Advanced Therapies CDMO

Manufacturing Advanced Therapies to Reach More Patients.

Investing in technology to lower costs.

The science of cell and gene therapy has moved fast. The manufacturing economics haven't kept pace. At ElevateBio, we're making sustained investments in automation, digital systems, and process standardization to change that — and building the facility designed to prove it's possible at scale.

The Challenge

Cell Therapy Manufacturing Costs Have to Come Down.

Today's autologous cell therapy manufacturing relies on labor-intensive, largely manual processes that produce small, variable batches at high cost. Automation and industrial-scale process design are the clearest path to getting there.

Source: ARM Advanced Manufacturing Whitepaper

$100K–$290K
Estimated COGS per autologous CAR-T batch today.

Automation is projected to drive this **below $40K**.

Our Approach

Technology Investment as a Permanent Operating Principle

At ElevateBio, we can translate and improve your process based on industry-leading expertise. We invest continuously in automation, analytics, and digital manufacturing so partners can benefit from those advances. Partners decide how far to go. We make sure the options are there.

Automation, Actively Deployed

Supporting a breadth of advanced therapies requires selecting the best technology for each program. Closed and automated platforms are evaluated and selected based on individual program needs. For example, our partnership with Sartorius on the Eveo Cell Therapy Platform is designed to increase scale and throughput of CAR-T therapies.

Digital Manufacturing Infrastructure

Electronic batch records, MES, and LIMS are fully integrated to improve right-first-time performance and shorten release cycles, while providing partners real-time visibility into their product disposition.

Science, Manufacturing, and Quality — ONE TEAM

Process development, manufacturing, analytics, and quality operate within the same organization. Quality by design is built into the process from the start, not added at release. That means knowing what a product needs to look like before a batch begins.

Built To Scale With You

Your Program. One Partner. From IND to Commercial Supply

Processes are designed with commercial scale in mind from day one. Efficiency gains made during development carry into manufacturing — because reaching more patients requires bringing costs down, not just keeping them stable. Partners stay within the same facility network from IND through BLA filing and commercial supply.

IN 2025

98%+	10	40+
manufacturing batch success rate	tech transfers completed or initiated	QC release methods in-house

Modalities

Across the Advanced Therapies Landscape

CAR-T / TCR-T · Allogeneic Cell Therapy · Lentiviral Vector · AAV · mRNA · Engineered T & B Cells · HSC / iPSC · In Vivo Gene Therapy

Expanding Manufacturing Network · PITTSBURGH, PA

A Facility Designed to Industrialize Cell Therapy

Our 125,000 sq ft Pittsburgh facility at Hazelwood Green is built for where manufacturing needs to go: modular automation-ready suites, a digital backbone, and supply chains built to lower cost of goods. First GMP batches estimated in 2027.

Technology and Scale. Delivering Better Outcomes.

ElevateBio has built and continues to invest in automation, digital systems, and process standardization to lower manufacturing costs for advanced therapies and to make manufacturing more reliable. Digital batch records, real-time process monitoring, and integrated quality systems improve manufacturing consistency and give partners direct visibility into their product.

That visibility changes what a manufacturing partnership feels like.

> **"Real-time visibility lets us focus on science rather than worrying about what's happening in the cleanroom."**
> — Partner feedback

ICMC™ CERTIFIED

Our Waltham facility is certified by the Initiative for Certification of Manufacturing Capabilities — a rigorous third-party audit covering viral gene delivery, non-viral gene delivery, and cell therapy manufacturing against U.S. and E.U. commercial-level evaluation standards.

Our Capabilities

Process Development & Tech Transfer

- Scalable process design built for commercial use from day one
- Dedicated tech transfer team: process engineering, MSAT, QC, supply chain
- PD and GMP run on aligned equipment — what works in development works in the GMP suite
- Emerging technology evaluation and closed system integration

Analytics & Release Testing

- 40+ in-house QC release methods
- Custom potency assay development (cell-based and molecular)
- NGS across all CGT modalities — amplicon results in under one week; NGS-based sterility testing in development
- Advanced assay data 2–4 weeks faster than industry standard

CGMP Manufacturing

- 98%+ batch success rate across cell therapy, viral vector, and mRNA
- Preclinical through commercial supply — cell therapy, LVV, AAV, mRNA
- Multiple dedicated suites for cell therapy, viral vector, and mRNA; digital-first manufacturing floor
- Electronic batch records, MES/LIMS — real-time process monitoring

Regulatory & Quality

- Regulatory team with direct experience taking programs through BLA
- CMC strategy coordinated with manufacturing from IND-enabling activities forward
- BLA Readiness Workshops for pivotal-stage programs
- FDA Six Systems Inspection Model — built for inspection readiness

Our Facilities

WALTHAM, MASSACHUSETTS

Flagship Facility

140,000 sq ft

Our flagship cGMP and process development center supporting cell therapy, lentiviral vector, AAV, and mRNA — from early process development through clinical and commercial manufacturing.

PITTSBURGH, PENNSYLVANIA · IN DEVELOPMENT

Expansion Facility

125,000 sq ft

Designed from the ground up to industrialize cell therapy — modular automation-ready suites, a digital backbone, and supply chains built to lower cost of goods. First GMP batches estimated in 2027.

Start the Conversation →

Every program starts the same way — with a conversation about where you are and where you need to go.

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