Supporting Cell & Gene Therapy (CGT) Applications with Ancillary Materials (AMs)

At STEMCELL Technologies, we are committed to supporting your Cell & Gene Therapy (CGT) development and/or manufacturing process by supplying innovative ancillary materials (AMs). AMs are components used in manufacturing but not intended to be present in the final CGT product. Whether you're working in a small biotech, a large pharmaceutical company, or a contract development and manufacturing organization (CDMO), developing a robust AM strategy is critical to success as you enter the clinic and progress toward commercialization. However, developing such strategies can be challenging because of the lack of a standardized regulatory framework for AMs and the need to work closely with suppliers to meet your specific needs. When you choose STEMCELL's products to culture, maintain, and activate your cells, you're not just selecting the optimal media and reagents for your clinical applications, you're also gaining access to our expert support team who can facilitate your path forward to the clinic.

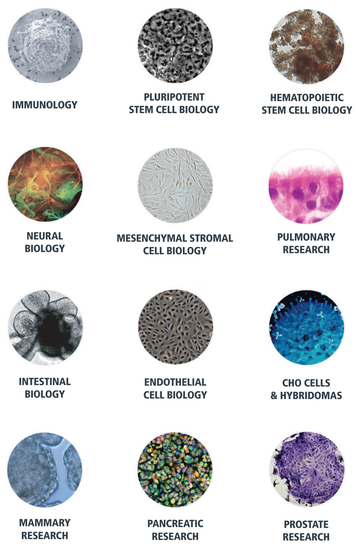
STEMCELL TECHNOLOGIES - A TRUSTED SUPPLIER OF ANCILLARY MATERIALS

> 2500 high-quality reagents, tools, and services for life science research and cell therapy development.

Our innovative products can be used as ancillary materials for applications of cell and gene therapy development and manufacturing.

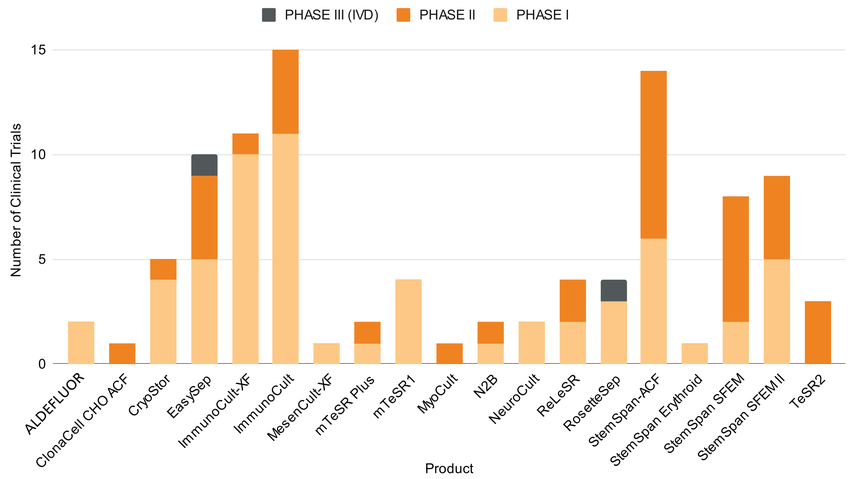
● STEMCELL Locations

Major Research Areas:



STEMCELL-SUPPORTED CLINICAL TRIALS

Both cGMP and non-cGMP products can be qualified as AMs for clinical use.



STEMCELL has a growing portfolio of cGMP-manufactured products; however, in some cases non-cGMP products may be the best fit for your workflow. Our dedicated Services for Cell Therapy Program is designed to identify custom solutions that enable the use of non-cGMP products in clinical trials.

Download Now

Flyer: Services for Cell Therapy by STEMCELL Technologies

cGMP MANUFACTURING CAPABILITIES: OUR COMMITMENT & WAY FORWARD

cGMP Manufacturing

- Compliant to relevant parts of 21 CFR 820 & 21 CFR 211
- Occupied building space including offices: 73,196 sqft
- 500 L batch capacities

cGMP Pipeline

We have an active cGMP pipeline that's driven by demand and unique client-specific scenarios

2006
First STEMCELL product used as an AM in a clinical trial

2016
Launched first cGMP cell isolation product - SepMate™

2017
Launched cGMP-manufactured media products for:
PSC Applications: mTeSR™1, mTeSR™ Plus, TeSR™-AOF, ReLeSR™, GCDR
HSC Applications: StemSpan™-AOF (bottles & bags)
Immune Cell Applications: ImmunoCult™-XF

2023
Expanding cGMP portfolio to further support **Immune Cell Applications**

Future / Priority

Cell therapy sponsors have unique challenges and product requirements, and to best support their needs, STEMCELL has developed an active cGMP pipeline. Clear two-way communication will ensure alignment between your timelines and STEMCELL's cGMP pipeline.

STEMCELL'S APPROACH TO SUPPORTING CGT APPLICATIONS

To best tailor solutions to the particular needs of cell therapy sponsors, STEMCELL takes a customized approach by identifying custom solutions based on unique material qualification criteria. Below are examples of custom manufacturing and testing services provided through our Services for Cell Therapy Program.

Custom Quality Services

Quality Measure	Description
Raw Material Release	Primary inspection performed by raw material receivers
	Secondary inspection (verification of supplier documentation and testing regime defined in 21 CFR 211) performed by the QC Raw Materials team
Environmental Monitoring	Dynamic environmental monitoring performed during batch production
Product Contact Materials	Single-use product contact materials and dedicated glassware used for product manufacture
Filter Integrity Testing	Filter integrity testing performed post-use following bubble point or diffusive flow methods
Personnel	STEMCELL Quality Assurance (QA) Person-in-Plant oversees production
Enhanced Batch Record	Increased documentation and verification of manufacturing steps
Additional Validated QC Testing	Sterility <USP 71>
	Endotoxin Testing <USP 85>
	Mycoplasma Testing <USP 63>

Summary

STEMCELL Technologies is committed to supporting your company's vision to create groundbreaking therapies for patients living with cancer and other diseases. Contact your local representative to learn more and initiate discussions related to your unique project.

Get in Contact

Developing Cell and Gene Therapies? We're Here to Help—Ask Us How!

STEMCELL™ TECHNOLOGIES

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