

From Licensing to Acquisition: End-to-End CMC Enablement for a Clinical-Stage Biotech

A fractional, senior-led CMC operating model that carried two monoclonal antibody assets from Phase 2 through a successful acquisition with zero supply disruptions and 100% on-time regulatory filings.



Background

A newly formed, clinical-stage biotech had licensed two monoclonal antibody (mAb) assets and prepared to advance its lead program from Phase 2 to Phase 3 across a global clinical footprint. While the company possessed strong scientific leadership and a clear development thesis, lacked internal CMC infrastructure. The organization had no dedicated Drug Substance, Drug Product, Analytical Development, Supply Chain, Regulatory CMC, or Quality function, and no appetite to take on the fixed cost of building them before the program was fully de-risked.

With clinical trials underway in multiple regions, an aggressive near-term IND/IMPd cadence to maintain, and investors closely watching the runway, the team needed senior CMC leadership capable of executing on day one.

The Challenge

The client was effectively starting CMC operations from zero while the clinical clock was already ticking. Any gap in functional coverage risked supply interruption, a missed regulatory deadline, or a critical CMC finding, all of which would severely erode the company's valuation during future transaction discussions.

The critical complexities include:

- **Immediate Tech Transfer and Infrastructure Setup:** Absorbing a complete technical and documentation transfer from the licensor without stalling ongoing trials, while simultaneously engaging a new CDMO network for Drug Substance manufacturing, Drug Product fill/finish, analytical testing, and global clinical trial material (CTM) storage and supply.
- **Aggressive Global Regulatory Cadence:** Authoring and submitting IND Module 3 content, IMPDs, amendments, and Health Authority responses on a rolling basis across multiple regions, alongside preparing for pivotal Type B regulatory meetings.
- **Diligent Quality Compliance:** Building a phase-appropriate Quality Management System (QMS) from scratch and maintaining strict CDMO quality oversight to ensure the assets and data would withstand intense scrutiny during eventual buyer due diligence.

Hiring 5 to 6 full-time, senior CMC leaders to cover this multi-disciplinary scope was neither financially viable nor fast enough for the client's aggressive timeline.

Timeline:

< 3 Years

2 Monoclonal
Antibody Assets

0 Clinical Trial
Material Shortages

100% On-Time
CMC Regulatory
Submissions

~1–2 FTE Average
Monthly Utilization
(delivering 5–6 FTE
of senior expertise)

From Licensing to Acquisition: End-to-End CMC Enablement for a Clinical-Stage Biotech

Case Study

The Syner-G Solution

Syner-G deployed a fractional, fully integrated CMC operating model that completely bypassed the need for an internal buildout. A single Syner-G CMC program director, backed by a strategic advisor and senior subject matter experts (SMEs) across Drug Substance, Drug Product, Analytical Development, Supply Chain, Regulatory CMC, and Quality Assurance, was embedded into the client's operation from day one. Because every functional lead brought more than 20 years of specialized industry experience, the team delivered immediate productivity.

Agile Resource Scaling: The engagement was precisely sized to the actual technical workload rather than an arbitrary headcount plan. Part-time senior SME hours flexed up and down dynamically based on active project milestones, delivering the functional breadth of a large pharma development team at a fraction of the cost. As the program matured and workload increased, execution-level resources were layered in seamlessly underneath the leads. This preserved operational continuity through the onboarding of the client's first two internal CMC hires and, ultimately, through the complete acquisition transition.

Full-Spectrum CMC & Quality Ownership: Across the nearly three-year engagement, Syner-G owned the entire breadth of the CMC enterprise:

- **Strategic Planning:** Leading end-to-end CMC program management and phase-appropriate development planning to bridge Phase 2 data into Phase 3 readiness.
- **Supply Chain & Vendor Management:** Executing technical due diligence and a comprehensive documentation transfer from the licensor; managing the global CDMO network; and negotiating Master Service, Supply, and Quality Agreements.
- **Operations & Quality Control:** Overseeing investigational product manufacturing, clinical batch release, and analytical testing, while building out a phase-appropriate QMS to ensure total audit readiness.
- **Regulatory & Knowledge Transfer:** Authoring all global regulatory submissions (IND Module 3, IMPDs, and amendments), driving Type B meeting preparations, and executing a structured, meticulous knowledge transfer to the acquiring sponsor.

Timeline

2022 — Engagement begins. The licensing deal closes and Syner-G is engaged. The full CMC operating model is stood up immediately, with no internal buildout required on the client side.

2022–2023 — Program execution. Phase 2 trials run across global sites. The CDMO network is transitioned and stabilized, IND and IMPD filings are submitted on schedule, and the client's first internal CMC and Supply Chain hires are onboarded, all without a break in program delivery.

2023–2024 — Phase 3 readiness. The lead mAb asset advances into Phase 3. Clinical supply continuity is maintained globally, and the QMS and documentation infrastructure are brought to audit-ready status.

2024 — Successful acquisition. A large pharmaceutical company acquires the client. CMC systems, documentation, and the CDMO supply chain are fully transitioned to the buyer, and CMC is designated a low-risk function during buyer diligence.

Outcomes

In under three years, the client progressed from a complex two-asset licensing deal with no internal CMC infrastructure to a highly successful strategic exit, powered entirely by Syner-G's operational backbone.

Clinical & Supply Continuity: The lead mAb asset successfully advanced from Phase 2 into Phase 3. Global clinical trials proceeded without a single CTM shortage or supply disruption, even during multiple CDMO contract transitions.

Flawless Regulatory Execution: Every single CMC regulatory deliverable—including IND Module 3 updates, IMPDs, clinical amendments, and Health Authority responses—was submitted on time, achieving a 100% on-time regulatory rate across the life of the program.

Value Protection in Diligence: The QMS, analytical validation data, and batch records built under the engagement held up cleanly under intense M&A scrutiny, with the buyer designating the CMC function as a highly controlled, low-risk asset.

Capital Efficiency: This entire corporate arc was delivered at an average monthly utilization of just 1 to 2 full-time equivalents, maximizing investor runway while preserving absolute operational quality.

Conclusion

A fractional, senior-led CMC model accomplishes what an internal buildout cannot: It moves faster, reduces fixed overhead, and remains fully scalable up to the point of exit. For clinical-stage biotech companies, this framework de-risks early development without committing early capital to a permanent internal organization. It holds regulatory and supply reliability steady across global trials from day one, scales expertise precisely when milestones demand it, and positions the company's assets perfectly for a high-value strategic transaction. Syner-G's integrated model brings elite senior expertise, at the exact intensity required, at the most critical moments in a program's life cycle.