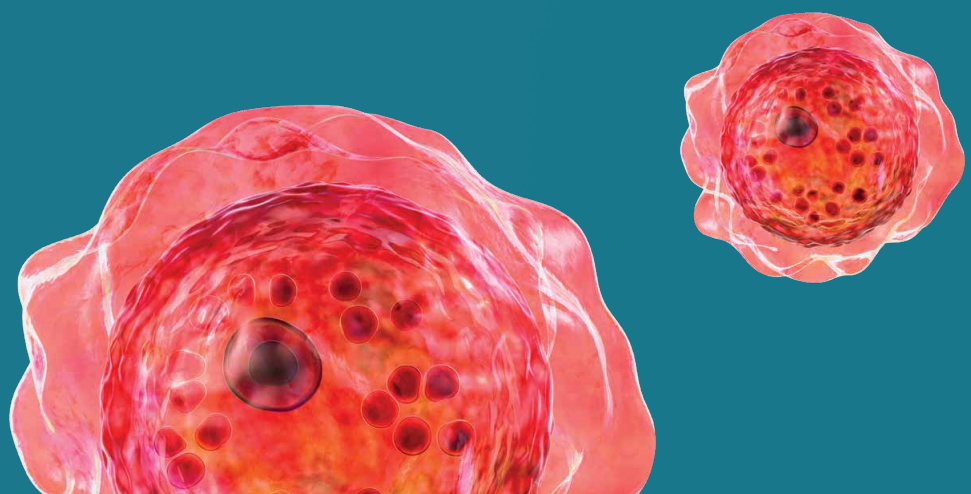
ThermoFisher SCIENTIFIC

CELL THERAPY
FROM CULTURE TO CURE

Enabling your path from discovery to commercialization

YOU PUSH THE BOUNDARIES OF INNOVATION
TO DELIVER THE NEXT LIFE-CHANGING TREATMENT

As a leading supplier for the scientific community, Thermo Fisher Scientific offers the quality products, services, and support needed to advance your cell therapy from discovery to the clinic and beyond. We work alongside you to navigate the complexities of cell therapy development by offering flexible, scalable solutions. Like you, we believe in the promise provided by these therapies to fundamentally transform the treatment of human diseases. And we won't stop until this is a reality.



CONTENTS

OUR COMMITMENT TO CELL THERAPY

Quality comes first

Providing quality products and services for our customers drives everything we do. With more than 30 years of CGMP-compliant manufacturing experience and more than 60 years of experience manufacturing Gibco™ media, our operational excellence is reflected by the proven legacy of supporting our customers through clinical and commercial scale. We have a robust quality management system and a track record of supplying the top biotech, biopharma, and translational organizations in the world with solutions to help them succeed.

Scale and security of supply are critical

Our products are backed by our robust global supply chain, professional regulatory support, and global CGMP-compliant manufacturing facilities. Our risk mitigation strategies help you scale while helping you stay compliant. Cloud-connected equipment, along with a range of informatics and laboratory information management systems (LIMS), offers peace of mind and workflow efficiency, and facilitates regulatory reporting. This translates to consistent supply and scalable solutions that help clear the path to commercialization.

Continued advancement requires continued investment

Our investments in innovation, workforce development, contract research organization (CRO) and contract development and manufacturing organization (CDMO) capacity, and cell therapy manufacturing facilities mean you can accelerate your work and rely on us to connect you to the support you need. We will continue to invest so we can deliver advanced innovation, regulatory support, and CGMP manufacturing capabilities to advance your milestones with agility.

Your loyal partner, from the bench to the market

Whether you're developing in-house capabilities or outsourcing all or part of your projects, we work with you as your reliable, single-source partner at every phase. We support our customers with a full suite of products, instruments, and services ranging from the Gibco™ Cell Therapy Systems™ (CTS™) product line to bioprocessing solutions, laboratory equipment, and state-of-the-art analytics. Our Gibco™ PeproGMP™ portfolio offers customers a variety of GMP human recombinant cytokines for use in cell therapies. PPD™ CRO services, Patheon™ CDMO services, and Unity™ Lab Services compliance services are available should you choose to outsource any part of your process.

CGMP QUALITY
OUR NUMBER ONE PRIORITY

CGMP facilities and manufacturing excellence

Over 30 years of experience with CGMP manufacturing and ongoing facility-focused investments enable us to provide high-quality products and services to support cell therapy development. Our manufacturing sites are ISO 13485– and ISO 9001–certified, and FDA-registered. Our global footprint facilitates supply of the highest-quality products to all our customers, regardless of location. To support our customers' quality assurance efforts, we host more than 200 customer audits per year.

Quality manufacturing and adherence to regulatory requirements

High-quality products and proper documentation and support are essential for a streamlined transition from research to the clinic. We offer a broad array of media, ancillary reagents, cytokines, kits, and instrumentation to support your cell therapy development, including the CTS* line of products, which are specifically designed for use in cell therapy manufacturing applications. Our CTS series of laboratory products, featuring CO_2 incubators, centrifuges, cold storage, and biological safety cabinets, are supported by high-quality materials, factory acceptance certifications, and on-site compliance services.

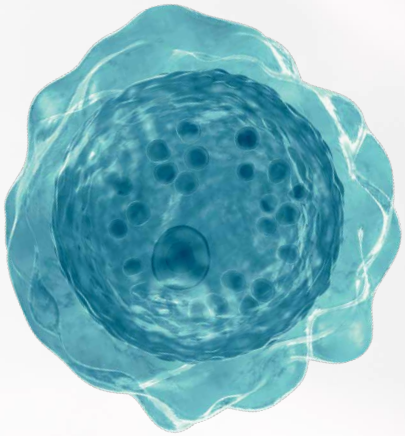
Improving quality, consistency, and reliability through integrated CRO and CDMO solutions

By partnering with an integrated CRO/CDMO, or CRDMO, capable of managing key research, development, and manufacturing tasks under one roof, the process becomes streamlined. Drug developers can ensure all products and processes are guided by the same high-quality standards throughout the research, development, and manufacturing journey—reducing the risk of errors and inconsistencies that could compromise the safety and efficacy of new drugs. Additionally, a single vendor can more easily control the employees who have access to information, which can help enhance the security of intellectual property.

Professional support

By collaborating with our customers, we are able to provide solutions that optimize quality, service, and cost while delivering results.

- Our dedicated regulatory and quality teams will provide product-specific traceability documentation to help support your regulatory filing. Regulatory specialists streamline access to critical raw material master files, enhancing filing efficiency and addressing specific information requests.
- Experienced cell therapy professionals leverage decades of cumulative translational and commercial experience to help answer your questions.
- Regional technical support teams and highly specialized scientific teams are available to provide detailed product and protocol consultation, as well as customization services.



* CTS products are manufactured to meet the ancillary material supplier responsibilities for cell, gene, and tissue-engineered products. Other aspects of USP <1043> are the responsibility of the end user to assess. Thermo Fisher Scientific cannot fulfill USP <1043> in regard to application and therapy-specific aspects (e.g., use in a finished therapeutic, assessment of removal from a finished therapeutic, and possibly biocompatibility, cytotoxicity, or adventitious agent testing).

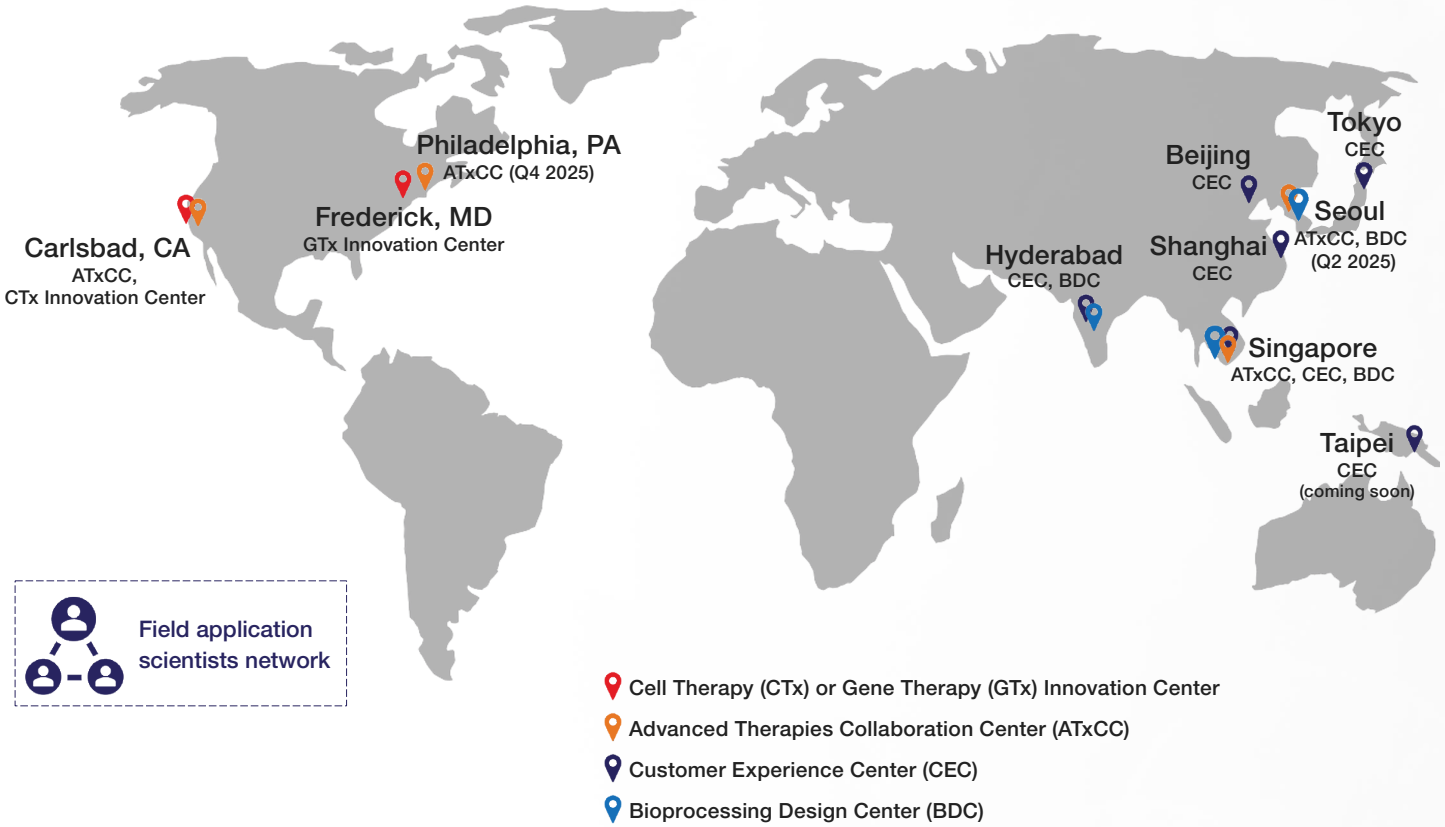
ACCELERATING DEVELOPMENT THROUGH COLLABORATION

PARTNERING TODAY FOR TOMORROW'S BREAKTHROUGH THERAPIES

Translating a cell therapy candidate from concept to commercialization can be a complex and lengthy process, potentially involving extensive validation studies, supply chain issues, and regulatory approval, all demanding significant time, money, and resources.

Whether you are a large biotech company with a portfolio of commercialized therapeutics or a startup looking to bring your innovative product to market, industry collaborations can provide valuable resources and support to navigate obstacles and help accelerate speed-to-market.

Global network for advanced therapies



Advanced Therapies Collaboration Program

To assist customers in overcoming challenges associated with manufacturing and scaling, Thermo Fisher Scientific established an Advanced Therapies Collaboration Program. Through this program, customers can leverage our global network of facilities, expansive product portfolio, and process optimization knowledge to create comprehensive, end-to-end manufacturing workflows that can scale for commercialization.

Early access to innovative technologies from Thermo Fisher Scientific

Developers gain access to our instrumentation, media and reagents, analytical solutions, and laboratory equipment to advance their work—sometimes even before these products and technologies are available to the broader market. By using our advanced technologies designed specifically for cell therapy manufacturing, along with our collection of closed, modular, and automated instruments, developers can streamline manufacturing, help limit the risk of contamination, standardize production, and promote product consistency. When integrated with digital automation, these solutions enable customers to monitor key metrics, adjust parameters as needed, and maximize data utility.

Protocol and process optimization from our technical product specialists

Our dedicated professionals provide support and assist in creating optimized manufacturing processes and protocols utilizing our products. Our teams can also help implement and adapt our broad range of analytical assays, tools, and instruments to help meet cell therapy manufacturing requirements. Additionally, we can connect our customers to internal specialists to discuss lab, cleanroom, and CGMP manufacturing facility needs.

Product-specific regulatory support to enable your regulatory filings

Our regulatory and quality teams are focused on providing product support for customer filings. In addition to our comprehensive CTS portfolio of products, we offer regulatory documentation to ease the burden on your quality systems by helping support your regulatory submission and reduce risk.

Ongoing support as cell therapy programs grow and advance

Progress in cell therapy means finding a partner that can help you strengthen your connections. Our partnership management team connects you to fit-for-purpose products and services, technical expertise, and regulatory professionals. As new needs arise and your cell therapy program evolves, our team remains readily available to answer questions and provide ongoing platform-specific support.

To learn more about our Advanced Therapies Collaboration Program, please visit **thermofisher.com/celltherapycollaborations**

DEVELOPMENT STAGES
SOLUTIONS FROM DISCOVERY TO COMMERCIALIZATION

Regardless of where you are in your cell therapy development, we have solutions to help you achieve your cell therapy goals—all the way through to commercialization.

Research and discovery

Identifying the right target and approach

Begin with the end in mind through easy access to our innovative cell therapy technologies and translational services.

Media and reagents

Classical media and sera, as well as xeno-free and animal origin–free media and reagents, support cost-effective research. CTS CGMP-manufactured products then facilitate a smooth transition to the clinic.

Cell culture equipment

Thermo Scientific™ CO_2 incubators, biosafety cabinets, and filtration devices are designed to help avoid contamination and variarion, increasing reproducibility. We also offer a broad range of centrifuges, culture vessels (including single-use hardware), and consumables to maximize workflow efficiency.

Cell isolation and activation solutions

Closed, automated magnetic separation systems, together with fit-for-purpose consumables, provide support for cell isolation and activation.

Cell engineering

Solutions include gene editing, lipid-based delivery and electroporation tools, viral vector production and purification products, and plasmid and viral vector CDMO services.

Nonviral cell engineering solutions include lipid nanoparticle–based gene delivery platforms and electroporation tools. Key viral gene editing solutions include viral vector production and purification products, as well as plasmid and viral vector CDMO services.

Gene synthesis and cloning platforms

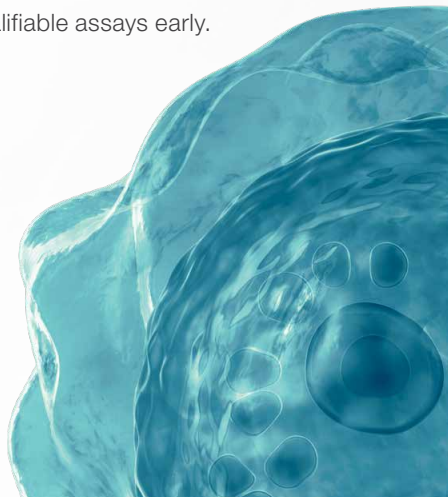
Invitrogen™ GeneArt™ Gene Synthesis services provide reliable and cost-efficient options for synthesis of custom DNA constructs.

Broad characterization portfolio

The portfolio includes equipment, tools, kits, and reagents for cell counting, whole cell analysis, protein analysis, and genetic analysis, along with safety testing including screening for endotoxin. Our technologies, such as Invitrogen™ EVOS™ cell imaging, quantitative PCR (qPCR), digital PCR (dPCR), Invitrogen™ Attune™ flow cytometry, mass spectrometry, and Ion Torrent™ AmpliSeq™ sequencing, help to characterize vectors and transduced cells.

Translational services

Our translational services team helps speed up and reduce the risk during transition to CGMP manufacturing by establishing standardized processes and qualifiable assays early.



Process development and optimization

Optimizing cell isolation, activation, and modification

Advance seamlessly with closed and automation-friendly, CGMP-manufactured solutions and professional services to develop protocols to meet your requirements.

Gibco™ CTS™ media and reagents

Scale your cell and gene therapies with confidence using the CTS portfolio. Our CGMP-manufactured, safety-tested products are backed by regulatory documentation, helping to ensure a smooth transition from research to clinical and commercial manufacturing. Rely on CTS solutions to streamline development, reduce risk, and support your quality systems.

Gibco™ PeproGMP™ cytokines

The ongoing investment in Gibco™ PeproTech™ GMP protein manufacturing capabilities helps ensure a reliable supply of quality materials for cell therapy and vaccine development. Human recombinant proteins are often among the key raw materials used in clinical manufacturing of biotherapeutics. PeproGMP cytokines are designed to help you seamlessly scale your cell production process while meeting all clinical requirements.

Laboratory equipment CTS series

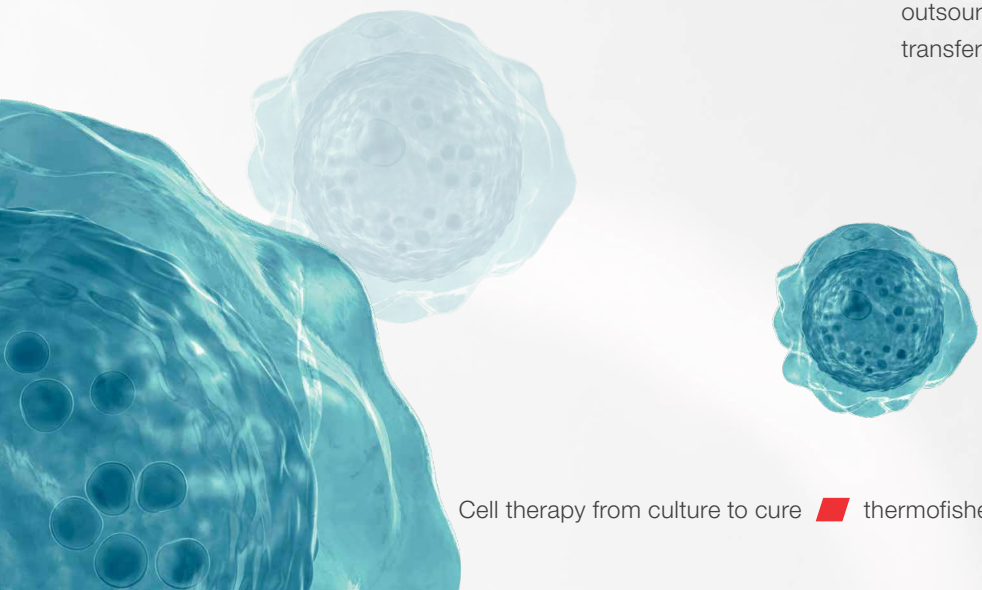
Explore our selection of CGMP-compatible equipment with enhanced documentation and certifications to speed up the validation process. Choose from cleanroom-certified CO_2 incubators, connectivity-enabled biological safety cabinets, standard centrifuges, counterflow centrifugation systems, magnetic bead–based cell isolation and activation systems, and electroporation instruments.

In-process and lot release testing assays and services

We provide rapid sterility and mycoplasma testing with turnaround times of less than 5 hours. This is critical to purity analysis during process optimization. Our extensive analytical solutions enable assessment of identity, purity, potency, and safety of cell therapy products. Flow cytometry–based cell characterization helps ensure the identity and purity of the cell therapy in development.

In-house CGMP lab operation

We offer extensive support to help customers establish and operate in-house CGMP labs. Customers can also outsource scale-up process development and CGMP transfer to our cell therapy manufacturing facilities.



Preclinical phase

Evaluating safety and efficacy

Create a robust clinical development plan with specialized analytical capabilities and consultation with our regulatory specialists.

Regulatory and early development consulting services

Strategic development consulting services can help you determine quality and validity of preclinical data and be compliant with regulatory requirements. Our regulatory experts assist with first-in-human (FIH) trial planning and protocol optimization.

Lab services and assays to support preclinical studies

Our analytical platforms and assays can be used for preclinical studies, and our specialized lab support services can provide tailored testing services for cell therapies. We provide gene expression analysis, microbiome analysis, mutational analysis, and methylation analysis solutions related to patient stratification.

Preserving valuable samples with rapid turnaround

Cell therapy products have a short shelf life and require rapid contamination testing methods. Our multiplexed qPCR-based mycoplasma testing takes less samples, and only a few hours compared with compendial testing, which takes 14–28 days. Similarly, rapid sterility testing enables quality control for cell therapy products.

CTS product portfolio

An extensive selection of CGMP-manufactured media, reagents, and instruments that are designed for cell therapy applications.

Clinical phases I–III

Clinical manufacturing and trials

Meet your critical timelines with support from our clinically proven bioprocessing solutions, insightful analytics, and professional CRO and CDMO services. Experience, resources, global competence, and infrastructure from Patheon™ Pharma Services provide clinical trial support.

Closed, automated manufacturing solutions

Our portfolio of scalable and timely solutions helps ensure high cell purity and viability, and consistently high-quality cell therapy products.

Rapid characterization and lot release

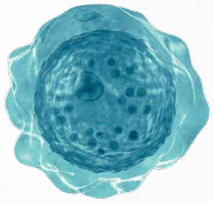
Our comprehensive analytical solutions enable characterization and lot release testing for cell therapies during clinical phase development. The rapid and accurate testing capabilities facilitate timely lot release, helping to accelerate the development process and bring therapies to patients faster.

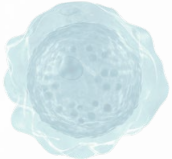
Patient recruitment and retention

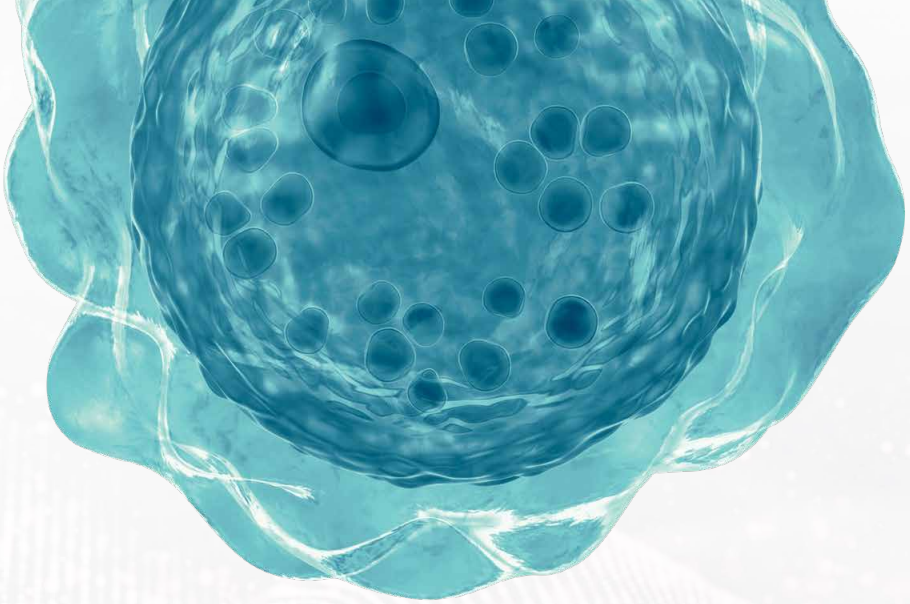
We support access to more than 130 million patients. Ongoing education and support to patients and caregivers, and digital and decentralized study capabilities, help ensure retention.

Support for clinical trial operations and logistics

Our end-to-end global clinical supply chain services provide support for investigational medicinal product (IMP), comparator, co-medication, and ancillary clinical supplies, including strategy, sourcing, quality management of supply chain, packaging and labeling, storage, and distribution.







Commercialization and production

Commercial manufacturing and supply

Launch your product with support from our integrated services, compelling evidence generation, and robust supply chain and logistics.

Scale-up and scale-out solutions

Proven, robust, and scalable solutions span the entire cell therapy development process, from CGMP-manufactured custom media to bioreactors, cultureware, and cell culture bags.

Analytical solutions for cell characterization and lot release

Advanced cellular analysis tools are available for your in-process and lot-release development testing needs, including qPCR-based microbial detection and identification, contamination and impurity testing, and flow cytometry and imaging-based cellular analysis tools.

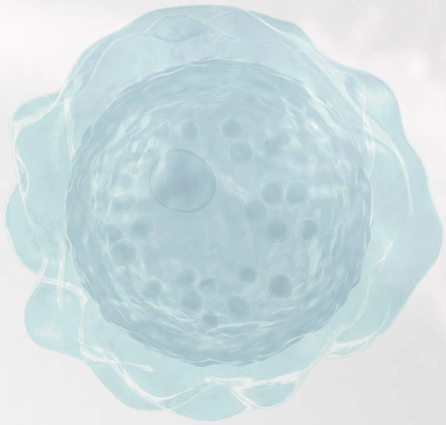
Global cold chain logistics services

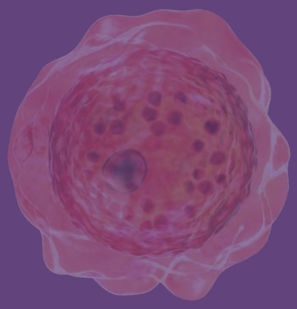
Experience a global infrastructure, leveraged to help ensure the integrity of your valuable material from collection and storage through delivery to patients. Our unified quality systems and global network of cryopreservation centers support distribution and storage services.

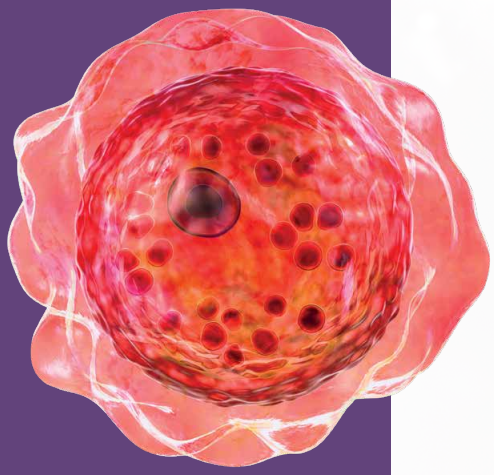
We have more than 35 years of experience handling ultracold and cryogenic material and cold chain management for advanced therapeutic products.

Monitoring and improvement

Launch your product with support from our integrated services, compelling evidence generation, and robust supply chain logistics. We support peri- and post-approval studies, including real-world evidence generation to evaluate the long-term safety and efficacy of the drug. We also provide product lifecycle management to drive continuous improvements and revalidation throughout the therapy's lifespan.

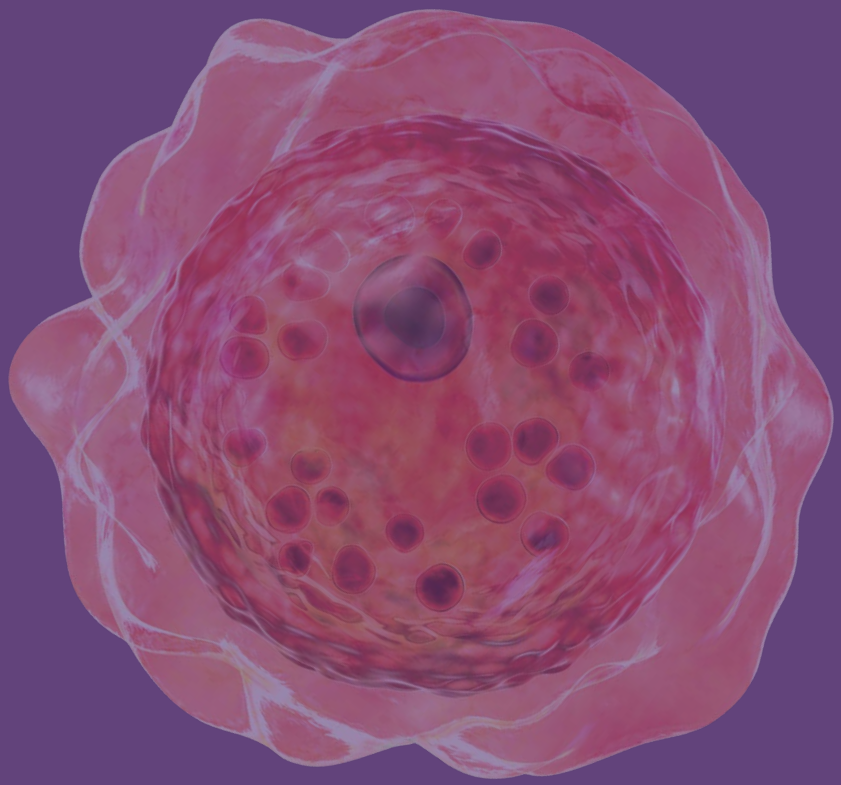






CELL THERAPY WORKFLOW

INTEGRATED SOLUTIONS FROM COLLECTION TO PATIENT ADMINISTRATION



Collection and tracking

Apheresis

Supply and cold chain logistics

Documentation

Chain of custody

Cell isolation, activation, and processing

Closed modular cell processing systems

Magnetic bead–based cell isolation and activation

Single-use platforms

High cell purity and viability

Flexible, high-speed, and scalable solutions

Cell engineering and genome editing

Genome editing technologies–CRISPR and TALEN tools

Closed modular electroporation system

Lentiviral production system

Lipid nanoparticles

Sequence confirmation, verification, and QC

Cell expansion

Custom and catalog media

PeproGMP cytokines and recombinant proteins

Premium fetal bovine serum (FBS) that meets USP/EP guidelines

Serum-free and xeno-free reagents

Closed modular cell processing systems

Single-use technologies (SUTs), incubators, bioreactors, centrifuges, and biosafety cabinets

Formulation, fill, finish, and cryopreservation

Automated formulation and filling

Broader compatibility to various outputs and volume ranges

Precise and consistent volumes

Cryopreservation platforms

Lot release, characterization, and purity analysis

Identity, purity, and potency assays

Contamination and impurity solutions

Microbial safety

Genomic, proteomic, and cellular analytical tools

Supply and logistics

Supply and cold chain logistics

Clinical trial support

Global distribution

CELL THERAPY SYSTEMS (CTS) PRODUCTS

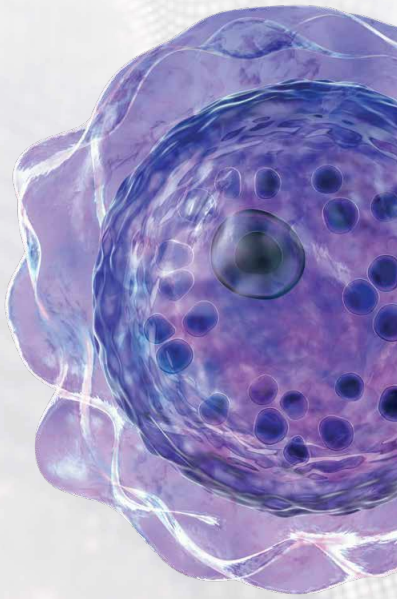
Products designed to enable clinical and commercial cell therapy manufacturing

As you scale your cell therapies beyond research, products designed to enable clinical and commercial manufacturing are essential to your success.

The CTS portfolio of products are CGMP manufactured, safety tested, and backed by regulatory documentation. Through our CTS solutions, we are committed to helping customers streamline therapeutic development, minimize risk, and ease the burden on their quality systems.

CGMP-manufactured products designed for cell therapy manufacturing

- Designed to meet the latest guidance for ancillary materials for cell and gene therapies (USP <1043>,* ISO 20399, Ph. Eur. 5.2.12*)
- Products manufactured under global quality standards (ISO 9001 or 13485)
- 30 years of CGMP-compliant manufacturing



Safety testing with accompanying traceability documentation

- Extensive qualification and testing of critical raw materials
- Final product testing (e.g., sterility, endotoxin level, and mycoplasma detection)
- Types of traceability documentation: Certificate of Origin (COO), Certificate of Analysis (COA), Safety Data Sheet (SDS)

Dedicated regulatory and quality teams provide product support for customer filings

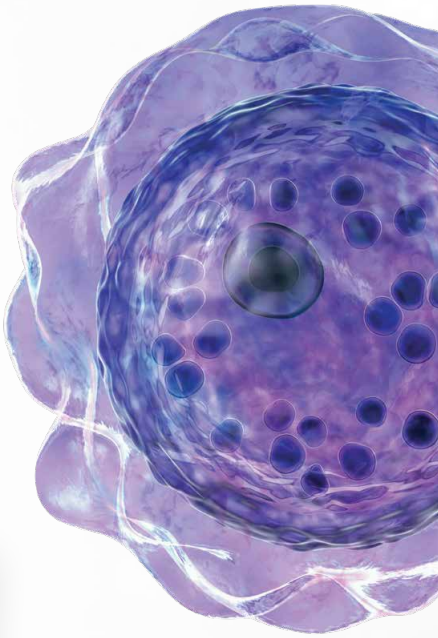
- Types of specialized documentation include: Drug Master Files (DMFs), Regulatory Support Files (RSFs), validation, and regulatory agency letters**
- Products used in over 200 clinical trials and commercialized therapies
- Global regulatory affairs teams for cell and gene therapies with regional expertise

* CTS products are designed to meet USP <1043>, ancillary material responsibilities for cell, gene, and tissue-engineered products, under a robust quality management system certified to ISO 9001 or 13485. All aspects of USP <1043> are the responsibility of the end user to assess. We are dedicated to supporting our customers' clinical translation. For regulatory documentation support, please contact us.

** For regions without an equivalent DMF mechanism for raw materials used in further manufacturing, we can provide access to confidential RSFs for select products used in regulated environments.

CLOSED MODULAR CELL THERAPY MANUFACTURING

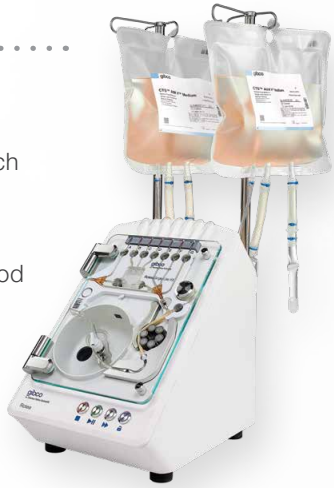
STREAMLINE AND STANDARDIZE YOUR CELL THERAPY PROCESS



A closed, modular, end-to-end approach to cell therapy manufacturing—Thermo Fisher Scientific has designed a portfolio of modular instruments that can efficiently scale to commercial manufacturing and support a diverse range of cell therapy manufacturing workflows. These instruments are compatible with the CTS portfolio of cell therapy products that are CGMP manufactured, safety tested, backed by regulatory documentation, and supported globally by field-based experts.

Our experienced cell and gene therapy professionals, technical support teams, and highly specialized field application scientific teams are available to answer your questions, provide detailed product and protocol consultation, and implement customization services.

Find out more at **thermofisher.com/ctxmanufacturing**



Gibco™ CTS™ Rotea™ Counterflow Centrifugation System

The CTS Rotea system enables scaling of cell processing from research through commercial manufacturing. With its closed, counterflow centrifugation technology, it can be used in a broad range of cell processing applications including leukopak processing, peripheral blood mononuclear cell (PBMC) separation, cell washing and concentration, buffer exchange, platelet elutriation, red blood cell (RBC) lysis, and dissociation of pluripotent stem cell spheroids.

Find out more at **thermofisher.com/rotea**

Gibco™ CTS™ DynaCellect™ Magnetic Separation System

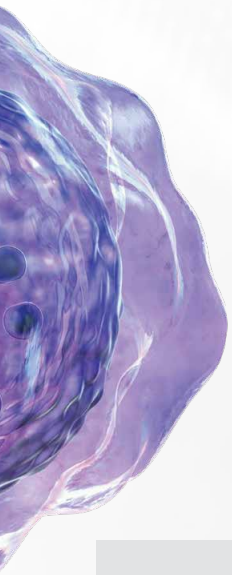
This closed, automated isolation and debeading system provides high throughput and increased scalability to support protocols using Gibco™ CTS™ Dynabeads™ magnetic beads. As a stand-alone instrument or as part of an integrated workflow, the system is designed to isolate the right cells, minimize failures in manufacturing, and reduce contamination while providing increased robustness and precision. The process flexibility, speed, scalability, and sterile single-use kits allow you to seamlessly scale from research through clinical manufacturing.

Find out more at **thermofisher.com/dynacellect**

Gibco™ CTS™ Xenon™ Electroporation System

This closed, modular, large-scale platform offers full control over electroporation parameters for optimal performance. The CTS Xenon Electroporation System delivers high-performance nonviral transfection by enabling electroporation of up to 2.5 billion T cells in 25 mL per run for cell therapy process development and manufacturing.

Find out more at **thermofisher.com/xenon**



Gibco™ CTS™ Compleo™ Fill and Finish System*

Experience flexibility in cell therapy drug formulation and filling with the CTS Compleo Fill and Finish System. This system supports various input and output volumes, ensures accurate dosing even at small volumes, works with cryobags and vials, allows adjustable dosing per output line, and includes software for easy simulation and formulation recommendations.

* Coming soon.

Software to enable 21 CFR Part 11 compliance

When scaling up to commercial manufacturing, we recommend upgrading to one of the two software options available, which include security, audit, and e-signature (SAE) software or Gibco™ CTS™ Cellmation™ Software for DeltaV™ Systems to enable 21 CFR Part 11 compliance. Both software options help customers prepare for audit and regulatory filing processes through SAE functionality while customers maintain the final responsibility for 21 CFR Part 11 compliance.

Security, audit, and e-signature (SAE) software

The SAE software available for the CTS DynaCellect, Rotea, and Xenon systems is designed for customers who want to upgrade these stand-alone instruments. The capabilities include password policies, user role designations, role permissions, tracking of actions and information via an audit log, and electronic signature configuration for specific functions. Customer preferences for these SAE settings are managed within the SAE Administrator Console (separate software application), which is recommended to be installed on the co-located system computer to enable uninterrupted communication between the system and the software for continuous tracking.

CTS Cellmation Software

CTS Cellmation Software enables automation of your cell therapy manufacturing processes by connecting multiple instruments from Thermo Fisher Scientific across your workflow. CTS Cellmation Software can connect to and control the following systems:

- CTS DynaCellect Magnetic Separation System
- CTS Rotea Counterflow Centrifugation System
- CTS Xenon Electroporation System
- Thermo Scientific™ CryoMed™ Controlled-Rate Freezer
- Thermo Scientific™ Heracell™ VIOS™ CR CO_2 Incubator

Learn more about CTS Cellmation Software for DeltaV Systems in the automation section (page 18) and at **thermofisher.com/cellmation**.

AUTOMATION

FLEXIBLE, MODULAR AUTOMATION FOR CELL THERAPY MANUFACTURING

Discover how to navigate CGMP manufacturing complexities, minimize errors and contamination, and get therapies to patients faster by introducing a flexible, modular, and automated cell therapy manufacturing workflow.

Our series of closed, modular instruments can operate together or independently, based on your requirements, while carrying out critical functions of the cell therapy manufacturing process.

Through digital automation, workflow components can be both physically and digitally integrated to increase standardization and help you successfully reach your milestones.

CTS Cellmation Software for DeltaV Systems

CTS Cellmation Software is an off-the-shelf solution designed to help simplify and optimize cell therapy manufacturing processes by providing digital connectivity for modular cell therapy instrumentation offered by Thermo Fisher Scientific.

The software's open platform provides a flexible system for managing and integrating multiple instruments (Figure 1), streamlining the cell therapy workflow, and enabling 21 CFR Part 11 or EU Annex 11 regulatory compliance.

CTS Cellmation Software is powered by the **DeltaV Distributed Control System (DCS)** and has been developed following GAMP™ 5 methods to help ensure compatibility with CGMP-compliant processes. CTS Cellmation Software is optimized to easily scale from process development through clinical manufacturing and commercialization.

Monitor, control, and automate your workflow all in one place with CTS Cellmation Software. Create user-specific batch recipes to control the flow of your cell therapy manufacturing processes utilizing multiple instruments simultaneously.

Figure 1. Digital integration of cell therapy instruments.

CELL ENGINEERING SOLUTIONS
VIRAL AND NONVIRAL DELIVERY TOOLS

Viral

We have products that span the entire viral production workflow including Invitrogen™ GeneArt™ Elements™ Vector Construction, and a platform for cost-effective lentiviral production. The Gibco™ CTS™ LV-MAX™ Lentiviral Production System is a complete suspension production system that has been widely used and can help accelerate your project towards the clinic and beyond. The CTS LV-MAX system is supported by extensive technical expertise and uses a CGMP-banked suspension cell line and a suite of CGMP-manufactured products for lentiviral vector production. In addition to viral production platforms, our viral vector solutions include a full portfolio of products for plasmid production and purification, as well as products for downstream viral vector purification and impurity testing. We also offer products for lentivirus titer testing to help you meet regulatory requirements.

Nonviral

Lipid delivery reagents

We offer a wide range of lipid-based delivery reagents for both *in vitro* and *in vivo* delivery for discovery and clinical development applications. These reagents are built around both cationic and ionizable lipids and can be used to encapsulate a variety of RNA or DNA payloads for cell therapies using either liposomes or lipid nanoparticles. Invitrogen™ Lipofectamine™ and Vivofectamine™ delivery reagents are highly advanced, thoughtfully designed, and rigorously tested. Their components have been selected for their performance, delivery efficiency, and excellent safety profiles.

Our lipid delivery reagents, combined with the expertise of our experienced support team, can help accelerate the development of your cell therapy project. These reagents provide an efficient pathway to help you transition from discovery to development, produce a clinically suitable cell therapeutic, and move faster toward the clinic with your therapy.

Electroporation

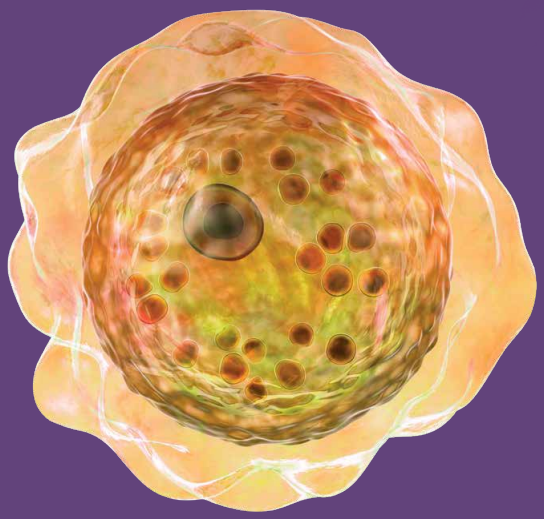
Our large-scale CTS Xenon Electroporation System offers cell therapy developers a nonviral platform to modify virtually any cell type of interest, using any payload as part of a closed, modular, and automated workflow. The instrument has single-use consumables (a 1 mL Gibco™ CTS™ Xenon™ SingleShot chamber and a 5–25 mL Gibco™ CTS™ Xenon™ MultiShot cartridge) and a selection of buffers that enable both process development and CGMP manufacturing. The Gibco™ CTS™ Xenon™ Electroporation Buffer is a universal buffer that supports the transfection of a variety of human primary cells and payloads (e.g., plasmid DNA, mRNA, miRNA, and siRNA) for gene upregulation or downregulation applications. The Gibco™ CTS™ Xenon™ Genome Editing Buffer was designed to improve performance with gene editing–specific payloads (e.g., CRISPR-Cas9) for knock out– or knock in–based applications in a variety of human primary cells. The Gibco™ CTS™ Xenon™ Lower Conductivity Electroporation Buffer was designed for use with cell types that require higher-energy electroporation settings to achieve successful transfection.

To assist our customers in their discovery and process development journey, the small-scale Invitrogen™ Neon™ NxT Electroporation System can be used to optimize electroporation conditions and cell densities, which can then be translated to the large-scale CTS Xenon system without the need for extensive re-optimization.

Gene editing solutions

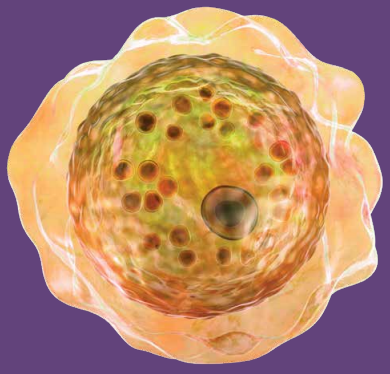
Gibco™ CTS™ TrueCut™ Cas9 Protein is our highest-performing CRISPR-Cas9 protein, delivering over 90% editing efficiency across various cell types. We also offer high-fidelity Gibco™ CTS™ HiFi Cas9 Protein, which was engineered to reduce off-target effects while maintaining high on-target activity. CTS TrueCut and CTS HiFi Cas9 proteins are manufactured in compliance with USP <1043> standards for ancillary materials for cell, gene, and tissue-based products and are subject to stringent quality specifications. They are provided in a high-concentration and large-scale format for process development and clinical research applications.

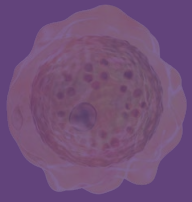
We also offer research-grade CRISPR-Cas9 reagents—Invitrogen™ TrueCut™ Cas9 Protein, TrueCut™ HiFi Cas9 Protein, and TrueGuide™ synthetic gRNA—to support discovery and process development activities. These reagents are optimized to transition seamlessly from bench to manufacturing scale.



SOLUTIONS BY CELL TYPE MANUFACTURING WORKFLOW GUIDES

We have capabilities that span immunotherapy and stem cell therapy workflows. Our products, services, and support can facilitate a seamless transition from research to commercialization, with a goal to help you reduce the time from your initial discovery to an approved therapy.





GENE-MODIFIED T CELLS

Cell isolation and activation

Isolation and activation

- CTS Detachable Dynabeads CD3/CD28
- CTS Detachable Dynabeads CD4
- CTS Detachable Dynabeads CD8

* For research use only.

- CTS Dynabeads CD3/CD28
- Dynabeads Human T-Expander CD3/CD28*
- CTS Dynabeads Treg Xpander

Instrumentation

- CTS Rotea Counterflow Centrifugation System
- CTS DynaCellect Magnetic Separation System

Genome editing and cell engineering

Nonviral instrumentation

- CTS Xenon Electroporation System

Nonviral platforms

- CTS TrueCut Cas9 Protein
- CTS HiFi Cas9 Protein
- TALEN products and services
- TrueGuide Synthetic gRNA
- Vivofectamine Delivery Solutions

Viral platforms

- CTS LV-MAX production system
- CTS AAV-MAX production system
- ViralSEQ Lentivirus Physical Titer Kits
- ViralSEQ Lentivirus Proviral DNA Titer Kits

Confirmation of gene edits

- BigDye Terminator and BigDye Direct Sanger sequencing reagents
- ExoSAP-IT and BigDye XTerminator reagents
- 3500, SeqStudio, and SeqStudio Flex Genetic Analyzers
- SeqScreener Gene Edit Confirmation App

Cell culture and expansion

Catalog and custom media

- CTS OpTmizer One SFM
- CTS OpTmizer T Cell Expansion SFM
- CTS OpTmizer T Cell Expansion SFM, no phenol red
- CTS OpTmizer Pro SFM
- CTS AIM-V SFM
- CTS AIM-V Medium, without phenol red, without antibiotics
- Custom media and services

Cell culture supplements

- CTS GlutaMAX-I Supplement
- CTS L-Glutamine
- CTS Immune Cell SR
- Premium FBS

Equipment

- HyPerforma Rocker Bioreactor with bioprocess controllers and software
- Single-use technologies: bioprocess containers, transfer assemblies, rocker bags
- Herasafe 2030i Biological Safety Cabinets, CTS Series
- Heracell Vios CR CO_2 Incubators, CTS Series
- General Purpose Pro Centrifuges, CTS Series

Growth factors

- Human GM-CSF Recombinant Protein
- Human IL-4 Recombinant Protein
- Human IL-7 Recombinant Protein
- PeproGMP Human IL-2 Recombinant Protein
- PeproGMP Human IL-7 Recombinant Protein
- PeproGMP Human IL-15 Recombinant Protein

Formulation, fill, finish, and cryopreservation

Wash and concentrate

- CTS DPBS, without calcium chloride, without magnesium chloride
- CTS HBSS

Cryopreservation

- CTS Synth-a-Freeze Medium

Instrumentation

- CTS Compleo Fill and Finish System*

* Coming soon.

Cryopreservation

- CryoMed Controlled-Rate Freezer
- CryoPlus LN_2 Storage Systems
- CryoExtra High-Efficiency Cryogenic Storage Systems
- Nunc Internally Threaded Universal Cryotubes

Lot release and characterization

Assays

- PureQuant $CD8^+$ T Cell Assay
- PureQuant Treg Assay
- PureQuant Th17 Assay
- MycoSEQ Mycoplasma Detection Kit
- SteriSEQ Rapid Sterility Testing Kit (in-process testing)
- resDNASEQ Human Residual DNA Quantitation Kit
- resDNASEQ Quantitative HEK293 DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit
- AmpFLSTR Identifiler Direct PCR Amplification Kit

Cell line authentication

- CLA IdentiFiler Plus PCR Amplification Kit
- CLA GlobalFiler PCR Amplification Kit

Cell population and characterization analysis

- Attune Xenith Flow Cytometer
- Attune CytPix Flow Cytometer
- CytKick Autosampler
- Attune flow cytometer software, compliant with 21 CFR Part 11
- Bigfoot Spectral Cell Sorter
- eBioscience Essential Human Treg Phenotyping Kit
- eBioscience Essential Human Th1/Th17 Phenotyping Kit
- eBioscience Essential Human T-Cell Phenotyping Kit
- Flow cytometry antibodies
- Flow cytometry reagents
- Flow Cytometry Panel Design Service and Panel Builder Tool
- UltraComp eBeads Plus Compensation Beads
- EVOS cell imaging systems
- Countess automated cell counters

Cytokine release assay

- ProcartaPlex Human Th1/Th2/Th9/Th17 Cytokine Panel, 18plex
- ProcartaPlex Human Cytokine/ Chemokine/Growth Factor Convenience Panel 1, 45plex
- ProcartaPlex Human Immune Checkpoint Panel, 37plex
- ProcartaPlex Human Immune Response Panel, 80plex
- ELISA kits
- KingFisher Apex Purification System
- CyQUANT LDH Cytotoxicity Assay
- Pierce Chromogenic Endotoxin Quant Kit

NATURAL KILLER CELLS

Cell isolation

PBMC isolation

- CTS Rotea Counterflow Centrifugation System
- CTS DPBS
- CTS HBSS
- CTS ACK Lysing Buffer

Genome editing and cell engineering

Gene editing

- CTS Xenon Electroporation System
- CTS TrueCut Cas9 Protein
- CTS HiFi Cas9 Protein
- TrueGuide Synthetic gRNA
- Donor DNA

Confirmation of gene edits

- BigDye Terminator and BigDye Direct Sanger sequencing reagents
- ExoSAP-IT and BigDye XTerminator reagents
- 3500, SeqStudio, and SeqStudio Flex Genetic Analyzers
- SeqScreener Gene Edit Confirmation App

NK isolation, activation, and expansion

Natural killer (NK) cell isolation

- CTS Rotea Counterflow Centrifugation System

NK cell activation

- CTS NK-Xpander Medium
- Human Serum, Type AB
- PeproGMP Human IL-2 Recombinant Protein
- PeproGMP Human IL-15 Recombinant Protein
- BioProcess Containers (BPCs)
- Fluid transfer assemblies
- HyPerforma Rocker Bioreactor and automation and control solutions
- Single-use bioreactors

NK cell expansion

- CTS NK-Xpander Medium
- PeproGMP Human IL-2 Recombinant Protein
- PeproGMP Human IL-15 Recombinant Protein
- Human Serum, Type AB
- CTS Immune Cell Serum Replacement
- BPCs
- Fluid transfer assemblies
- HyPerforma Rocker Bioreactor and automation and control solutions
- Single-use bioreactors

Formulation, fill, finish, and cryopreservation

Instrumentation

- CTS Compleo Fill and Finish System*

* Coming soon

Wash

- CTS DPBS, no calcium, no magnesium
- CTS HBSS

Cryopreservation

- CryoMed Controlled-Rate Freezer
- Ultralow temperature and cryogenic freezers

Lot release and characterization

Cell population and characterization analysis

- Attune Xenith Flow Cytometer
- Attune CytPix Flow Cytometer
- CytKick Autosampler
- Attune flow cytometer software, compliant with 21 CFR Part 11
- eBioscience CD56, CD3, and CD16 antibodies
- eBioscience CD107a antibody
- MycoSEQ Mycoplasma Detection Kit
- SteriSEQ Rapid Sterility Testing Kit (in-process testing)
- Flow cytometry antibodies
- Flow cytometry reagents
- Flow Cytometry Panel Design Service and Panel Builder Tool
- UltraComp eBeads Plus Compensation Beads

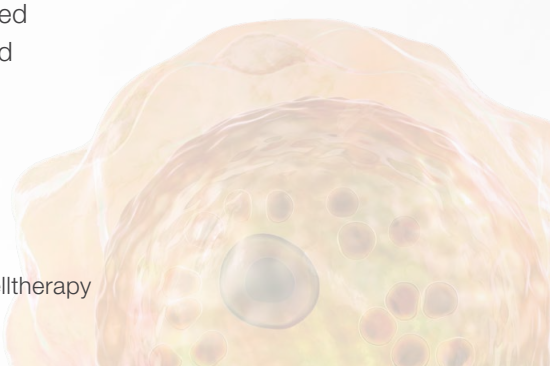
Cytokine release assay

- KingFisher Apex Purification System
- ProcartaPlex Human Cytokine/ Chemokine/Growth Factor Convenience Panel 1, 45plex
- ProcartaPlex Human Immune Checkpoint Panel, 37plex
- ProcartaPlex Human Immune Response Panel, 80plex
- ELISA kits
- Pierce Chromogenic Endotoxin Quant Kit

Product spotlight:

Gibco™ CTS™ NK-Xpander™ Medium

Specifically formulated for expansion of human natural killer (hNK) cells for cell therapy manufacturing applications. When hNK cells are enriched from human PBMCs and expanded in a feeder-free system using CTS NK-Xpander Medium supplemented with 5% human AB serum and 500 U/mL IL-2, ≥90% of the hNK cells generated maintain $CD56^{+}/CD16^{+}/CD3^{-}$ surface marker expression. Additionally, these hNK cells demonstrate degranulation and killing of K562 cancer cells. CTS NK-Xpander Medium is manufactured without cytokines and growth factors and does not contain human or animal-derived components.



MESENCHYMAL STEM CELLS

Cell isolation

Gibco cells

- StemPro Human Adipose-Derived Stem Cells
- Custom cells and services

Cell culture plastics

- Nunc cell cultureware
- Nunc Cell Factory systems

Instrumentation

- CTS Rotea Counterflow Centrifugation System

Cell culture and expansion

Expansion systems

- StemPro MSC SFM XenoFree
- StemPro MSC SFM
- MesenPRO RS Medium
- FBS, MSC-qualified
- CELLstart Substrate

Differentiation media and enzymes

- StemPro Osteogenesis Differentiation Kit
- StemPro Chondrogenesis Differentiation Kit
- StemPro Adipogenesis Differentiation Kit
- CTS TrypLE Select Enzyme

Instrumentation

- CTS Rotea Counterflow Centrifugation System

Growth factors

- TGF-β 1
- FGF-basic
- PeproGMP Human FGF-basic
- PDGF-BB

Single-use technologies

- Bioreactors and liners
- Transfer assemblies
- Nunc Cell Factory systems
- Equipment and consumables

Cell culture and bioproduction systems

- Nunc cell cultureware
- Equipment and consumables

Formulation, fill, finish, and cryopreservation

Wash

- CTS DPBS, calcium, magnesium
- CTS HBSS

Instrumentation

- CTS Compleo Fill and Finish System*

* Coming soon.

Cryogenic storage

- CryoMed Controlled-Rate Freezer
- Rigid containment solutions
- Nalgene General Long-Term Storage Cryogenic Tubes
- Nunc Biobanking and Cell Culture Cryogenic Tubes

- Biobanking services
- Cold-chain logistics solutions
- Ultralow temperature and cryogenic freezers

Lot release and characterization

Lot-release testing

- MycoSEQ Mycoplasma Detection Kit
- SteriSEQ Rapid Sterility Testing Kit (in-process testing)
- GeneChip PrimeView Global Gene Expression Profile Assay

In-process characterization

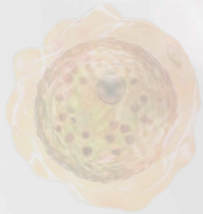
- Functional analysis
- Cellular analysis
- Protein assays and analysis
- Genetic analysis

See page 26 for more information about cell characterization

Product spotlight:

CTS Rotea system for harvesting MSCs

In a research collaboration with A STAR, it was demonstrated that the CTS Rotea system can harvest, wash, and concentrate human mesenchymal stem cells with little-to-no impact on phenotype, differentiation potential, recovery, or viability.



Learn more at **thermofisher.com/rotea-hmsc-processing**

PLURIPOTENT STEM CELLS

Cell isolation

Media
- CTS StemScale PSC Suspension Medium
- CTS StemFlex Medium
- StemPro-34 SFM
- CTS KnockOut SR XenoFree Medium

Dissociation reagents
- CTS TrypLE Select Enzyme
- CTS Versene Solution

Instrumentation
- CTS Rotea Counterflow Centrifugation System

Reprogramming and genome editing

Reprogramming kit
- CTS CytoTune-iPS 2.1 Sendai Reprogramming Kit

Nonviral instrumentation
- CTS Xenon Electroporation System

Gene editing
- CTS TrueCut Cas9 Protein
- CTS HiFi Cas9 Protein
- TrueGuide Synthetic gRNA
- CTS StemFlex Medium
- TALEN products and services
- Lipofectamine Stem Transfection Reagent
- Lipofectamine MessengerMAX Transfection Reagent
- Lipofectamine 3000 Transfection Reagen

Cell culture and expansion; gene editing

Expansion and gene editing systems
- CTS Essential 8 Medium
- CTS Essential 6 Medium
- CTS Vitronectin (VTN-N)
- CTS KnockOut SR XenoFree Medium
- CTS KnockOut DMEM/F-12
- CTS KnockOut DMEM
- CTS Versene Solution
- Custom media and services
- CRISPR-Cas9 products and services
- CTS StemScale PSC Suspension Medium
- CTS StemFlex Medium

Single-use technologies
- BPCs
- Transfer assemblies
- Equipment and consumables

Cell differentiation

Differentiation reagents
- PSC Cardiomyocyte Differentiation Kit
- PSC Dopaminergic Neuron Differentiation Kit
- PSC Definitive Endoderm Induction Kit
- CTS N-2 Supplement
- CTS KnockOut DMEM/F-12
- CTS Neurobasal Medium
- CTS Neurobasal-A Medium
- CultureOne Supplement
- CTS PSC Cryopreservation Kit

Growth factors
- TGF-β 1
- PeproGMP Human SCF
- PeproGMP Flt-3 Ligand
- PeproGMP FGF-basic

Formulation, fill, finish, and cryopreservation

Instrumentation
- CTS Compleo Fill and Finish System*

* Coming soon.

Wash
- CTS DPBS
- CTS HBSS

Cryopreservation
- CTS Synth-a-Freeze Medium
- CTS PSC Cryopreservation Kit
- CTS PSC Cryomedium
- CTS RevitaCell Supplement
- CTS Essential 8 Medium
- rhLaminin-521
- Herasafe 2030i Biological Safety Cabinet

Cryogenic storage and logistics
- CryoMed Controlled-Rate Freezer
- Rigid containment solutions
- Nalgene General Long-Term Storage Cryogenic Tubes
- Nunc Biobanking and Cell Culture Cryogenic Tubes
- Biobanking services
- Cold-chain logistics solutions
- Ultralow temperature and cryogenic freezers
- CryoPlus LN_2 Storage Systems
- CryoExtra High-Efficiency Cryogenic Storage Systems

Lot release and characterization

Characterization products
- GeneChip PrimeView Global Gene Expression Profile Assay
- TaqMan hPSC ScoreCard Panel
- MycoSEQ Plus Mycoplasma Detection Kits
- SteriSEQ Rapid Sterility Testing Kit (in-process testing)
- KaryoStat Assay
- Pluripotent Stem Cell Immunocytochemistry Kits

HEMATOPOIETIC STEM CELLS

Cell isolation and activation

Instrumentation
- CTS Rotea Counterflow Centrifugation System

Cell culture and expansion

Expansion systems
- CTS StemPro-34 SF XenoFree Medium
- Custom media and services
- CTS GlutaMAX-I Supplement

Growth factors
- PeproGMP Human IL-2, IL-3, IL-6, IL-7, SCF, Flt-3 Ligand, TPO Recombinant Proteins

Single-use technologies
- BPCs
- Fluid transfer assemblies
- Single-use bioreactors
- Nunc Cell Factory systems
- Rigid containment solutions

Formulation, fill, finish, and cryopreservation

Wash and cryopreservation
- CTS DPBS, calcium, magnesium
- CTS HBSS
- CTS Synth-a-Freeze Medium

Instrumentation
- CTS Compleo Fill and Finish System*

* Coming soon.

Cryogenic storage and logistics
- CryoMed Controlled-Rate Freezer
- CryoPlus LN_2 Storage Systems
- CryoExtra High-Efficiency Cryogenic Storage Systems
- Rigid containment solutions
- Nalgene General Long-Term Storage Cryogenic Tubes
- Nunc Biobanking and Cell Culture Cryogenic Tubes
- Biobanking services
- Cold-chain logistics solutions
- Ultralow temperature and cryogenic freezers

Lot release and characterization

Lot-release testing
- MycoSEQ Mycoplasma Detection Kit
- SteriSEQ Rapid Sterility Testing Kit (in-process testing)

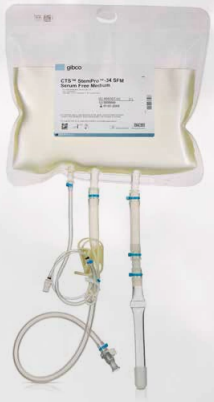
In-process characterization
- Cellular analysis
- Protein assays and analysis

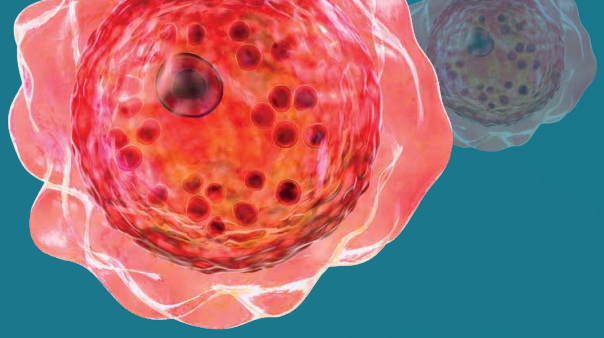
Stem cell quality control
- CLA IdentiFiler Plus PCR Amplification Kit
- CLA GlobalFiler PCR Amplification Kit
- KaryoStat and KaryoStat HD karyotyping kits
- GeneChip PrimeView Global Gene Expression Profile Assay
- TaqMan hPSC Scorecard Panel
- Pluripotent stem cell immunohistochemistry kits

Product spotlight:

Gibco™ CTS™ StemPro™-34 SF XenoFree Medium

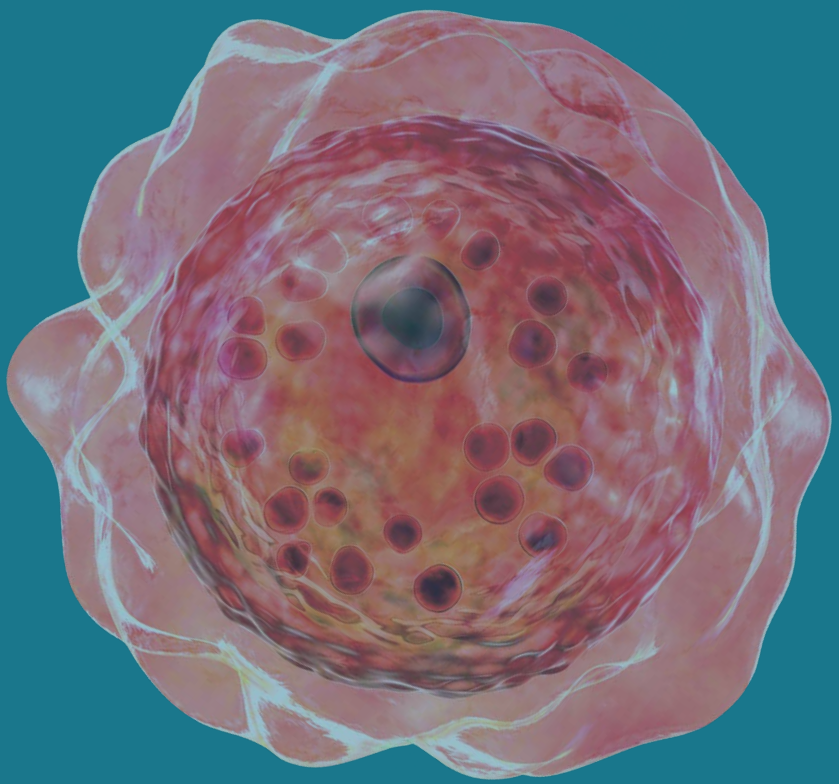
- **Serum-free and xeno-free:** CTS StemPro-34 medium is formulated without serum or nonhuman-derived components to comply with global regulations for ancillary materials in cell therapy manufacturing. The medium is formulated with L-glutamine and without phenol red.
- **Supports cell differentiation:** Facilitates the differentiation of induced pluripotent stem cells (iPSCs) to hematopoietic stem cells (HSCs) and further differentiation into immune cells (e.g., NK cells, T cells, B cells, macrophages).
- **CGMP manufactured:** Produced in accordance with 21 CFR Part 820 and ISO 9001 standards to ensure high quality and safety.
- **Compliance:** Designed to meet USP <1043> standards for ancillary materials used in cell, gene, and tissue-engineered products.



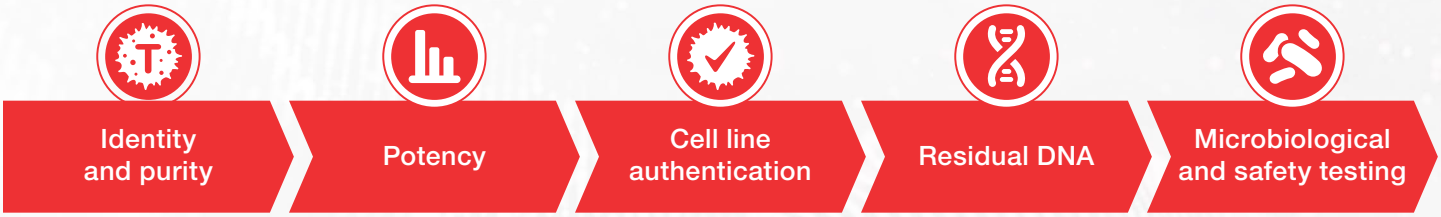


CELL CHARACTERIZATION AND QUALITY CONTROL

Our goal is to help protect each cell therapy dose with automated, rapid analytical solutions and exceptional data quality throughout all development phases from research and discovery to commercialization.



ANALYTICAL SOLUTIONS TO HELP ENSURE SAFETY, STERILITY, AND POTENCY



Research and discovery	Discover new targets, identify biomarkers, modify genes, and construct vectors for research and drug discovery applications.
Process development and optimization	Design or leverage ready-to-use protocols to build and iterate processes for drug development, enabling faster analytical methods transfer for release testing and QC. Characterize and ensure the right cell populations as you move into preclinical development. Rapid turnaround times with sample assessment help ensure flexibility in protocol optimization.
Preclinical phase	Continue to characterize cell populations and verify genetic stability and integrity of cells, preventing early stage failures, using automated genetic analysis and other quality control measures.
Clinical phases I–III	Precisely characterize patient-specific cell populations for autologous cell therapies and ensure the consistency, purity, and potency of cell products for lot release in clinical settings.
Commercialization and production	Evaluate critical quality attributes of the product prior to batch release in accordance with CGMP standards. Optimize the analysis of large sample volumes with high-speed, scalable analytical solutions.

Tools and products for monitoring critical quality attributes throughout the cell therapy research, development, and manufacturing processes and for QC release testing

A fundamental attribute to creating a successful cell therapy product is quality and patient safety. The ability to accurately assess process-related impurities, rule out potential microbial contaminants, and confirm the purity and potency of the final product is essential. In-process analytical testing and environmental monitoring are also critical components of an optimal cell therapy manufacturing process.

Our scientists have developed and verified reliable products for impurity and contamination testing:

- **Applied Biosystems™ MycoSEQ™ Plus Mycoplasma Detection Kit**—identification of possible mycoplasma contamination
- **Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit**—rapid and accurate detection of bacteria and fungi in complex bioproduction samples
- **Applied Biosystems™ ViralSEQ™ Lentiviral Titer Kit**—rapid quantification of the proviral and physical titer of lentivirus samples
- **Applied Biosystems™ resDNASEQ™ DNA Quantitation Kit**—quantification of residual DNA from various host-cell and gene-expression systems
- **Applied Biosystems™ MicroSEQ™ Microbial Identification System**—identification of possible microbial contaminants

The complete Applied Biosystems™ SEQ analytical testing solution is an integrated, rapid real-time PCR (qPCR) workflow.* Comprising functionally confirmed sample-to-answer protocols, commercially available kits for sample preparation and qPCR, and instruments with analytical software to help enable regulatory compliance, the SEQ workflow enables a flexible approach to meet a variety of cell therapy testing applications.

* The MicroSEQ Microbial Identification System utilizes PCR and sequencing platforms.

Sample prep

Applied Biosystems™ AutoMate *Express*™ Nucleic Acid Extraction System and PrepSEQ™ Express Nucleic Acid Extraction Kit

Assays

Applied Biosystems™ MycoSEQ Plus Mycoplasma Detection Kits

Detection

Assays run on the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System.

Analysis

Applied Biosystems™ AccuSEQ™ software

Sensitive detection method for mycoplasma testing

Cell therapy products have a short shelf life and require rapid methods when testing for contamination. The inherent complexity of cell therapy characteristics renders traditional sterility testing technically challenging.

Mycoplasma testing should be performed throughout the workflow at several key points, including cell banking, various stages of scale-up, and harvest, to mitigate risk throughout your process.

The MycoSEQ Plus Mycoplasma Detection Kit is an Applied Biosystems™ TaqMan™ Assay–based qPCR kit that builds on the success of the MycoSEQ Mycoplasma Detection Kit. Both are designed and verified to help cell therapy customers meet regulatory requirements for mycoplasma detection for in-process and lot-release testing in less than 5 hours.

The MycoSEQ and MycoSEQ Plus Mycoplasma Detection Kits are part of an integrated workflow solution that includes automated sample prep, quantitation instrumentation, and analysis and documentation software.

Features of the MycoSEQ and MycoSEQ Plus Mycoplasma Detection Kits include:

- Same day, actionable results
- Meets or exceeds the recommended regulatory guidance of 10 colony forming units per mL (CFU/mL) or 10 genome copies per mL (GC/mL) for a variety of mycoplasma species
- Optimized, fully automated sample preparation
- Integrated software solution with features to support 21 CFR Part 11 compliance
- Extensive network of experienced field application specialists offering support

Learn more at **thermofisher.com/mycoseq**

Rapid sterility testing for process and analytical development

Sterility testing is mandatory for all manufactured biological materials. Rapid in-process testing results can be used to assess microbiological safety and facilitate the release of short shelf-life products such as cell therapies, while awaiting final 14-day test results using traditional sterility testing methods.

The SteriSEQ Rapid Sterility Testing Kit is a TaqMan Assay–based qPCR kit for the detection of bacteria and fungi in complex bioproduction samples. Designed and tested using criteria for rapid bacteria and fungi detection in biotherapeutic manufacturing cell culture lots, the kit meets or exceeds sensitivity and specificity guidance provided in European Pharmacopoeia (Ph. Eur. 2.6.27) and U.S. Pharmacopoeia (USP <1071>).

Features of the SteriSEQ Rapid Sterility Testing Kit include:

- Fast sample-to-answer turnaround time of less than a day; delivers results in <5 hours
- Specific primers and probes designed for bacteria (16S rRNA) and fungi (18S rRNA)
- Detects bacterial and fungal species at 5–25 genome copies per reaction
- Minimizes use of sample material by simultaneously testing for bacteria and fungi, preserving precious cells for the final product and enhancing efficiency
- The discriminatory positive control helps eliminate false positives, and an internal positive control helps ensure PCR reaction consistency in the samples

Learn more at **thermofisher.com/steriseq**

Luminex® xMAP INTELLIFLEX® System

The Luminex xMAP INTELLIFLEX System is an advanced and versatile multiplexing platform, featuring an embedded PC with a touchscreen interface and a minimal footprint. It comes with automated start up, shut down, and maintenance routines, and provides fast read times for both 96- and 384-well plate formats.

Advantages of Luminex xMAP technology include:

- Helps reduce costs and labor through multiplexing
- Smaller sample size requirements compared to single result assays
- Enables fast, reproducible results from favorable kinetics of liquid bead array approach
- Broad coverage of applications, including protein expression and gene expression profiling

Residual DNA quantitation solutions

In the development of *ex vivo* gene-modified cell therapies, viral vectors are often used. In these cell-based production processes, regulatory agencies worldwide require that host cell DNA and other undesirable DNA impurities are below specified amounts in the final drug product. The Applied Biosystems™ resDNASEQ™ quantitative DNA system is a qPCR-based assay designed to enable sensitive and accurate quantitation of residual host cell DNA and residual plasmid DNA during in-process and lot-release testing.

Applied Biosystems™ ViralSEQ™ Lentivirus Proviral DNA Titer Kit

The ViralSEQ Lentivirus Proviral DNA Titer Kit is a qPCR assay for the quantitation of integrated proviral DNA in transduced cells. Proviral copy number can be used to calculate infectious lentiviral titers (TU/mL) and subsequently, the volume of vector supernatant needed to transduce cells at the desired multiplicity of infection (MOI). The assay can also be used to measure vector copy number (VCN), a critical quality attribute (CQA) in cell and gene-modified cell therapy development.

Features of the ViralSEQ Lentivirus Proviral DNA Titer Kit:

- Lentiviral genome-specific qPCR assay for provirus quantitation
- Assay design compatible with more than 200 lentivirus transfer plasmids
- Includes master mix, TaqMan Assay mix, and DNA control
- Configuration with Applied Biosystems™ PrepSEQ™ kit available for optimized DNA recovery

Applied Biosystems™ ViralSEQ™ Lentivirus Physical Titer Kit

The ViralSEQ Lentivirus Physical Titer Kit is a one-step reverse transcription quantitative PCR (RT-qPCR) assay for the quantitation of genome-containing lentiviral particles in supernatants from cell-based bioproduction systems. Lentiviral quantitation is a CQA in viral vector manufacturing for cell and gene-modified cell therapy development.

Features of the ViralSEQ Lentivirus Physical Titer Kit:

- Lentiviral genome–specific RT-qPCR assay for accurate viral particle count
- Assay design compatible with more than 200 lentivirus transfer plasmids
- Includes master mix, TaqMan Assay mix, and RNA control
- Configuration with PrepSEQ kit available for optimized RNA recovery

Applied Biosystems™ QuantStudio™ Absolute Q™ Digital PCR System

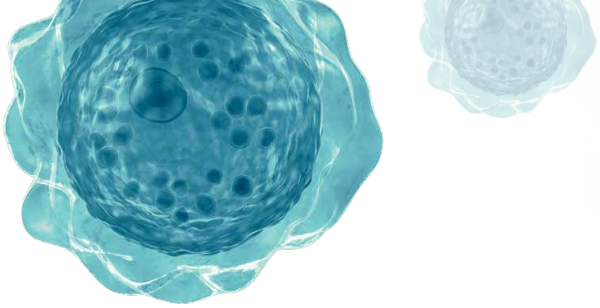
The QuantStudio Absolute Q Digital PCR System is a plate-based digital PCR (dPCR) platform powered by proprietary microfluidic array plate (MAP) technology that enables all the necessary steps for dPCR—compartmentalizing, thermal cycling, and data acquisition—to be conducted on a single instrument. The qPCR-like workflow helps improve ease of use, minimizes hands-on steps, and maximizes consistency.

Features of the QuantStudio Absolute Q Digital PCR System

- **Single instrument, single plate, simple workflow:** Eliminate cumbersome and challenging sample and reagent preparation steps from your dPCR workflow. The QuantStudio Absolute Q system requires only one hands-on step that takes under five minutes to complete with minimal technical skill.
- **Exceptional consistency:** Powered by MAP technology, the QuantStudio Absolute Q system and Applied Biosystems™ QuantStudio™ Absolute Q™ MAP16 dPCR plates enable excellent consistency in total microchambers analyzed.
- **Minimize wasted sample volume:** Leveraging MAP technology and precise reagent loading, over 95% of your input sample is analyzed per reaction compared to the 25–60% analyzed in other dPCR platforms.
- **Fast time to answer:** Reagent digitization, thermal cycling, and data collection are integrated into a single system with no manual transfer steps for run completion in <90 minutes.

Thermo Scientific™ Orbitor™ RS2 Microplate Mover

The Orbitor RS2 Microplate Mover was engineered to be a reliable and efficient productivity partner with QuantStudio qPCR and dPCR instruments. Whether you're identifying new leads and biomarkers, finding a gene of interest, or screening preclinical and clinical samples, you'll need high-throughput screening solutions to meet your timelines. Save precious time, reduce human errors, and enhance efficiency as you scale your operations.



Applied Biosystems™ Diomni™ Enterprise Software

Data analysis and organization are consistent pain points during the development process. Diomni Enterprise Software is a web application that can help automate your workflow and assist in error-free data analysis. Diomni software organizes everything from your assay selection to your quality control in one straightforward interface that allows you to track and prioritize important processes.

Applied Biosystems™ TaqMan™ Cells-to-C_T™ Express Kit

This RT-qPCR kit provides an extraordinarily fast and easy way to quantify cellular RNA by eliminating the RNA isolation step. In doing so, this kit removes the need for heating, centrifugation, or filtration of your reaction. Removing these steps helps streamline your workflow and facilitates the high-throughput operations that may be needed during molecular drug development.

To streamline your process, this kit only requires five reagents:

- Applied Biosystems™ TaqMan™ Cells-to-C_T™ Express Lysis Solution
- Invitrogen™ ezDNase™ Enzyme
- Applied Biosystems™ SuperScript™ IV VILO™ Master Mix
- Applied Biosystems™ SuperScript™ IV VILO™ No RT Control
- Applied Biosystems™ TaqMan™ Fast Advanced Master Mix for qPCR

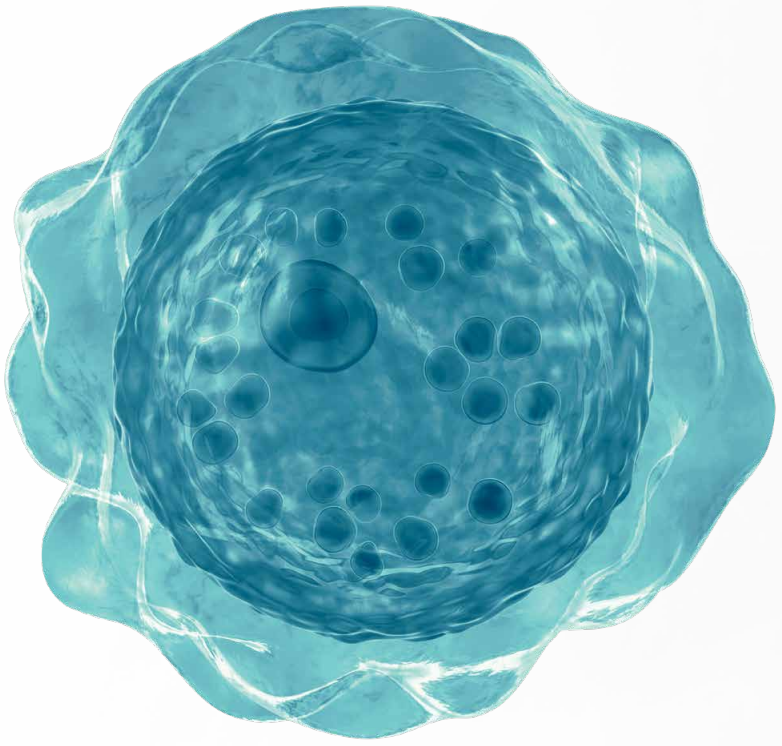
Applied Biosystems™ TaqMan™ Array Cards and Plates

Expedite target screening with Applied Biosystems™ TaqMan™ Gene Expression Assays dried down in three array formats: 96-well and 384-well TaqMan Array Plates, 384-well TaqMan Array Cards (microfluidic cards), and Applied Biosystems™ OpenArray™ Plates. These qPCR arrays are excellent for gene expression profiling and verification applications that may require analysis of up to thousands of targets.

Applied Biosystems™ TaqPath™ master mixes

Quality qPCR products allow you to conduct your science with confidence. All TaqPath master mixes are manufactured at ISO-certified facilities that follow CGMP principles. In addition, TaqPath master mixes have rigorous analytical and functional lot-release quality control, detailed in the lot-specific Certificate of Analysis (COA), enabling lot-to-lot consistency.

Master mixes are designed with biopharma in mind and for any stage in the biologics development process. We also provide compliance documentation, so you don't spend valuable time chasing down the necessary forms.



Invitrogen™ Attune™ flow cytometers

The Invitrogen™ Attune™ NxT, Attune™ CytPix™, and Attune™ Xenith™ flow cytometers are an advanced suite of instruments designed to meet diverse research needs in cellular analysis. Central to all three systems is the core acoustic hydrodynamic focusing technology, which enables high-speed performance and significantly reduces the risk of clogging, helping to ensure reliable and efficient operation.

The Attune NxT Flow Cytometer is renowned for its high-speed, high-sensitivity performance, allowing detailed analysis of complex cell populations with ease.

The Attune CytPix Flow Cytometer adds advanced imaging capabilities to flow cytometry, allowing for simultaneous cell imaging and analysis, providing researchers with comprehensive insights into cell morphology and phenotype.

Specifically, the instrument enables cell characterization, identity, and purity analysis in cell therapy research and development via the following:

- Starting donor cell quality and health assessment, target cell yield, and isolation efficiency
- Target cell isolation, activation, memory, and exhaustion assessment
- Post-editing and end-of-expansion cell quality and health assessment
- Functional characterization of the final product (cytotoxicity assays)

The Attune Xenith Flow Cytometer offers innovative features, including advanced spectral capabilities with ultraviolet (UV) and near-infrared (NIR) lasers, supporting both conventional and spectral unmixing analysis. These attributes solidify the Attune portfolio of flow cytometers as the premier choice for researchers demanding accuracy, efficiency, and versatility in their cellular studies.

Learn more at **thermofisher.com/attune**

Invitrogen™ Bigfoot™ Spectral Cell Sorter

The Bigfoot Spectral Cell Sorter is designed with up to 9 lasers and 60 detectors, using conventional compensation, or spectral analysis to resolve even more markers and cell populations. Integrated biocontainment and aerosol management help protect you and your samples. With sort rates exceeding 70,000 events per second, the system can sort a 96-well plate in less than 8 seconds and a 384-well plate in less than 11 seconds. Simple enough for an individual lab and robust enough for a core facility, the Bigfoot Spectral Cell Sorter can help you master the full range of sorting experiments, from sorting cells labeled with fluorescent proteins to deep immunophenotyping, genomics, cell and gene therapy research, and other high-performance, high-throughput applications.

Learn more at **thermofisher.com/bigfoot**

Cell therapy characterization capabilities

We offer a wide variety of analytical platforms and assays to support cell therapy development.

	Assay type	Assay platform	Assay kits and reagents	Instrument
Identity, purity, and potency	Biomarker profiling	Flow cytometry	Antibodies and other reagents	Attune CytPix Flow Cytometer
		Luminex® xMAP® system	Multiplex assays (Invitrogen™ ProcartaPlex™ assays)	Luminex® xMAP INTELLIFLEX, Luminex 200™, or FLEXMAP 3D® systems
		ELISA	Invitrogen™ ELISAs	Thermo Scientific™ Varioskan™ LUX Multimode Microplate Reader
		High-content screening (HCS)	Antibodies and other reagents	Thermo Scientific™ CellInsight™ CX7 LZR Pro HCS system
		Immunocytochemistry (ICC)	Antibodies and other reagents	Invitrogen™ EVOS™ M7000 Imaging System
		Immunoprecipitation (IP)	Antibodies	Standard IP
		qPCR and dPCR	Applied Biosystems™ PureQuant™, TaqMan™, TaqPath™, and QuantStudio™ Absolute Q™ assays	Applied Biosystems™ QuantStudio™ 6 and 7 Pro and Absolute Q systems
	Functional	Flow cytometry	Antibodies for flow cytometry reagents	Attune CytPix Flow Cytometer
			Flow cytometry reagents	Flow cytometry reagents
		Luminex xMAP system	Invitrogen™ ProcartaPlex™ multiplex assays	Luminex® MAGPIX®, Luminex 200 with xPONENT 3.1, Luminex xMAP INTELLIFLEX, Luminex 200, and FLEXMAP 3D systems
			Invitrogen™ QuantiGene™ Plex assays	
	Molecular	qPCR and dPCR	PureQuant, TaqMan, TaqPath, and QuantStudio Absolute Q assays	QuantStudio 6 and 7 Pro and Absolute Q systems
		Array-based	Applied Biosystems™ Human Genome U219 and U133 arrays, Applied Biosystems™ Clariom™ S and D assays	Applied Biosystems™ GeneChip™ Scanner 3000 7G
				Applied Biosystems™ Clariom™ D Assay, human
				Applied Biosystems™ Clariom™ S Array, human
				Applied Biosystems™ GeneTitan™ MC Fast Scan Instrument, international (220V)
		NGS-based	Ion AmplSeq™ custom targeted NGS testing panels, Ion Torrent™ Oncomine™ Focus Assay	Ion GeneStudio™ S5 systems
				Ion AmpliSeq™ Custom Targeted NGS Testing Panels
				Oncomine Focus Assay
Cell line authentication, safety, and microbiological testing	HLA typing	Reverse sequence-specific oligonucleotide typing (rSSO) combined with the Luminex xMAP system	One Lambda™ LABType™ rSSO assays	LABScan3D™ system
		Sanger sequencing	One Lambda™ SeCore™ sequence-based typing (SBT) kits	Applied Biosystems™ 3100, 3730, 3500xL, and 3500xL Dx Genetic Analyzers; SeqStudio Flex Genetic Analyzer
	Sample tracking and authentication	Capillary electrophoresis	Applied Biosystems™ Identifiler™ STR assays, GlobalFiler™ STR assays	Applied Biosystems™ Thermal cycler and 3500, 3500xL, and SeqStudio Flex Genetic Analyzers
				GlobalFiler PCR Amplification Kit
				3500/3500xL Genetic Analyzer User Guide—Data Collection Software v3.3 (Pub. No. 100079380 Rev.E)
				SeqStudio Flex Genetic Analyzers
	Mycoplasma	Applied Biosystems™ SYBR™ Green RT-PCR assay	MycoSEQ kits	Applied Biosystems™ 7500 Fast Real-Time PCR System
		qPCR	Applied Biosystems™ TaqPath™ BactoPure™ Microbial Detection Master Mix	Applied Biosystems™ QuantStudio™ instruments
	Sterility testing	qPCR	SteriSEQ Rapid Sterility Testing Kit	7500 Fast Real-Time PCR System
	Endotoxin	Chromogenic assay	Thermo Scientific™ Pierce™ Chromogenic Endotoxin Quant Kit	Thermo Scientific™ Multiskan™ Sky Microplate Spectrophotometer

BASICS TO CONSIDER WHEN SETTING UP A CELL THERAPY PRODUCTION FACILITY

CTS Series laboratory equipment

Thermo Scientific™ CTS™ Series laboratory equipment supports your ISO Class 5, EU CGMP, and cleanroom needs for cell and gene therapy manufacturing, and helps you get up and running faster, stay compliant, support regulatory audits, and stay on schedule.

Included are:

- Selected products with high capacity, enhanced cleanability, contamination prevention technologies, and documentation functionalities
- Documentation package including factory acceptance test (FAT) documentation and certifications, as well as recommended protocols
- Compliance services including installation qualification (IQ), operation qualification (OQ), and (depending on product) cycle testing or temperature mapping

Learn more at **thermofisher.com/ctslabequipment**

CO_2 incubators (cleanroom compatible)

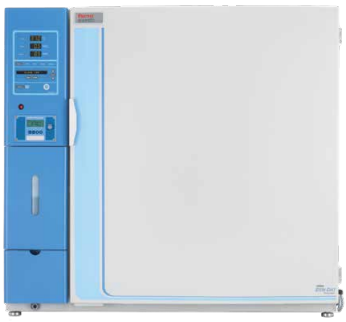
Heracell VIOS CR CO_2 incubators are suitable for CGMP-grade A/B environments. They are available in two model sizes: 165 L (5.8 cu ft) and 255 L (9.0 cu ft) in a compact footprint and readily stackable. Thermo Scientific™ CultiMaxx™ Shelving Systems are dedicated to optimize the inner space of the larger 250i model for large vessel types such as G-Rex™ 500M-CS bioreactors by Wilson Wolf and Thermo Scientific™ Nunc™ Cell Factory™ systems, enabling increased production per footprint and better vessel access.

Biological safety cabinets

The Thermo Scientific™ Herasafe™ 2030i Biological Safety Cabinet, CTS Series, is designed to maximize sample protection and user safety, with an emphasis on containment, comfort, and convenience. Equipped with smart self-monitoring safety features, an intuitive touchscreen, and built-in connectivity, this safety cabinet is available with a complete documentation package and compliance services.

Centrifuges

Thermo Scientific™ General Purpose Pro Centrifuges, CTS Series, provide optimal spin performance and easy programming with an intuitive touchscreen interface. These 4 L bench and floor models are available with a documentation package and compliance services to enable fast setup in a CGMP environment.



CO_2 incubators

Thermo Scientific™ Forma™ Steri-Cult™ CO_2 Incubators, CTS Series, provide excellent protection for high-value cultures. With two model sizes, 232 L (8.2 cu ft) and 322 L (11.4 cu ft), these stackable incubators are ideal for high-volume culturing. Features include proven 12-logarithmic-unit sterilization, in-chamber HEPA filtration, an active humidification system, and compatibility with common CGMP facility protocols.

Controlled-rate freezers with OPC UA

CryoMed Controlled-Rate Freezers provide precise, repeatable freezing results that protect precious samples from intracellular ice formations. There are three size options: 17 L, 34 L, and 48 L; and their firmware comes integrated with an OPC UA protocol, enabling equipment communication via the DeltaV system and other distributed control systems. They are compliant with 21 CFR Part 11.

Thermo Scientific™ DynaDrive™ Single-Use Bioreactor (S.U.B.) with bioprocess controllers and software

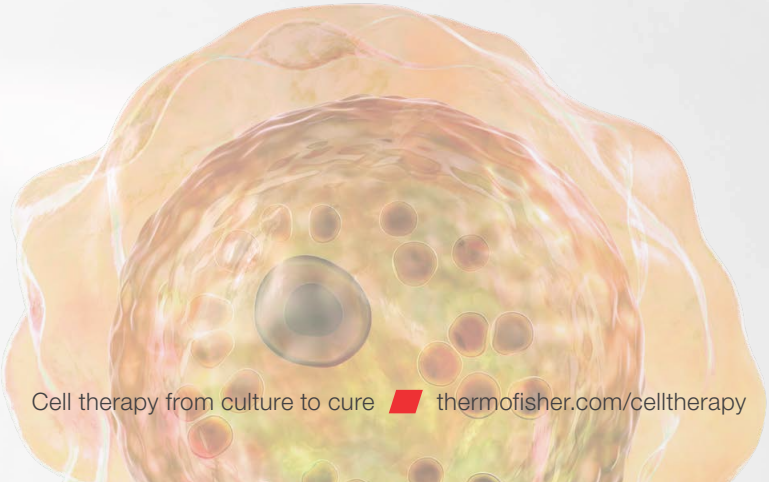
At the forefront of innovation in the cell therapy field are the development of allogeneic therapies and developing manufacturing processes that scale for commercial use. The DynaDrive S.U.B. is the latest advancement based on our history of innovation, offering superb performance to accommodate larger volumes as programs progress to commercialization. The DynaDrive S.U.B. can decrease the cost of production by up to 25% through a reduction in equipment, materials, consumables, and labor. This is enabled by the increased reactor size that lowers the number of production batches required for a given volumetric demand. The DynaDrive S.U.B. is able to fully integrate with Thermo Scientific™ HyPerforma™ bioprocess controllers with Thermo Scientific™ TruBio™ software, powered by the DeltaV Distributed Control Platform. The system consists of a control tower that leverages intelligent transmitters, mass flow controllers (MFCs), pumps, sensors, and TruBio bioprocess automation software that facilitates easy, reliable, and repeatable process development and commercial cell culture processes.

Learn more at **thermofisher.com/dynadrive**

Thermo Scientific™ Labtainer™ Pro BioProcess Container (BPC)

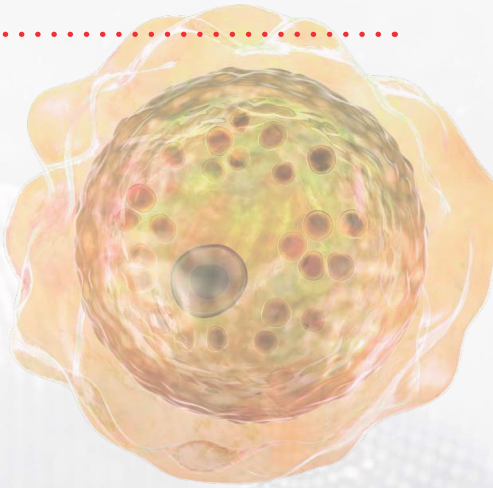
As technology and innovation advance within the bioprocessing industry, single-use technologies have also made considerable progress in the drug and vaccine manufacturing space. Some of the well-established and well-known advantages of single-use systems are lowered costs, reduced contamination risks, decreased facility footprint, increased flexibility, and production throughput efficiency with less cleanup; all resulting in quicker turnaround and increased production capabilities. The innovative concept of the Labtainer Pro BPC provides flexibility and assurance—without compromise.

Learn more at **thermofisher.com/labtainerpro**



CDMO SERVICES
FROM DEVELOPMENT TO DELIVERY

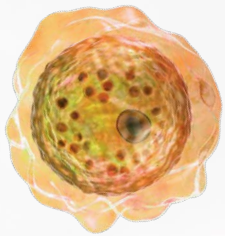
When outsourcing the production of your advanced therapeutic products, finding a CDMO partner with the right expertise, capacity, and global supply network is increasingly important to seamlessly transition from preclinical research and development to commercial manufacturing with confidence. Thermo Fisher Scientific offers the assurance of partnering with an experienced and adaptable CDMO, combining scale with breadth of services and an extensive support network to help meet your critical timelines. Save time and effort with integrated solutions to advance scale-up of cell therapy product manufacturing and get to market faster.

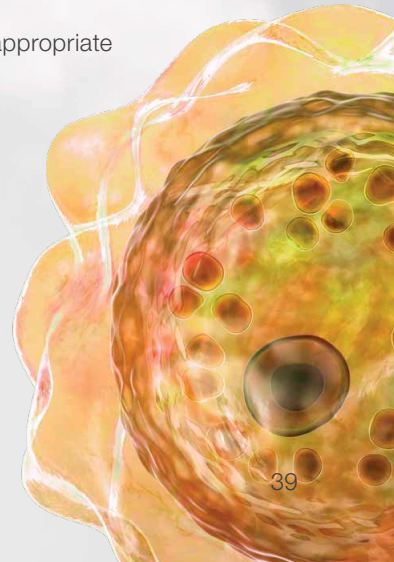


Translational services

Lack of early establishment of manufacturing controls introduces risk when transitioning from early discovery work to clinical manufacturing and can lead to unnecessary delays and added cost. Streamline your translational research to rapidly identify lead therapeutic drug candidates by leveraging high-quality material to generate reliable proof-of-concept data. Translational services utilize established, scalable processes with advanced analytical testing representative of future CGMP workflows to support candidate drug selection. With us by your side, you can accelerate the journey from innovation to impact, reaching your goals with speed and confidence.

- Access to emerging technologies through R&D, operational, and regulatory support
- Use of research use only (RUO) materials with CGMP-equivalent counterparts
- Qualified equipment, robust training, starting and raw materials vendor management, and processes to monitor performance drift
- Scaled-down processing models using qualified reagents and analytics
- Robust in-process testing and monitoring
- Methods based on the latest regulatory guidance, continuous understanding, and incorporation of regulatory requirements
- Qualifiable assays built on platforms transferable to QC, with inclusion of appropriate controls and standards





Viral vector development and manufacturing services

Our viral vector services team has extensive experience and a proven track record of manufacturing diverse CGMP viral vector products to support cell and gene therapies for more than 20 years, including AAV, adenovirus, lentivirus, HSV, retrovirus, and numerous others. Our end-to-end solutions encompass process and analytical development, cell line development, master cell banking, viral vector assembly, scale-up to CGMP for clinical or commercial manufacturing (50 L to 2,000 L), and sterile fill and finish of viral vectors.

Cell therapy development and manufacturing services

To address the evolving needs of the cell therapy field, we provide process and analytical development capabilities as well as clinical and commercial manufacturing for a variety of modalities, including:

- Autologous and allogeneic cell therapies
- Viral and nonviral modified gene delivery systems
- T cells, NK cells, iPSCs, MSCs, APCs, hESCs, blood- and bone marrow–derived stem cells, and more

With a flexible approach to partnership and user-configurable CGMP production suites, we are well equipped to support your cell therapy program requirements, balancing the need for speed with an unwavering focus on quality.

mRNA development and manufacturing services

To support the increasing number of clinical applications for mRNA technology, we offer a flexible end-to-end service model inclusive of process and analytical development, CGMP manufacturing for mRNA synthesis and lipid nanoparticles (LNP), and sterile fill-finish capabilities, all under one roof at our Monza center of excellence site in Italy. Our team is equipped to meet your complex mRNA manufacturing needs, with flexibility to address both small-volume requests and larger projects up to 100 g. Leverage the full suite of integrated services or just choose those that help fill immediate gaps in your capabilities or capacity.

Advanced therapy supply chain solutions

Through our expansive global network of biorepositories, integrated quality systems, and a proven track record of safeguarding the integrity of millions of samples, Thermo Fisher Scientific excels in storing, processing, and transporting specialized cell and gene therapies across the globe, spanning from cold to cryogenic temperatures. Our diverse offering of supply chain solutions includes:

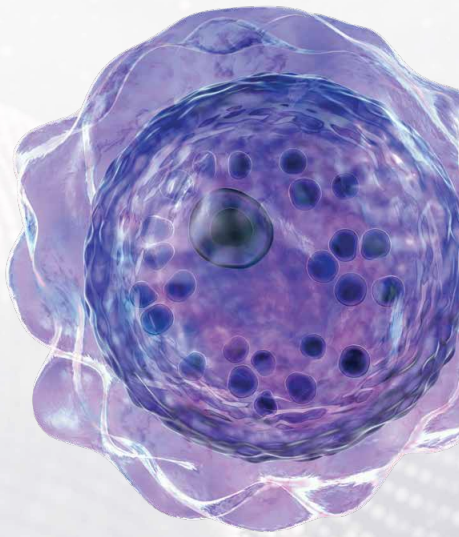
- CGMP biologics management and storage
- Cold chain logistics and distribution
- Clinical site and specialty courier services
- Continuous monitoring for cryogenic shipments
- Comprehensive chain of custody and identification capabilities (inclusive of serialization)
- Custom temperature-controlled packaging and labeling
- Kit production

CRO SERVICES
LEADING THE WAY IN CLINICAL RESEARCH

The unique demands of cell therapy clinical trials call for a prepared development partner. The extensive therapeutic and functional expertise of the PPD clinical research business of Thermo Fisher Scientific has guided a diverse range of cell and gene therapy assets through the development pipeline.

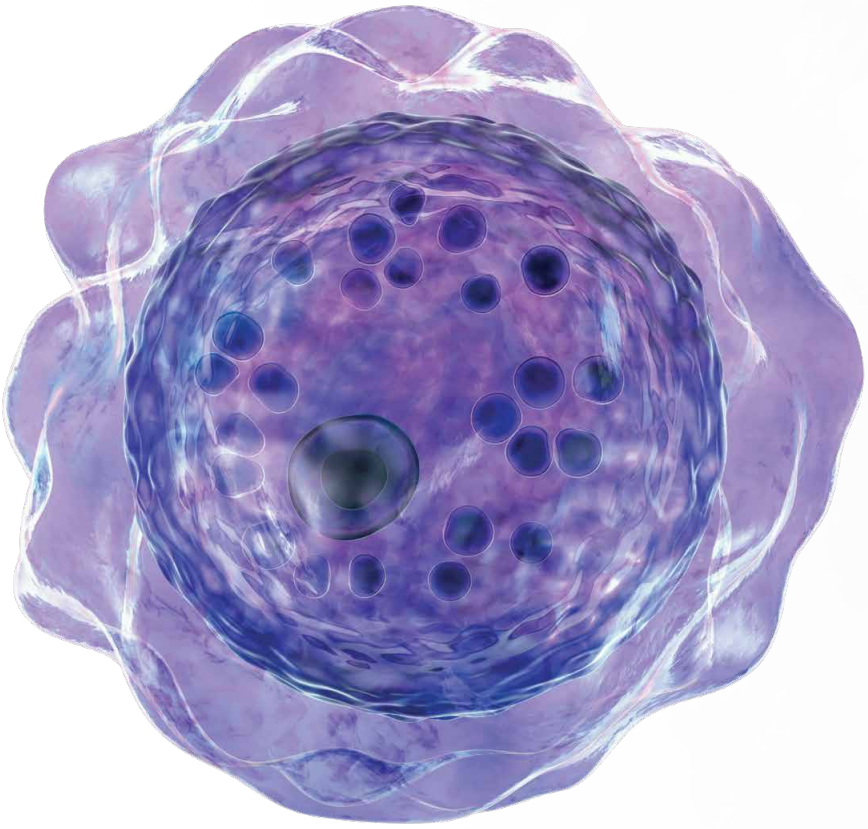
Our comprehensive, end-to-end cell and gene therapy CRO solutions leverage more than two decades of experience—including more than 55 cell therapy trials spanning both autologous and allogeneic cell types, such as tumor-infiltrating lymphocytes (TILs), chimeric antigen receptor (CAR) T cells, CAR NK cells, B cells, and dendritic cells.

Moreover, we can seamlessly integrate manufacturing, laboratory services, ultracold chain logistical support, and clinical trial management to better serve sponsors needing a streamlined process to reduce vendor management risks and burden.



How we support customers across all phases:

- **Tailored patient support:** We recognize the complexities of participation in cell and gene therapy trials for patients. Our commitment to and support of patients enables them and their caregivers to be well-informed of the study protocol, risks, and potential benefits and to stay engaged through the duration of the study, from day one through long-term follow-up.
- **Extensive safety protocols:** Because of the inherent unknowns associated with many cell and gene therapy studies, we put patient safety at the forefront of each step in our strategies to closely monitor and mitigate risks. Our capabilities include developing sound dose-finding and dose escalation strategies and using PPD™ Preclarus™ dashboards that combine study and lab data to identify trends and preemptively identify toxicities.
- **Full-spectrum laboratory services:** Our specialized, advanced, and customizable lab capabilities include cell-based, bioanalytical, and genomic testing capabilities to serve clients from preclinical through CGMP product testing.
- **Expert logistics management:** Whether it's shipping viral vectors or cryopreserved autologous cell therapy investigational medicinal products, our global logistics management team securely maintains chain of custody and chain of identity for every product and ancillary component. We skillfully navigate the sensitive timelines and storage demands of cell and gene therapy development.
- **Comprehensive training:** We facilitate extensive team training in cell and gene therapy through our employee development programs, which include ongoing education and development for sites and investigators.
- **Diligent regulatory expertise:** We are dedicated to keeping pace with the evolving regulatory landscape (globally and regionally) for advanced therapy medicinal products (ATMPs). We work with clients to develop and execute regulatory strategies based on their business desires for current and future market access.
- **Clinical trial services:** Our comprehensive, end-to-end cell therapy CRO solutions leverage more than two decades of experience—including more than 130 clinical trials in the past five years—to meet the distinct needs of patients, sites, caregivers, and sponsors.
- **Evidence generation strategies:** Our team of specialists routinely develops advanced models to generate total evidence packages (e.g., real-world evidence) for stakeholders to identify novel pricing, such as outcome-based reimbursement plans, for curative therapies.



Accelerator™ Drug Development by Thermo Fisher Scientific—360° CDMO and CRO drug development solutions

Being an integrated CDMO and CRO, we provide you with expertise and exceptional resources for all phases of your drug development and manufacturing, from early development through clinical research and commercialization. Thermo Fisher offers an end-to-end suite of drug development and clinical services spanning drug substance and drug product manufacturing for small molecule, large molecule, and advanced therapies, as well as clinical supply, clinical research, and commercialization. Our end-to-end approach helps ensure collaboration across the drug development process, helping to enable increased speed, simplicity, and scalability.

To learn more visit **patheon.com/acceleratordrugdevelopment**

BIOPROCESSING SERVICES

As a leader in quality, innovation, and capacity, we offer tailored media manufacturing services across all stages through to commercial manufacturing. With experience in media manufacturing, scalable solutions, and format conversion, our exceptional team and leading services can help enhance your workflows and support your entire media manufacturing journey.

Gibco™ Rapid Prototyping Services

Accelerate media development and scale-up with fast, non-CGMP, custom media manufacturing at pilot scale.

CGMP media manufacturing services

Outsource the manufacturing of your media formulation and benefit from supply assurance, consistent quality, and our global site equivalency.

Gibco™ Media by Design™ Services

Benefit from tailored media and process development services, designed to help meet your goals.

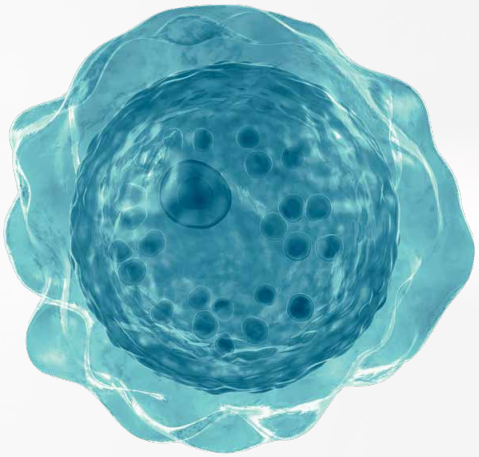
Media development and customization services

Customize Gibco™ catalog products—add or remove components, create customized packaging options, select QC tests, and more. Optimize your medium for growth, expansion, and functionality. Our custom media and feed development service offers the potential to elevate process productivity and consistency and help improve product quality.

Gibco™ Bioprocessing Analytical Services

Gain rapid quantitative answers about changes to nutrient components and utilization profiles over time in your process. This analytical service is available for both fresh and spent media, as well as for a supplement analysis.

Learn more at **thermofisher.com/bioprocessing**



Purification solutions

Our advanced purification technologies have been used in numerous commercial biotherapeutic downstream processes. Our affinity resins are available as a platform for purification of all AAV subtypes and other vectors. Combining the innovative Thermo Scientific™ CaptureSelect™ affinity technology and Thermo Scientific™ POROS™ large-pore beads allows for high-throughput chromatography of large biomolecules. Our proprietary technology provides high product purity in a single step while maximizing yield, helping to simplify the purification process. We offer a novel platform with scalable resins, starting from 96-well plates, designed for bench-scale to process-scale purification of a range of viral vectors.

Global facilities

We have a large network of CGMP facilities, strategically located around the world to support our customers. These advanced, ISO-certified facilities help ensure that we can supply the high-quality products to all of our customers globally, uninterrupted. Our team will work closely with you to understand your demand and set safety stocks to help keep you on a steady path to success.

Production Chemicals and Sourcing Services; Process Liquid Preparation Services

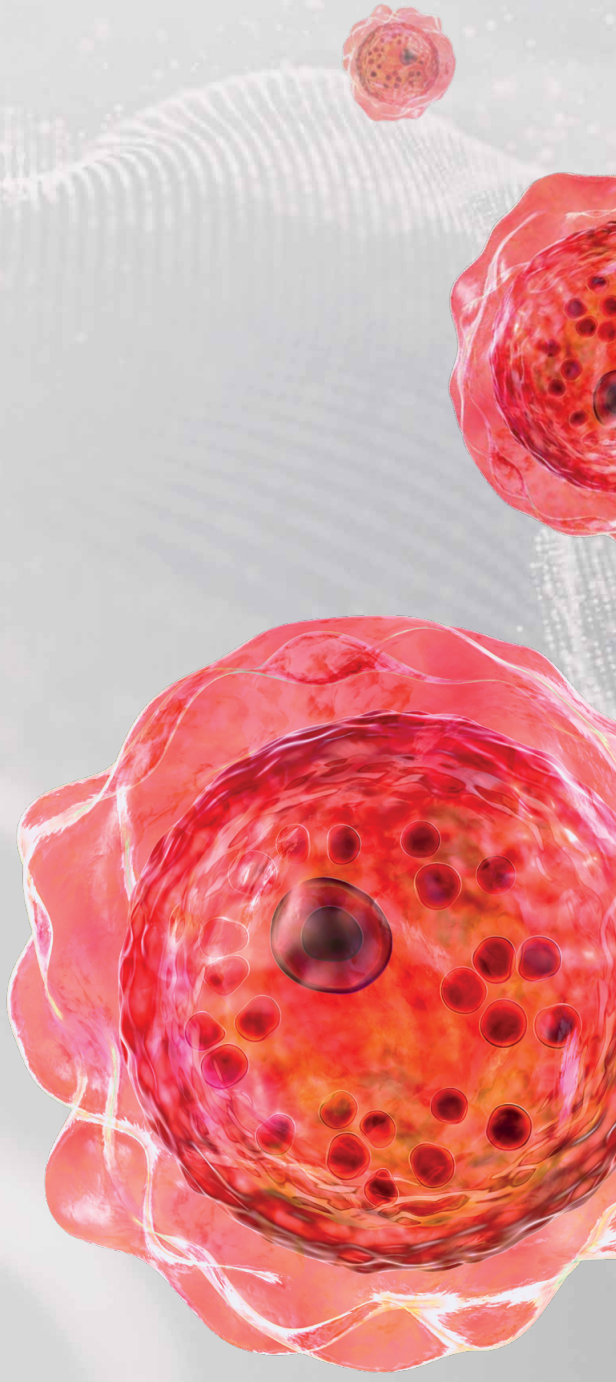
Leveraging over 30 years of experience delivering CGMP chemicals and sourcing services, process liquids manufacturing services, and supply chain services, the Thermo Scientific™ Production Chemicals and Services team can take on the work of right-sizing your key CGMP chemical requirements and delivering on it with our Production Chemicals and Sourcing Services. Additionally, our Thermo Scientific™ Process Liquid Preparation Services are designed to deliver your specified chemical and brand in the container you designate in trusted-weight dry powders or liquid formats. Depending on your specific needs—chemicals vs. process liquids and buffers—we can help streamline your supply chain to simplify your orders and deliveries without increasing your facility's footprint or inventory on hand.

Connect with us to start streamlining your CGMP chemical and process liquids supply chain at **thermofisher.com/innovateproductivity**

ThermoFisher SCIENTIFIC

ADVANCING YOUR CELL THERAPY FROM DISCOVERY TO PATIENT CARE

Contact us today to find out how we can help you in your efforts to meet patient needs through cell therapy.



Streamline your path to the clinic at **thermofisher.com/celltherapy**