

Cell therapy

CTS Cellmation Software for DeltaV Systems

Digital automation for your cell therapy manufacturing workflows

Cell therapy manufacturing involves multiple instruments and several manual touchpoints, increasing the likelihood of contamination and error. This can make it difficult to manage workflows, ensure traceable data connectivity, and maintain cGMP compliance. To streamline this process, manufacturers seek 21 CFR Part 11/Annex 11-compliant solutions that are easy to integrate into their current workflow. Thermo Fisher Scientific now offers a closed, modular, flexible benchtop solution of instrumentation and software with regulatory documentation and support across the cell therapy manufacturing workflow.

Introducing CTS Cellmation Software for DeltaV Systems

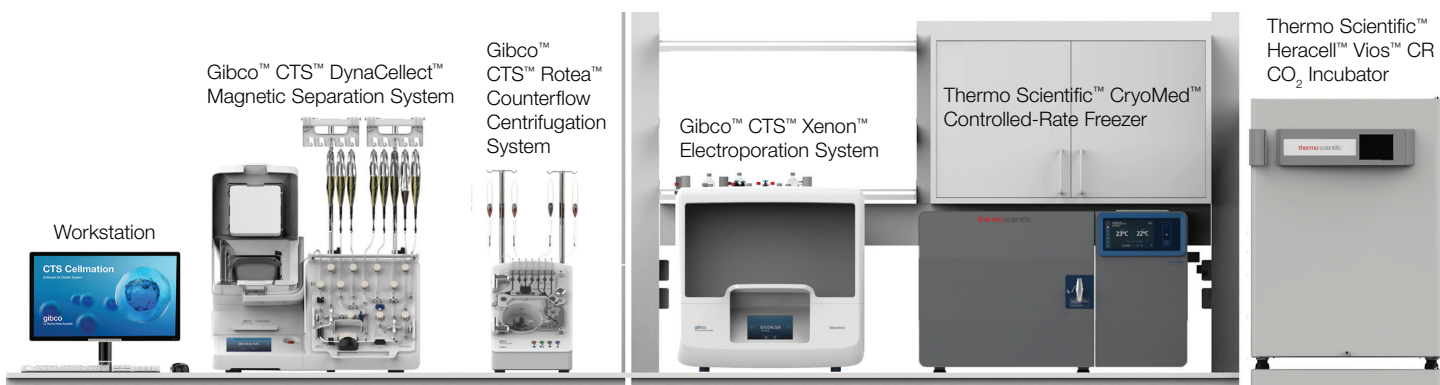
Gibco™ CTS™ Cellmation™ Software is an off-the-shelf solution designed to help simplify and optimize cell therapy manufacturing processes by providing digital connectivity for modular cell therapy instrumentation offered by Thermo Fisher Scientific. The software's open platform provides a flexible system for managing and integrating multiple instruments, streamlining the cell therapy workflow, and helping ensure regulatory compliance, while minimizing cost and time. CTS Cellmation Software is powered by the Emerson™ 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.

CTS Cellmation Software offers customers the following benefits:

- **Off-the-shelf solution**—removes the need for costly custom software projects and extensive validation, helping save time and resources in the manufacturing process
- **Seamless integration**—connect and control your cell therapy workflow across multiple instruments through a single, user-friendly interface
- **Data security and compliance using DeltaV Live software**—help ensure traceable, reproducible, and secure data storage with the DeltaV Continuous Historian, helping enable compliance with the requirements of 21 CFR Part 11/Annex 11 for cGMP
- **Streamlined data management**—direct connection to the Emerson DeltaV DCS layer simplifies the transfer of data streams to manufacturing execution system (MES) and enterprise resource planning (ERP) systems
- **Workflow control**—create user-specific batch recipes to control the flow of your cell therapy manufacturing process

CTS Cellmation Software library*

CTS Cellmation Software automates your cell therapy manufacturing process by connecting multiple instruments in your workflow. Below are the Thermo Fisher Scientific instruments that the CTS Cellmation system can connect and control:



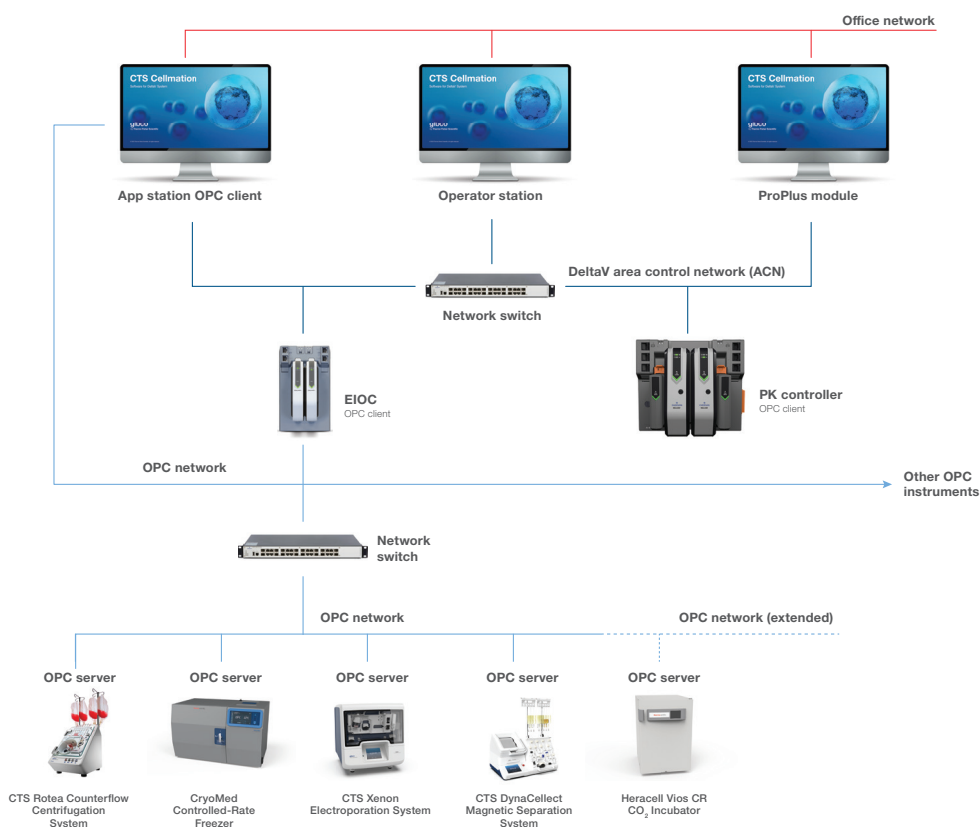
* Not all instrument modules are available. Please contact your sales representative to learn more about module availability.

CTS Cellmation Software and DeltaV DCS connectivity

The diagram to the right shows the interaction between the DeltaV and CTS Cellmation systems and connection to each cell therapy instrument.

Requirements:

1. The software must be imported on a DeltaV ProfessionalPLUS Station that utilizes DeltaV Version 14 software for controlling and viewing cell therapy manufacturing operations.
2. Optional items include the DeltaV Application Station, which may be used for purposes other than control (e.g., Continuous Historian, Batch Executive, and Batch Historian), and the DeltaV Operator Station, which allows users to easily monitor and control the process, manage alarms, and view events and historical trends.
3. CTS Cellmation Software requires DeltaV OPC UA Client Implementation interface and a DeltaV controller. The DeltaV OPC UA client interface can reside on an ethernet input-output card (EIOC), the recommended option, or the Application Station.



Learn more at thermofisher.com/cellmation

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