Cryopreservation Techniques for Cell and Gene Therapies Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The rapid commercialization and regulatory approval of Cell and Gene Therapies (CGTs), including CAR-T, T-cell receptors (TCRs), and iPSC-derived products, have established cryopreservation as the single most critical step for supply chain logistics and maintaining product quality and viability. Cryopreservation Techniques for Cell and Gene Therapies Training Course provides a comprehensive deep dive into the foundational principles of cryobiology and the cutting-edge, GMP-compliant techniques essential for successfully banking and handling viable cellular materials. Participants will master the science of mitigating ice crystal formation and osmotic stress using optimized Cryoprotective Agents (CPAs), moving beyond basic laboratory methods to develop and validate robust controlled-rate freezing and thawing protocols suitable for clinical-grade advanced therapy medicinal products

The program emphasizes hands-on proficiency in managing the ultra-cold chain, from optimizing cryo-media formulations to implementing real-time monitoring and risk mitigation strategies required for global cryogenic logistics. A core focus is placed on process optimization for high-value cell types specifically CAR-T cells, MSCs, and iPSCs ensuring maximum post-thaw viability and functional recovery. By integrating Quality-by-Design (QbD) principles and regulatory compliance, this training empowers technical and manufacturing staff to significantly reduce Cost of Goods (CoGs), minimize product loss, and ensure the consistency, integrity, and safety of life-saving CGT products throughout their entire vein-to-vein journey.

Programme Curriculum

Cryopreservation Techniques for Cell and Gene Therapies Training Course

Introduction

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Course Objectives

1. Master the fundamental principles of Cryobiology and Ice Crystal Formation mechanisms.
2. Optimize Cryoprotective Agent (CPA) selection and formulate GMP-grade cryo-media for specific cell modalities.
3. Demonstrate Proficiency in both Controlled-Rate Freezing and Vitrification techniques for cellular products.
4. Develop and Validate cell-specific Thawing Protocols to maximize Post-Thaw Viability and functional recovery.
5. Apply current cGMP/GxP standards to all cryopreservation workflows and documentation.
6. Implement robust Quality Control (QC) and Quality Assurance (QA) procedures for cryo-banked products.
7. Manage the Ultra-Cold Chain and Cryogenic Logistics to ensure product integrity during transport.
8. Mitigate Risk associated with Temperature Excursions and critical equipment failure in cryogenic storage.
9. Troubleshoot common Cryopreservation Challenges specific to CAR-T Cells and iPSCs.
10. Analyze the utility of Emerging Technologies like Nanoparticle-based CPAs and AI-Driven Freezing.
11. Design a compliant Biobanking Strategy for master and working cell banks of ATMPs.
12. Calculate and achieve target Cell Concentration and Cell Viability metrics for clinical release.
13. Streamline cryopreservation for Scalability in commercial CGT Manufacturing.

Target Audience

1. Manufacturing & Process Engineers in Biopharma/Biotech.
2. Quality Control (QC) & Quality Assurance (QA) Personnel in CGT Facilities.
3. Research Scientists developing novel cell lines and therapies.
4. Biobank Managers and Cryo-Storage Technicians.

5. Cold Chain & Logistics Managers handling biological materials.
6. Process Development Scientists (Upstream & Downstream).
7. Clinical Trial Associates involved in cell handling and delivery.
8. Regulatory Affairs Professionals focused on ATMPs.

Course Modules

Module 1: Fundamentals of Cryobiology

- Effects of low temperatures on cellular structure and function.
- Ice crystal formation and the "two-factor hypothesis."
- Understanding supercooling, nucleation, and the importance of the phase transition zone.
- Osmotic stress, solute concentration effects, and membrane destabilization.
- Case Study: A clinical trial failed due to low post-thaw viability. Analyze the cooling curve data to pinpoint the freezing rate error.

Module 2: Cryoprotective Agents (CPAs) and Media Selection

- Classification of CPAs
- How CPAs reduce the freezing point and minimize osmotic shock.
- Protocols for safe CPA addition and subsequent removal during thawing.
- Selection and custom formulation for serum-free/xeno-free clinical applications.
- Case Study: A manufacturer is developing a new CPA-free protocol to eliminate the toxicity and washing steps for a final product.

Module 3: Controlled-Rate Freezing (CRF)

- Balancing dehydration and intracellular ice formation.
- Programming and validation of controlled-rate freezers.
- Step-by-step procedures for the standard ?êÆ1?êÿC/minute method.
- Passive freezing methods.
- Case Study: A laboratory transitions from a manual ?êÆ80?êÿC method to an automated CRF. Develop the required validation plan.

Module 4: Advanced Freezing: Vitrification

- Vitrification theory.
- High CPA concentration.
- Rapid cooling techniques.
- Advantages and disadvantages of Vitrification and Slow-Freezing for different ATMPs.
- Case Study: Assessing the high-risk, high-reward use of vitrification for a sensitive tissue-engineered construct.

Module 5: Cell Preparation and Aseptic Technique

- Pre-cryopreservation criteria.
- Cell counting and viability
- Aseptic technique
- Determining the ideal cell density for high-viability post-thaw recovery.
- Case Study: A manufacturing run is flagged for microbial contamination post-cryopreservation. Investigate the failure of aseptic technique.

Module 6: Thawing and Post-Thaw Handling

- Rapid warming and dissolution of ice to minimize damage.
- Gentle and effective removal of residual CPA/DMSO to prevent toxicity.
- Selection of appropriate recovery media and incubation conditions.
- Measuring Cell Viability, count, and functional assays
- Case Study: A lab reports low function in CAR-T cells post-thaw, despite high viability. Optimize the recovery/wash step to improve functional potency.

Module 7: Cryopreservation of Key CGT Cell Types I: CAR-T and T-Cells

- Sensitivity of activated and expanded T-cells to freezing stress.
- Optimizing CPA and cooling for maximum T-cell viability and expansion potential.
- Specialized thawing procedures at the point of care/hospital setting.
- Cryopreservation of the final therapeutic product
- Case Study: Develop a robust, closed-system cryopreservation protocol for an allogeneic CAR-T cell bank.

Module 8: Cryopreservation of Key CGT Cell Types II: MSCs and iPSCs

- Maintaining stemness and differentiation potential post-cryo.
- Cryopreserving single cells vs. cell aggregates.
- Techniques for avoiding core injury and managing size distribution.
- Assays for pluripotency (iPSCs) and immunomodulatory function (MSCs).
- Case Study: A biotech company is banking iPSCs for a clinical trial. Design a QC plan for genetic stability and pluripotency markers post-thaw.

Module 9: Cryogenic Storage Systems

- Types of storage.
- Risk assessment and contamination control in LN2 systems.
- Criteria for choosing cryo-vials, straws, and bags for clinical use.
- Protocols for safe operation and minimizing exposure.
- Case Study: A biobank is expanding its storage capacity. Recommend the best system based on cost, safety, and sample security.

Module 10: The Ultra-Cold Chain and Logistics

- Cryogenic temperature requirements (<?êÆ150?êÿC) and phase change materials.
- Evaluating Dry Shippers (LN2 vapor) and specialized cryogenic dewars.
- Use of data loggers, GPS, and IoT sensors for continuous tracking.
- Chain of Custody (CoC) and Identity (CoI).
- Case Study: A shipment of leukapheresis material experienced a 24-hour freight delay. Develop a risk mitigation and exception management plan.

Module 11: GMP and Regulatory Compliance

- Ensuring compliance from cell isolation to final product storage.
- Documenting and verifying the consistency of freezing and thawing SOPs.
- Understanding requirements from the FDA (21 CFR) and EMA for ATMPs.
- Protocol for handling and documenting temperature excursions.

- Case Study: Audit a simulated cryopreservation facility and identify three major GMP non-conformances related to documentation and equipment calibration.

Module 12: Quality Control (QC) and Testing

- Defining and calculating post-thaw recovery, cell viability, and functionality.
- Proficiency in using a hemocytometer, automated counters, and flow cytometry.
- Required microbial testing for cryopreserved clinical products.
- Designing a program to confirm long-term storage viability.
- Case Study: A final product batch fails the QC test for post-thaw viability. Use the Root Cause Analysis (RCA) process to trace the failure back to the CPA addition step.

Module 13: Emerging Technologies and Future Trends

- Using predictive models to optimize cooling and warming rates.
- Exploring polymer and nanoparticle-based cryoprotectants to reduce DMSO toxicity.
- Integration of robotics and closed-system platforms for scale-up.
- Tissue and Organ Cryopreservation.
- Case Study: Evaluate a proposal to integrate an AI-driven automated freezer into a manufacturing line. Assess the technical and regulatory challenges.

Module 14: Cryopreservation for Large-Scale Biobanking

- Design of a robust, tiered Master Cell Bank and Working Cell Bank system.
- Utilizing multi-well plates or automated cell processing systems.
- Implementing computerized systems for sample tracking and location.
- Developing a back-up plan and an emergency transfer protocol for critical samples.
- Case Study: Design a plan for a new CGT biobank to store 5,000 vials of a viral vector-transduced cell product, including all necessary equipment and QA measures.

Module 15: Economic Impact and CoGs Reduction

- Determining the true Cost of Goods for cryopreservation per patient dose.
- Identifying bottlenecks and areas for resource optimization.
- Cost-benefit analysis of premium vs. standard cryo-vials and media.
- Planning for the transition from clinical trials to commercial manufacturing volume.
- Case Study: A manufacturer calculates that their current CoGs are too high. Recommend three process changes in the cryopreservation step to achieve a 15% reduction.

Training Methodology

This course utilizes a high-engagement, blended learning approach to ensure practical skill acquisition and regulatory comprehension:

- Interactive Lectures & Group Discussions.
- Hands-on Laboratory Sessions.
- Live Equipment Demonstrations.
- Case Studies & Collaborative Problem-Solving.
- Practical Assessments & SOP Development.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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