Owner's Technical Leadership for Life Sciences Capital Projects

Lifecycle-Driven Owner's Representation to Enable Predictable Delivery, Flexibility, and Operational Readiness

Executive Summary

Life sciences organizations are investing aggressively in new facilities, technology upgrades, and capacity expansions to support growth, pipeline acceleration, and new product introductions. These capital programs are increasingly complex, highly regulated, and frequently executed through phased or iterative deployments across multiple buildings or sites. At the same time, lean operating models require internal leaders to prioritize strategic initiatives while maintaining effective oversight of execution.

Without intentional resourcing and sustained time commitment across the project lifecycle, owners face challenges in decision-making, requirements definition, structured governance, testing rigor, and readiness for both operations and new product introductions. These gaps increase the risk of schedule delay, scope creep, rework, and long-term operational inefficiency.

This whitepaper outlines how life sciences organizations can strengthen their existing execution models by engaging a **dedicated Owner's Representation Technical Leadership team**—providing lifecycle-driven oversight, fact-based decision support, structured accountability, and continuity from Front-End Loading (FEL) through operations.

1. Life Sciences Capital Projects: Increasing Complexity, Increasing Risk

OT automation in life sciences Capital projects must balance speed, compliance, scalability, and future flexibility. Unlike single-purpose builds, these programs often support:

- Multiple product lifecycles
- Scale-up from pilot to commercial manufacturing
- Evolving regulatory requirements

- Iterative deployments of automation across facilities

While execution frameworks and delivery partners are well-established, the owner's ability to remain continuously engaged at the technical and decision-making level is increasingly constrained. This creates a clear need for owner-side technical leadership that protects long-term value while enabling execution success.

2. Five Challenges Life Sciences Owners Face in Capital Projects

a. Effective, Timely Decision-Making

Successful OT automation projects require timely, data-driven technical decisions. When decision ownership or data-driven governance is lacking, delays and scope creep quickly follow.

b. Weak or Late User Requirements Definition

Without experienced owner-side leadership driving requirements early, downstream design, testing, and validation efforts become reactive, increasing rework and compliance risk.

c. Lack of Structured Milestones and Gated Accountability

Many projects lack clearly defined technical milestones and decision gates, limiting the ability to measure progress, enforce accountability, and take corrective action early with system integrators, and reduces the ability to intervene early when issues emerge.

d. Underestimated Testing and Verification Effort

Testing requirements, particularly in automation systems, are often compressed or deferred, impacting right-first-time delivery, destabilizing startup, and shifting risks into operations.

e. Misalignment with Corporate Standards and Infrastructure

Automation solutions that are not aligned with corporate control platforms, network architectures, cybersecurity frameworks, and delivery standards introduce avoidable integration risk and long-term operational burden.

3. Owner's Representation as Technical Leadership in Life Sciences

In life sciences automation programs and project, Owner's Representation must go beyond coordination and reporting. It must function as technical leadership on behalf of the owner.

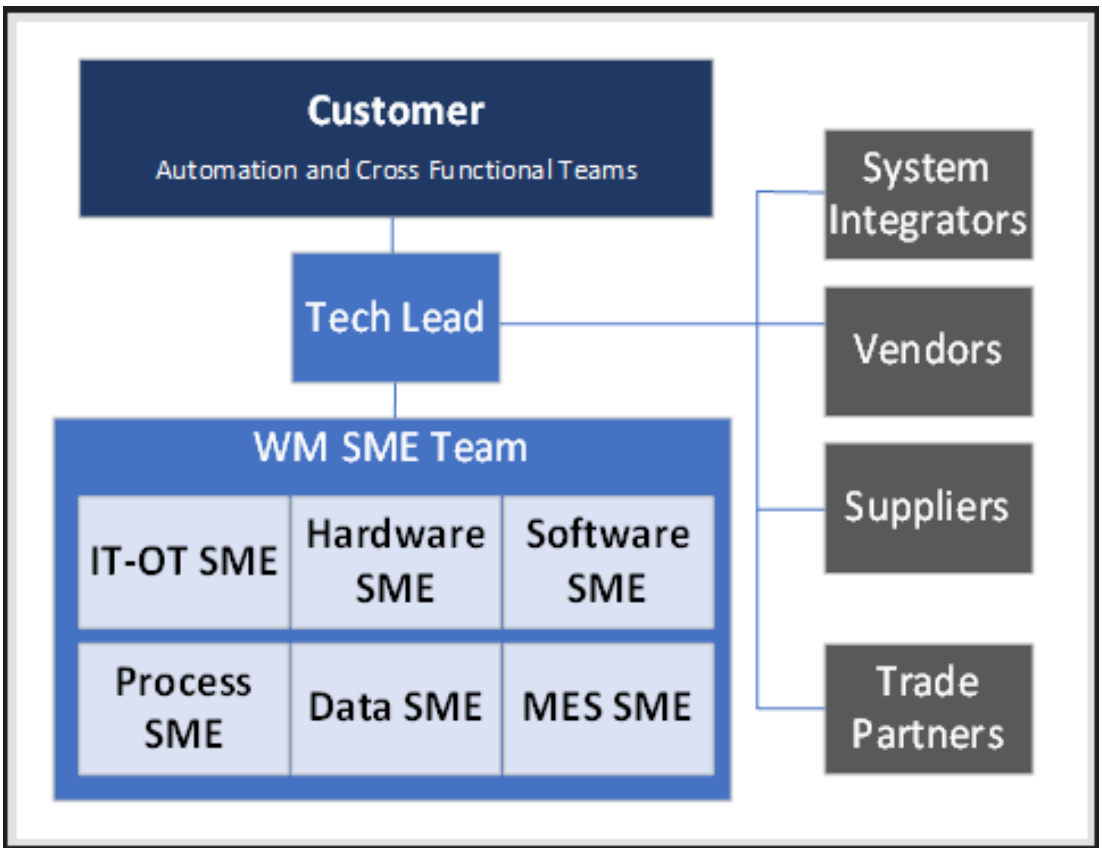
A **dedicated Owner's Technical Leadership** role ensures:

- Clear ownership of technical decisions
- Strong user requirements and design inputs
- Alignment across Automation, Engineering, IT, Quality, and operations
- Fact-based governance that enables timely decisions

This role protects both project outcomes and long-term operational performance.

4. SME Team Model: Beyond Individual Expertise

Life sciences owners derive significantly greater value by engaging a **dedicated SME team**, rather than relying on individual independent resources.



This team-based model provides:

- Collective experience across end-user and system integrator roles
- Rapid access to a broad range of expertise—from panels to platforms to implementation
- Scalable support aligned to project phase, risk, and complexity

This depth of coverage provides owners additional assurance that the right expertise is available when needed—and backed up if required.

5. Business Continuity and No Single Point of Failure

Multi-year capital program and projects demand continuity.

A SME model ensures:

- Resource backup during temporary absences
- Shared context and institutional knowledge
- Continuity across design, implementation, and testing phases

This eliminates single points of failure and supports uninterrupted owner-side leadership.

6. Project Management and Technical Governance in Life Sciences Automation

Modern automation platforms such as DeltaV and PlantPAx rely on object-oriented, class-based software architectures that demand deliberate project management and strong technical governance. These environments amplify both the value and the risk of software reuse, making enterprise alignment essential from start.

Owner-side Technical Leadership is critical to:

- Defining and enforcing a robust Software Development Lifecycle (SDLC) aligned with corporate quality systems (QMS) and enterprise automation standards
- Establishing clear Project Execution Plans (PEP) and Quality Plans that govern software design, testing, validation, and release
- Implementing configuration management, including version control, object ownership, and formal impact assessment for shared software assets

- Governing change management beyond cost and schedule, ensuring changes to software objects, libraries, and templates are assessed for site-wide and enterprise-wide impact

Without this structure, shared class-based software modules, libraries, and templates can be modified across projects or facilities without proper assessment or approval. This creates uncontrolled divergence from enterprise standards, undermines validation and traceability, and introduces significant compliance, cybersecurity, and long-term operational risk.

7. Design Inputs, Milestones, and Gated Delivery

Successful delivery depends on clearly defined and controlled design inputs.

Owner's Representation ensures:

- Formal identification of required design inputs (e.g., P&IDs, process narratives, functional specifications)
- Clear handoff points that start controlled effort
- Milestone-based tracking with objective completion criteria

Avoiding ambiguous "draft" or interim inputs prevents rework, protects schedule, and forces early accountability.

8. New Product Introduction (NPI) and Recipe Flexibility

Life sciences facilities must support frequent change, rapid product transitions, and evolving process requirements.

Owner's Technical Leadership enables:

- Recipe strategies that reduce complexity and qualification burden
- Separation of batch-specific parameters from equipment control logic
- Standardized change-over concepts to streamline recipe management
- Faster turnaround for new or modified products

This flexibility is essential for NPI success while maintaining compliance and control.

9. Aligning Pilot and Production Requirements

Many life sciences programs seek to standardize solutions across pilot and production environments.

Early owner-led design reviews are critical to:

- Align security, workflow, and flexibility needs
- Prevent "one-size-fits-all" solutions that satisfy neither environment
- Ensure pilot teams can operate effectively within the aligned software strategy, rather than developing local deviations to accommodate speed, experimentation, or ease of use

Owner's Representation provides the balance needed to enable innovation without compromising production integrity.

10. Supporting Site Readiness and Operational Readiness

From the owner's perspective, success is achieved when systems are stable, usable, scalable, maintainable, and support daily operations.

Lifecycle-driven **Owner's Technical Leadership** ensures:

- Testing strategies align with operational needs
- FAT/SAT execution supports effective startup
- Operators and maintenance teams are prepared
- Knowledge transfer and transition to operations are intentional

Conclusion

OT automation Life sciences capital program and projects demand more than traditional oversight. They benefit from a **dedicated Owner's Representation technical leadership** that spans the full lifecycle: driving decisions, enforcing structured governance, ensuring flexibility for new products, and protecting long-term operational value.

By engaging a dedicated SME team that brings collective experience, continuity, and lifecycle focus, owners can strengthen execution confidence, reduce risk, and ensure their capital investments deliver sustained value well beyond project delivery.