

CELL AND GENE THERAPY

# YOUR CELL AND GENE THERAPY JOURNEY FROM DISCOVERY TO COMMERCIALIZATION

Connect with the solutions, capabilities,  
and guidance you need to advance  
your cell and gene therapies






# WE'VE GOT YOU COVERED

## FROM OFF-THE-SHELF TO CUSTOM SOLUTIONS

Whether you're a start-up, a growing biotech, or a global organization, progress in cell and gene therapy requires connections.

**Connections** between experts, colleagues, and partners who collaborate from early research and discovery through to clinical trials and commercialization.

And **connections** that can deliver your novel therapeutics to the people who need them.



**Thermo Fisher Scientific connects you with the technical expertise, regulatory guidance, and custom or off-the-shelf solutions you need to overcome obstacles, streamline processes and advance your cell and gene therapies.**



# YOUR LOYAL PARTNER

## FROM THE BENCH TO THE MARKET

No matter what your stage of research, development, or manufacture, our dedicated experts will connect you with the cutting-edge scalable solutions to meet your unique specifications across workflows, timelines, and locations.

Whether you're developing in-house capabilities or outsourcing all or part of your projects, we work with you as your reliable, full-service partner at every phase.



### **Innovation**

Quality solutions designed to give you speed and flexibility. Our innovative products are widely cited and leveraged in clinical trials and approved cell and gene therapies globally.



### **Collaboration**

Our scientists, manufacturing and regulatory professionals connect with you to provide the support you need. From lab setup to product selection, process development to documentation, and more.



### **Scalability**

Our scalable cGMP solutions and capabilities can grow with your work, giving you greater control and the freedom to plan ahead. Scale across the workflows and hit your milestones time and time again.



### **Proven solutions**

Connect to time- and cost-efficient technologies, over 30 years of cGMP manufacturing experience, a global supply chain, and a proven legacy of supporting our customers through clinical and commercial scale to take your novel therapeutic to market.



### **Acceleration**

With integrated end-to-end solutions and products that are designed with your commercial end point in mind you can help accelerate your timelines from discovery through commercial manufacturing.



### **Flexibility**

Continual investment in our cell and gene therapy product manufacturing and CDMO capacity, personnel, and reach means you can be agile. Whether you are manufacturing in-house or outsourcing, connect to a partner who can flex with you.



# RISK MITIGATION

## FROM REGULATORY COMPLIANCE TO SUPPLY CHAIN SUPPORT

Optimizing yields and improving consistency. Navigating quality controls and compliance. Scaling up and out from discovery to manufacturing within budget and timeframes. Mitigating risk. The research and development of your novel therapeutic is a journey filled with myriad moving parts and variables throughout.

Our flexible solutions can help scale with you as you grow and help accelerate your cGMP manufacturing, giving you greater control over your budgets and your processes. All the while, assisting you with regulatory compliance thanks to our traceability documentation and robust testing, essential for getting it right the first time.



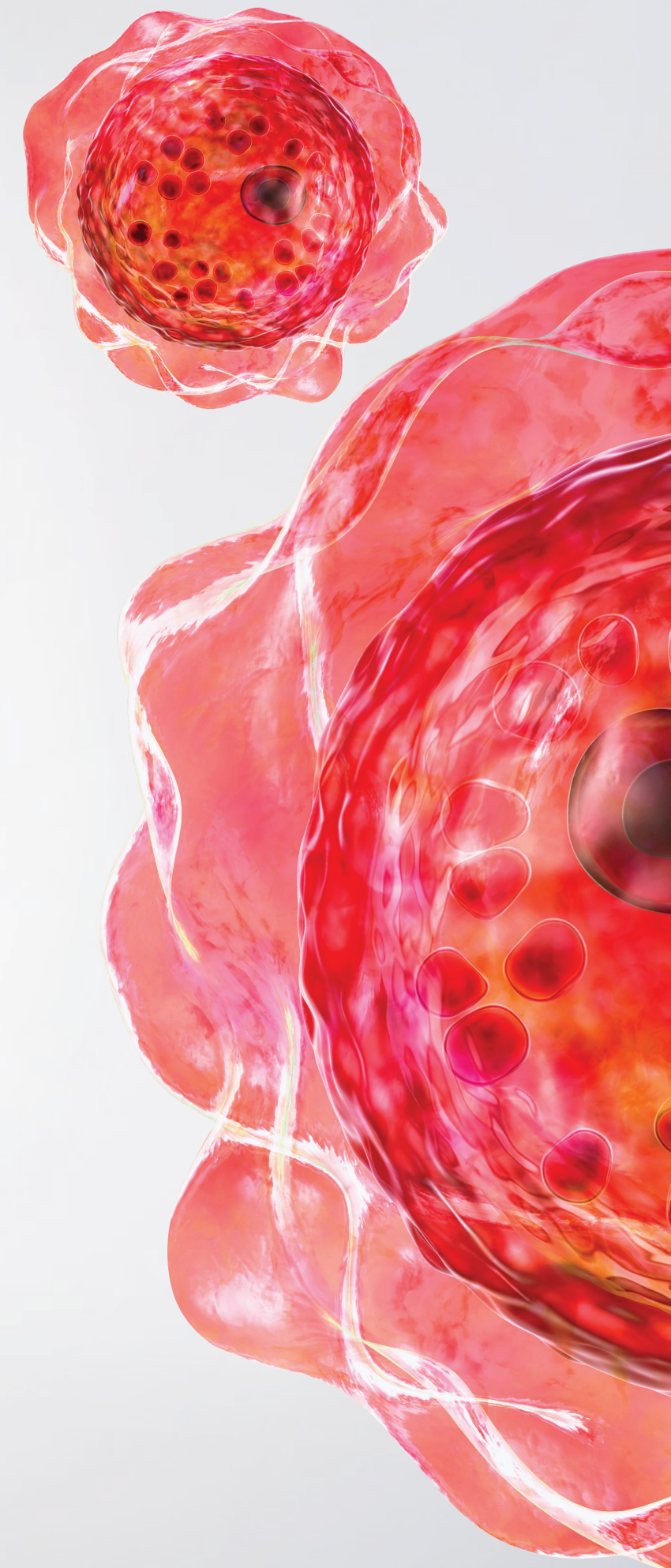
### GLOBAL cGMP SUPPLY CHAIN

Our ISO 13485-certified, FDA-registered manufacturing facilities play a critical role in delivering high-quality products, stable supply chain, and robust risk mitigation strategies.



### REGULATORY SUPPORT

Our products are designed to meet regulatory requirements to help you translate your therapeutic to clinical applications with extensive safety testing and traceability documentation to ease your regulatory burden.





# FROM CELL THERAPY RESEARCH TO cGMP MANUFACTURING

## WE'RE HERE TO SUPPORT YOU

To maximize the potential of our experiments and simplify the transition from basic cell therapy research to clinical manufacturing and beyond, we offer research-use products with complementary Gibco™ Cell Therapy Systems (CTS™) formulations. CTS reagents, consumables, and instrumentation are designed to work together to help streamline the transition to manufacturing and address production workflow challenges.

CTS ancillary materials are designed for cell therapy research through commercial use, are cGMP manufactured, and follow USP <1043> and Ph Eur 5.2.12 guidelines, making them the proven choice for clinical stem cell and immunotherapy. They have been used in:

- **Over 200 clinical trials**
- **FDA-approved and EMA-approved CAR T therapies**
- **The first FDA-approved therapeutic cancer vaccine**

Together, we can build and strengthen the connections to craft solutions that scale and flex with you, from early planning and discovery to manufacturing and delivery.



### Immunotherapy solutions:

Specialized CTS products to isolate or activate and expand T cells, dendritic cells, or other immune cell types.



### Induced pluripotent stem cell therapy solutions:

Solutions to support your pluripotent stem cell therapy workflow, from reprogramming to culture.



### Mesenchymal stem cell therapy solutions:

Cell therapy research products to help you advance your mesenchymal cell therapies to the clinic.



### Neural cell therapy solutions:

Specialized cell therapy research products for stem cell- and tissue-derived neural cell cultures.







**CELL THERAPY  
WORKFLOW**  
INTEGRATED  
SOLUTIONS FROM  
COLLECTION TO  
DELIVERY



**Our range of solutions include:**

**Collection and tracking**

Apheresis  
Supply/cold chain logistics  
Documentation  
Chain of custody



**Cell isolation and engineering**

Cell isolation  
Closed, modular cell processing systems  
Bead-based cell isolation and activation  
Single-use platforms  
CRISPR and TALEN genome editing technologies  
Lentiviral production solutions  
Nonviral gene delivery



**Cell expansion**

Custom and catalog media  
Sera, sera-free and xeno-free reagents and supplements  
Closed modular cell processing systems  
Single-use technologies (SUTs), cell factory systems, bioreactors, incubators, and biosafety cabinets  
Specialized laboratory equipment  
Bioprocess automation and control platforms  
cGMP chemicals and process liquids



**Characterization and cryopreservation**

Identity, purity, and potency assays  
Contamination detection  
Residual process-related impurity quantitation  
Microbial safety  
Genomic, proteomic, and cellular analytical tools  
Cryopreservation solutions



**Supply chain and logistics**

Supply/cold chain logistics  
Clinical trial support  
Global distribution



# GENE THERAPY

## FROM SETUP TO SCALE-UP

As the efficacy and robustness of gene therapy treatments improve, the future therapeutic implications are almost limitless. And as new ways of delivering healthy genetic material to target cells are found, the potential to treat or prevent genetic diseases is extraordinary.

Together, we can help guide you efficiently and swiftly towards developing more accurate and more effective gene therapies the world over.

### Viral vectors for gene therapy

**Adeno-associated virus:** Connect to our industry-leading and scalable solutions for adeno-associated viral (AAV) vector development to help you throughout your AAV manufacturing process.

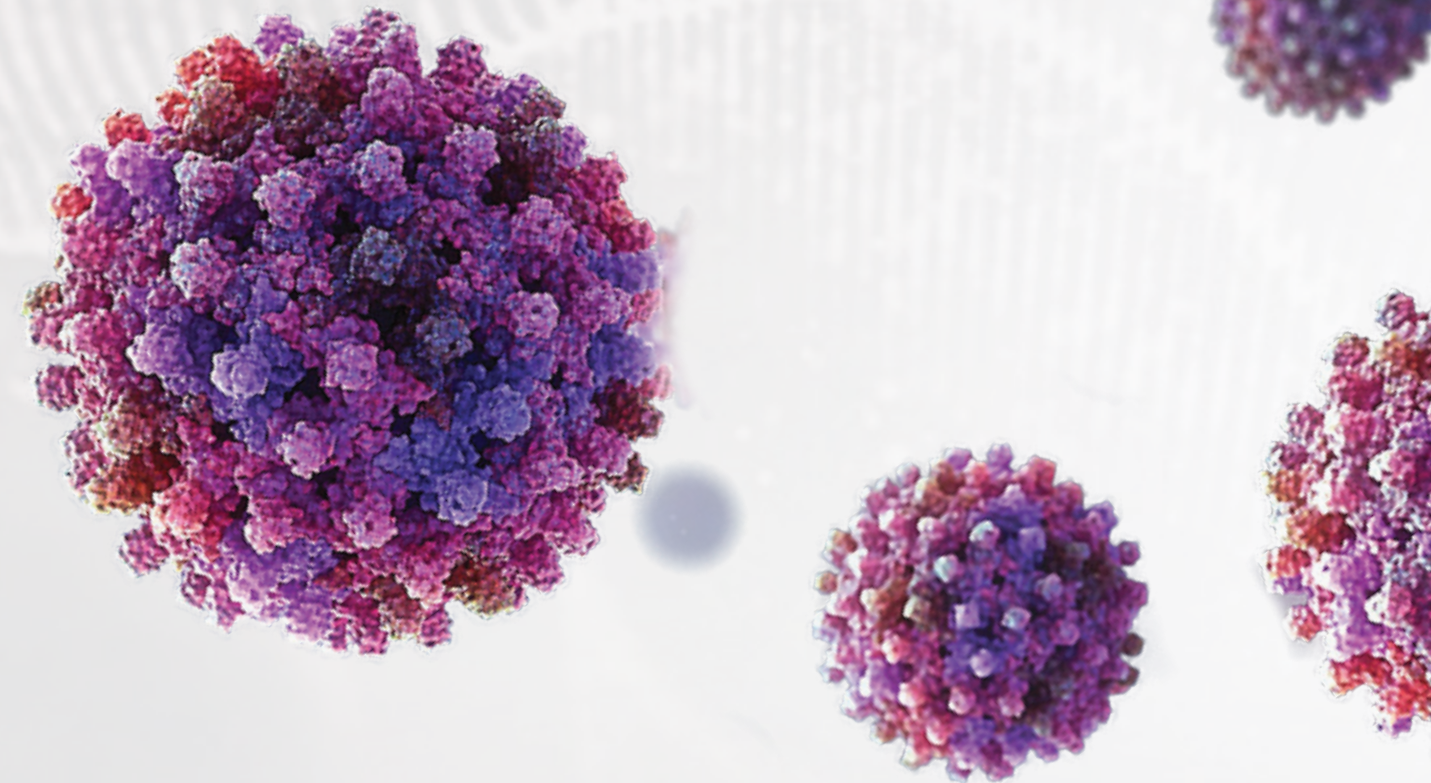
**Lentivirus:** For cost-effective lentiviral vector production and help meeting commercial demand, our optimized solutions help reduce production costs and streamline the transition from process development to manufacturing.

### VIRAL VECTOR CDMO SERVICES

Connect with over 20 years of process development experience and cGMP viral vector production. Using a range of manufacturing technologies, our deep technical and analytical expertise helps you to overcome the challenges associated with the path leading to these complex therapeutic products.

### GUIDANCE, CONTROL, AND CUSTOMIZATION

Whether you need equipment, consumables, or field applications support, we can connect you with solutions and guidance from gene therapy professionals. From customized fluid transfer products and chromatography resins to help with process development, optimization, scale-up, analytics, and qualification of viral vectors.







# GENE THERAPY WORKFLOW

## END-TO-END SOLUTIONS FROM VECTOR DESIGN TO DELIVERY



### Our range of solutions include:

#### Vector construction

Gene synthesis  
Cloning and assembly  
Large-scale plasmid production and purification  
Single-use fermentors  
SUT consumables  
cGMP chemicals and process liquids



#### Vector production

Catalog and custom media  
Suspension viral production cells  
Bioprocess automation and control platforms  
Sera  
Single-use bioreactors and mixers  
SUT consumables  
Reagents and supplements  
cGMP chemicals and process liquids  
Gene delivery



#### Vector purification

Affinity chromatography  
Ion exchange chromatography  
Centrifugation  
cGMP chemicals and process liquids



#### Lot release development and characterization

Identity, purity, and contamination assays  
Functional and physical titer  
Empty capsid analysis  
Genomic, proteomic, and cellular analytical tools



#### Fill/finish, supply chain, and logistics

Aseptic fill/finish  
Cryopreservation  
Supply/cold chain logistics  
Clinical trial support  
Global distribution



# CDMO SERVICES

## FROM PROCESS DEVELOPMENT TO COMMERCIAL SUPPLY

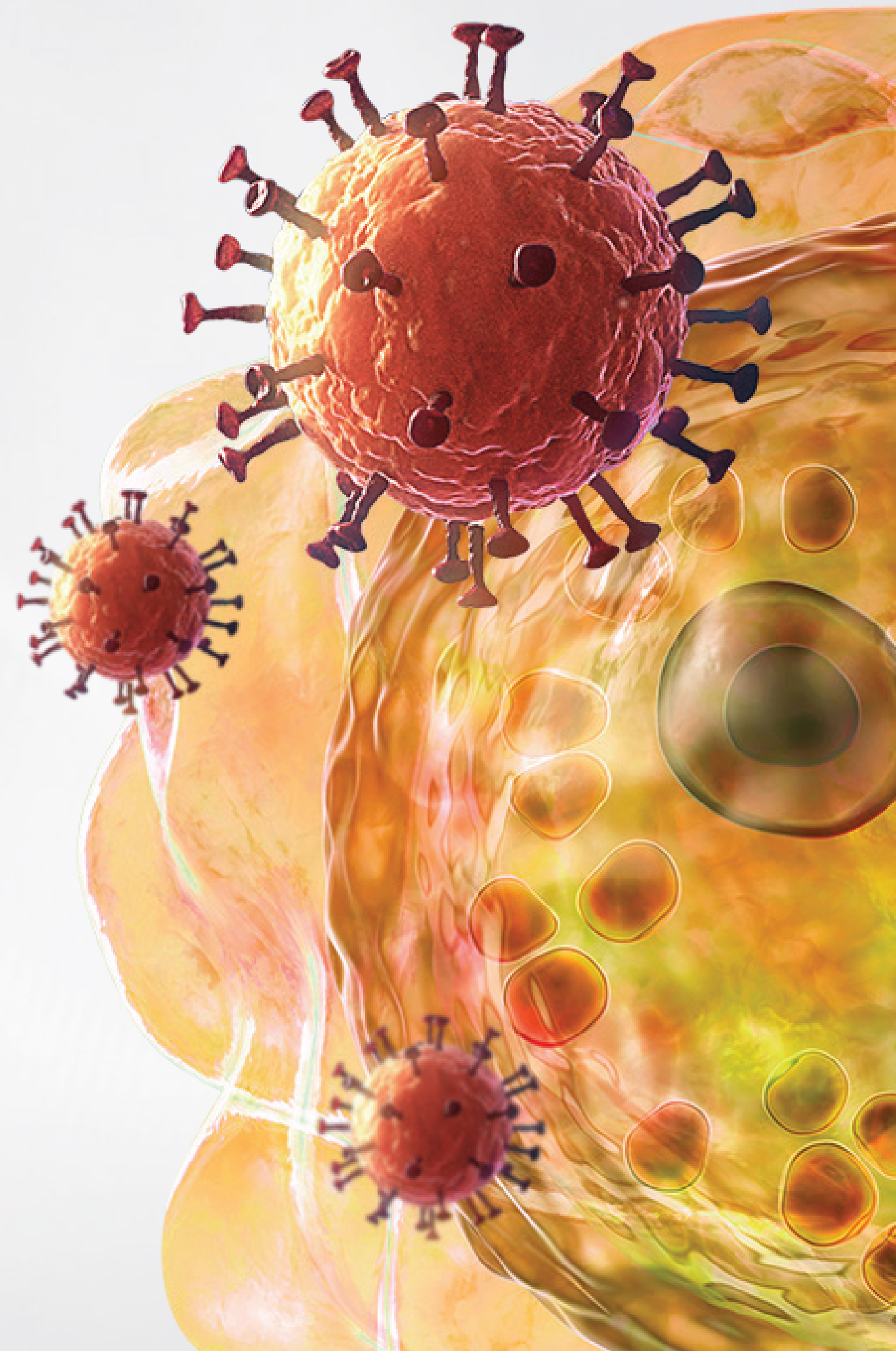
When outsourcing the production of viral vectors for clinical gene therapy applications, connect with the experienced knowledge base that has manufactured over 150 clinical lots of viral vectors and has supported countless first-in-human cell and gene therapy clinical trials. Partner with and leverage the leaders in viral vector manufacturing to take you from bench to bedside and ultimately, your commercial supply.



**>60 VIRAL  
VECTOR  
PRODUCTS**



**>250 cGMP  
CLINICAL OR  
COMMERCIAL  
BATCHES**





**CELL AND GENE THERAPY**

# **ADVANCING YOUR NOVEL THERAPEUTIC**

## FROM DISCOVERY TO PATIENT REALITY

Contact us today to find out how we can support and guide your projects, keep you agile, and help meet your needs to advance your therapeutic.

Find out more at [thermofisher.com/CGT](https://thermofisher.com/CGT)