Process Development & Tech Transfer

Your Process, Transferred Right.

Backed by the expertise and infrastructure to get your program to the clinic and keep it there.

The Challenge

Most Tech Transfer Problems Start Long Before the Suite.

Most tech transfer problems start earlier than the GMP floor: materials that can't survive inspection, unit operations that work in the lab but not at scale, or a handoff to operators following a batch record they never helped write. The result is repeat runs, deviations, and delays at exactly the moment a program can least afford it.

Common Transfer Failure Points

- Materials not qualified for GMP use
- Unit operations that don't scale cleanly
- Operators trained on steps, not scientific intent
- PD and GMP labs running different equipment
- Tech transfer handed to MSAT with no PD continuity

Our Approach

Scientists Who Own the Transfer. Not Just the Development.

At ElevateBio, the process development scientists who work through your process are the same people who lead your tech transfer. They design the batch records, train the operators, and stay engaged through manufacturing. That continuity is not common in this industry. We built the team around it.

> **"Half of our process development team is focused on tech transfer. Not as a side responsibility, but as their primary job. This is how we make sure the science doesn't get lost between development and the clinic."**
> — Jeff Cram, Vice President of Process Development, ElevateBio

Labs Built to Mirror the Suite

Our PD labs are a carbon copy of our cGMP manufacturing suites: same equipment, same setup. Operators train in PD and walk into the cleanroom without an adjustment period. What works in development works in the suite, because it's the same equipment.

Early Decisions Have Long Consequences

A bead that works in the lab. A wash step that recovers just enough cells to proceed. A unit operation with too many manual steps for the GMP suite. A material that isn't on a path to GMP grade. Early choices like these look fine until they don't, and by then the cost to change them is higher.

Innovation Is Available by Default

Our emerging technology team evaluates what's two to three years out: new automation platforms, novel cell processing equipment, and next-generation closed systems. We beta test with vendors before products reach the market. Unlike CDMOs with proprietary platforms, we have no incentive to push any particular technology. Our job is to know what's available and help you choose. Adoption is always your decision.

Your Process, Made Better

We maintain hands-on experience across the full range of commonly used cell therapy platforms. We can optimize your existing workflows or redesign them from scratch. Your choice. And we catch the upstream decisions that cause downstream problems: wrong materials, unscalable operations, container closure strategies that invite inspection risk later.

Built by People Who've Sat on Your Side of the Table

Our team has lived the sponsor reality: slow transfers, hidden failure modes, and decisions that quietly push timelines back. We know where programs lose time and money because we've watched it happen from the other side. We built this team to prevent it.

25+
tech transfers completed or initiated

98%+
batch success rate across all modalities in 2025

4
weeks to first training run for a therapeutics partner

What a Transfer Looks Like

No Two Transfers Run the Same Way. Here Is Ours.

Every engagement begins with knowledge transfer: our team works through your documentation, process history, and the scientific context that batch records alone don't capture. From there, we structure the work around your timeline and stage of development.

1 Observation & Demonstration Runs

Where feasible, we observe your process at your site before we touch it in ours. Then we run it in the PD lab. Issues surface in a non-GMP environment, where they're far cheaper to resolve.

2 GMP Equipment in Parallel

Suite readiness, equipment procurement, and qualification run in parallel with development work, compressing the timeline rather than sequencing it.

3 EBR & Batch Record Development

Batch records are developed by PD scientists who understand the process intent, not assembled after the fact by operators following instructions.

4 Transfer Closure

Analytical method transfer, aseptic process simulation, and engineering runs proceed against a defined closure target. Partners are welcome in our suites throughout — not watching from outside, but working alongside our team during engineering runs.

Partner Story

Accelerating a Novel Modality Under an Urgent Timeline.

A leading gene therapy company needed a manufacturing partner for an investigational base editing therapy. The program required expertise in a novel modality, under an urgent timeline, without compromising quality. They turned to ElevateBio.

ElevateBio's process development, science and technology, and analytical teams completed the transfer ahead of schedule. The first training run was done within four weeks. Engineering runs began shortly after. Patient doses were supplied for a Phase 1/2 clinical trial.

> **"ElevateBio didn't just manufacture our therapy — they helped us establish a blueprint for base editing manufacturing."**
> — President, clinical-stage biotech

What a partnership with ElevateBio looks like in practice:

- Your process led by experienced process scientists, from first run through manufacturing
- A transfer timeline built around your program, not a fixed template
- Real-time visibility into your program — your team integrated into our systems and welcome in our labs and suites
- Access to emerging technology your team doesn't have bandwidth to evaluate, with no pressure to adopt it
- Experienced across CAR-T, TCR-T, Treg, TIL, NK, iPSC, HSC, lentiviral vector, AAV, and mRNA

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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