SERVICES FOR CELL THERAPY BY STEMCELL TECHNOLOGIES

Supporting Your Clinical Vision

Whether you're working in a small biotech, a large pharmaceutical company, or a contract development and manufacturing organization (CDMO), developing a robust ancillary material (also known as raw material) 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 ancillary materials and the need to work closely with suppliers to meet your specific needs. At STEMCELL Technologies, we are committed to supporting your company's vision to create groundbreaking cell and gene therapies for patients living with cancer and other diseases. That's why we created our **Services for Cell Therapy Program**, a team of specialists that can work with you as a reliable partner from the clinical process development stage to commercialization. Through the Services for Cell Therapy Program, STEMCELL has enabled the use of a wide range of our products as ancillary materials in many active clinical trials across a broad range of applications and indications.

After working with you to gain a detailed understanding of your clinical timelines and requirements, your STEMCELL sales representative will introduce you to a Services for Cell Therapy Program manager, who can support the qualification of our products as ancillary materials and provide customized solutions to meet your specific clinical needs, including:

- Letters of Authorization (LoA) to reference FDA Master Files for GMP products
- Custom quality services, including enhanced manufacturing and QC testing controls **(Table 1)**
- Custom product modifications (e.g. formulations, packaging, dedicated manufacturing runs)
- Quality and Supply Agreements

Table 1. Examples of Custom Manufacturing and Testing Services Provided by the 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) 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>

Request a complete menu of STEMCELL's custom solutions by contacting **custom.services@stemcell.com.**

STEMCELL has a growing portfolio of GMP products; however, in some cases non-GMP products may be the best fit for your workflow. The Services for Cell Therapy team can work with you to identify custom solutions to enable the use of non-GMP products in clinical trials, as illustrated in the case study below.

Customer Case Study

Recently, a TCR-T cell therapy developer was preparing an Investigational New Drug (IND) application for a cell therapy product manufactured using one of STEMCELL's non-GMP immune cell expansion media. By following a stringent ancillary material qualification process, the developer identified additional quality and regulatory requirements for the medium. Specifically, they determined that the product formulation would need to be shared with their FDA reviewer, and that a human-origin raw material in the product formulation must be sourced according to 21 CFR 640.

The developer was put in touch with a Services for Cell Therapy Program manager, who worked across STEMCELL departments to deliver the required solutions:

1. An abridged FDA Master File for the T cell expansion medium was put in place for the sponsor to reference.
2. Custom product manufacturing runs were arranged using specific raw materials sourced in accordance with 21 CFR 640.

Through the sponsor's proactive risk assessment and support from the Services for Cell Therapy Program, their IND was cleared by the FDA with no further information required, with several subsequent INDs also gaining clearance.

> "During a recent IND submission, we were challenged with a fast-approaching deadline. Our solution-oriented program manager helped us navigate the complex regulatory requirements to support us through our clinical journey by providing quality documentation and customized reagents for use in our clinical trial. By leveraging STEMCELL's global experience and knowledge, we were able to meet our regulatory commitments and achieve a successful IND filing."
>
> **Senior Manager,**
> **External Manufacturing at a biotechnology company developing TCR-T cell therapies**

To learn more about STEMCELL's Services for Cell Therapy Program and how it can support your project, speak with your sales representative or contact **custom.services@stemcell.com**.

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Finding products that meet both the needs of researchers and the requirements for cell therapy applications can be challenging. That's why it's crucial to have the right support to help you through all stages of your research. Try our products in your own lab—we offer a range of high-compliance cell culture media and reagents for your cell therapy research.

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