR TIMELY SIGN-OFF

During the project, PV encountered a critical challenge when it became apparent that time was slipping away, and the documentation was returning slower than expected. Recognizing the urgency to meet the project deadline, we swiftly adapted our approach. Instead of waiting for all aspects of the documentation to be available, we implemented a proactive tracking system to track the portions ready for review.

As soon as a section of the documentation became available for review, we immediately sent it through an internal peer review process to initiate the approval phase promptly. Given the scale of the project, which involved hundreds and hundreds of pages, it was imperative to ensure a streamlined and efficient review process.

By adopting this approach, we were able to capitalize on the available time and expedite the review process. As a result, when the critical day for sign-off arrived, a remarkable 75% of the comments had already been addressed and approved. This proactive approach significantly reduced last-minute rush and stress, providing ample time for thorough revisions, and ensuring a successful and on-time completion of the project.

PV's commitment to proactive project management and an agile documentation review process proved to be pivotal in maximizing efficiency, minimizing delays, and achieving an impressive approval rate, enabling our team to deliver results that exceeded the client's expectations.

LEVERAGING SITE FAMILIARITY AND CLIENT RELATIONSHIPS TO OVERCOME PROCESS PINCH POINTS AND MAXIMIZE EFFICIENCY

In every project, we proactively anticipate potential challenges and strategize ways to overcome them. For this project, our team fostered strong connections with the client's technicians and external contractors, letting us familiarize ourselves deeply with the site's operations. Through extensive discussions with the client's technicians, we gained a comprehensive understanding of their original plan to print over 1,200 drawings, which would have taken an entire week to accomplish.

Leveraging our well-established relationships and familiarity with the site, we identified a potential pinch point in the process - the time-consuming printing operation. Drawing upon our expertise and collaborative approach, the team at PV devised an alternate plan that would allow the printing of all the drawings in just two hours. This innovative solution surpassed the initial plan and returned five full working days to the client, optimizing efficiency and productivity. Our strong relationships and in-depth knowledge of the site played a crucial role in facilitating this remarkable achievement.

YOUR VALIDATION PARTNER FOR WHAT'S NEXT

Performance Validation (PV) is a global validation partner for pharmaceutical and medical device manufacturers. Headquartered in Indianapolis, IN, we specialize in turning compressed timelines into compliant ones using innovative, adaptive approaches that balance production realities with strict regulatory requirements. Our best-in-class, cGMP-compliant services cover diverse needs from fully managed CQV to on-demand temperature mapping, smoke studies, software assurance, and more. With a dedicated team consisting of more than 95% engineers, we work closely with regulators and equipment suppliers to keep validation ahead of production curves and keep quality moving forward.

PERFORMANCE VALIDATION
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