

Scientific Resourcing

Transforming environmental monitoring testing from client-owned operations to fully managed services

Enabling rapid scale-up, integrated workflows and reduced operational burden

Background

A biopharmaceutical client operated environmental monitoring (EM) and utilities monitoring (UM) testing internally across a complex, GMP-regulated environment. While the infrastructure supported approximately 50,000 tests annually, our client faced increasing pressure to meet evolving needs, including scaling operations, maintaining audit readiness and reducing the internal management burden associated with high-volume compliance testing.

Unlike traditional insourced staffing, which often fragments accountability, our client wanted to preserve institutional knowledge while transitioning to a more efficient, outcome-driven operating structure. Our partnership helped us serve as an extension of their organization

Situation: Our customer's challenges

- **Operational burden:** Managing approximately 50,000 EM/UM tests per year required significant oversight, diverting resources from core research, manufacturing and quality objectives.
- **Scalability pressure:** Rapid expansion of testing capacity to new facilities was required without compromising cGMP compliance or data integrity.
- **Compliance & data integrity:** Increasing regulatory scrutiny demanded robust documentation, qualified data review and consistent adherence to our client's quality management system (QMS) and cGMP standards.

Collaboration

We deployed a phased transition to a fully managed service model, designed to deliver immediate continuity while enabling scalable, KPI-driven performance improvements.

In six weeks, our Scientific Resourcing solution delivered a seamless managed service transition that retained 90% of the workforce—preserving critical institutional knowledge—while scaling operations. This achieved a **>400% increase** in testing capacity within one year. Through end-to-end operational ownership and expanded service capabilities including data review, trending, and project management, the program **reduced costs by 43%**, eliminated operational burden, and improved turnaround times.

- **Continuity:** Scientific Resourcing rebadged 90% of existing client's EM/UM staff to preserve institutional knowledge and ensure uninterrupted operations.
- **Compliance-driven standardization:** Our operational team implemented controlled documentation aligned to the client's QMS and cGMP requirements, improving audit readiness and reducing deviation risk.
- **Capacity expansion:** We onboarded 14 additional client dedicated resources within 6 weeks, accelerating throughput while maintaining quality standards.
- **Scope expansion:** The team introduced qualified data review and LIMS data entry, strengthened ALCOA+ data integrity and reduced review cycle times.
- **Managed service delivery:** We transitioned to fully integrated workflows across sampling, testing, data review and reporting. This lifecycle management eliminated handoffs and improved turnaround times.

Microbiology and EM/UM scientific study support

Importance of having a technical partner

- **Facility expansion:** Performed facility expansion activities through execution of EM and UM qualifications, ensuring environmental control, operational readiness and compliance throughout manufacturing scale-up and expansion efforts.
- **Preventative emergency response:** Led rapid HVAC loss study, including cleaning, recovery sampling and controlled state restoration to minimize future operational impact.
- **Cleaning modification:** Supported implementation of revised cleaning strategy that removed Spor-Klenz and enhanced monitoring of spore forming bacteria, confirming continued manufacturing state of control.
- **Method optimization:** Optimized incubation methodology by demonstrating equivalent microbial recovery with single temperature incubation, reducing operational complexity while maintaining acceptance criteria compliance.

Practical process improvements

Thermo Fisher operational excellence focus

- **Gemba Walk program:** Implemented routine leadership Gemba walks to strengthen process oversight, reinforce aseptic behaviors and proactively identify operational risks.
- **Tiered accountability model:** Established structured accountability practices across leadership and operational teams to improve ownership, communication escalation, training compliance and execution consistency.
- **Lab modernization and LIMS SME leadership:** Appointed as LIMS SMEs to support workflow optimization, laboratory modernization and data integrity initiatives that improved operational efficiency and scalability.
- **Audit readiness:** Maintained continuous inspection readiness through technical preparation, operational coaching and direct engagement support during regulatory inspections.

Results and impact

The phased transformation delivered significant operational and financial impact:

- **>400% testing capacity:** Scaled EM/UM operations from ~50,000 to ~225,000 EM/UM tests annually while supporting manufacturing growth and facility expansion activities.
- **43% reduction in cost per test:** Achieved within 12 months through workflow optimization and resource alignment.
- **Enhanced compliance performance:** Standardized cGMP processes and strengthened data review practices, reduced audit risk and ensured inspection readiness.
- **End-to-end operational efficiency:** Utilization of Gemba Walks improved operational efficiency and decreased deviations. Integrated workflows reduced delays, minimized rework and accelerated reporting timelines.
- **Expanded compliance coverage:** Supported routine and investigational sampling, routine testing (bioburden, endotoxin, total organic carbon, bacterial identification, growth promotion, etc.) and return-to-service activities across Grade A–D classified cleanrooms within five manufacturing buildings.

Our Scientific Resourcing phased services approach and fully managed services delivered **>4x testing capacity** growth and **reduced cost/test by 43%**, cutting through complexity while eliminating operational burden.



Contact our [Scientific Resourcing team](#) to evaluate how a fully managed, KPI-driven service model can reduce operational burden while accelerating performance and compliance outcomes.