

ENGINEERING INTELLIGENCE INTO CELL THERAPY

TOGETHER WE ENGINEER BREAKTHROUGH THERAPIES FOR PATIENTS IN NEED.

GeneFab is a Contract Development, and Manufacturing Organization (CDMO) dedicated to Cell and Gene Therapies. We partner with innovators to confidently design, manufacture, and commercialize the next generation of advanced medicines — from synthetic biology to commercial supply.



SynBio Genetic Design



Viral Vector



Ex Vivo Cell Therapy



In Vivo Gene Therapy



GMP Cell Banking

CURRENT CAPABILITIES

- Ex vivo cell therapy (autologous & allogeneic)
- In vivo gene therapy (viral vector)
- Synthetic biology & ML-guided design
- Technology transfer & gap assessment
- Process development
- Analytical & assay development
- Method validation & qualification
- Pilot to commercial scale
- GMP cell banking & storage
- In-house cGMP lot release & stability
- Sterile fill-finish (vials & bags)

PRODUCT TYPES

- **Allogeneic & autologous cell therapies** — suspension and adherent cell types: T-cells, CAR-T, Tregs, TILs, NK cells, CAR-NK cells, MSCs, HSCs, and iPSCs
- **Gene therapy** — lentivirus and gamma-retrovirus
- **Synthetic gene control** — validated cell-type specific promoters and drug-induced switches

ABOUT GENEFAB

GeneFab is a co-development partner for cell and gene therapy innovators—not a transactional vendor. Our team brings firsthand experience from the innovator side, applying hard-earned insights across every program. We stay with you from discovery through commercial supply, preserving continuity of expertise, teams, and processes under one roof.

At the intersection of **genetic design** and clinical manufacturing.

8+ yrs

CGT DRUG PRODUCT
DEVELOPMENT

75+

GMP LOTS
MANUFACTURED

100k+

SQ FT EXPANDABLE
FOOTPRINT

~80

CGT EXPERTS ON STAFF

MODALITIES WE DEVELOP & MANUFACTURE

From autologous CAR-T to allogeneic NK to in vivo gene therapy — one integrated CDMO.

GeneFab's platforms are designed to support the full breadth of cell and gene therapies. We optimize process development and execute manufacturing with consistent, end-to-end teams from discovery to commercial production.

AUTOLOGOUS

Patient-derived cell therapies

- CAR-T & TCR-T (CD3+)
- Tumor-infiltrating lymphocytes (TILs)
- Personalized starting material → manufactured drug product
- End-to-end isolation, transduction, expansion, fill & cryo

ALLOGENEIC

Off-the-shelf cell therapies

- Allogeneic CAR-T & TCR-T
- CAR-NK and engineered NK (CD56+)
- Regulatory T-cells (Tregs) for autoimmune & tolerance
- Donor- and iPSC-derived starting material, scalable supply

CELL THERAPIES

High-potency, scalable, donor-independent

- CAR-T & -NK with cryopreservation validated for post-thaw activity
- In-vivo activity demonstrated in AML mouse models
- G-Rex, WAVE, and Vertical-Wheel expansion platforms

IN VIVO THERAPIES

Viral vector platforms

- Lentivirus & gamma-retrovirus, adherent and suspension
- Lentiviral & AAV vector development and supply for in-vivo gene therapy
- Transient production or stable producer cell lines
- 1.5 L IND-enabling to 200 L GMP

ENGINEERED CELL LINES

iPSC, stable producers & cell banks

- Engineering, Master, and Working cell banks
- Adherent and suspension scale-up to batch needs
- Stable producer line generation for vector supply
- X-Rad 320 irradiator for qualified feeder cells

FILL-FINISH

Drug product configurations

- Crystal M1 vial filler & bag filling
- Closed and functionally-closed assemblies
- Controlled-rate freezing and LN₂ storage
- COI / COC controls integrated end-to-end

THE SYN BIO ADVANTAGE

Begin with the end in mind.

Decisions made at the bench determine what is possible at commercial scale. Our SynBio Center of Excellence brings synthetic-biology expertise, ML-guided analysis, and high-throughput screening to your program early — pressure-testing your design for manufacturability, potency, and scale so it transfers to GMP cleanly, instead of being patched in later.

Cell-specific promoters

We help optimize promoter strategies that restrict transgene expression to target lineages — supporting therapeutic index while keeping the process manufacturable.

ML-guided design screening

High-throughput screening of regulatory elements, payloads, and pseudotypes to identify the most robust, manufacturable candidates before tech transfer.

Molecular switches

Characterizing inducible, drug-responsive, and kill-switch elements for tunable potency and built-in safety — de-risked early for GMP.

SynBio → GMP continuity

The same partner from early design through commercial supply — choices pressure-tested for manufacturing mean shorter handoffs and fewer surprises at scale.

PROCESS DEVELOPMENT

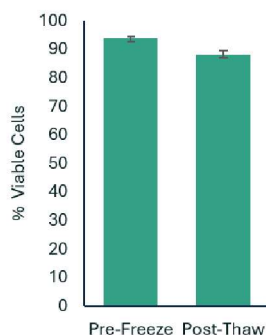
Eliminating bottlenecks in the CGT lifecycle

Optimization for successful cGMP manufacturing & scale

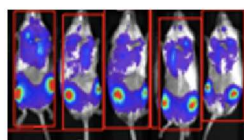
Over 4,000 CGT therapies are in development and the industry expects a 1,000× increase in demand in the years ahead. GeneFab's Innovator-Centered Manufacturing Center is built to accelerate speed to clinic — reaching GMP runs in roughly seven months from initiation (4 months to engineering run, 3 to GMP) and converting early programs into high-volume, high-quality commercial supply.

Cell Therapy Development	Vector Development
Primary cell expansion to >1,000 fold across G-Rex, WAVE/Xuri, and PBS vertical-wheel platforms	High-titer, highly purified vector meeting regulatory standards for purity
Established processes for high recovery of cells with known cryopreservation challenges	Adherent (2L–20L) and suspension (1.5L–200L GMP) enveloped vector platforms
Scale-down models for process characterization & optimization for GMP	Transient production of GOI or custom stable producer cell lines
Increased throughput of cell isolation, selection, and enrichment technology	Multiple envelope pseudotype options for ex vivo cell modification

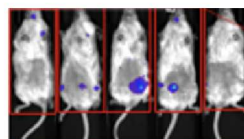
Optimized cell cryopreservation



CAR-NK cell viability retained post-thaw in vitro



Vehicle



Post-Thaw CAR NK

In vivo activity of CAR-NK cells in AML mouse model (10 days after single dose)

Function preserved through thaw

CAR-NK cells retain viability and potent anti-tumor activity after thaw — confirming function is preserved through cryopreservation. Our processes deliver **high recovery** even for cells with known cryopreservation challenges, with post-thaw potency built into release testing.

QUALITY CONTROL

Examples of qualified release assays

Extensive on-site QC labs and qualified outsourced partners support a full panel of established cell and gene therapy assays. GeneFab has qualified >20 in-house analytics, reducing the need for method development and qualification on your IND timeline.

Cell Therapy Drug Product Release Assays		
Category	Assay	Method
Safety	Replication competent virus	Cell-based assay
	Sterility / Rapid sterility	USP <71> / BacT
	Endotoxin	USP <85>, EP 2.6.14
	Mycoplasma	Compendial / qPCR
	Adventitious agents	qPCR
	Human viruses panel	qPCR
	Vector copy number	dPCR
Identity	Transgene ID	dPCR
	Phenotype (T, NK, Treg, Memory)	Flow cytometry
Purity	CD3+ / CD14+ / CD19+ residuals	Flow cytometry
	Residual feeder	dPCR
Potency	Cell count & viability	Cell counter
	Transduction efficiency	Flow cytometry
	Cytokine production	ELISA / Luminex
	Cytotoxicity	XCELLigence

Gene Therapy & Vector Release Assays		
Category	Assay	Method
Safety	Replication competent virus	Cell-based assay
	Sterility	USP <71>
	Endotoxin	USP <85>, EP 2.6.14
	Mycoplasma	Compendial / qPCR
	Adventitious agents	qPCR
	Human viruses panel	qPCR
Identity	Transgene protein expression	ELISA / Western
	Molecular identity	dPCR
Purity	Residual host cell DNA	ddPCR
	Residual HCP / BSA	ELISA
	Residual plasmid / nuclease	ddPCR / ELISA
Potency	Transducing units (titer)	Cell-based, dPCR
	Capsid titer (p30)	ELISA

>99.5% aseptic processing track record

Across 75+ GMP cell therapy batches, 50+ PBMC/PBNC enrichments, 100+ media & buffer lots, and 20+ cell banking batches. Maintained by experienced manufacturing and MSAT teams on a unidirectional, fully qualified GMP floor.

A different quality philosophy

Right the first time — without fear to improve. Phase-appropriate quality and qualified methods ready from day one, so your program plugs into a system that's already moving.

INNOVATOR-FOCUSED CGMP MANUFACTURING

Cell & Gene Therapy GMP Operations

Capabilities overview

Established GMP equipment, protocols, and trained staff for end-to-end support

7 suites

FLEXIBLE CLEANROOMS

US ISO 7 / EU-B Grade Cleanrooms

CLASSIFICATION

42K → 92K

SQ FT, EXPANDABLE

South San Francisco, CA

SynBio R&D Center of Excellence — genetic design, optimization, and ML-driven screening that feed directly into our GMP programs.



Alameda, CA

Cell & Gene Therapy cGMP facility opened in 2023, purpose-built and designed to expand to 42,000 sq ft for commercial scale.



Seven Cleanroom Suites

Flexible suites designed to US ISO 7 and EU Grade B, with HVAC and airflow configurations that support both cell therapy and viral vector operations under one roof.



Unidirectional GMP Flow

Segregated material, personnel, waste, and equipment paths across drug substance, drug product, and starting materials — fully qualified and validated.

End-to-end cell therapy

Isolation, transduction, expansion, formulation, fill, and cryopreservation — autologous and allogeneic CAR/TCR-T, NK, Tregs, and TILs.

Viral vector scales

Adherent 2–20 L, suspension IND-enabling 1.5–5 L, and suspension GMP 50–200 L for LV, γRV, and AAV.

Cryopreservation & cold chain

CryoMed CRF controlled-rate freezing, validated post-thaw cell activity, and 2–8 / –20 / –80 °C / LN₂ storage on site.

Quality & partnership

FDA- and EU-aligned quality system, flexible partner agreements, and on-the-floor MSAT through every stage.

Stability studies

ICH and product-specific protocols — real-time, accelerated, and stress studies with OOT/OOS trending and shelf-life extension.

Stability sample storage

Qualified, temperature-mapped chambers from ambient to ultra-low, continuous monitoring, and full chain of custody.

A proven GMP track record

Cumulative through 2025 across cell therapy & engineering production

75+

Cell therapy GMP batches

50+

PBMC / PBNC enrichment batches

100+

Media & buffer GMP lots

20+

Cell banking & intermediate batches

>99.5%

Aseptic processing success rate

RAPID TECHNOLOGY TRANSFER

Technical solutions for every stage of development

A proven, **risk-based** approach to tech transfer — leveraging integrated facilities, in-house qualified methods, and on-the-floor MSAT. Innovative therapies come with unknowns; we built the team and process to work through them with you. The result: **Right First Time** implementation, accelerated to the clinic.



~7 mo
 Start → cGMP (typical)

~16 wk
 Initiation → ENG run

≥99.5%
 Aseptic processing success

Knowledge transfer as a discipline
 Most transfers fail in translation, not at the bench. ~99% of out-of-spec results trace to a knowledge gap between teams — so we close those gaps together, structured and documented at every step.

Qualified methods, ready day one
 A library of qualified analytics and standard processes already running on cadence — your program plugs into infrastructure that's already moving, saving months of method development.

Built for our partners.

Patients are waiting. GeneFab was built to be the partner that makes that race winnable — not a vendor that executes from arm's length, but a co-development team that has lived on the innovator side of the table. Four things our partners say set us apart:

- 01 Co-development, not only execution.**
 We map your goals — yield, robustness, CQAs, COGS — and work backward into a study plan, with you in the room at every gate.
- 02 On your side of the table.**
 Many of us came from innovator-side companies — we know the urgency, runway pressure, and regulatory calendar firsthand.
- 03 One roof. One team.**
 SynBio, process, manufacturing, analytical, and quality are steps away — issues resolved in an afternoon, not a week of emails.
- 04 Transparent by design.**
 Real-time Gantt charts, data packages, and process information — building toward live-batch visibility on our floor.

LET'S WORK TOGETHER.

At the intersection of genetic design and clinical manufacturing — GeneFab partners with cell and gene therapy innovators to confidently design, manufacture, and commercialize advanced medicines for patients in need.

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