

2026 Q1 Bioqore Case Study

Predictable Biomanufacturing: Years to Months

Traditional biomanufacturing development is slow, expensive, and unpredictable.

Traditional Model	Bioqore
• 2-5-year scale-up cycles • \$5-10M+ in early manufacturing development (CMC), frequently exceeding tens of millions • Uncoordinated iteration and fragmented outsourcing (CDMO) handoffs • High process and clone attrition during scale-up	• <1 month to actionable signal • \$500K-\$2M per program • Closed-loop automated optimization • 6-8-month scale-up readiness • 75-85% predictive scale confidence, validated across CHO, HEK, Pichia pastoris, and human immune cell programs

Bioqore converts multi-year, multi-million-dollar development cycles into predictable, capital-efficient execution.

Leadgene Biosolutions: Mammalian Cell Line Development



CHO Cell Line Development: From Single Cell to Production Scale in Weeks, Not Years

Before a biologic drug can enter clinical trials, companies must identify a single cell line (a “clone”) capable of producing the drug reliably at manufacturing scale. Under traditional workflows, this process takes 12-15+ months and requires 3+ rounds of trial and error, because the clones that look best in early screening frequently fail when scaled up to production volumes.

Bioqore's AI pipeline identified a counterintuitive pattern hidden in the data: the clones that perform

best in early lab screening are usually not the ones that succeed at production scale. Moderate performers scale better. By applying predictive modeling at the earliest stage (single-cell selection), Bioqore collapsed what is normally months of trial and error into a single run, eliminating the costly cycle of picking winners that fail at scale.

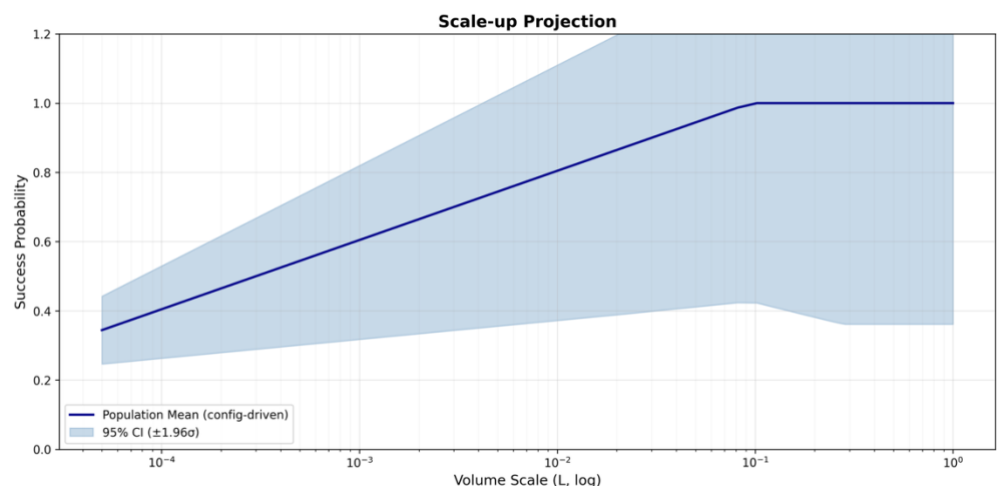


Figure 1. Predictive modeling identified clone profiles with a high probability of maintaining performance as production volume increased, reducing scale-up attrition and accelerating manufacturing readiness.

Completed: CHO cell line development through 1 L bioreactor readiness delivered in 3 months at \$300K, versus 9-16+ months and \$430K-\$1.1M through a comparable CDMO engagement.

"We're excited to celebrate a great milestone with Bioqore. Bioqore is delivering biomanufacturing-ready therapies in weeks versus years, so lifesaving medicines reach patients that much sooner."

- Leadgene Biosolutions (LinkedIn, March 2026)

Capital Efficiency & Cost Savings

Most biologics companies spend \$5-10M+ on early manufacturing development, much of it on repeated failed scale-up attempts through CDMOs, charging per run with no guarantee of success. Bioqore's Leadgene engagement proved a different model: fixed-price, predictive, and delivered in a fraction of the time and cost. The result is order-of-magnitude reductions in capital deployment, lower monthly burn, extended runway, and reduced financial exposure prior to clinical inflection.

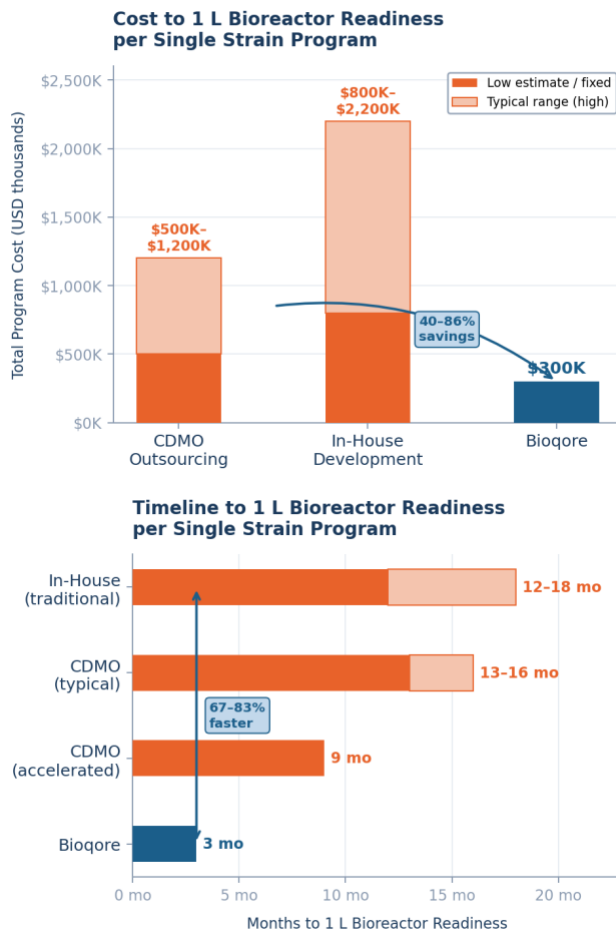
Why Bioqore, and Why Now

Traditional CDMOs optimize one experiment at a time, with process knowledge siloed inside each engagement. Bioqore's approach is structurally different: a closed-loop automation platform backed by proprietary datasets spanning upstream and downstream processing, from microscale through scaled manufacturing. Every engagement compounds the model's accuracy, creating a flywheel that no single CDMO or in-house team can replicate. The result is not incremental improvement but a fundamentally different cost and timeline structure for biomanufacturing development.

The urgency is real. The BIOSECURE Act is accelerating the push to reshore biomanufacturing, and CDMO capacity constraints are lengthening timelines industry-wide. Companies that locked in 18-month CDMO slots two years ago are now facing 24-month queues. Bioqore offers a way to bypass that bottleneck entirely—reaching manufacturing readiness before a traditional engagement would even begin.

Client Ownership, IP, and Regulatory Readiness

Every Bioqore engagement delivers a complete, IND-ready data package that the client owns outright: predictive models, validated clone recommendations, full experimental datasets, and a CMC section structured for regulatory submission. Bioqore also provides pre-IND meeting preparation, document review, and filing support to streamline the path from development to clinic. No licensing fees, no data holdbacks, and no vendor lock-in. Clients leave with everything they need to move forward independently—with any CDMO, in-house team, or directly into an FDA submission.



Figures 2 & 3. Bioqore delivers equivalent development outcomes at 40-86% lower cost and in 67-83% less time than traditional CDMO or in-house pathways, reaching 1 L bioreactor readiness in 3 months for a fixed \$300K per strain.

Standardized Data Pipeline and Execution Framework

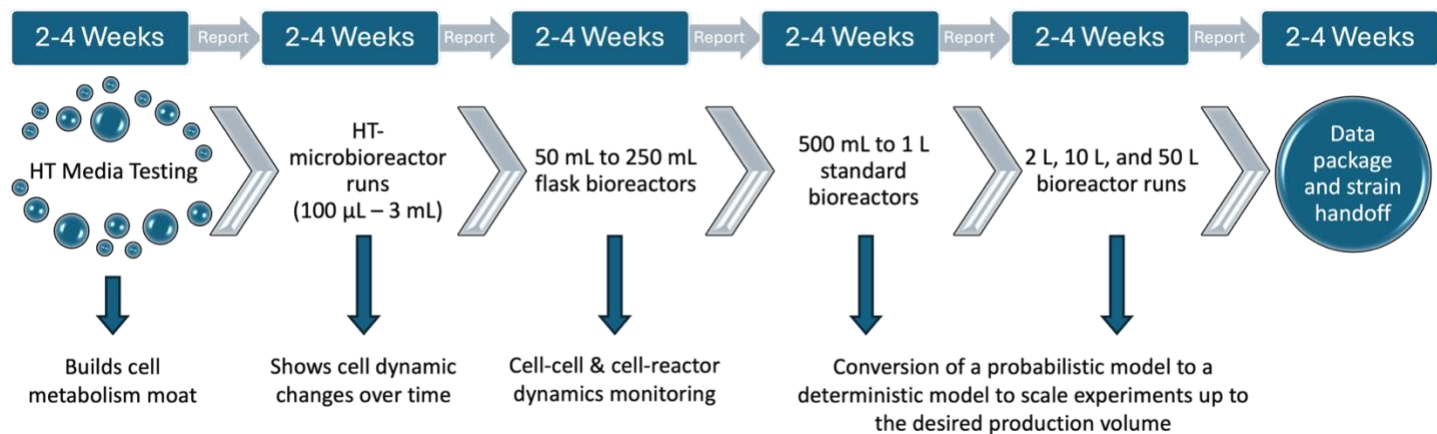


Figure 4. Bioqore advances every program through a structured, multi-stage pipeline with defined 2-4-week cycles at each step, progressively increasing scale and data fidelity. This standardized framework converts early microscale insights into production-ready process and strain recommendations, delivering quantified scale confidence and a complete data package for client handoff.

Bioqore’s pipeline follows a structured, repeatable path from initial screening to a production-ready clone. Each stage takes 2-4 weeks and progressively increases scale and data fidelity, with explicit go/no-go decision points between stages. If a clone’s performance diverges at intermediate scale, the model flags it before significant capital is committed—not after. This staged risk mitigation means there are no surprises at handoff:

- Small-scale screening to identify which clones have real production potential
- Automated bioreactor runs to observe how cells actually behave over time
- Intermediate-scale validation to confirm performance holds as volume increases
- Production-scale runs to lock in final manufacturing conditions
- Complete data package and clone handoff: everything needed to begin manufacturing

This is what Leadgene experienced: a production-ready clone in 3 months at \$300K, versus 9-16+ months and \$430K-\$1.1M through a traditional CDMO. The same framework is now active across CHO, HEK, Pichia pastoris, and human immune cell programs (PBMCs, CAR-T, and NK cells), and Bioqore continues to support clients through clinical trials—not just through handoff.

Ready to accelerate your program? [Connect with the Bioqore team →](#)