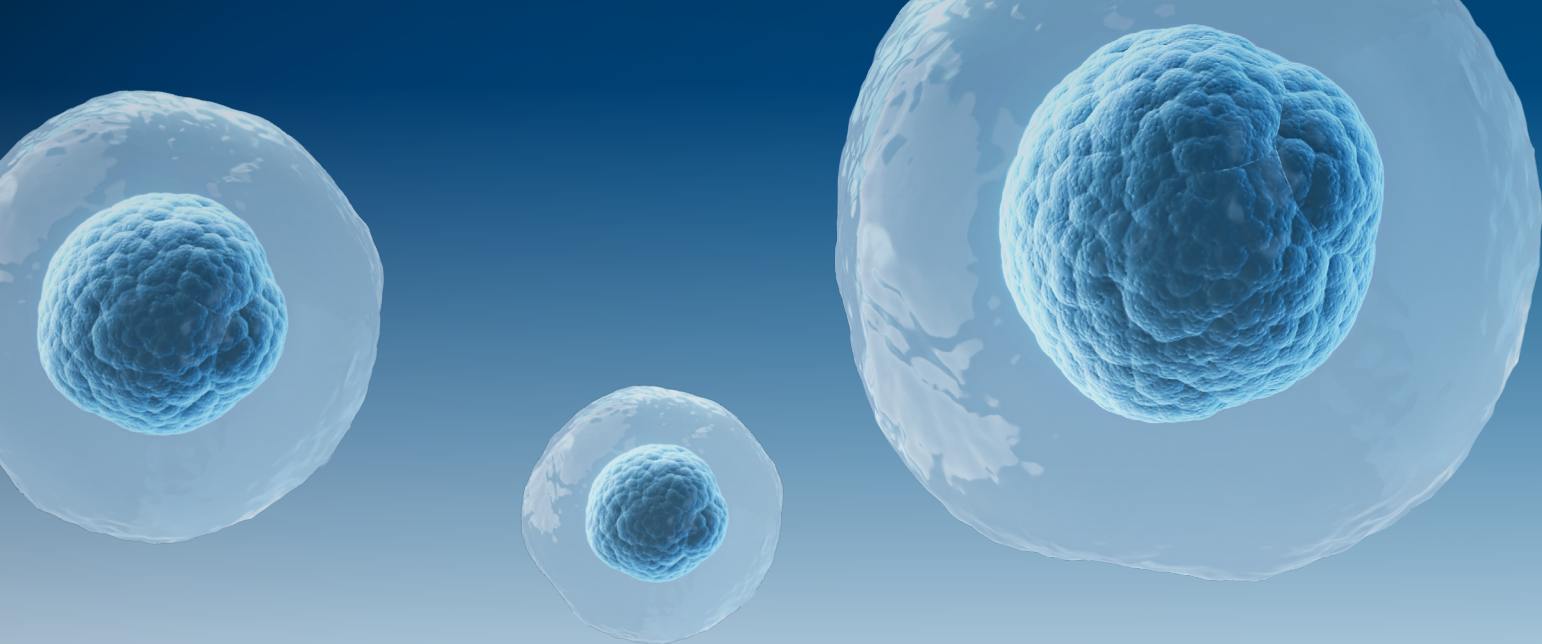




Cell therapy

CTS Compleo Fill and Finish System

Formulation and filling for cell therapy manufacturing



CTS Compleo Fill and Finish System

The Gibco™ Cell Therapy Systems™ (CTS™) Compleo™ Fill and Finish System is a functionally closed, modular system that offers users options to automate formulation and filling to suit their cell therapy manufacturing needs. It enables solutions to help overcome common challenges that arise during the manual formulation and fill workflow. The system's flexibility not only offers the convenience of adaptability, but also helps reduce risk in manufacturing by streamlining and automating these processes.

The CTS Compleo system is an addition to our well-regarded portfolio of Gibco™ CTS™ solutions, which are recognized by scientists worldwide for enabling efficient clinical and commercial manufacturing of cell and gene therapies.



Benefits include:

- A compact, functionally closed, automated system that reduces formulation and fill process variability while using minimal bench space
- High accuracy of $\pm 10\%$ at a broad range of fill volumes
- Flexible input and output configurations
- User-friendly formulation software that handles variable batch inputs in real time without requiring manual protocol modification or requalification
- A proprietary software algorithm that automates calculations and helps reduce potential errors while optimizing cell usage to minimize unnecessary cell waste
- Software option to support 21 CFR Part 11 compliance





Automating formulation helps reduce risks that can impact quality and safety

The CTS Compleo system positively transforms formulation and filling by combining automation, accuracy, and ease of use to help ensure quality and safety in every batch.

Compared to alternative methods, the CTS Compleo system helps:

- Minimize risk
- Increase quality and manufacturing consistency
- Simplify operations

Advantages of the Compleo system over a manual formulation and fill workflow

Process impact	Manual workflow	CTS Compleo system
Helps ensure aseptic integrity through closed system processing including in-process sampling and automated or manual air removal* from cryobags	–	+++
Reduces manual effort and documentation errors with automated pre-run system checks, volume verification, and optional software** to support cGMP lab use	–	+++
Software algorithm automates calculations, reduces manual errors, and optimizes cell usage to minimize cell waste	–	+++
Software supports scaling to accommodate variable batch sizes without requiring manual protocol modification or requalification	–	+++
Minimizes active ingredient exposure† through rapid, automated processing that reduces operator-dependent variability	–	+++

* Automated and manual air removal from cryobags without the need to disconnect the output bag, transfer to a biosafety cabinet, and use a syringe to remove air. 'Air removal' refers to burping—the controlled release of trapped air, not complete air elimination.

** Optional security, audit, and e-signature (SAE) software enables 21 CFR Part 11 compliance.

† As little as 15 min for CTS Compleo system compared to an average of 45 min for manual methods. A lower cryoprotective agent exposure time minimizes unwanted side effects.

An automated, flexible formulation and filling system

Each part of the system has been designed to enable users to easily and effectively optimize formulation and filling*

Instrument

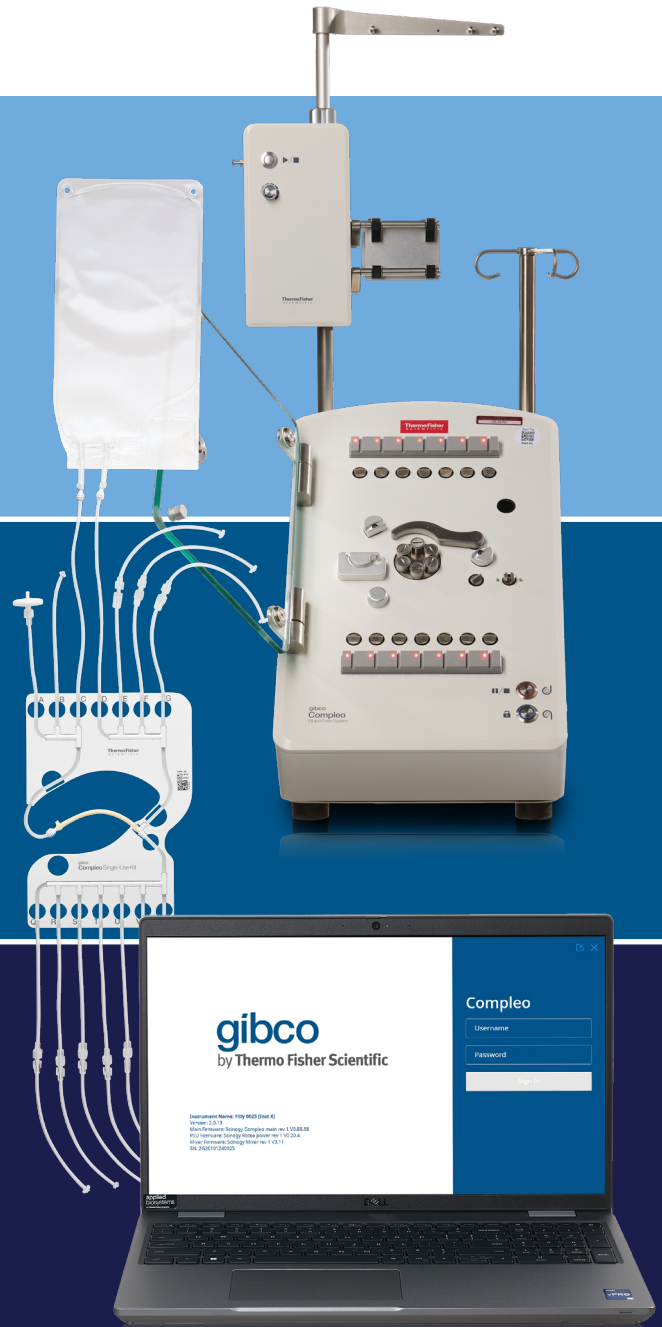
- Functionally closed, compact, and modular
- Suitable for GMP manufacturing
- Mixing module for comprehensive, efficient, and gentle mixing**

Single-use kit

- Gamma-irradiated, individually packaged, sterile kit
- 11 user-configurable lines that support attachment through sterile-welding or luer lock connection
- 1 L mixing bag supports maximum of 750 mL for filling

Software

- Intuitive, user-programmable Protocol Builder software with a proprietary algorithm
- Flexibility to support variable batch size input without protocol requalification
- Software options enable 21 CFR Part 11 compliance to support commercial manufacturing



* Optional configuration coming soon: a clean-room compatible tablet and keyboard as an alternative to the laptop for the CTS Compleo system.

** Patent pending.

Download the specification sheet for the CTS Compleo system at thermofisher.com/compleo-specs

The CTS Protocol Builder software - empowering streamlined formulation and fill workflows

The easy-to-use Gibco™ CTS™ Compleo System Protocol Builder software, standard on all instruments, efficiently guides users through the protocol development process.

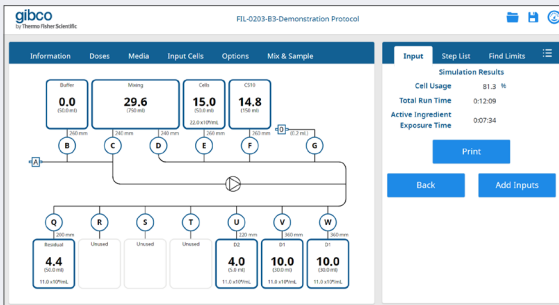
Benefits of the Protocol Builder:

- Supports user-driven protocol design and simulation to help optimize cell usage
- Reduces cryoreagent (active ingredient) exposure with rapid processing
- Handles variable batch sizes without requiring requalification

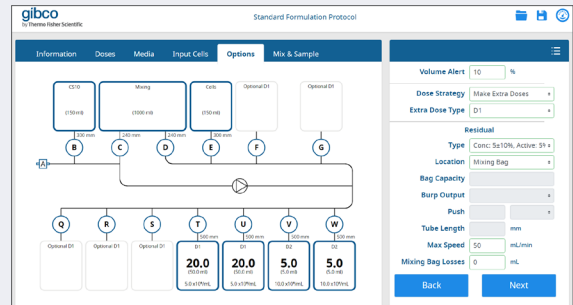
As easy as 1-2-3 using the Protocol Builder software

Step 1	Step 2	Step 3
<p>Specify the outputs (doses) required</p> <ul style="list-style-type: none"> • Dose specifications: number, volume, and cell concentration • Required diluent, cryoreagent volumes, and active ingredient percentage 	<p>Define the input variables</p> <ul style="list-style-type: none"> • Input cell volume • Input cell concentration 	<p>Run the simulation to preview key information</p> <ul style="list-style-type: none"> • Kit configuration and media volumes for formulation • Estimated protocol run time • Cell usage percentage • Active ingredient exposure time • Confirm specified outputs can be achieved using the inputs defined

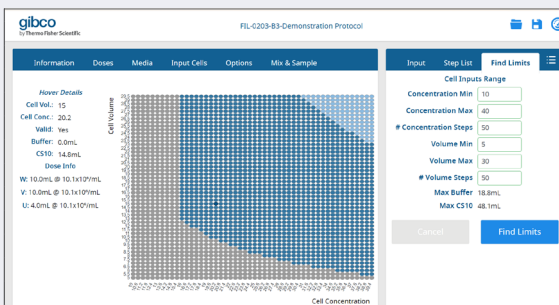
Snapshots of the Protocol Builder software showing how it can simplify and streamline your workflow



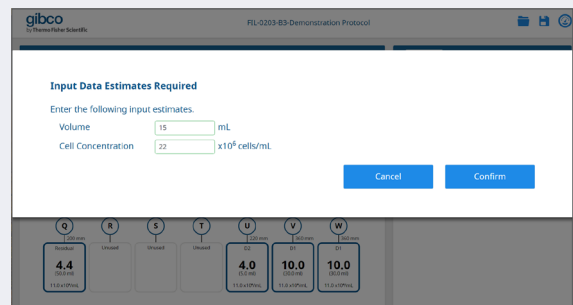
Key protocol information at your fingertips. Easily view dose information, cell concentrations, required diluent volume, cell use percentage, and active ingredient exposure time.



Optional “make extra doses” strategy. Scale and support a batch size greater than what is required for the minimal dose specification for a given protocol without protocol requalification. This helps ensure maximal usage of the final formulation.



Example of finding limits. The simulator displays the input cell volume and concentration limits within which the protocol can be used.



Using the batch protocol. On the day the batch protocol is to be run, a user loads a protocol (previously created using the Protocol Builder) into the Compleo system user interface and simply enters the required input values.

To see the full workflow and setup, download the Quick Start Guide for the CTS Compleo system at

thermofisher.com/compleo-qsg





Modular by design for easy integration with a cell processing system of your choice



Discover the easy integration of the Gibco™ CTS™ Rotea™ Counterflow Centrifugation System and the CTS Compleo system, where exceptional cell processing meets precise formulation and filling.

- **Easy integration**—The CTS Compleo system works in harmony with the CTS Rotea system to enable efficient formulation and filling coupled with exceptional cell processing
- **System-agnostic**—The CTS Compleo system can be implemented with other cell processing platforms to enhance the formulation and filling efficiency of other workflows

	Application	Benefits
<p>CTS Rotea system</p> 	<p>Engineered for exceptional cell processing</p>	<ul style="list-style-type: none"> • Offers flexibility: cell separation, concentration, washing, and buffer exchange • Typically >95% cell recovery with high viability • The output bag from the CTS Rotea system can be placed directly onto the CTS Compleo system
<p>CTS Compleo system</p> 	<p>Designed for formulation and filling</p>	<ul style="list-style-type: none"> • Streamlines formulation calculations and planning • Maximizes cell sample usage with multiple dosing options • High accuracy of $\pm 10\%$ at low dosing volume





CTS Rotea system

CTS Compleo system

CTS Compleo and CTS Rotea systems side by side. Shown here with the CTS Rotea system (left), the CTS Compleo system (right) is platform-agnostic and can be integrated with other cell processing technologies to enhance formulation and filling efficiency across diverse workflows.

Enabling GMP compliance

CTS cell and gene therapy products are GMP manufactured, safety tested, and backed by regulatory documentation to support your transition from discovery to clinical and commercial manufacturing.

- The Regulatory Support File (RSF) for the CTS Compleo Fill and Finish System and CTS Compleo Single-Use Kit are available upon request at [thermofisher.com/regulatory](https://www.thermofisher.com/regulatory)
- The RSF includes detailed information about the instrument and the single-use consumables, including materials of construction, biocompatibility, and extractable testing summaries
- User guides provide information about instrument safety compliance standards
- The CTS Compleo Fill and Finish System and the CTS Compleo Single-Use Kit are manufactured in facilities that meet ISO 13485 standards
- The following software is included with the CTS Compleo System: graphical user interface (GUI), Protocol Builder, and OPC-UA interface that has capability to connect to DCS, MES, or other 21 CFR Part 11 compliant systems.
- Gibco™ CTS™ Compleo™ SAE Software is an option for customers who require GMP manufacturing; the off-the-shelf solution enables 21 CFR Part 11 compliance for stand-alone CTS Compleo systems.

Cost-effective benefits of closed, modular systems

The CTS Compleo system includes a modular, closed cell therapy instrument that can enable a path from process development to commercial manufacturing, helping to deliver efficiency and cost savings.

- **Closed systems reduce the cost of cleanroom spaces**—a closed system that operates in a Class C manufacturing facility can reduce the size of Class B lab space required for open processing systems by up to 90%*
- **Modular designs enable increased instrument efficiency and utility**—manufacturing processes can be optimized using technologies that are ideally suited to each step; time-consuming processes such as cell expansion can be decoupled from rapid processes such as buffer exchange and concentration, reducing the investment in facilities and capital equipment by up to 70%*
- **Avoid process development delays**—utilizing the same system or platform through process development and commercial manufacturing can help you avoid process delays associated with changing systems

* Claims based on CAR T therapy, 7-day incubation, 2,000 patients per year, from: James D. (2017) How short-term gain can lead to long-term pain. *Cell Gene Therapy Insights* 3(4): 271-284.



Getting started with the CTS Compleo System

Services and support

Thermo Fisher Scientific offers a comprehensive range of services and support to keep your Gibco CTS Compleo System performing at peak level. Each system purchase includes a standard one-year factory warranty and SmartStart Orientation to help your team get up and running confidently. For added peace of mind and long-term protection, extended warranty coverage is also available at the time of purchase.

SmartStart Orientation Training

Unlock the full potential of your Gibco CTS Compleo System with our 2-day SmartStart Training. Learn how to confidently operate the system, build and optimize protocols, and run formulation, fill, and finish workflows with precision and ease. Through professional-led, hands-on instruction from a Field Application Scientist, you'll gain the skills needed to support fast adoption, reliable performance, and high-quality results from day one.

Designed for both new operators and experienced users seeking a structured refresher, this course helps provide a strong foundation in operating and maintaining the system. Participants will also receive practical training on the CTS™ Compleo™ Protocol Builder Application, enabling them to create, modify, and save protocols for use on the instrument.

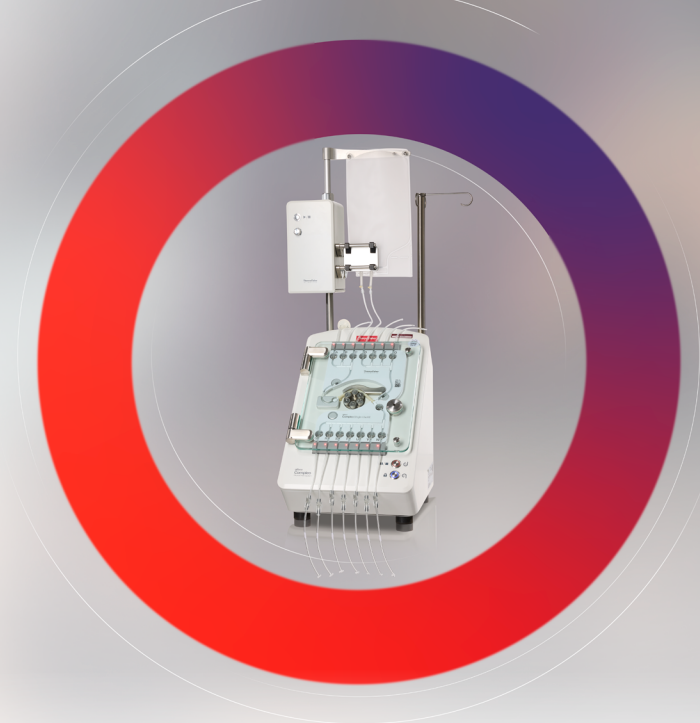
By the end of this course, participants will be able to:

- Confidently operate instrument
- Build, edit, save, and optimize protocols using the Protocol Builder Application
- Set up and run formulation, fill, and finish workflows

Qualification services

Instrument qualification services for the CTS Compleo System include installation qualification (IQ) and operational qualification (OQ). Our experienced qualification specialists partner with you to deliver timely, cost-effective, and reliable qualification services, supported by audit-ready documentation. These services help ensure your CTS Compleo solution meets your documentation and compliance requirements. Contact an instrument qualification specialist to learn more.

Contact an instrument qualification specialist at [thermofisher.com/iqoqpg](https://www.thermofisher.com/iqoqpg)



Comprehensive warranty and service plans to protect your investment

Choose from a range of extended-coverage service plans to meet your budget and needs. In addition to the standard 1-year warranty, these plans offer:

- Preventive maintenance
- Access to Remote Support
- Prioritized response time

To build your personalized service quote, go to [thermofisher.com/serviceselector](https://www.thermofisher.com/serviceselector)

AB Assurance: preferred coverage for peace of mind

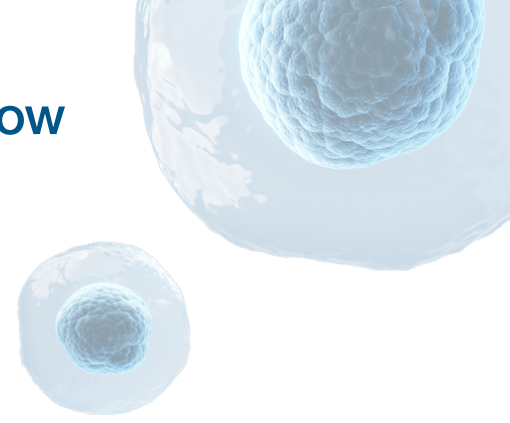
Our most popular instrument service plan, Applied Biosystems™ AB Assurance™ service plan, takes the guesswork out of enabling instrument uptime. All parts, labor, and travel costs are included for standard repairs, and the annual planned maintenance (PM) makes it easy to keep up with instrument care.





Find out more about the AB Assurance service plan at [thermofisher.com/abassurance](https://www.thermofisher.com/abassurance)

CTS products for every step of your workflow

Choose from our comprehensive portfolio of high-quality CTS products to meet your clinical and commercial cell and gene therapy manufacturing needs*.

- Safety testing with accompanying traceability documentation
- Global CGT regulatory affairs teams with regional expertise
- GMP-manufactured products designed for CGT manufacturing



CTS products*	
Instruments	Media, buffers, supplements, and reagents
 Cell isolation and activation	<ul style="list-style-type: none">• Gibco™ CTS™ DynaCollect™ Magnetic Separation System• Gibco™ CTS™ Rotea™ Counterflow Centrifugation System
 Cell engineering	<ul style="list-style-type: none">• Gibco™ CTS™ Xenon™ Electroporation System
 Cell expansion	<ul style="list-style-type: none">• Gibco™ CTS™ media for<ul style="list-style-type: none">◦ Immune cells◦ Hematopoietic progenitor cells◦ Neural stem cells◦ Pluripotent stem cells• Gibco™ CTS™ cell culture supplements• Gibco™ CTS™ TrypLE™ Select Enzyme
 Cell wash, formulation, and cryopreservation	<ul style="list-style-type: none">• CTS Rotea Counterflow Centrifugation System• CTS Compleo Fill and Finish System

* To see our full list of CTS products and learn more, visit thermofisher.com/cts.

Set your manufacturing up for consistency

Gibco™ PeproGMP™ cytokines: optimized for use in your cell therapy workflows with exceptional lot-to-lot purity and bioactivity.

Learn more at thermofisher.com/peprogmp

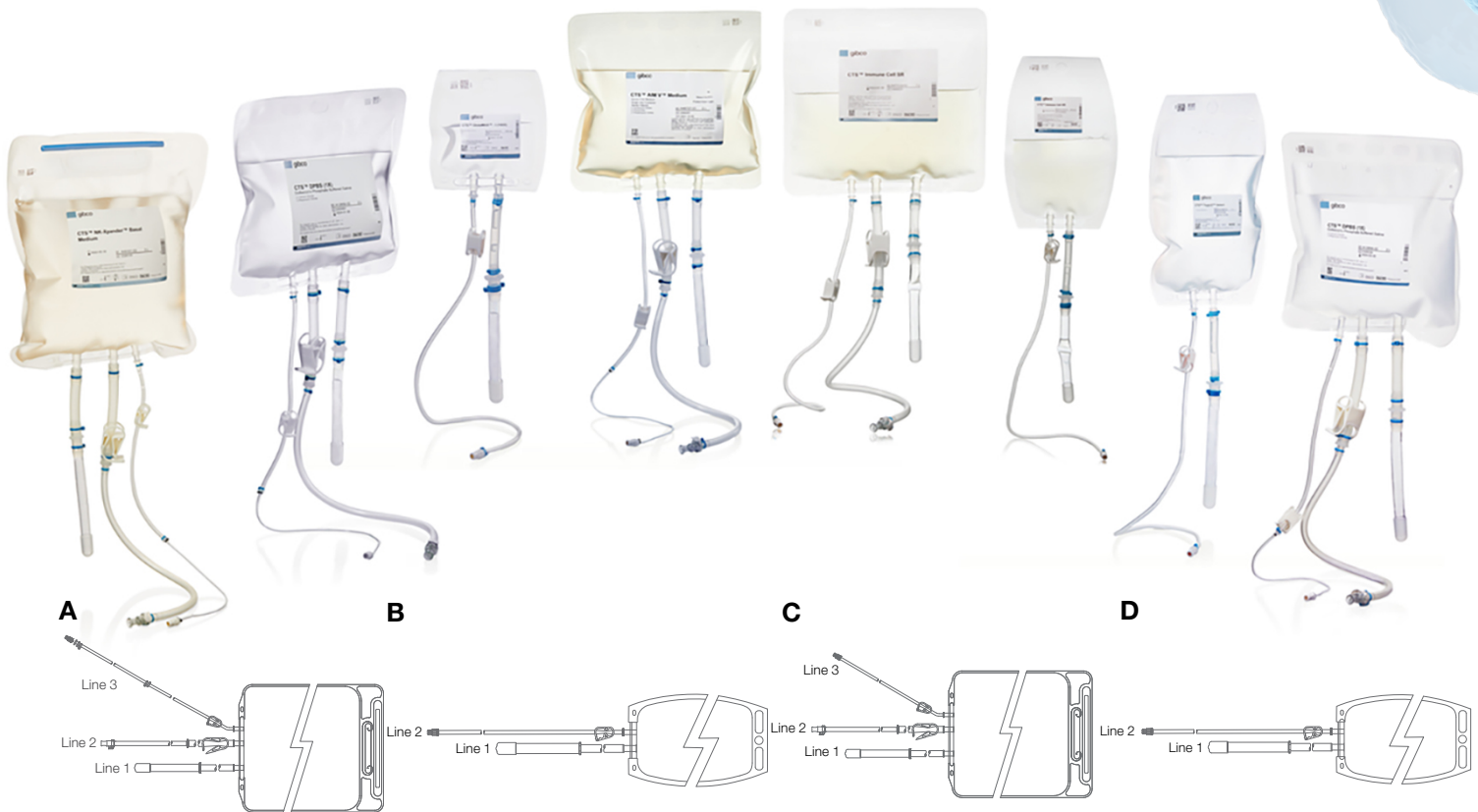
CTS closed system–compatible media and reagents

Reagents in flexible, adaptable bioprocess containers for cell and gene therapy workflows

From process development through commercial manufacturing, Gibco™ CTS™ closed system–compatible media and reagents are off-the-shelf solutions that can help scale up or scale out your cell and gene therapy manufacturing for clinical translation.

Each bagged media formulation:

- Is available in packaging formats suitable for aseptic integration into your workflow
- Helps provide options to incorporate into your closed manufacturing system through the use of luer locks, MPC connectors, or sterile welding
- Has undergone rigorous quality testing and is backed by regulatory documentation such as Drug Master Files, Regulatory Support Files, Certificates of Analysis, and Certificates of Origin



Bioprocess container options for closed system media and reagents for cell and gene therapy. Thermo Scientific™ Labtainer™ BioProcess Containers (BPCs) are constructed from Thermo Scientific™ Aegis™ film; tubing sets and BPCs are double polybagged. **(A)** BPC option A features 2 lines (hybrid line (C-Flex™/PVC tubing) with luer/septum and C-Flex tubing with MPC). **(B)** BPC option B features 1 line (C-Flex tubing with luer/septum). **(C)** BPC option C features 2 lines (C-Flex tubing with luer/septum and C-Flex tubing with MPC). **(D)** BPC option D features 1 line (hybrid line (C-Flex/PVC tubing) with luer/septum).

To see our full list of products and learn more, visit thermofisher.com/closed-system-compatible-reagents

Ordering information

CTS Compleo system, consumables, and software	Quantity	Cat. No.
CTS Compleo Fill and Finish System (instrument, mixing module, computer system)	1 system	A57164 (with laptop) A40009441 (with tablet and keyboard)*
CTS Compleo Single-Use Kit	5 pack	A58165
CTS Compleo SAE Software Solution for 21 CFR Part 11	each	A40002971

Service plan bundle	Cat. No.
CTS Compleo Fill and Finish System, 2-year AB Assurance service, and IQ/OQ	A40007219
CTS Compleo Fill and Finish System, 2-year AB Assurance service	A40007220
CTS Compleo Fill and Finish System, 2-year AB Assurance service, IQ/OQ, and SAE	A40010193

Other workflow products	Quantity	Cat. No.
CTS instrumentation		
CTS DynaCollect Magnetic Separation System, 2-year service, and IQ/OQ	1	A55868
CTS Rotea Counterflow Centrifugation System, 2-year service, and IQ/OQ	1	A50757
CTS Xenon Electroporation System, 2-year service, and IQ/OQ	1	A53520

CTS media and reagents	Quantity	Cat. No.
CTS Synth-a-Freeze Medium	50 mL	A1371301
CTS closed system-compatible media and reagents (bagged products)		thermofisher.com/cell-therapy-mfg-rgts
All formats of CTS products, media, and reagents		thermofisher.com/cts

Recombinant proteins	Quantity	Cat. No.
PeproGMP cytokines and growth factors		thermofisher.com/peprogmp

Safety testing	Quantity	Cat. No.
Applied BioSystems MycoSEQ Plus Mycoplasma Detection Kit	1 kit	A55124
MycoSEQ Plus Mycoplasma Detection Kit with PrepSEQ 1-2-3 Nucleic Acid Extraction Kit	1 kit	A57925
MycoSEQ Plus Mycoplasma Detection Kit with PrepSEQ Express Nucleic Acid Extraction Kit	1 kit	A57926
Applied Biosystems SteriSEQ Rapid Sterility Testing Kit	50 reactions	A57186
	100 reactions	A57185

Freezers	Quantity	Cat. No.
Thermo Scientific CryoMed Controlled-Rate Freezers		thermofisher.com/cryomed

* Coming soon

Learn more at thermofisher.com/compleo

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