

Systematic Strategy to Reduce the Cost of Goods Sold

A Smart Approach to Sustainable Cost Management in Biologics

In biologic product development, reducing the cost of goods sold (COGS) has long been a formidable challenge. Traditional cost-cutting measures, such as minimizing raw material expenses or streamlining individual process steps, often create tradeoffs that compromise supply chain stability, regulatory compliance, or product quality. Moreover, these incremental adjustments fail to address the root cause of inflated costs, leading to unsustainable manufacturing models that struggle to reconcile increasing market and regulatory pressures.

A more effective approach requires a fundamental shift in strategy—one that integrates advanced technology, process optimization, and global network efficiencies to drive systemic cost reduction.¹ WuXi Biologics has pioneered such a model, leveraging next-generation technology and a contract research, development, and manufacturing organization (CRDMO) framework to achieve sustainable, long-term cost efficiencies without compromising speed or quality (Figure 1).

Beyond Traditional Cost-Cutting

Developing and manufacturing biologics is 11 times more expensive than developing and manufacturing small-molecule drugs.² Historically, biologics manufacturers have implemented piecemeal strategies to lower COGS, creating inefficiencies that limit cost savings:

- Reducing raw material costs risks supplier dependency and regulatory hurdles.
- Scaling up production requires significant capital investment and limits flexibility.
- Outsourcing processes can introduce quality inconsistencies and loss of control over timelines.

In contrast, WuXi Biologics employs a holistic, technology-driven strategy that aligns innovations across cell line development, upstream and downstream process development, material selection, and supply chain.



Figure 1: Automation, high-throughput (left), and disposable manufacturing (right) accelerate process development. Data from over 100 batches show that disposable manufacturing alone reduces COGS to < \$80/g at a 12,000 L-scale by eliminating cleaning and sterilization steps.

Technology-Driven Efficiency

WuXi Biologics harnesses proprietary technology platforms to enhance productivity and cost efficiency, passing these benefits to clients (Table 1). Compared to traditional technology, our technology platforms increase productivity 3- to 6-fold and reduce COGS by 60 to 80%.³

Technology Platform	Description
WuXia™	High-yield, high-quality cell line development
WuXiUI™	Ultra-intensified fed-batch manufacturing
WuXiUP™	Ultra-high productivity continuous bioprocessing
WuXiHigh™	High-concentration, high-throughput drug product development

Table 1. WuXi Biologics’ technology platforms form a cost-reduction toolbox.

Process Optimizations for Higher Productivity

Productivity directly impacts cost, and process improvements in one area can create inefficiencies elsewhere. For example, increasing yields might extend processing times, and scaling up batch sizes can introduce variability. WuXi Biologics comprehensively optimizes cell line development, upstream processing, and downstream purification to eliminate these bottlenecks (Figure 2).

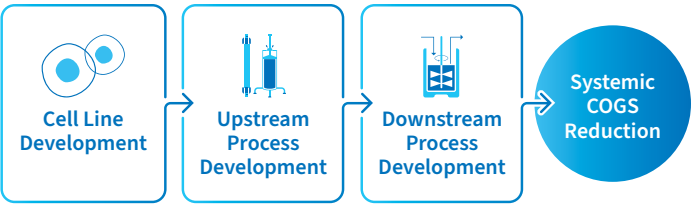


Figure 2: Optimized development processes drive meaningful COGS reduction.

Our process optimizations drive savings without compromising speed, quality, or regulatory compliance. Higher titers and yields lower the cost per gram by maximizing biologic output per batch and reducing raw material use, labor, and processing cycles. At the same time, stringent quality control minimizes batch failures, rework, and costly deviations, further enhancing the efficiency that lowers COGS.

Cell Line Development

Traditional cell line development is slow and resource-intensive, prolonging timelines and reducing titers. The WuXia technology platform accelerates productivity at the source, advancing from DNA to master cell bank in as little as 9 weeks. Throughout cell line development, WuXi Biologics employs a custom lab data management system to manage large volumes of critical biologic data with accuracy and efficiency.

WuXia capabilities extend to intensified clone screening, maximizing titer through advanced processing. This approach consistently achieves titers averaging 6 g/L for CHO K1 monoclonal antibody clones—significantly outperforming industry standards (Figure 3). With a 98.8% stability guarantee for lead clones and zero sequence variants, WuXi Biologics delivers cell lines that are both highly productive and commercially reliable.

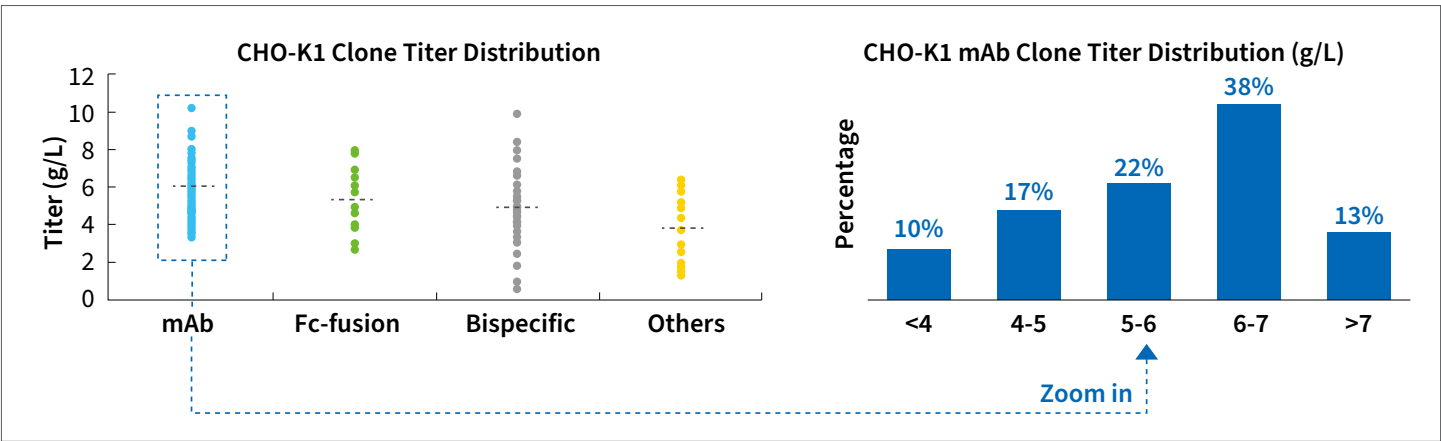


Figure 3: The WuXia technology platform’s clone titer distributions demonstrate superior productivity and stability.

Upstream Process Development

Upstream process development lays the foundation for biologic manufacturing, driving efficiency, yield, and cost-effectiveness. By increasing titers and reducing batch numbers, we minimize material, labor, and operational costs.

WuXi Biologics tailors culture modes to suit program needs, deploying WuXiUI for ultra-intensified fed batch processes or WuXiUP for continuous culture. Both technology platforms enhance productivity through multiple tactics:

- Advanced feeding strategies and temperature shift protocols
- Proprietary boosting additives that improve cell viability and output
- Media that reduces costs by 40% while maintaining superior performance

Downstream Process Development

Downstream process development follows upstream cell culture, encompassing purification and final formulation to meet stringent quality, purity, and regulatory requirements. Traditional methods, such as 3-column chromatography, introduce complexity, increase costs, and extend timelines. WuXi Biologics has pioneered innovative solutions to optimize downstream processes and reduce COGS:

- **Optimized chromatography**—Replacing the 3-column purification method with a 2-column approach reduces resin consumption, shortens processing time, and lowers operational complexity.⁴
- **Lean buffer system**—Using the Eliminate, Combine, Reduce, Simplify (ECRS) method, WuXi Biologics reengineers buffer systems to minimize preparation steps,

reduce variability, and enhance process robustness. ECRS reduces buffer consumption by ~6 tons per year, lowering resource use and environmental impact in alignment with environmental, social, and governance (ESG) principles.

- **Membrane chromatography**—A high flow, high capacity alternative to traditional bead-based columns, membrane chromatography accelerates binding kinetics, reduces processing time, and readily scales to meet the needs of large-scale manufacturing.⁵
- **Continuous direct product capture (CDPC)**—CDPC integrates continuous bioreactor operation with immediate, ongoing protein capture, reducing resin usage by 80% and increasing productivity fivefold.

Additionally, for high-concentration formulations, the WuXiHigh technology platforms overcomes viscosity challenges to develop injectable biologics up to 230 mg/mL. A high concentration reduces dosing volumes, further lowering manufacturing costs.

Strategic Materials Selection

When reducing the cost of raw materials, focusing on price rather than performance is a common pitfall that introduces efficiencies and batch failures. We optimize media and resin selection.

High-Performance, Low-Cost Media

WuXi Biologics’ high-performance media delivers 40% cost savings over commercial alternatives with comparable or superior titers. Regulatory acceptance for IND and BLA filings ensures a seamless submission process.

Designed for GMP and non-GMP runs, the high-performance media supports production at scales as small as 50 L and

Stage	Media	Normalized Catalog Price (%) ^a
Cell culture	Medium A	100 (baseline)
	Medium B	107
	WuXi Biologics’ high-performance media	60

^a Estimated

Table 2. Cost advantage of in-house media versus commercial alternatives

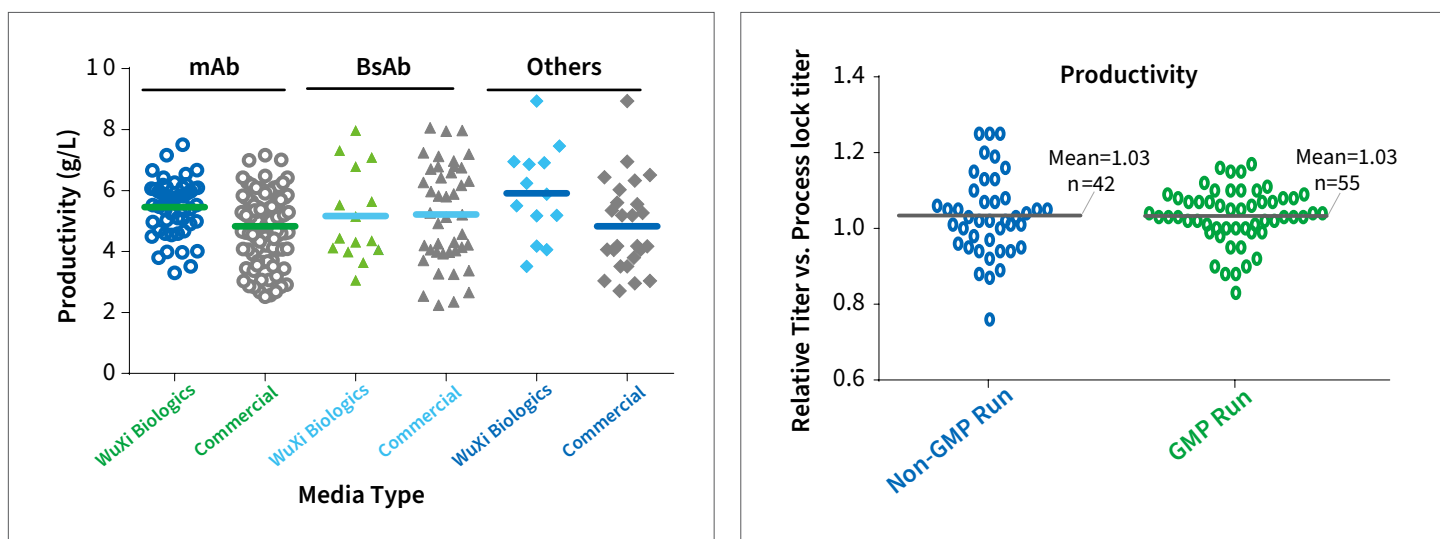


Figure 4: A comparison of WuXi Biologics' high-performance media versus commercial media for cell line development demonstrates a productivity advantage (left). The in-house media consistently delivers high titers across GMP and non-GMP runs for reliable performance at any scale (right).

extends up to $6 \times 2,000$ L or $3 \times 4,000$ L. This flexibility facilitates the transition from early-stage development to large-scale commercial production. Both run types demonstrate consistent productivity and robust process performance, ensuring reliability across various manufacturing scales (Table 2, Figure 4).

Cost-Effective Resin Management

Sourcing cost-effective resins can significantly reduce

downstream purification costs without sacrificing performance. Strategic supplier partnerships, bulk procurement, and advanced resin recycling protocols ensure cost savings while maintaining a 99.8% purification success rate.

WuXi Biologics' expertise in resin selection has identified cost-effective options for each purification step (Table 3). In addition to reducing expenses, the resins have supported more than 90 IND filings.

Stage	Resin	Normalized Catalog Price (%) ^a
Affinity chromatography	Brand A	100 (baseline)
	Brand B	119
	Cost-effective brand C	48
	Cost-effective brand D	47
Anion exchange chromatography	Brand E	100 (baseline)
	Brand F	89
	Cost-effective brand G	57
Cation exchange chromatography	Brand H	100
	Brand I	111
	Cost-effective brand J	44

^a Estimated

Table 3. Cost comparison of commercial resins

Supply Chain Resilience

A fragmented supply chain increases risk and cost. By relying on a single supplier or regional production sites, manufacturers can expose programs to material shortages and pricing volatility. WuXi Biologics proactively mitigates these risks with a global network spanning the US, Germany, Ireland, Singapore, and China. Our large global footprint unlocks several advantages:

- Dual sourcing for critical raw materials reduces dependency on single suppliers.
- Regionalized production strategies leverage cost efficiencies in labor and logistics.
- Supply continuity minimizes the risk of the production pauses that drive up COGS.

Conclusion

Traditional COGS reduction methods fall short because they take a fragmented approach that cannot address systemic inefficiencies. WuXi Biologics has redefined cost management in biologic manufacturing by integrating cutting-edge technology, comprehensive process optimization, calculated material selection, and supply chain resilience into a single, streamlined strategy that reduces COGS, speeds time-to-market, and improves commercial viability for biologics developers.

With a proven track record of successful cost optimizations across hundreds of projects plus ESG, WuXi Biologics is well-positioned to help clients navigate the challenges of biologics manufacturing, delivering cost savings that are both substantial and sustainable.

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About WuXi Biologics

WuXi Biologics is a leading contract research, development, and manufacturing organization (CRDMO) that provides end-to-end capabilities to healthcare organizations worldwide. With operations in China, the United States, Ireland, Germany, and Singapore, we enable our partners to effectively and efficiently bring biologics and vaccines to patients worldwide through our comprehensive and high-quality drug development model.

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