

We Make Your Science Manufacturable

The Translational Partner for Cell Therapy

NueCell Bio is a US-based translational partner for advanced cell therapies. We bridge discovery science and GMP manufacturing—designing, engineering, de-risking, and locking your cell therapy process for clean transfer. At the core of our approach is NueStack™, our library of proven, modular technology stacks configured to each program's complexity.

Built for the Space Between Discovery and GMP

● Manufacturing Readiness

Processes and analytics built on cGMP-equivalent materials, so tech transfer is a replicate exercise, not a reinvention

● Complex Cell Workflows

Early cell-source and engineering decisions built to scale from discovery to commercial manufacturing

● Cell Engineering

Reprogramming and gene-editing platforms matched to your biology, not chosen for convenience

● Risk Mitigation

Gap assessments and QbD-driven workflows de-risk the highest-cost decisions before clinical entry

● Differentiation & Tissue Engineering

Defined xeno-free 2D/3D differentiation; adherent and suspension formats matched to target scale

By the Numbers

26,300 ft²

Purpose-built
San Diego facility

5 years

Continuous ISO 9001
certification

40+

Projects delivered
to date

95%+

Right-first-time rate

20+

Scientific publications

Wide-Ranging Modality Expertise

Cell Types

- Primary (T, NK, Myeloid)
- Stem & progenitor (HSC, PSC, MSC)
- iPSC
- Specialized/differentiated

Architecture

- Autologous & allogeneic
- Adherent & suspension
- Scale-up & scale-out
- 2D-3D expansion

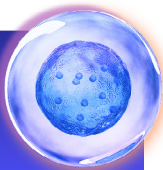
Engineering

- Reprogramming
- Gene editing (CRISPR, ZFN, TALEN)
- Viral & non-viral delivery
- Tissue engineering

Let's Bridge Your Science to GMP

From Early Feasibility Through GMP Technology Transfer

NueCell Bio provides the services and expertise to bridge discovery science and GMP manufacturing – designing, engineering, de-risking, and locking your cell therapy process for clean transfer. We integrate advanced technologies, including AI/ML-based decision tools, and automate where possible to improve quality and efficiency.



NueStack has facilitated **40+** programs with a **95% on-time delivery** track record.

Core Capabilities

Program Design & Feasibility

Cell Engineering, Reprogramming & Gene Editing

Manufacturing Process Design

Analytical Design & Development

Cell Banking & Characterization

Quality, Supply Chain & Logistics

GMP Preparation & Tech Transfer

NueStack

Pre-Built Stacks.
Expertly Assembled.

NueStack packages decades of team expertise for every program—a library of proven, modular technology stacks deployed across modalities and tailored to your program's scale, workflow, and target product profile. Pre-tested modules let you skip the riskiest months of process development, so your team starts on a solid foundation.

1

How NueStacks Work

Pre-Built Technology Stacks

Blood cells, iPSC, cell engineering, genome editing, cell banking, analytics

Expert Assembly

Right stacks for your modality, process tuned to your scale and goals

Your Bespoke Process

Faster (no blank-page penalty), lower risk (pre-tested stacks eliminate early unknowns), fully bespoke to your modality and clinical strategy

2

Behind Each Module: A Qualified Technology Stack

Every NueStack module is built from vetted technology layers, each already qualified on its own – reprogramming, gene editing, differentiation, core assays, advanced analytics, and genome analysis. Take reprogramming as an example:

GMP-compatible reagents, source-matched SOPs, in-process checkpoints (Day 7/14 colony counts, live TRA-1-60 staining), and a validated release panel for pluripotency, vector clearance, and identity.

3

Every module is:

Priced

Unit price and turnaround fixed at the layer level

Defined

Report, data package, and release criteria specified per layer

Configurable

Add, drop, or swap layers without re-scoping the program

Quotable in days

Selections roll directly into a costed program plan

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