

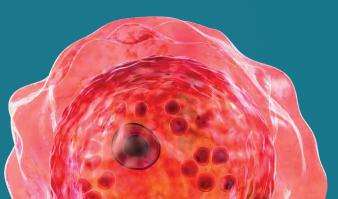
Streamline the path from discovery to commercialization

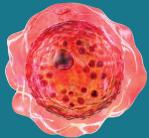


YOUR WORK HOLDS THE POTENTIAL TO DELIVER THE NEXT LIFE-CHANGING TREATMENT

As the world leader in serving science, Thermo Fisher Scientific provides the quality products, services, and support you need to advance your cell therapy from discovery to the clinic through to commercialization.

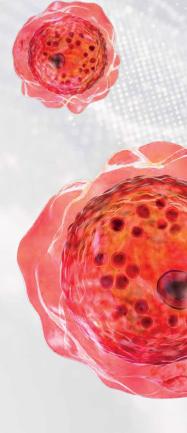
We are working alongside the scientific community to accelerate the pace of cell therapy development. Like you, we believe in the promise provided by these therapies to fundamentally transform the treatment and cure of a range of diseases. And we won't stop until this is a reality.





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OUR COMMITMENT TO CELL THERAPY



Quality comes first

With over 30 years of cGMP-compliant manufacturing experience and 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 biopharma companies 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, workflow efficiency, and facilitates regulatory reporting. This translates to consistent supply and scalable solutions that help clear the path to commercialization.



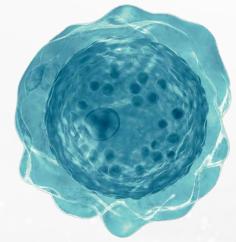
Continued advancement requires continued investment

Our investment in innovation, workforce development, 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 state of the art innovation, regulatory support, and cGMP manufacturing capabilities to advance your milestones with agility.



A good partner goes the distance

We support our customers from discovery through to commercialization 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. Unity Lab Services™ compliance services, i.e., installation qualification (IQ) and operation qualification (OQ), and Patheon™ contract development and manufacturing services are available through our services teams should you choose to outsource any part of your process.



GMP QUALITY OUR NUMBER ONE PRIORITY

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.

Providing quality for our customers drives everything we do.

We take every measure to deliver the best possible experience, from the products we develop to the services we provide.

GMP 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 of 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

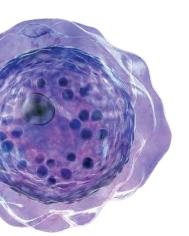
High-quality products and proper documentation and support are essential for a streamlined transition from research to the clinic.

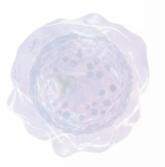
We offer a broad array of media, reagents, kits, and instrumentation to support your cell therapy development, including the CTS* line of products, which are specifically designed for use in cell therapy manufacturing applications.

Our CTS series laboratory products, featuring CO₂ incubators, centrifuges, cold storage, and biological safety cabinets, are supported by high-quality materials, factory acceptance certification, and on-site compliance services.

Testing and regulatory documentation

The CTS products undergo QC testing for sterility and presence of endotoxins, adventitious agents, and mycoplasmas. The high degree of qualification and traceability documentation, including FDA Drug Master Files (DMFs) and Regulatory Support Files (RSFs), certificates of analysis, and certificates of origin, ease the burden on your quality systems by helping to support your regulatory submission and reduce risk.



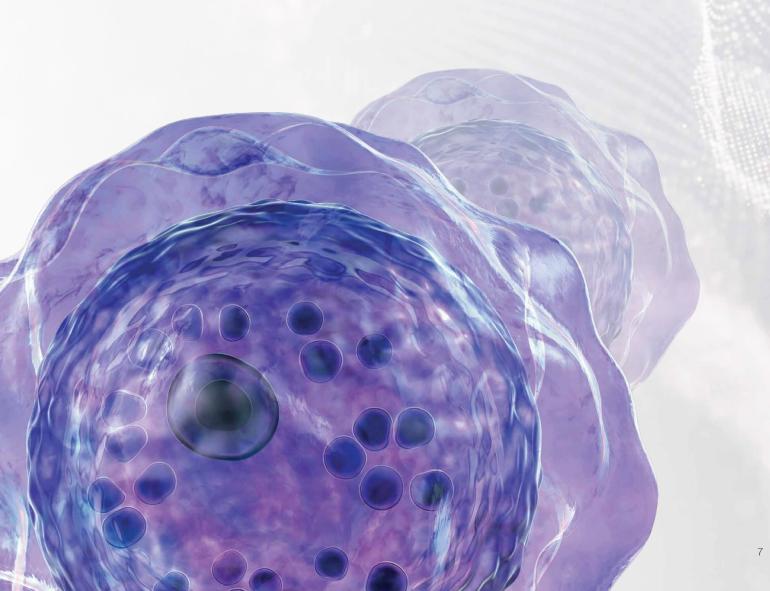


^{*} CTS products are manufactured to meet the ancillary material supplier responsibilities for cell, gene, and tissue-engineered products. Other aspects of USP <1043> are the responsibility of the end-user to assess. Thermo Fisher Scientific cannot fulfill USP <1043> in regard to application and therapy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

Professional support

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

- Our knowledgeable regulatory team will provide product-specific traceability documentation to help support your regulatory filing
- 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



CELL THERAPY SYSTEMS (CTS) PRODUCTS

Designed for cell therapy applications

The CTS product line provides you with cGMP-manufactured products and instruments designed for cell therapy applications, so you can transition your therapy to the clinic with confidence.

cGMP manufacturing

- Manufactured in conformity with cGMP for medical devices and 21 CFR Part 820, and following USP<1043> and Ph Eur 5.2.12
- Manufacturing sites that are FDA-registered and ISO 13485–certified and regularly audited





Testing and documentation

- Traceability documentation, including Drug Master Files, Regulatory Support Files, and certificates of origin
- Product safety testing, including sterility, endotoxin, and mycoplasma, on media and reagents

Proven use

- Used in FDA-approved and EMA-approved CAR T therapies [1,2]
 and the first FDA-approved therapeutic cancer vaccine [3]
- Used in over 200 clinical trials



^{1.} Tangying LL et al. (2016) Hum Gene Ther Methods 27(6):209-218.

^{2.} http://thermofisher.mediaroom.com/2017-08-30-First-FDA-Approved-Cell-Therapy-for-Leukemia-Utilizes-Thermo-Fisher-Scientifics-CTS-Dynabeads-Technology

^{3.} Madan RA et al. (2011) Expert Rev Vaccines 10(2): 141-150.

DEVELOPMENT STAGES

Solutions for 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.

Discovery

Cell therapy discovery holds extraordinary promise. We have an extensive portfolio of solutions to aid in your journey.



Media and reagents

Classical media and sera, and product-level xeno-free and animal origin–free media and reagents support cost-effective research, and then complementary CTS products support a smooth transition to the clinic.

Cell culture equipment

Thermo Scientific™ CO₂ incubators, biosafety cabinets, and filtration devices are designed to help avoid contamination. We also offer a broad range of centrifuges, culture vessels (including single-use hardware), and consumables to maximize workflow efficiency.

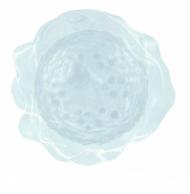
Cell engineering

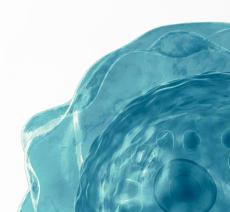
Solutions include gene editing and electroporation tools, viral vector production and purification products, and plasmid and viral vector CDMO services.

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 and mycoplasmas.









Development

Advancing your cell therapy product requires careful material selection and thoughtful process development. Our solutions can help you translate your therapy to the clinic.

CTS products

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

Laboratory equipment CTS series

Explore our selection of GMP-compatible products with enhanced documentation and certifications to speed up the validation process. Choose from cleanroom-certified CO₂ incubators, connectivity-enabled biological safety cabinets, and controlled-rate freezers.

Custom media and process development services

Gibco media formulations are available in packaging and formats that meet your unique needs.



Commercialization

As you move toward commercialization, our solutions can scale with you to meet the clinical need.

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

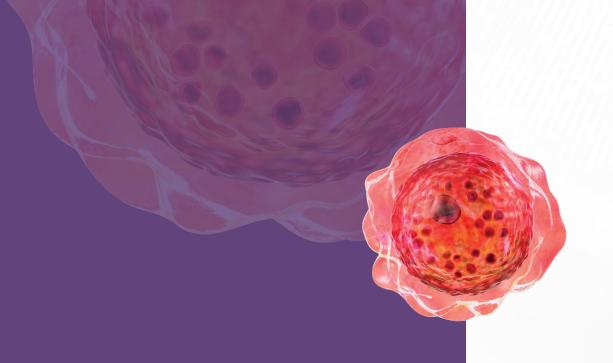
State-of-the-art cellular analysis tools are available for your in-process and lot-release development testing needs, including microbial detection and identification, contamination and impurity testing, and cellular analysis tools.

Global cold chain logistics services

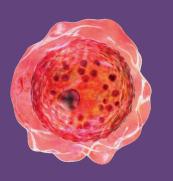
Experience and a global infrastructure are leveraged to seamlessly collect patient cells, safely transport them to a manufacturing site, then bring them back to the patient's bedside. Get comprehensive end-to-end supply chain management and benefits from cGMP-compliant kit production, global biobanking capabilities, and cryogenic distribution for total peace of mind.

Clinical trial support

Experience, resources, and global competence and infrastructure from PatheonTM Viral Vector Services, a leading provider to the cell and gene therapy community, provide clinical trial support.



CELL THERAPY WORKFLOW INTEGRATED SOLUTIONS FROM COLLECTION TO PATIENT ADMINISTRATION





Collection and tracking

Apheresis
Supply/cold chain logistics
Documentation
Chain of custody



Cell isolation and engineering

Cell isolation

Closed modular cell processing systems

Bead-based cell activation

Closed modular electroporation system

Single-use platforms

Genome editing technologies-CRISPR and TALEN

Lentiviral production system



Cell expansion

Custom and catalog media

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



Characterization for final lot release, formulation and cryopreservation

Identity, purity, and potency assays

Contamination and impurity solutions

Microbial safety

Genomic, proteomic, and cellular analytical tools

Cryopreservation platforms



Supply and logistics

Supply/cold chain logistics
Clinical trial support
Global distribution

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 can support a diverse range of cell therapy manufacturing workflows.

Find out more at thermofisher.com/cellmation



Gibco™ CTS™ Rotea™ Counterflow Centrifugation System

The instrument offers exceptional flexibility in a cell therapy development and manufacturing system. This versatile closed system applies the proven counterflow centrifugation method to a broad range of cell processing applications, such as CAR T therapy, stem cell therapy, and peripheral blood mononuclear cell (PBMC) isolation, enabling you to scale from research through commercial manufacturing.

Gibco™ CTS™ DynaCellect™ Magnetic Separation System

Coming soon! A closed, automated isolation and debeading system provides high throughput and increased scalability. As a stand-alone instrument or as part of a workflow, 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.

To support the field's rapid growth and the dense clinical pipeline of emerging therapeutics, we are committed to providing innovative and scalable cell therapy manufacturing solutions that enable the flexibility to optimize processes for accelerated speed to clinic.

- Betty Woo Vice President, Cell Therapy Thermo Fisher Scientific



Gibco™ CTS™ Cellmation™ Software for DeltaV™ System

A platform for digital automation

Gibco™ CTS™ Xenon™ Electroporation System

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

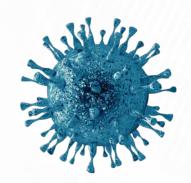


Thermo Scientific™ CryoMed™ Controlled-Rate Freezer

This system provides precise, repeatable freezing results that protect precious samples from intracellular ice formations. The firmware comes integrated with an Open Platform Communications Unified Architecture (OPC UA) protocol, enabling equipment communication via the DeltaV™ and other Distributed Control Systems (DCS).

CELL ENGINEERING SOLUTIONS

VIRAL AND NON-VIRAL DELIVERY TOOLS



Viral

We have products that span the entire viral production workflow including Invitrogen™ GeneArt™ Elements™ Vector Construction, and a platform for high-titer, cost-effective lentiviral production. The Gibco™ CTS™ LV-MAX™ Lentiviral Production System is a complete suspension production system that 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 downstream viral vector purification solutions and impurity testing to help you meet regulatory requirements.

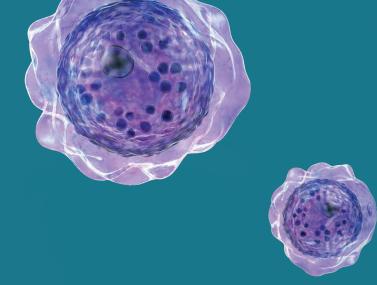
Non-viral

Our new large-scale CTS Xenon Electroporation System for cell therapy manufacturing offers cell therapy developers a non-viral platform to modify virtually any cell type of interest, using any payload as part of a closed, modular, and automated workflow. Designed to scale for commercial use, the instrument has single-use consumables to facilitate adoption into a clinical manufacturing process. To assist our customers in their discovery and process development journey, the small-scale Invitrogen™ Neon™ Transfection 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. The CTS Xenon Electroporation System can be used with the Gibco™ CTS™ Xenon™ Electroporation Buffer, a universal buffer that supports the transfection of a variety of human primary cells and payloads (e.g., plasmid DNA, mRNA, miRNA, or siRNA) for gene upregulation or downregulation applications. Gibco™ CTS™ Xenon™ Genome Editing Buffer is 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.

Gene editing solutions

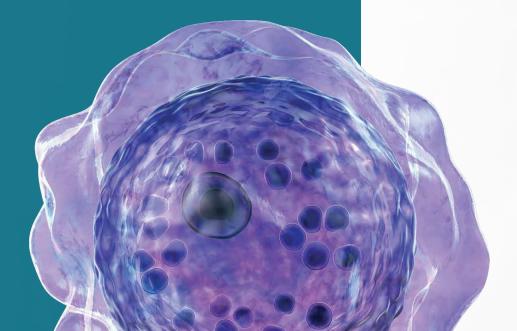
Gibco™ CTS™ TrueCut™ Cas9 Protein is our highest-performing CRISPR-Cas9 protein, engineered to deliver maximum ribonucleoprotein (RNP)-editing efficiency. This protein is manufactured in compliance with USP <1043> standards for ancillary materials for cell, gene, and tissue-based products and is subject to stringent quality specifications. It is provided in a high-concentration and large-scale format for process development and clinical research applications.





COMPLETE CAPABILITIES FROM RESEARCH TO THE CLINIC AND BEYOND

Gene-modified T cell therapy



Gibco™ CTS™ Dynabeads™ T cell products for isolation and activation

Mimic *in vivo* T cell activation via antigen-presenting cells. This gentle and efficient technology provides a trusted platform from which the beads can be used to isolate T cells and provide both the primary and co-stimulatory signals required for activation and expansion [4–6].

- Can be used for the isolation and the activation of polyclonal T cells, gene-modified T cells, and other T cell subtypes [4,5]
- Isolated and activated T cells enable efficient gene transduction [6]
- Expanded T cells have central and early phenotype with in vivo persistence [7]
- Delivers 100- to 1,000-fold expansion in 9–14 days [8]
- Optimized for the ex vivo activation and expansion of regulatory T cells (Tregs)

CTS LV-MAX Lentiviral Production System

A scalable and high-yield lentiviral vector production platform that is based on a suspension culture of HEK293-derived Gibco™ CTS™ Viral Production Cells adapted to a special chemically defined, serum-free, and protein-free Gibco™ CTS™ CTS LV-MAX Production Medium. The CTS LV-MAX Lentiviral Production System offers:

- High titers—greater than 1 x 10⁸ TU/mL (unconcentrated lentiviral vector-GFP)
- Scalable suspension system—from a 96 deep-well plate to a bioreactor
- Serum-free components—eliminating animal-origin components and associated risks
- Easy, robust culture and transfection protocols—fits into existing transient production workflows



^{4.} Maus MV et al. (2014) Annu Rev Immunol 32:189-225.

^{5.} Rapoport AP et al. (2015) Nat Med 21:914–921.

^{6.} Qasim W et al. (2007) Mol Ther 15:355-360.

^{7.} Barrett DM et al. (2014) Cytotherapy 16:619-630.

^{8.} Hami L et al. (2003) BioProcess J 2:23–34.

Gibco[™] CTS[™] OpTmizer[™] Pro Serum-Free Medium (SFM)

A novel medium, developed for the growth and expansion of human T lymphocytes (e.g. CD4+, CD8+, polyclonal, and antigen-specific T cells) used in allogeneic cell therapies. CTS OpTmizer Pro SFM improves central memory phenotype and cell growth by shifting the cell's metabolism. The result is a larger population of central memory cells in a shorter period of time. Available in bottle or Thermo Scientific™ Aegis™5-14 bioprocessing film bag format for compatibility with closed systems.



Gibco™ CTS™ OpTmizer™ T Cell Expansion Serum-Free Medium

A complete serum-free and xeno-free medium for the growth and expansion of human T lymphocytes. The medium, specifically developed to help you scale to clinical and commercial manufacturing, has been widely adopted in clinical and commercial T cell applications, including CAR T cells. It works with multiple culture formats, including culture flasks, culture bags, and rocking bioreactor systems.

- Supports high-density T cell culture (>3 x 10⁶ CD3+ T cells/mL) in static culture, including CAR T cells
- Maintains phenotype, function, and viability (e.g., cytokine secretion profile) similar to T cells cultured with conventional medium supplemented with human AB serum
- Minimizes the risk of contamination and variability in your manufacturing
- Comes with extensive traceability documentation including FDA
 Drug Master Files and Regulatory Support Files

Gibco™ CTS™ Immune Cell Serum Replacement (SR)

A defined xeno-free formulation proven for clinical use and designed to support expansion of *in vitro* cultured human T cells when added as a supplement to a basal cell culture medium such as CTS OpTmizer T Cell Expansion SFM or Gibco™ CTS™ AIM V™ Medium.

- Minimizes the supply and safety risks associated with human serum
- Supports T cell phenotype (CD4, CD8, and CD62L), similar to human serum [9]
- Supports expansion, efficacy, and persistence of lentiviral gene-modified CAR T cells

Invitrogen™ eBioscience™ Essential Human Treg Phenotyping Kit

Designed for flow cytometry-based identity testing of regulatory T cells (Tregs). This kit leverages high-quality eBioscience antibodies, isotype controls, and fixation and permeabilization reagents (for the intracellular marker *FOXP3*) and includes a ready-to-use protocol for experimental setup, gating strategy, and analysis.

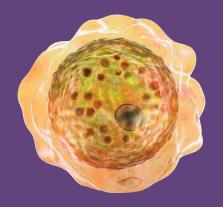
Gibco™ CTS™ DynaMag™ Magnet

A magnetic cell isolation device for use with Gibco™ Dynabeads™ magnetic beads for medium- to large-scale isolation of cells and bead removal using positive isolation of target cells or depletion of unwanted cells in a sterile and closed system.

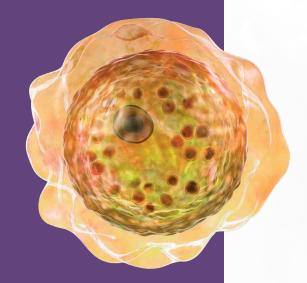
- Positively isolate bead-bound cells for subsequent stimulation and expansion of T cells with CTS Dynabeads magnetic beads and then remove the beads after expansion
- Deplete unwanted cell types by discarding magnetically captured bead-bound cells with customized Gibco™ CTS Dynabeads™ CD3/CD28 products for depletion of specific cell populations



Learn more about our CTS products for immunotherapy at thermofisher.com/ctsimmunotherapy







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 reduce the time from your initial discovery to an approved therapy.

GENE-MODIFIED T CELLS



Isolation and activation

Cell processing

CTS Rotea Counterflow Centrifugation System

Gibco isolation and activation

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

Gibco instrumentation

- CTS DynaMag Magnet
- CTS DynaCellect Magnetic Separation System*
- * Coming soon.

Engineering

Non-viral platforms

- CTS Xenon Electroporation System
- Neon Transfection System

Gene editing

- CTS TrueCut Cas9 Protein
- CRISPR-Cas9 and designer TALEN products and services
- TrueGuide Synthetic gRNA

Viral platforms

• CTS LV-MAX Production System

Confirmation of gene edits

- BigDye Terminator and BigDye Direct Sanger sequencing reagents
- ExoSAPIt and BigDye XTerminator reagents
- 3500, SeqStudio, and SeqStudio Flex Genetic Analyzers
- SegScreener Gene Editing Confirmation App

Gibco catalog and custom media

- 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

Gibco cell culture supplements

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

Thermo Scientific equipment

- HyPerforma Rocker Bioreactors with bioprocess controllers and software
- Single-use technologies: bioprocess containers, transfer assemblies, rocker bags
- Herasafe 2030i Biological Safety Cabinets CTS Series
- Heracell Vios CR CO₂ Incubators CTS Series
- Sorvall X4 and X4F Pro Centrifuges CTS Series

Gibco growth factors

• IL-2, IL-4, IL-7, IL-15, GM-CSF



Expansion

cryopreservation

Gibco wash and concentrate

- · CTS DPBS, without calcium chloride, without magnesium chloride
- CTS Rotea Counterflow Centrifugation System

Thermo Scientific cryopreservation

- CryoMed Controlled-Rate Freezer
- CryoPlus LN₂ Storage Systems
- CryoExtra High-Efficiency Cryogenic Storage Systems
- Nunc cryogenic tubes

Applied Biosystems assays

CTS Synth-a-Freeze Medium

Gibco cryopreservation

- PureQuant CD8+ T Cell Assay
- PureQuant Treg Assay
- PureQuant Th17 Assay
- MycoSEQ Mycoplasma Detection Kit
- 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

- Identifiler CLA STR analysis kit
- Globalfiler CLA STR analysis kit

Invitrogen instrumentation

- Attune Cytometric Software, compliant with 21 CFR Part 11
- CytKick Autosampler

Invitrogen assays

- eBioscience Essential Human Treg Phenotyping Kit
- eBioscience Essential Human Th1/Th17 Phenotyping Kit
- · eBioscience Essential Human T-Cell Phenotyping Kit
- CyQUANT LDH Cytotoxicity Assay

Thermo Scientific assay

 Thermo Scientific™ Pierce™ Chromogenic Endotoxin Quant Kit





MESENCHYMAL STEM CELLS



Isolation

Gibco cells

- StemPro BM Mesenchymal Stem Cells*
- StemPro Human Adipose-Derived Stem Cells
- · Custom cells and services

*For Research Use Only.

Thermo Scientific cell culture plastics

Nunc cell cultureware

Gibco expansion systems

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

Gibco differentiation media and enzymes

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

Gibco growth factors

- TGF-β 1
- FGF-basic
- PDGF-BB

Thermo Scientific single-use technologies

- Bioreactors and liners
- Transfer assemblies
- Cell culture factories
- Equipment and consumables

Thermo Scientific cell culture and bioproduction systems

- Nunc cell cultureware
- Equipment and consumables



Expansion

Wash, fill, finish, and cryopreservation

Gibco wash

• CTS DPBS

Cryogenic storage

- Rigid containment solutions
- Biobanking services
- Cold chain logistics solutions
- Ultra-low temperature and cryogenic freezers

Lot release and characterization

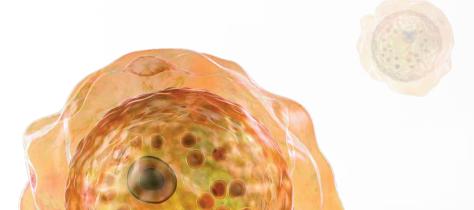
Lot-release testing

- Safety
- Identity
- Potency
- Purity
- GeneChip PrimeView Global Gene Expression Profile Assay

See page 33 for more information

In-process characterization

- Functional analysis
- Cellular analysis
- Protein analysis
- Genetic analysis



PLURIPOTENT STEM CELLS



Isolation

Gibco media

- StemPro-34 SFM
- CTS KnockOut SR XenoFree Medium

Gibco dissociation reagents

- CTS TrypLE Select Enzyme
- CTS Versene Solution



Reprogramming and gene editing

Invitrogen reprogramming kit

 CTS CytoTune-iPS 2.1 Sendai Reprogramming Kit

Non-viral delivery

- CTS Xenon Electroporation System
- Neon Transfection System

Gene editing

- CTS TrueCut Cas9 Protein
- Designer TALEN products and services
- Lipofectamine Stem Transfection Reagent
- Lipofectamine MessengerMAX
 Transfection Reagent
- Lipofectamine 3000 Transfection Reagent



Growth, banking, and recovery

Gibco cryopreservation

- CTS Synth-a-Freeze Medium
- CTS PSC Cryopreservation Kit
- CTS PSC Cryomedium

Gibco recovery

- CTS RevitaCell Supplement
- CTS Essential 8 medium

• rh-Laminin 521

Thermo Scientific equipment

- Liquid handling instrumentation
- · Biological safety cabinets
- Cryogenic storage consumables
- Ultra-low and cryogenic freezers



Expansion

Gibco expansion systems

- CTS Essential 8 Medium
- CTS Essential 6 Medium
- CTS VTN-N
- CTS KnockOut SR XenoFree
- CTS KnockOut DMEM/F-12
- CTS KnockOut DMEM
- CTS Versene Solution
- Custom media and services

Thermo Scientific single-use technologies

- BioProcess Containers (BPCs)
- Transfer assemblies
- Equipment and consumables



Differentiation

Gibco 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

Gibco growth factors

- TGF-β 1
- Stem cell factor (SCF)
- Flt-3 Ligand
- FGF Basic



Wash, fill, finish, and cryopreservation



Gibco wash

CTS DPBS

Gibco cryopreservation medium

- CTS Synth-a-Freeze Medium
- CTS PSC Cryopreservation Kit
- CTS PSC Cryomedium

Cryogenic storage and logistics

- Rigid containment solutions
- Banking services
- Cold chain logistics solutions
- Ultra-low temperature and cryogenic storage freezers

Characterization products

- GeneChip PrimeView Global Gene Expression Profile Assays
- TaqMan hPSC ScoreCard Panel
- KaryoStat assays
- Pluripotent stem cell immunocytochemistry kits

NATURAL KILLER CELLS



Isolation

PBMC isolation

- CTS Rotea Counterflow Centrifugation System
- CTS DPBS

Z?

Engineering

Gene editing

- CTS Xenon Electroporation System
- CTS TrueCut Cas9 Protein
- TrueGuide sgRNA

Confirmation of gene edits

- BigDyeTerminator and BigDye Direct Sanger sequencing reagents
- ExoSAPIt and BigDye XTerminator reagents
- 3500, SeqStudio, and SeqStudio Flex Genetic Analyzers
- SeqScreener Genome Editing Analysis Software
- Single-Use Bioreactors

Natural Killer (NK) cell isolation

- CTS Dynabeads CD3/CD28
- CTS DynaMag Magnet
- CTS DynaCellect Magnetic Separation System*

NK cell activation

- CTS NK-Xpander Medium
- IL-2/IL-15
- hAB serum
- CTS Immune Cell SR
- BioProcess Containers (BPCs)
- Fluid transfer assemblies
- HyPerforma Rocker Bioreactor and automation and control solutions

NK cell expansion

- CTS NK-Xpander Medium
- IL-2/IL-15
- hAB serum
- CTS Immune Cell SR
- BPCs
- Fluid Transfer Assemblies
- HyPerforma Rocker Bioreactor and automation and control solutions
- Single-Use Bioreactors
 - * Coming Soon





Wash, fill, finish, and cryopreservation

Wash, fill, finish, and cryopreservation

- CTS Rotea Counterflow Centrifugation System
- CTS DPBS
- Ultra-low and cryogenic freezers

Lot release and

Lot release and characterization

- eBioscience antibodies CD56, CD3 and CD16
- Attune CytPix Flow Cytometer
- eBioscience antibody CD107a
- MycoSEQ Mycoplasma Detection Kit
- Chromogenic Endotoxin Quant Kit, LAL
- Identifiler CLA STR analysis kit
- Globalfiler CLA STR analysis 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% hAB 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.

HEMATOPOIETIC STEM CELLS



Isolation



Gibco isolation

• CTS DynaMag Magnet

Gibco expansion systems

- StemPro-34 SFM
- Custom media and services
- CTS GlutaMAX-I Supplement

Gibco growth factors

 IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, GM-CSF, SCF, FLT3 ligand, TPO, M-CSF

Thermo Scientific single-use technologies

- BPCs
- Fluid Transfer Assemblies
- Single-Use Bioreactors
- Cell Factory systems
- Rigid containment solutions



Wash, fill, finish, and cryopreservation

Gibco wash

- CTS Rotea Counterflow Centrifugation System
- CTS DPBS

Gibco cryopreservation medium

CTS Synth-a-Freeze Medium

Cryogenic storage

- Rigid containment solutions
- Biobanking services
- Cold chain logistics solutions
- Ultra-low temperature and cryogenic freezers



Lot-release testing

- Safety
- Identity
- Potency
- Purity

In-process characterization

- · Functional analysis
- Cellular analysis
- Protein analysis

Stem cell quality control

- Identifiler CLA STR analysis kit
- · Globalfiler CLA STR analysis kit
- KaryoStat and KaryoStat HD karyotyping kits
- GeneChip PrimeView Global Gene Expression Profile Assay
- TaqMan hPSC Scorecard Panel
- Pluripotent stem cell immunohistochemistry kits

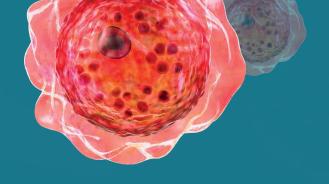
See page 33 for more information

PRODUCT SPOTLIGHT:

Gibco™ StemPro™-34 SFM

- A serum-free medium (SFM) specifically formulated to support the development of human hematopoietic stem cells (HSCs) in culture
- Enables superior expansion of CD34+ cells compared to classical serum-supplemented medium (IMDM + FBS and cytokines)
- Appropriate for HSCs isolated from bone marrow, peripheral blood, or cord blood
- Manufactured without cytokines and hematopoietic growth factors





CHARACTERIZATION AND LOT RELEASE

Tools and products for monitoring critical quality attributes throughout your cell manufacturing process 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 your 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 validated reliable molecular methods for the rapid and accurate detection of possible mycoplasma contamination (Applied Biosystems™ MycoSEQ™ Mycoplasma Detection System), the identification of possible microbial contaminants (Applied Biosystems™ MicroSEQ™ Microbial Identification System), and tools for quantification of residual DNA from various host-cell and gene-expression systems (Applied Biosystems™ resDNASEQ™ DNA Quantitation Kits).

Learn more at thermofisher.com/pharmaanalytics

Regulatory-accepted method for mycoplasma testing

Cell therapy products have a short shelf life and require rapid methods when testing for contamination.

The MycoSEQ Mycoplasma Detection Kit is a real-time PCR assay designed and validated to help cell therapy customers meet regulatory requirements for mycoplasma detection for in-process and lot-release testing in less than 5 hours.

Mycoplasma testing should be performed throughout the workflow at several key points, including cell banking, various stages of scale-up, and harvest, in order to mitigate risk throughout your process. The MycoSEQ Mycoplasma Detection Kit is part of an integrated workflow solution that includes automated sample prep, quantitation instrumentation, and analysis and documentation software.

- Same day, actionable results
- Highly sensitive at 1–3 genome copies/reaction
- Optimized, fully automated sample preparation
- Integrated software solution with features to support 21 CFR Part 11
- Extensive network of experienced field application specialists offering instrument training and support on validation design and regulatory requirements



Integrated workflow solution to support process development and GMP environment

Learn more at thermofisher.com/mycoseq

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 resDNASEQ Quantitative DNA System is a quantitative PCR-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.



Learn more at thermofisher.com/resdnaseq

Invitrogen™ Attune™ flow cytometers

The Invitrogen™ Attune™ CytPix™ Flow Cytometer is an advanced cell analyzer that shares common features with the Invitrogen™ Attune™ NxT model cytometer.

The Attune CytPix Flow Cytometer and Invitrogen™ CytKick™ MAX Autosampler are distinguished by a high-speed brightfield camera that records images of individual events as they pass through the flow cell.

The camera and Attune Cytometric Software help to ensure that the events you analyze are single cells as opposed to doublets, clumps, or debris. This is crucial in cell and gene therapy research applications, but is useful in almost any flow cytometry experiment to help researchers understand the morphology of each cell population identified for analysis. The images can also aid in identifying debris and optimizing protocols.



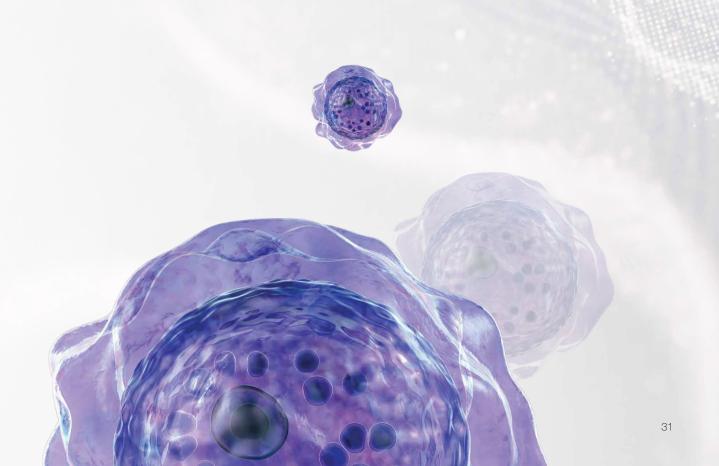
Learn more at thermofisher.com/attune

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 will 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

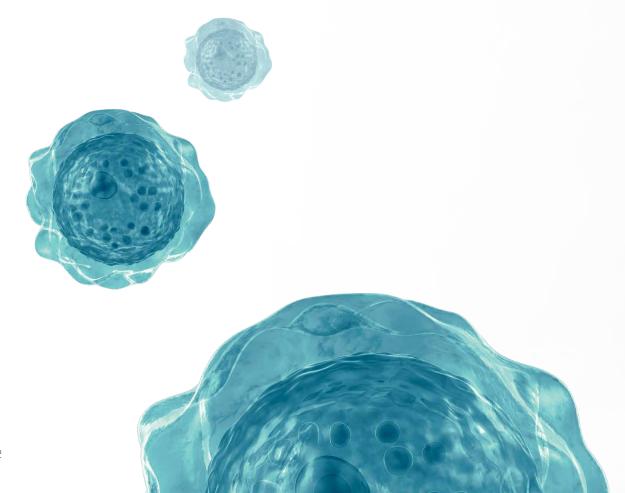


The Invitrogen[™] portfolio offers a variety of assays for quantitation of single proteins and mRNA as well as mix-and-match and ready-to-use panels for correlated multiplexing using the Luminex[®] platform. Our extensive selection of Invitrogen[™] assays includes:

- ELISA and antibody pair kits
- ProQuantum[™] high-sensitivity immunoassay kits
- ProcartaPlex[™] multiplex immunoassay kits
- QuantiGene[™] Plex gene expression assays
- Luminex[™] xMAP[™] INTELLIFLEX[™] system

Additionally, Thermo Fisher Scientific supports your quantitation assay needs with accessory reagents and instruments for a comprehensive offering.

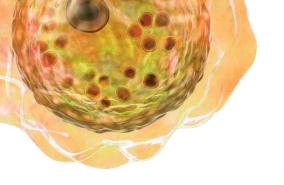
thermofisher.com/immunoassays

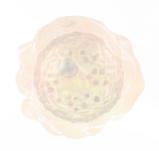


Cell therapy characterization capabilities

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

	Assay type	Assay platform	Products	Instrument
Identity, purity, and potency	Biomarker profiling	Flow cytometry	Antibodies and reagents	Attune CytPix Flow Cytometer
		Luminex xMAP	Multiplex assays	IntelliFlex, Luminex 200, or FLEXMAP 3D systems
		ELISA	Invitrogen ELISAs	Varioskan Lux Multimode Reader
		HCS	Antibodies and reagents	CellInsight CX7 LZR Pro system
		ICC	Antibodies and reagents	EVOS M7000 Imaging System
		IP	Antibodies	Fluoroskan fluorometer
		qPCR and dPCR	PureQuant assays, TaqMan, TaqPath, and Absolute Q dPCR assays	QuantStudio 6 and 7 Pro and Absolute Q systems
	Functional	Flow cytometry	Antibodies and reagents	Attune CytPix Flow Cytometer
		Luminex xMAP system	ProcartaPlex multiplex assays, QuantiGene Plex assays	Luminex 200 with xPONENT 3.1, IntelliFlex, Luminex 200, and FLEXMAP 3D systems
	Molecular	qPCR and dPCR	PureQuant assays, TaqMan, TaqPath, and Absolute Q dPCR assays	QuantStudio 6 and 7 Pro and Absolute Q systems
		Array-based	Human Genome U219 and U133 arrays, Clariom S and D assays	GeneChip Scanner 3000, GeneAtlas, and GeneTitan instruments
		NGS-based	Ion AmpliSeq panels and Oncomine assays	Ion GeneStudio S5 systems
Genomic stability and safety	Genomic stability	Array-based	KaryoStat and KaryoStat HD assays	GeneChip Scanner 3000 instrument
	HLA typing	Reverse sequence specific oligonucleotide typing (rSSO)-Luminex xMAP system	LABType rSSO	LABScan3D instrument
		Sanger sequencing	SeCore SBT kit	3100, 3730, 3500xL, and 3500xL Dx Genetic Analyzers, and SeqStudio Flex Genetic Analyzer
	Sample tracking and authentication	Capillary electrophoresis	Identifiler STR assays, GlobalFiler STR assays	Thermal cycler and 3500, 3500xL, SeqStudio, SeqStudio Flex Genetic Analyzers
	Mycoplasma	SYBR Green RT-PCR	MycoSEQ kits	7500 Fast Real-Time PCR System
		qPCR	TaqPath BactoPure master mix	QuantStudio instruments
	Endotoxin	Chromogenic assay	Pierce LAL Chromogenic Endotoxin Kit	Multiskan Sky Plate Reader







SETTING UP YOUR OWN CELL THERAPY PRODUCTION FACILITY?

CTS Series laboratory equipment

Thermo Scientific™ CTS™ Series laboratory equipment supports your GMP 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



CO₂ incubators (cleanroom compatible)

Thermo Scientific™ Heracell™ Vios™ CR CO₂ incubators—CTS™ Series are third party-certified cleanroom-compatible CO₂ incubators suitable for use in ISO Class 5 and GMP 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. Dedicated shelving systems optimize the inner space of the 250i model for large vessel types such as G-Rex™ 500M-CS bioreactors by Wilson Wolf and Thermo Scientific™ Nunc™ Cell Factory Systems, enabling high throughput, and better circulation and 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, the CTS Series 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 progamming with an intuitive touchscreen interface. These 4 L bench and floor models are available with a documentation package and compliance services to ensure fast setup in a GMP environment.



CO₂ incubators

Thermo Scientific™ Forma™ Steri-Cult™ CO₂ 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), the stackable incubators are ideal for high-volume culturing. Features include proven 12-logarithmic-units sterilization, in-chamber HEPA filtration, 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. Their firmware comes integrated with OPC UA protocol, enabling equipment communication via the DeltaV and other DCSs. They are compliant with 21 CFR Part 11.



Thermo Scientific™ Nunc™ Standard Closed Cell Factory™ System

Having a clean and closed system that provides consistent and high-quality results should be a standard among your adherent cell culture processes. The Nunc Standard Closed Cell Factory Systems are built with standard components to help ensure quality and assurance of supply.

Learn more at thermofisher.com/cellfactory



Thermo Scientific™ Nalgene™ PETG Platinum Certified Clean Bottles

Our Nalgene rigid containment tiered portfolio includes standard and custom bottles and carboys to cover a wide range of applications, sizes, and connection systems. Platinum clean rigid containment products are designed specifically for the storage and transport of active, high-value pharmaceutical ingredients and bulk intermediates. They are certified to contain less than one-third of the allowable particulate limits specified in USP <788>. These sterile products come ready-to-use with robust triple-layer packaging for cleanroom use. Complete compliance with cGMP regulations helps reduce the risk of drug recall postlaunch.

Learn more at thermofisher.com/rigidcontainment



Thermo Scientific™ standard fluid transfer assemblies

The Thermo Scientific standard fluid transfer assemblies and manifolds allow you to reduce the number of customized stock keeping units (SKUs), helping to save costs, simplifying the product ordering process, and helping to reduce your product storage requirements.

Learn more at thermofisher.com/fluidtransfer





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



Thermo Scientific™ Standard Single-Use Bottle Assembly Systems

Fluid transfer systems can easily consist of multiple components that all need to be sourced, purchased, inventoried, and assembled. With the Thermo Scientific Standard Single-Use Bottle Assembly Systems, we can relieve you of the burden of managing individual components and validating the systems in-house. Realize labor savings and mitigate risk by leaving the assembly and processing to us.

These easy-to-order configured solutions include rigid support containers with preconfigured cap sets, and are delivered gamma-irradiated for use right out of the package.

Learn more at thermofisher.com/standardbottleassembly

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

At the forefront of innovation in the cell therapy field is 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 proven innovation, offering superior performance to accommodate larger volumes as programs progress to commercialization. The DynaDrive S.U.B. can decrease the cost of production by 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 the 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[™] HyPerforma[™] Rocker Bioreactors with bioprocess controllers and software

Combine exceptional control and measurement—
to enhance research, process development, and
seed train production applications. The HyPerforma
Rocker Bioreactor is integrated with the Thermo
Scientific™ HyPerforma™ G3Lab™ Controller and TruBio
software, powered by the DeltaV Distributed Control
Platform, providing a complete, ready-to-use solution.
The HyPerforma Rocker Bioreactor uses Thermo
Scientific™ Rocker BioProcess Containers (BPCs) that
provide up to 25 L of working volume and integrates
to the pH+dO₂ sensor for combined pH, DO, and
temperature monitoring.

Learn more at thermofisher.com/rockerbioreactor



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 proven 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-GMP, 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™ PD-Express Services

These services are available for T cell therapy applications.

Media customization services

Customize Gibco™ catalog products—add or remove components, create customized packaging options, select QC tests, and more.

Bioproduction analytics 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. Customized analytical projects are available through our investigative analytics service to help you troubleshoot any problems you encounter.

Media development services

Optimize your unique medium for growth, expansion, and functionality. Our media development options include the traditional workflow (sequential DoE steps) and our newer multiomics workflow that utilizes state-of-the-art metabolomic and proteomic analyses, offering a more reliable predictive model to help you characterize your process and improve productivity.

Purification solutions

Our superior purification technology has been used in numerous commercial biotherapeutic downstream processes. Our affinity resins are available as a platform for purification of all AAV subtypes. Combining the innovative 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 simply the purification process. We offer a novel platform with scalable resins 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 state-of-the-art, ISO-certified facilities help ensure that we can supply the highest-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 keep you on a steady path to success.

Professional support

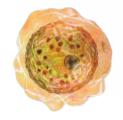
Bioproduction teams provide support for early phases through commercial scale-up and scale-out; this includes access to a large global supply of cell therapy–ready ancillary materials, equipment, and consumables; characterization platforms to help confirm product quality and safety; and process development services to help you achieve your goals in a cost-effective, efficient way.

Production Chemicals and Sourcing Services; Process Liquid Preparation Services

With over 30 years of experience delivering cGMP chemicals and sourcing services, process liquids manufacturing services, and supply chain services, our Production Chemicals and Services team can take on the work of right-sizing your key cGMP chemical requirements and delivering on it. Additionally, our Process Liquid Preparation Services are designed to deliver your specified chemical and brand in the container you specify 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

Learn more at thermofisher.com/bioprocessing



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 pre-clinical research and development to commercial manufacturing with confidence. Thermo Fisher Scientific offers the assurance of partnering with an experienced 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.



Viral vector manufacturing services

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



Plasmid DNA manufacturing services

In alignment with rapidly evolving regulatory guidance, our plasmid DNA cGMP manufacturing and QC analytical capabilities ensure you get the quality material you need at all stages of development and commercialization. Our end-to-end solutions in this area include process development, QC and analytical testing, and cGMP manufacturing (30 L to 1,000 L). Offerings are available for plasmid starting material for viral vector manufacturing, or linearized plasmid DNA for mRNA synthesis.



Cell therapy manufacturing services

The cell therapy services capabilities of Thermo Fisher span process development and optimization, analytical assay development and QC testing, as well as cGMP manufacturing for both autologous and allogeneic workflows across a variety of immune and stem cell types. Specific examples include viral and non-viral modified NK and T cells, HSCs, and iPSCs. With a flexible, "just-in-time" strategy for facility build-out, customized GMP suites can be completed to meet your unique manufacturing needs in as little as six to nine months.



mRNA therapeutics services

The emergence of mRNA therapeutics, including the development of new vaccines and gene therapies, has created a market constraint on access to critical raw materials and scientific and technical competence. Thermo Fisher has responded quickly by ramping up a flexible solutions model for mRNA vaccine and therapeutics development. Options are available to self-manufacture or leverage our end-to-end development and manufacturing services inclusive of pDNA manufacturing, mRNA synthesis, lipid nanoparticle (LNP) encapsulation, and sterile fill and finish.



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. Specific service offerings include: molecular biology, viral vector packaging, viral vector purification, analytics, and support.



Advanced therapy supply chain solutions

With strict temperature and delivery time requirements, successfully navigating supply and logistical issues for cell and gene therapy products can be quite complex. Thermo Fisher brings 35+ years of experience handling ultracold and cryogenic materials so you can focus on your path to commercialization. Specific service offerings include:

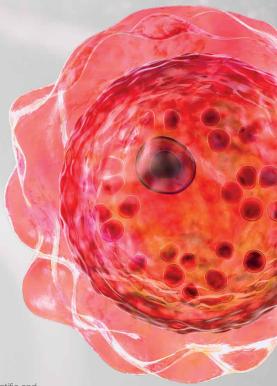
- GMP biologics management and storage
- Cold chain logistics and distribution
- Clinical site and specialty courier services
- Continuous monitoring for cryogenic shipments
- Comprehensive chain of custody and identification capabilities (inclusive of serialization)
- Secondary packaging and labeling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

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



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