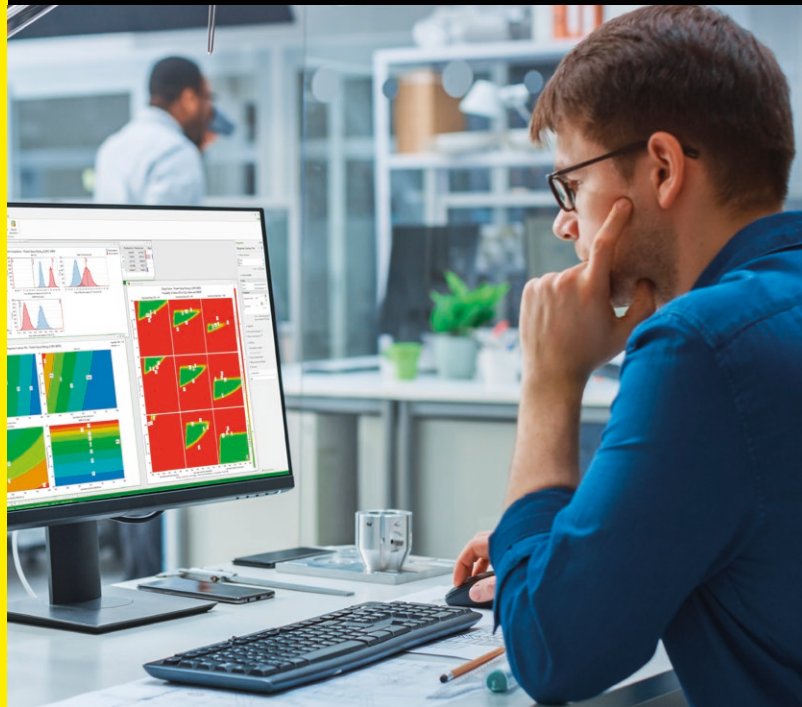


Process Development Service for Advanced Therapies

Process Development & Clinical Production Service for the Next Generation of Innovative Therapeutics



Product Information

Process Development Service

In the rapidly evolving landscape of emerging and novel therapies, the journey from concept to market can be potentially delayed by various challenges, including process variability, poor scalability, high costs, and complex regulatory demands. Navigating these complexities requires both innovative technologies and deep expertise in process development.

Our process development service for advanced therapies are designed to provide you with the tools, knowledge, and support necessary to bring your groundbreaking therapies to fruition.

Clinical GMP Production Services

Clinical GMP Production in the Emerging therapy and Novel Modality space faces challenges such as complex processes, scalability issues, and stringent regulatory requirements. Ensuring quality and managing specialized supply chains add to the difficulty, alongside high costs and a shortage of skilled professionals. Access to advanced technology is essential but costly, and the time-intensive nature of development can delay availability. Patient-specific customization further complicates manufacturing. By partnering with Sartorius, you are working with a partner to simplify your path to clinic, addressing these challenges through innovation, collaboration, and investment in technology and talent.

Features and Benefits

- Leverage four process development & two clinical GMP production suites tailored to Advanced Therapies.
- Benefit from direct access to process experts and the latest innovative technologies
- De-risk your process with access to our extensive and reliable portfolio, including cutting edge technology and critical raw materials .
- Gain in-depth process knowledge enabled by our state-of-the-art bioanalytics and AI/ML-driven data analytics tools.

Introduction

Relevant Applications

- **Immune Cells** – CAR-T, Natural Killer (NK) cells and tumor-infiltrating lymphocytes (TILs)
- **Stem Cells** – Mesenchymal stem cells (MSCs) and induced pluripotent stem cells (iPSCs)
- **Gene Therapy** – Adeno-associated virus (AAV) and lentivirus (LV)
- **ExtraCellular Vesicles** – MSC- and iPSC-derived

Relevant Process Steps

- Proof of concept
- Upstream process development
- Downstream process development
- Analytical development & validation
- Formulation | fill finish

Benefits of Our Process Development Service for Advanced Therapies

Our process development service combine direct access to innovative technologies, process development expertise, and the comprehensive Sartorius portfolio. Leveraging such a comprehensive service simplifies your path to the clinic, reduces time to market and risk, and provides the necessary data package to support your journey.

Expert Support

We understand that developing the next generation of therapies requires continuous innovation and flexibility. Our team of experts will ensure that you benefit from cutting-edge solutions tailored to meet your specific needs, which could include advanced bioprocessing equipment, analytical tools, novel production techniques, continuous processing, and process automation.

Our process development expertise is built on years of experience and a deep understanding of the unique challenges associated with emerging therapies. Our specialists work closely with you to design, develop, and refine processes that are reproducible, scalable, and compliant with regulatory standards. This collaborative approach ensures that your therapy is developed efficiently and effectively, minimizing risks and accelerating time to market.

Comprehensive Solutions for Risk Mitigation: A Proven Portfolio for Advanced Therapies

Developing an advanced therapy is inherently risky, but comprehensive support throughout the development lifecycle and a proven portfolio of products and services forms an effective risk mitigation strategy.

Our portfolio includes a wide range of bioprocessing solutions, such as scalable bioreactors, cell culture media and other critical raw materials, filtration systems, cell analysis tools, purification systems and membranes, single-use technologies, automation and digital solutions.

Strong Data Package

A strong data package not only supports regulatory submissions but also provides valuable insights into the performance and scalability of your process. Our Development Service for Advanced Therapies is designed to deliver comprehensive data packages that demonstrate the robustness and reproducibility of your processes.

We employ advanced data analytics and process monitoring techniques to generate detailed datasets that cover all aspects of process performance. This data-driven approach ensures that you have the evidence needed to support your therapy's safety, efficacy, and manufacturability.

*With future offering including RNA, LNP's & Automated novel process platforms.

Technical Specifications

Modalities	Immune Cells	Stem Cells	Gene & Gene Modified Therapy		EV's
	Car-T (auto & allo), NK, Tils	iPSC's & MSC's	AAV, rAAV, LV,	RNA, LNP's	MSC or iPSC derived
Proof of Concept	■	■	■	■	■
Upstream Process Development & Clinical Manufacturing					
Media Optimization	■	■	■	■	■
Process Optimization (fed batch perfusion) (2D to 3D & differentiation)	■	■	■	■	■
Scale Up & Scale Down Models	■	■	■	■	■
Harvest Optimization	■	■	■	■	■
Downstream Process Development & Clinical Manufacturing					
Chromatography	-	-	■	■	■
Virus Inactivation	-	-	■	■	■
UltraFiltration/Diafiltration where applicable	■	■	■	■	■
Formulation Optimization	■	■	■	■	■
Analytical Development & Validation	■	■	■	■	■

State-of-the-Art Facilities in Key Biotechnology Hubs: Comprehensive Support for Your Development Needs

- 12,200 sq. ft.
- EU Annex 1 Grade B and ISO Class 5 cleanrooms
- Four process development suites
- Two clinical GMP production suites
- Process development and clinical production support
- Quality and regulatory support

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