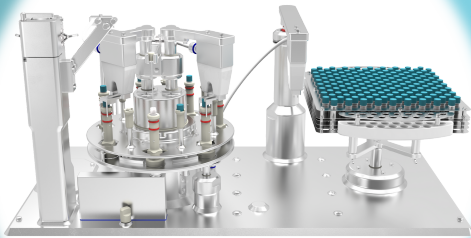




Optimizing Cryovial Filling and Cryopreservation for Reliable Cell Functionality

An Integrated Equipment Workflow for Consistent Post-Thaw Viability and Function Recovery



The scale-up of cell therapy manufacturing has exposed key limitations in common cryopreservation technologies. Challenges such as reduced post-thaw cell survival, diminished therapeutic potency, and limited process scalability can compromise batch consistency and hinder the broader adoption of cell-based therapies. In addition, cryopreservation workflows are frequently either manual or insufficiently controlled, leading to increased variability and elevated contamination risk associated with operator handling. Addressing these challenges requires integrated, reproducible solutions. The combined use of cryoFIL® and CELL enables a streamlined cryopreservation workflow designed to support consistency, scalability, and robust downstream performance. Cryopreservation success depends not only on post-thaw cell survival, but even more on the reproducible preservation of cellular function. While viability metrics provide a necessary baseline, they fail to capture the

functionality required for a reliable downstream performance. Evaluating post-thaw functionality – such as expansion kinetics and cytotoxic activity in NK cells or colony-forming capacity in stem and progenitor cells – is essential to ensure homogeneous, reproducible outcomes across batches. Preserving function is therefore critical not only for scalable, reproducible manufacturing, but also for generating meaningful data in early-stage research and development, supporting both translational research and clinical-scale cell therapy production.



1st Step: Reduce the time from cryopreservant addition to freezing



[View cryoFIL](#)

Cryovials are transferred from a rack to the filling module. Each vial is individually uncapped, filled, and recapped before being returned to its original position in the rack. To assure fast automation and quality with precise and reproducible vial filling, cryoFIL® includes:

- Minimizing vial open time with automatic vial filling
- Real-time 100% weight verification for precise dosing
- Integrated barcode scanning for product traceability
- Closed-loop filling
- Improved consistent thermal history entering freezing

With cryoFIL®, all the vials will be filled and sealed the same way, with reduced human-error and interaction.



2nd Step: Controlled-rate freezing with directional ice growth



[View CELL](#)

After all the vials are equally filled with cryoFIL®, the CELL offers a controlled-rate freezing with flexible cooling rates up to 5° C/min. This controlled-rate freezing system has a bottom-up heat-transfer geometry, allowing for:

- Limited natural convection
- Precise control of ice-nucleation
- Uniform ice growth velocity
- Minimized mechanical stress, aiding in preserving cellular integrity during freezing
- Consistent freezing outcome
- Nitrogen-free technology

Additionally, CELL bottom-up freezing method supports reduced cryoprotectant concentrations (e.g., DMSO), maintaining or even enhancing performance relative to conventionally used concentration ranges.

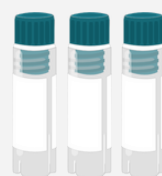
Integrated workflow

PRODUCT



→ cryoFIL →

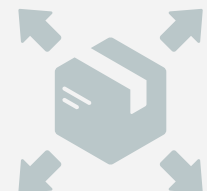
CRYOVIALS



CELL



DISTRIBUTION



Representative Results to Preserve Valuable Cell Therapies

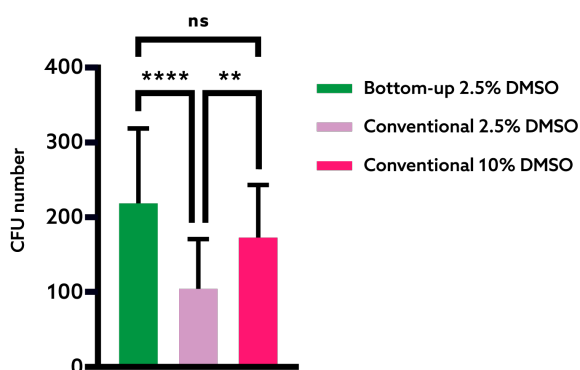


Fig. 1 - Colony forming units of HSPCs post-thaw.

In Fig. 1, we can observe functional recovery results 14 days post-thaw: 20% to 50% CFU (Colony Forming Units) even with 2.5% v/v DMSO with bottom-up freezing methods, compared with conventional radial methods with 10% v/v DMSO. Representative images of CFU results are present in Fig. 2.

Digital & Operational Capabilities

Compatibility

- Design of complete integration between cryoFIL[®] and CELL.
- Full method customization for customer specific workflow.
- Compatibility with major brands with anti-rotate/ self-standing feature at the base of the vials (hex shape or T cut).

Data & Security

- Touch displays and password protected user access control.
- Data export for a deep dive into process outcomes.

CELL

- CELL fits up to 48 vials / batch (bigger versions available upon request).
- CELL temperature range from -85° C to 25° C.
- CELL has a Digital Twin Available. Try it out by [clicking here](#).

3P cryoFIL[®]

- cryoFIL[®] fills 600 vials / hour, from 10 - 1000 vials per batch.
- cryoFIL[®] designed for EU Annex 1 and 1air principles.

Ensuring cell homogeneity and functional recovery across the entire process is critical to the success of cell therapies. cryoFIL[®] and CELL provide a robust, controlled approach to support these outcomes throughout vial preparation, cryopreservation and downstream use.

Contact

For questions related to implementation and a personalized study design, contact:

SmartFreez

www.smartfreez.com
info@smartfreez.com
+351 215 928 189



3P

www.3pinnovation.com
enquiries@3pinnovation.com
+44 (0) 1926 408 933

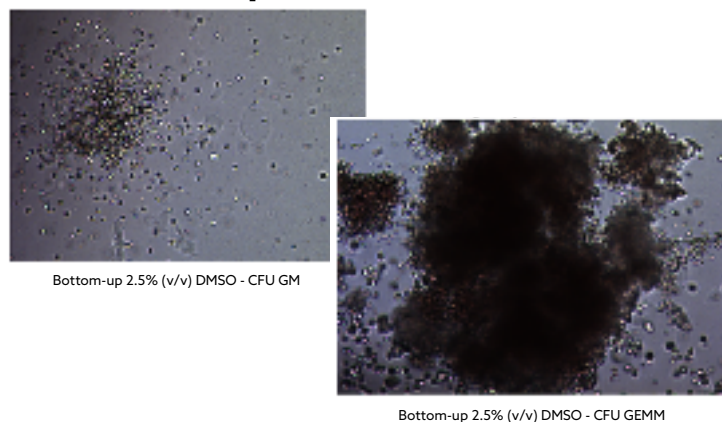


Fig. 2 - Microscopic view of colony forming units of HSPCs post-thaw.

Viability maintained results of 80% post-thaw even with 1% v/v DMSO concentration. For more details and additional results, read more about it in a newly published research paper by Neves et al. in the Biotechnology and Bioengineering journal: <https://doi.org/10.1002/bit.70116>