

TRUSTED VALIDATION LEADERSHIP: SUPPORTING A GROWING CRO THROUGH PROJECT MANAGEMENT

AT A GLANCE

A rapidly growing Contract Research Organization (CRO) in the Midwest needed a solid validation foundation to meet compliance standards and support ambitious growth. With prior experience working with Performance Validation (PV), the CRO's leadership chose PV to establish validation processes and provide ongoing project management support. This long-standing relationship enabled the CRO to quickly build internal capabilities while relying on PV's expertise during critical phases of their expansion.

BUILDING A ROBUST VALIDATION PROGRAM TO SUPPORT GROWTH



As a newly formed CRO, the client faced the challenge of completing essential validation projects while simultaneously managing live studies and preparing for frequent sponsor audits. They needed a partner who could develop SOPs, templates, and a Computer System Validation (CSV) master plan tailored to their unique needs—and one who could provide flexible support as projects evolved.

PV helped the CRO lay this foundation, then provided guidance on prioritizing validation tasks, ensuring resources were focused efficiently. PV's ability to step in at any phase—advising on validation requirements or leading full validation efforts—gave the client confidence during a period of rapid change.

SERVICES PROVIDED

- **Development of Validation SOPs and Templates** – Six SOPs and nine customizable templates tailored for in-house validation needs.
- **Creation of a Computer System Validation (CSV) Master Plan** – A comprehensive roadmap to ensure regulatory compliance and audit readiness.
- **Validation of Critical Systems** – Lab equipment, environmental monitoring systems (EMS), and laboratory information management systems (LIMS).
- **Project Management and Validation Leadership** – Flexible, on-demand support for validation planning, execution, and oversight.
- **Regulatory and Risk-Based Guidance** – Strategic advice on validation requirements, helping the client focus resources efficiently.

DELIVERING RESULTS: ENABLING COMPLIANCE AND DRIVING EFFICIENCY



With PV's support, the CRO maintained consistent, audit-ready validation across multiple systems, including lab equipment, environmental monitoring, and LIMS. PV's familiarity with the client's processes allowed projects to move forward efficiently, minimizing delays and reducing the need for internal ramp-up.

This partnership ensured:

- **Validation efforts were aligned with operational goals.**
- **Critical systems were validated on time to support ongoing studies.**
- **The client could respond swiftly to sponsor demands, backed by solid documentation.**

PV's practical, client-focused advice also helped the CRO avoid unnecessary validation, ensuring that every dollar spent contributed directly to compliance and business success.

SEAMLESS SUPPORT FOR SUSTAINED GROWTH



By partnering with PV, the CRO gained more than validation expertise—they gained the freedom to grow confidently. With validation processes streamlined and expertly managed, the client could focus on expanding their services, assured that quality and compliance were never compromised.

PV's deep knowledge of the client's systems enabled swift, seamless support, reducing downtime and ensuring each project was delivered accurately and efficiently. This trusted relationship continues to empower the CRO to meet new challenges, scale operations, and serve their clients with confidence.

KEY SUPPORT AREAS

- **Flexible Resource Augmentation:** Ongoing validation leadership to support the client's evolving needs.
- **Prioritization Support:** Helping the client align validation efforts with business goals and timelines.
- **Seamless Integration:** Acting as an extension of the client's team, familiar with systems and processes for quick, efficient project execution.
- **Audit Readiness Support:** Ensuring all documentation met sponsor audit expectations consistently.

YOUR VALIDATION PARTNER FOR WHAT'S NEXT



Performance Validation is a trusted CQV partner for regulated manufacturers. Our experts provide strategic and execution-level support for complex projects, from startup facilities to routine process improvements. When quality and compliance matter, PV brings clarity, continuity, flexibility, and commitment to every project.