

Innovative Quality Biosolutions

– ISO 13485:2016 Certified

Your trusted manufacturing partner, specializing in high-quality sterile media products. From standard to specialized formulations, our dedicated team ensures precision and excellence to meet your unique requirements and support your scientific and commercial goals.



Biopreservation

Cryopreservation for Cell & Gene Therapies

All Cell-Based therapeutics need cryopreservation. Whether it is the production of biologics (e.g. proteins, antibodies or therapeutic viruses) or cells used for direct implantation for regenerative medicine, optimizing the preservation of clinical cell samples is essential for advancing medicine. The remarkable growth in the number of investigational and approved immune cell therapies alone requires new high quality and safe cryopreservation solutions. These novel cryopreservation solutions and improved protocols are also the key to make Cell-based therapies more widespread and accessible.



Stem Cell Therapy Workflow

The transition from stem cell research to clinical applications such as regenerative stem cell therapies require high quality cGMP bio-solutions. In particular, the promise of human pluripotent stem cell (hPSC)-based cell therapies is being realized with the growing number of clinical trials (Blau and Daley, 2019; Ilic and Ogilvie, 2022). There are a few key steps in cell therapy workflows that require cryopreservation, which allows for banking and long-term storage of stem cells and stem-cell derivatives that can be used at multiple time-points and potentially with multiple patients for allogeneic therapies. Currently, most laboratories use DMSO based cryopreservation solutions that contain animal serum, human serum or serum derived proteins which can be limiting and undefined.



Kevin Flynn, PhD, Chief Scientific Officer

"The scientific team at CaseBioscience® with its leading cryobiologists, cell biologists, and development biologists, aims to bring in the market disruptive, innovative NON-DMSO formulations and improved methods of cryopreservation that offer safer and accessible alternatives in cell and gene therapies" says Chief Scientific Officer, Kevin Flynn, PhD.

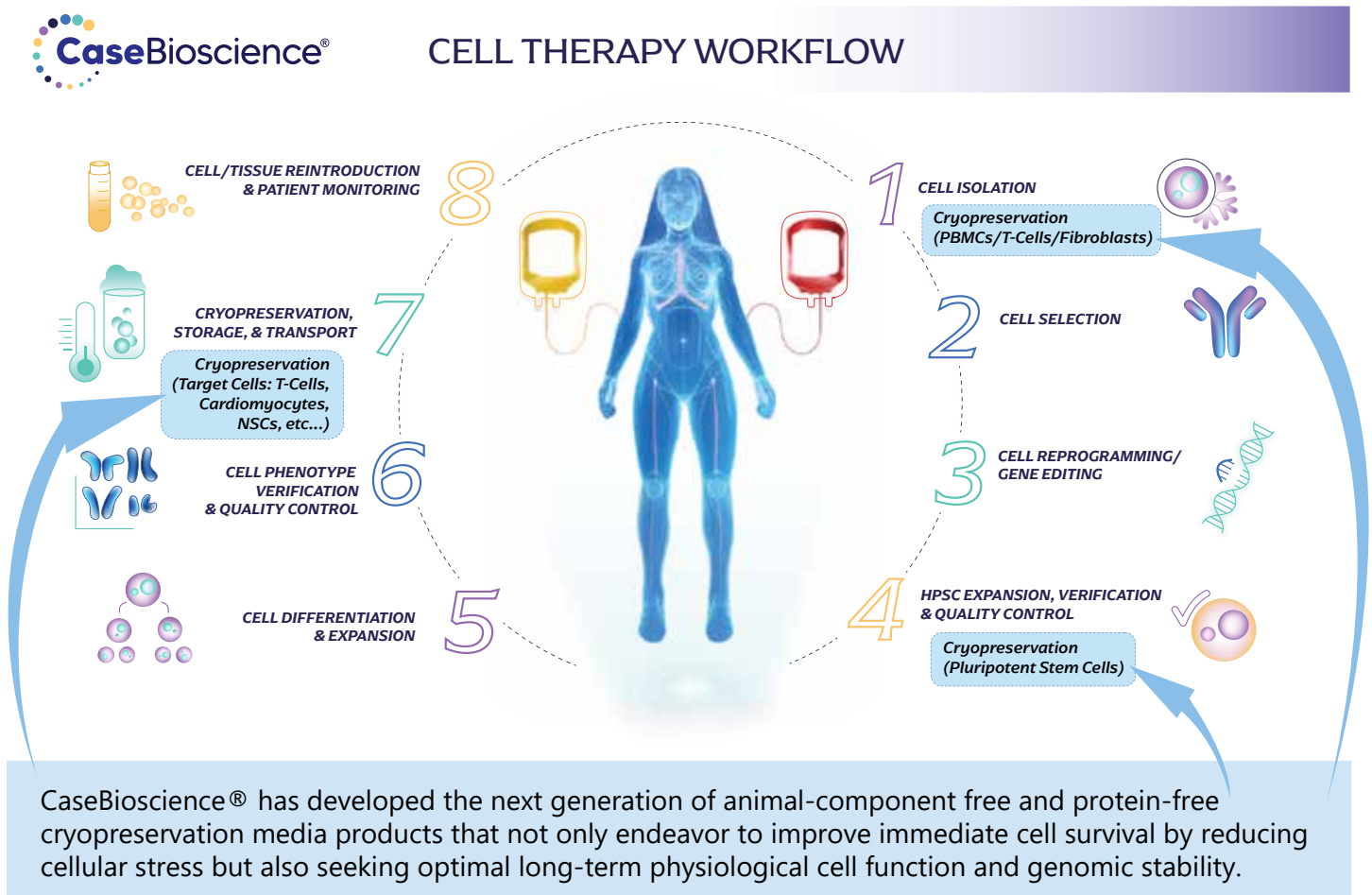
Developing the Next Generation of Cryopreservation Media

We are dedicated to addressing the challenges of cryopreservation in cell therapy workflows. Our innovative formulations are designed to be versatile, safer, and more effective than traditional solutions, providing a cost and time-saving alternative for banking stem cells and other crucial cell types used in various indications.

We are proud to highlight our recent breakthroughs in DMSO-free formulations, outperforming solutions containing DMSO while eliminating concerns of cellular and in vivo toxicity.

Our animal-free solutions are manufactured according to cGMP standards in our ISO-13485:2016 facility, offering simplicity and compatibility with any cell culture workflow without the need for specialized equipment or extensive training.

By enhancing the shelf-life and post-preservation viability of cryopreserved cells, we strive to contribute to the democratization of cell therapies, ensuring successful outcomes in research and clinical studies.



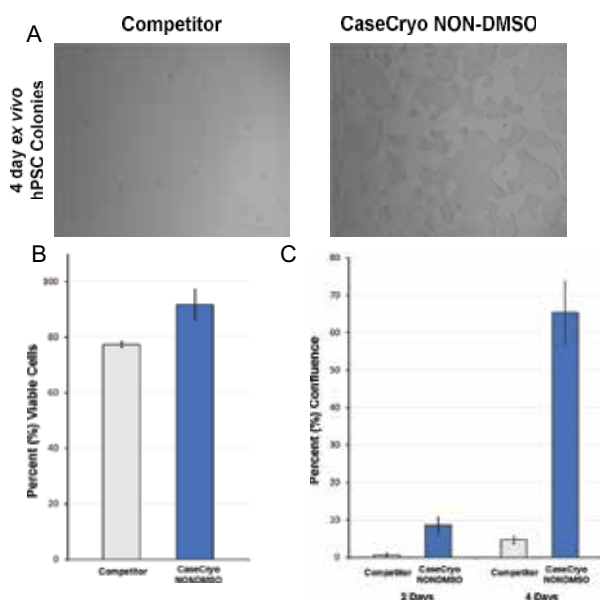
CaseCryo® NON-DMSO

CaseCryo® NON-DMSO is a chemically defined, completely animal-component and protein-free freezing medium with optimized alternative cryoprotectants eliminating the need for DMSO. This medium has been specially formulated and empirically tested for the cryopreservation of human pluripotent stem cells (hPSCs) and other human cell types. In direct comparisons to other commercially available DMSO-free freezing media, CaseCryo® NON-DMSO displays vastly superior viable cell recovery and long-term cell function and expansion. CaseCryo® NON-DMSO is also serum-free and animal-free which reduces immunogenicity providing a safer alternative to other freezing media. CaseCryo® NON-DMSO has been optimized for hPSCs, but it is versatile and displays excellent recovery of cell types derived from hPSCs and other human cells including HEK293 cells. This product can be used synergistically with CaseBase™ Dissociation Medium and CaseBase™ Washing Medium to improve cell survival and function in cryopreservation workflows.

- Chemically defined unique NON-DMSO formulation
- Safer alternative for cell and gene therapies
- Animal Component-Free
- Protein Free
- Physiological, optimized molecular composition and pH
- Batch-to-Batch Consistency
- Stringent analytical and functional QC testing
- Can be customized based on specific use and application along with formulation expertise and regulatory support
- Not only supports improved immediate survival of cells but also offers better long-term cell function and genomic stability
- **ISO 13485:2016 Certified Company** that also follows Good Manufacturing Practices (GMP)
- Sizes: 50mL, 100mL (other sizes available through custom ordering)
- Storage temperature: 2-8°C
- Shelf life: 1 year



Figure 1: CaseCryo NON-DMSO is vastly superior for viability and long-term expansion of hPSCs to an existing DMSO-free competitor.



A. Brightfield images of H1 hPSC colonies 4 days after plating show the increased area of the cell colonies that were previously frozen in CaseCryo NON-DMSO compared to DMSO-free competitor. Note the stark increase in the area of hPSC coverage in the CaseCryo NON-DMSO condition.

B. Immediately following thaw of the cells, the cells stored in CaseCryo NON-DMSO shows over 10% greater viability than those stored in the DMSO-free competitor using trypan blue exclusion.

C. Quantification of cell confluence (area occupied by hPSC colonies) at 2 days after plating and 4 days after plating indicates a considerably greater survival/growth of cells previously cryo-preserved in CaseCryo NON-DMSO compared to the DMSO-free competitor.

CaseCryo® DMSO 10%

CaseCryo® DMSO 10% is a chemically defined, completely animal-component and protein-free freezing medium containing 10% DMSO for the cryopreservation of human pluripotent stem cells (hPSCs) and other human cell types. With its serum-free and animal-free formulation which reduce immunogenicity, CaseCryo® DMSO 10% provides a safe alternative to other freezing media. While CaseCryo® DMSO 10% has been optimized for hPSCs, it is versatile and displays excellent recovery of cell types derived from hPSCs and other human cells including HEK293 cells. This product can be used synergistically with CaseBase™ Dissociation Medium and CaseBase™ Washing Medium to improve cell survival and function in cryopreservation workflows.

- Chemically defined unique DMSO formulation
- Safer alternative for cell and gene therapies
- Animal Component-Free
- Protein Free
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- Stringent analytical and functional QC testing
- Batch-to-Batch Consistency
- Can be customized based on specific use and application along with formulation expertise and regulatory support
- Not only supports improved immediate survival of cells but also offers better long-term cell function and genomic stability
- **ISO 13485:2016 Certified Company** that also follows Good Manufacturing Practices (GMP)
- Sizes: 50mL, 100mL (other sizes available through custom ordering)
- Storage temperature: 2-8°C
- Shelf life: 1 year



Figure 2: CaseCryo DMSO and CaseCryo NON-DMSO have improved viability and long-term expansion of hPSCs versus a leading commercially available Cryopreservation solution.

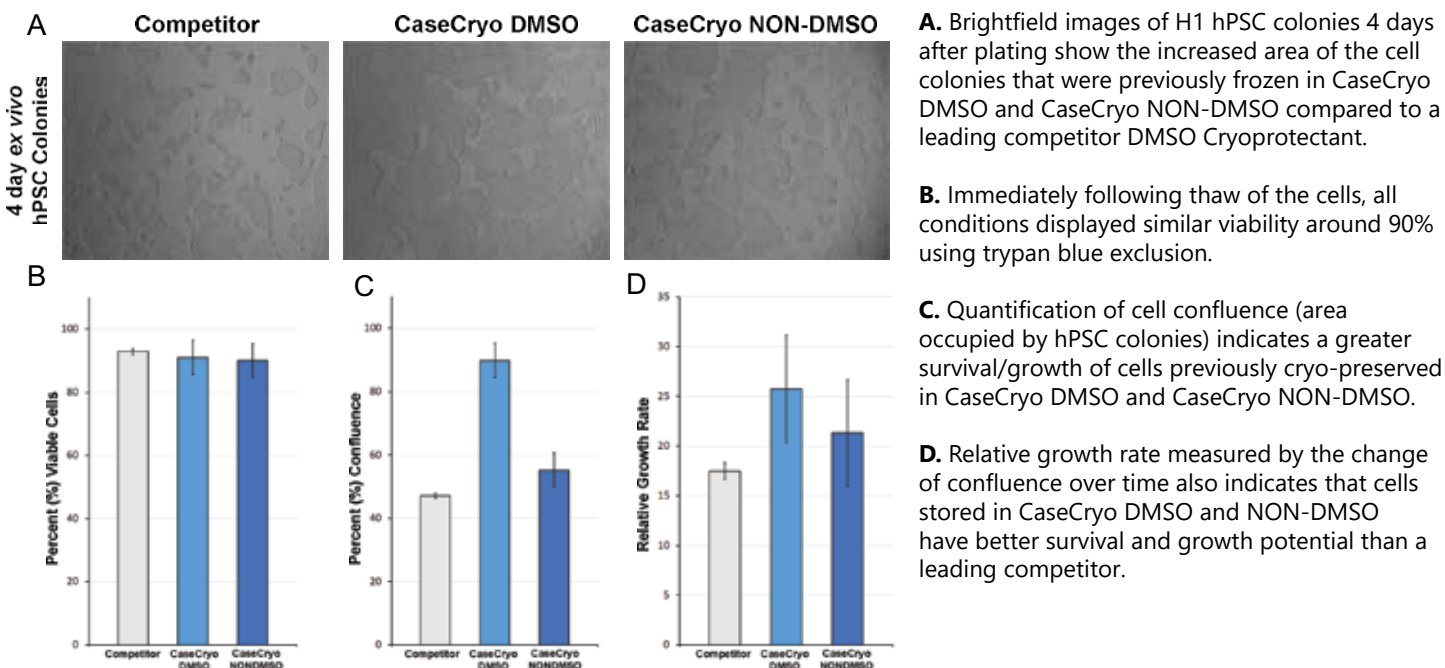
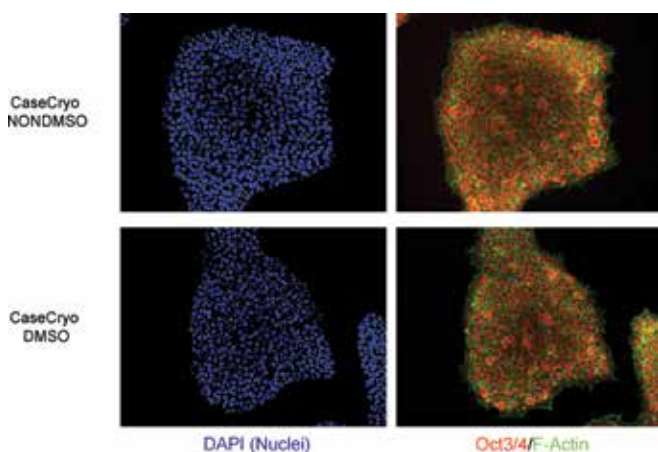
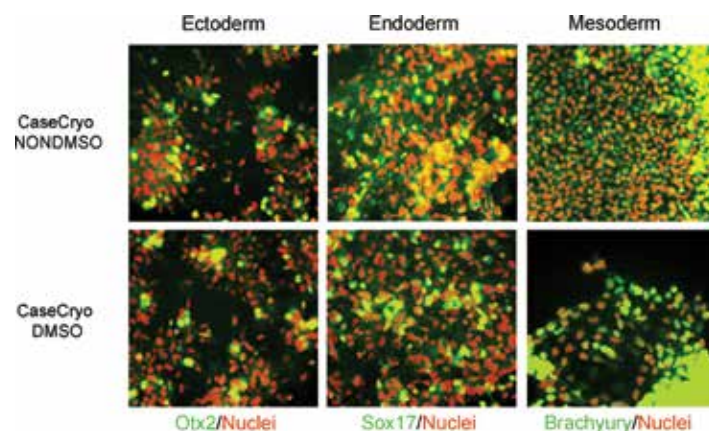


Figure 3: Maintenance of Pluripotency following Cryopreservation in CaseCryo DMSO and CaseCryo NON-DMSO.



H1 hPSCs were grown for 2 passages following cryopreservation in CaseCryo DMSO and CaseCryo NON-DMSO. The cells were immunostained for Oct-3/4 (red), a master regulator of pluripotency and counterstained with DAPI (Blue, nuclei) and F-Actin (Green, FITC-Phalloidin).

Figure 4: H1 hPSCs differentiate into the 3 germ layers following Cryopreservation in CaseCryo DMSO and CaseCryo NON-DMSO.



Following cryopreservation in the CaseCryo DMSO and CaseCryo NON-DMSO, H1 hPSCs were cultured, passaged and differentiated into the 3 germ layers using a Tri-lineage differentiation kit (Bio-Techne). Ectoderm differentiation was confirmed with Otx2 expression (left column). Endoderm differentiation was confirmed with Sox17 expression (middle column). Mesoderm differentiation was confirmed with Brachyury (right column).

CaseThaw[®]

CaseThaw[®] is a chemically defined, completely animal-component and protein-free medium for use in cell culture and cryopreservation workflows. Optimized based on the short-term metabolic needs of human stem cells, this isotonic medium provides an ideal environment for minimizing cell stress during cell culture manipulations.

- Chemically defined unique NON-DMSO formulation
- Safer alternative for cell and gene therapies
- Animal Component-Free
- Protein Free
- Physiological, optimized molecular composition and pH
- Batch-to-Batch Consistency
- Stringent analytical and functional QC testing
- Can be customized based on specific use and application along with formulation expertise and regulatory support
- Not only supports improved immediate survival of cells but also offers better long-term cell function and genomic stability
- **ISO 13485:2016 Certified Company** that also follows Good Manufacturing Practices (GMP)
- Sizes: 50mL, 100mL (other sizes available through custom ordering)
- Storage temperature: 2-8°C
- Shelf life: 1 year



CaseBase™ Washing Medium

CaseBase™ Washing Medium is a chemically defined, completely animal-component and protein-free medium for use in cell culture and cryopreservation workflows. Optimized based on the short-term metabolic needs of human stem cells, this isotonic medium provides an ideal environment for minimizing cell stress during cell culture manipulations. CaseBase™ Washing Medium can be used during routine cell culture and washing for experiments, gene transfer protocols, cell passaging, and short-term holding outside the incubator. This product can be used synergistically with CaseBase™ Dissociation Medium and CaseCryo® products to improve cell survival and function in cryopreservation workflows.

- Chemically defined and versatile washing medium
- Animal-Component free
- Serum Free
- Optimized molecular composition, Osmolality, and pH
- Batch-to-Batch Consistency
- Can be customized based on specific use and application along with formulation expertise and regulatory support
- **ISO 13485:2016 Certified Company** that also follows Good Manufacturing Practices (GMP)
- Sizes: 100ml, 500ml
- Long-term Storage temperature: 2-8°C
- Shelf life: 2 years



CaseBase™ Dissociation Medium

CaseBase™ Dissociation Medium is a chemically defined, completely animal-component and protein-free medium for use for the dissociation of adherent cells for cell culture passaging and cryopreservation. With optimized EDTA concentration, this calcium and magnesium free medium provides a means for gentle cell detachment. This isotonic medium also provides for the short-term metabolic needs of human stem cells, thereby minimizing cell stress during the cell dissociation and passaging process. Proteolytic enzymes can be supplemented to disperse strongly adherent cell types. CaseBase™ Dissociation Medium can be used during routine cell passaging, detaching cells for experiments, as well as collecting cells for cryopreservation. This product can be used synergistically with CaseBase™ Washing Medium and CaseCryo® products to improve cell survival and function in cryopreservation workflows.



- Chemically defined and versatile washing medium
- Animal-Component free
- Enzyme and protein free
- Optimized EDTA concentration, Osmolality, and pH
- Batch-to-Batch Consistency
- Can be customized based on specific use and application along with formulation expertise and regulatory support
- **ISO 13485:2016 Certified Company** that also follows Good Manufacturing Practices (GMP)
- Sizes: 100ml
- Long-term Storage temperature: 2-8°C
- Shelf life: 2 years

WHY CASEBIOSCIENCE®

Who We Are

CaseBioscience® is an ISO 13485:2016 Certified Manufacturer of Sterile BioSolutions used for cell biopreservation or in-vitro culture where Good Manufacturing Practices (GMP), quality, traceability, documentation, and compliance are important for any preclinical research or medical applications.

"We are your trusted manufacturing partner of high-quality sterile media products, offering a range of options from standard or modified classic formulations to any specialized or custom formulations."

Services

Quality driven cGMP biosolutions manufacturer of leading bioproduction tools and services used to facilitate basic and applied research and drive the commercialization of new cell and gene therapies.

- cGMP Custom Media Manufacturing
- Media Development & Optimization
- Rapid High Quality Prototyping
- Classical Media & Buffers (manufactured under GMP with the lowest endotoxin levels)

**FLEXIBLE &
RELIABLE
SERVICE**

**ISO 13485:2016
CERTIFIED**

**MANUFACTURING
EXPERTISE**

**QUALITY
FOCUS**