

## Solutions for cell & gene therapy manufacturing

### Empowering cell and gene therapies to deliver life saving treatments

Activated T-cell therapies, such as CAR-T, TCR-T and gene therapies, are offering transformative outcomes for diseases. Recent CAR-T approvals and the growing number of clinical trials for these treatments are accelerating the process from discovery through clinical to commercial manufacturing and delivery.

As a trusted supplier for the top 20 biopharmaceutical companies, the expertise and capabilities Avantor® offers are focused on solving the complexities of this evolving landscape. Our high purity production chemicals, sterile fluid transfer systems, cell culture components and excipient technologies can help advance the scalability and manufacturability of viral vector production to cell and gene therapies, helping you bring life saving new cell therapy products to market, safely and effectively.

#### **QUALITY AND REGULATORY EXPERTISE**

Manufacturing these therapies is complex: GMP-compliant materials at small scales and small packages, novel processes, improved and new facility designs, innovative logistics and smart delivery systems are all necessary. We understand the industry's needs, as well as the quality and regulatory requirements.

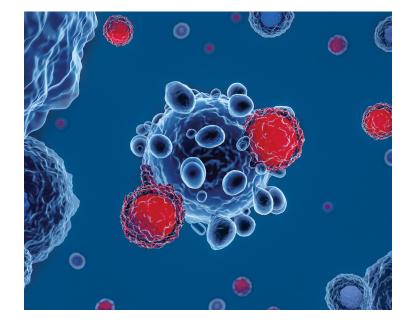
#### Supply chain risk management

Cleanroom management

- Certified to ISO Class 5 and 7 environments
- Microbial environmental monitoring

#### Sterility validation

- Compliant to ANSI/AAMI/ISO 11137 (VDmax25)
- Sterile barrier packaging validation



Lot release testing

- Endotoxin testing (USP 85) and particulate testing (USP 788)
- Full compendia testing

### Quality risk management

- Quality metrics monitoring and reporting
- Supplier evaluation and monitoring
- Business continuity planning
- Redundant manufacturing sites

Quality documentation system

# Scalable workflow solutions and unmatched choice

We provide compliant materials in scalable formats and single-use solutions for viral vector, CAR-T and gene therapies manufacturing, that help reduce contamination risk, improve resource efficiency and lower labour and energy costs. These include:

- Plasmid DNA production products
- Cell culture media and sera
- Plasmid transfection and T-cell transduction reagents
- Expansion and purification chemicals
- High purity and excipients
- Single-use fluid connectivity, sampling and sterile transfer

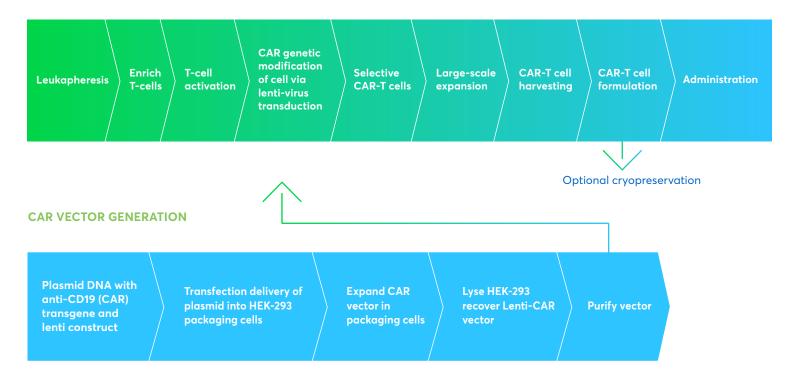
Avantor is the only open-architecture provider to offer complete design, consultative engineering services, manufacturing and logistics support to help create single-use workflows that meet the needs of your cell therapy processes. Through our global channel, VWR, part of Avantor, you can also access a range of products, services and solutions from other industry-leading brands to supplement your development and manufacturing:

- Equipment

- Life science reagents and consumables
- Critical environmental and safety products
- Tailored services

In addition, Avantor has a complete line of products suitable for viral vector and gene therapy manufacturing. Customisation for your evolving needs—including tailored products, specifications and packaging—is offered through our product development team. Contact your Avantor account manager to learn more.

#### **CAR-T CELL WORKFLOW**



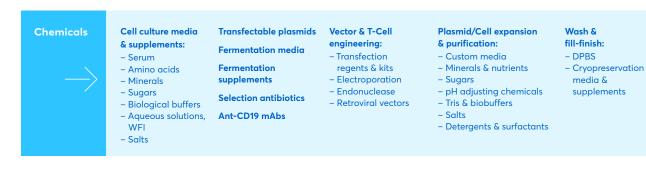
#### **CUSTOMER-SPECIFIC INNOVATIONS**

Avantor can work with you to design innovative solutions that solve your process challenges, such as:

- Customised single-use solutions—custom-designed, smallvolume (0,5 mL) closed-system sampling and transfer of sterile reagents to help ensure zero volume loss and greatly reduce contamination risks
- Custom-packaged buffers and excipients, and tailored combinations of these materials, pre-packaged at specified volumes and ready to use in your process
- Customised formats for media, sterile solutions, excipients and preservation reagents to help optimize processes and reduce costs



#### AVANTOR BIOPHARMA PRODUCTION CORE OFFERING Chemicals and single-use technology for CAR-T production workflow



#### **CAR-T** excipients:

- D-Glucose – NaCl – Plasmalyte
- . Fidshid

Single-use products

#### Aseptic fluid transfer:

- Standard products
- Customised products
- Integrated sensorsFiltration, TFF
- Flitration, TFF - Speciliased connectors
- Tubing management

- Final fill & delivery:
- Innovative delivery systemsSingle-use filling lines
- with needles
- Isolator multi-tube filling assemblies
- Pass-through manifolds

When you need an experienced, trusted partner to accelerate the commercial manufacturing of your cell therapies, choose Avantor. **Contact your sales representative today to learn more.** 

**Closed aseptic sampling:** 

- Conical tube sampling

- Syringe sample devices

- Sampling manifolds

- Micro sampling

Fluid collection

- Process bags

- BDS freeze bottles

- Collection bottles

- Closed transfer bottles

& storage:

Ready-to-use

reagents & buffers:

- Customised reagents &

bags and manifolds

buffers in ready-for-use



## Setting science in motion to create a better world

At Avantor<sup>®</sup> a new era has begun. From breakthrough discovery to agile delivery of advanced products and services across the globe, Avantor manufactures and distributes high-quality products, services and solutions to professionals in the life science and advanced technology industries.



VWR, part of Avantor provides an integrated, seamless purchasing experience optimised for your success.

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