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.

Table 1. Custom Manufacturing and Testing Services Provided by the Services for Cell Therapy Program

STEMCELL Custom Solutions		
Manufacturing	STEMCELL can accommodate additional manufacturing controls based on your requirements. Please inquire for details.	Examples of manufacturing solutions include: • Modified formulations (e.g removal of phenol red or use of select raw materials with a favorable viral safety profile) • Custom labeling and packaging (including custom formats)
Quality Control (QC)	QC testing (performed according to STEMCELL's standard assays)	• Appearance, pH, osmolality, sterility, performance testing
	Additional QC-validated testing options (may be conducted internally or at an external testing lab)	• Sterility <USP 71> • Endotoxin testing <USP 85> • Mycoplasma testing <USP 63>
	Product-specific quality and traceability documentation	• Certificates of Origin (to the secondary raw material level) • Certificates of Analysis • BSE/TSE risk statements
Quality/Regulatory	Quality system information and compliance support	• Quality questionnaires • Vendor audits • Quality and regulatory discussions
Agreements	Clinical-related agreements	• Confidential Disclosure Agreement • Master Service/Supply Agreement • Quality Agreement, including Change Notification
Shipping	Temperature data loggers	

To learn more about our services or discuss how we can support your project, contact **custom.services@stemcell.com.**

Customer Case Study: Custom Solutions

The Services for Cell Therapy team can work with you to devise custom solutions that enable the use of non-GMP products in clinical trials, as illustrated by this 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 we can support your project, speak with your sales representative or contact **custom.services@stemcell.com**.

Learn More

www.stemcell.com/cell-therapy-services

Try Products That Support Your Cell Therapy Development

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 clinical applications.

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