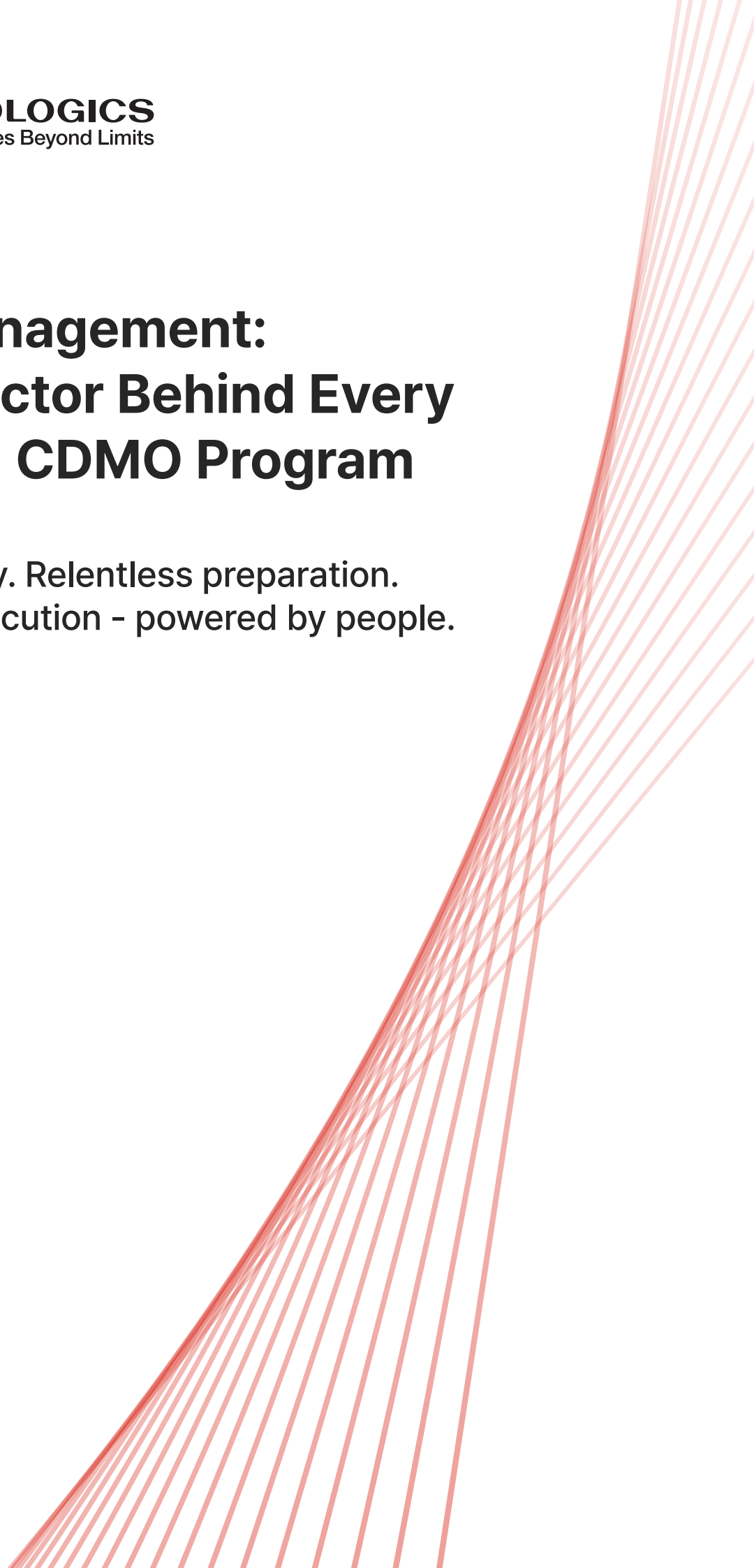
LOTTE BIOLOGICS
Possibilities Beyond Limits

Project Management: The Conductor Behind Every Successful CDMO Program

Molecule mastery. Relentless preparation. Orchestrated execution - powered by people.



Executive take

In biologics manufacturing, capacity and technology matter—but they don't run the program. **People and orchestration do.**

The difference between a "capable" CDMO and a truly high-performing partner is not how many reactors they operate—it is whether they can translate deep molecule understanding into a disciplined, cross-functional campaign that moves from tech transfer to GMP execution without losing intent, control, or momentum. That orchestration is the real role of Project Management (PM) in a CDMO: a conductor who understands the score (the molecule), rehearses the orchestra (readiness), and leads performance night (GMP execution). And importantly, the conductor is never alone. Great CDMO PM works because it activates an extended team—MSAT, manufacturing, QC/QA, validation, automation, supply chain—so the sponsor doesn't just "have a vendor," but gains a coordinated group that behaves like an extension of their own organization.

Why "Conductor-Grade" Project Management Matters More Than Ever

Today's programs are less forgiving because complexity is higher and tolerance for rework is lower.

- Molecules are more demanding (higher titers, tighter impurity profiles, process sensitivity)
- Timelines compress while dependencies multiply (analytics, materials, validation, quality review)
- Sponsors need a partner who can make the right calls early—before late-stage surprises force compromises

In this environment, Project Management cannot be reduced to schedules and meetings. It must function as program leadership—with enough technical fluency to guide choices, enough rigor to enforce readiness, and enough influence to align multiple disciplines under cGMP constraints.

What Elite CDMO Project Management Really Is

Strong PM is not "tracking work." It is owning the orchestration. A conductor-grade Project Manager does three things exceptionally well:

1) Understands the molecule well enough to lead the right conversations

Sponsors don't need a PM who only escalates issues. They need a PM who recognizes which issues matter—and why—because they understand:

- The molecule's Critical Quality Attributes (CQAs) and risk sensitivities
- Which process parameters are truly critical vs. merely monitored
- What "good" looks like at each phase of transfer, readiness, and execution
- Where variability will appear first (sampling, methods, raw materials, unit operations)

This technical fluency changes the program outcome because it lets the PM direct attention and resources to what actually drives success.

2) Rehearses the orchestra: preparation is where programs are won

Conductor-grade PM treats early preparation work as rehearsal and insists on proof of readiness:

- Fit-to-facility checks before the schedule is locked
- A ranked risk register with owners and mitigation due dates

- Batch record architecture and data requirements defined early
- QC throughput and method readiness modeled as part of the plan
- Validation/Computer System Validation (CSV) and quality readiness gates built into the critical path

Going the extra mile here is not “working harder.” It is doing the unglamorous work early, closing ambiguous assumptions, stress-testing dependencies, and validating the program’s “weak links” before they become late-stage surprises.

3) Leads execution under GMP reality, not idealized plans

A GMP campaign is a live performance under constraints—shift handoffs, equipment realities, QC testing queues, QA review cycles, and change control discipline.

An elite PM creates a system where:

- Decisions are made fast and documented well
- Changes are controlled, not chaotic
- Deviations are addressed with disciplined investigation governance
- Communications are structured, not noisy
- Cross-functional teams stay aligned despite pressure

Here, going the extra mile means stepping beyond the job description when needed: pulling the right Subject Matter Experts (SMEs) into the room quickly, simplifying decision paths, and mobilizing the extended project team so issues are resolved before they ripple downstream.

The Role of Project Management in a CDMO

At its core, CDMO Project Management is the integrative function that connects sponsor intent to CDMO execution—aligning technical work, manufacturing readiness, QC/QA and release governance, supply chain, and regulatory expectations into a single coordinated campaign.

Unlike internal project management, the CDMO PM is dual-accountable:

- Accountable to the sponsor’s objectives and time-to-clinic/commercial goals
- Accountable to disciplined execution within complex GMP systems

The best CDMO PM teams also know when to widen the circle: they deliberately activate an extended team—not as a “support group,” but as an integrated operating unit with clear ownership, fast escalation paths, and aligned priorities.

The Most Common Failure Modes—and How a Conductor Prevents Them

Experienced teams know the below failure modes. The difference is whether someone is orchestrating early enough to prevent them.

Failure Mode 1: The “molecule didn’t fit the facility” surprise

Late discovery of equipment range limits, transfer paths, hold times, automation constraints.

Conductor response: early fit-to-facility assessment, explicit assumptions, gap closure before the first at-scale manufacturing run.

Failure Mode 2: Method readiness and QC throughput become the hidden bottleneck

Sampling volume spikes; assay queues and review delays increase.

Conductor response: QC throughput modeled early; method readiness aligned to campaign cadence; peak-load staffing and escalation thresholds defined.

Failure Mode 3: Change control becomes either gridlock or chaos

Changes either stall the program or introduce compliance risk.

Conductor response: upfront change classification and decision authority; time-bound reviews; comparability rationale where needed.

Failure Mode 4: Lots of meetings, little progress

Updates without decisions; stakeholders leave meetings misaligned.

Conductor response: decision-driven governance; one source of truth logs; every meeting yields actions/owners/dates and recorded decisions.

Failure Mode 5: Deviations become confidence shocks

Investigation scope increases; client communication becomes reactive.

Conductor response: time-bound investigation playbook; clear escalation; transparent, rationale-based communications.

Failure Mode 6: Back-to-back manufacturing runs overwhelm shared resources

QC instrument availability, QA review capacity, line clearance cycles become limiting factors.

Conductor response: dedicated core team + extended team resourcing plan; turnover playbook; measured cycle times; decision making before PPQ. (Process Performance Qualification)

In many of these cases, the single best predictor of success is whether the CDMO can mobilize the extended team quickly and cohesively—without turning execution into chaos.

What Sponsors Should Look for in a CDMO PM Team

When selecting a CDMO, sponsors should evaluate the PM for their program leadership capability.

Look for evidence of:

- Molecule-aware leadership: PM can speak to what matters, not just what's next
- Readiness rigor: early stage gates, risk registers, facility fit logic
- Decision governance: decision rights, time-bound escalation, traceable trade-offs
- Extended-team orchestration: SMEs engage early, not only after issues occur
- Structured transparency: decision-ready dashboards and Risk/Decision/Change logs

A sponsor should feel:

"This project team will lead the orchestra—and the orchestra will show up when it counts."

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LOTTE Biologics' Approach: Project Management as Program Leadership

At LOTTE Biologics, Project Management is designed to function as program leadership.

Across the Syracuse Bio Campus (U.S.) and Songdo Bio Campus (Korea), our PM model is built to maintain continuity and alignment across sites—especially through tech transfer and scale-up.

Our operating principles

1) Molecule-aware leadership

PM is embedded with MSAT/manufacturing/quality discussions to keep the "why" behind the molecule intact through execution.

2) Readiness rigor

We front-load preparation—fit-to-facility, risk mitigation, documentation architecture, analytical readiness—so execution is performed with clarity.

3) Decision governance

We establish clear decision making pathways and hierarchies, enforce time-bound escalation, and document traceable trade-offs—so progress remains timely, accountable, and aligned.

4) Extended team orchestration

We mobilize the right SMEs early and keep a consistent campaign rhythm across functions—so issues are resolved quickly and decisions remain coherent.

5) Structured transparency

We provide decision-ready visibility into progress, risks, and changes—so sponsors can act quickly and confidently.

We don't promise a program without challenges.

We promise a conductor—and an extended team—that keeps the program coherent, prepared, and moving forward.

Conclusion

In biologics CDMO partnerships, the differentiator is often invisible: the presence of leadership that understands the molecule, rehearses readiness thoroughly, and orchestrates execution under GMP reality.

Project Management is that leadership.

Not an administrator. Not a scheduler. A conductor—supported by an extended team that goes the extra mile when it matters most.

About the Author

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Dr. Brett Budis is a seasoned professional with over 29 years of experience in the biopharmaceutical industry.
He has cultivated extensive expertise in regulatory operations, CDMO oversight, technology transfer and Process Performance Qualification (PPQ), quality compliance, inspection readiness, and quality validation.

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Minsun Shin is a seasoned project management professional with over 15 years of experience in the biologics CDMO industry. She has cultivated extensive expertise in downstream MSAT, technology transfer, project management, and business development.

About LOTTE Biologics

LOTTE Biologics is a global contract development and manufacturing organization delivering integrated biologics and bioconjugate services across the full product lifecycle.

With a unified Dual Hub Service model spanning the United States and South Korea, we strengthen supply chain security, enable scalable manufacturing pathways, and uphold consistent quality across regions.

Our capabilities encompass phase-appropriate drug substance manufacturing for mammalian-cell-based biologics, including monoclonal antibodies, fusion proteins, and multispecific modalities, as well as fully integrated Bioconjugate manufacturing supported by strategic investment in onsite conjugation facilities.

Guided by the vision “Possibilities Beyond Limits,” LOTTE Biologics is committed to serving as a long-term, trusted leading global CDMO partner, supporting efficient scale-up, dependable manufacturing execution, and the continuous advancement of clients’ therapeutic programs.

Contact us

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