ISCT
INSTITUTE OF TRAINING & DEVELOPMENT

CELL THERAPY MANUFACTURING: OPERATIONAL STRATEGIES FOR SUCCESS

Saturday, May 9, 2026 • ISCT 2026 Dublin, Ireland

COURSE OVERVIEW

This one-day, in-person, expert-led training is designed for senior lab professionals, including lab managers, lab directors, process development associates, and quality control and quality assurance associates seeking to optimize their cell product manufacturing processes. This course focuses on critical areas within the cell manufacturing workflow where inconsistencies and challenges frequently occur. Participants will benefit from real-world case studies presented by leading academic and industry experts from North America and Europe.

WHO IT IS DESIGNED FOR

- Senior laboratory professionals, including technologists, lab managers, directors, process development associates and QA/QC personnel.

KEY LEARNING TOPICS INCLUDE:

- Standardizing processes to ensure cell product quality, with emphasis on cryopreservation and thawing techniques.
- Product characterization methods for consistent and reliable results.
- Safety testing procedures to meet regulatory standards

DELIVERY METHOD

In-person interactive course

1-day training
Saturday, May 9, 2026

Hosted in the ISCT 2026 Annual Meeting at:
Spencer Dock, N Wall Quay,
North Wall, Dublin 1, D01 T1W6, Ireland

ASCP

ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)- approved provider.
This course consists of 5 CMLE credits.

International Society ISCT Cell & Gene Therapy®

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08:00–08:30	**Check-In, Registration and Coffee**
08:30 – 08:45	**Introduction & Overview**
08:00 - 08:20	Lecture 1 **Cell Product Manufacturing Considerations: Analytical and Safety Testing** Learning Objectives: • Review applicable regulatory requirements for performing critical assays on Human Cell, Tissue, or Cellular and Tissue-based Products (HCT/P). • Review current sterility, safety, and characterization methods. • Review common strategies for characterization. • Describe at what time points full analytical validations are required.
09:30 – 10:15	Lecture 2 **Cell Product Manufacturing Considerations: Cryopreservation, Stability, Storage, and Product Traceability** Learning Objectives: • Review and understand the advantages and challenges of cryopreserving cell therapy products. • Discuss factors surrounding cryopreservation that may impact quality of cell products and the need for stability assessments across the product shelf-life. • Establish the procedures required for tracking and traceability of products from manufacture to point of administration. • Review and explore new technologies for improving the quality of cryopreserving cell therapy products and their impact on manufacturing processes and patient safety compared to standard practices
10:15 - 10:30	**BREAK**
10:30-11:30	Lecture 3 **Basis for Quality and Regulatory Requirements: An Overview** Learning Objectives: • Review, understand and describe ICH Q5 key objectives (Viral Safety, Cell Banks, Stability and Comparability). • Review, Understand and describe ICH Q7 key objectives ((GMP for Active Pharmaceutical Ingredients). • Review, understand and describe ICH Q9 key objectives (Quality Risk Management) • Review, understand and describe ICH Q10 key objectives (Quality Monitoring, CAPA, Change Management and Management Reviews)

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11:30-12:15	Lecture 4 **Adapting to Emerging Technologies: Key Considerations, Scalability, and Limitations in Manufacturing** Learning Objectives: • Assess technology options to identify best-fit solutions and recognize their limitations. • Compare and apply strategies for manufacturing scale-up and scale-out. • Evaluate and select appropriate partners for scaling up, including developing contingency plans when vendors no longer support or exist. • Implement approaches to manage contamination risks when adopting new technologies or working with new suppliers.
12:45-14:00	**LUNCH**
14:00-14:45	Lecture 5 **Cell Therapy Products: Potency Assays vs. Characterization – A Regulatory Perspective and Practical Approaches** Learning Objectives: • Defining characterization and potency from a regulatory perspective. • Review of different types of cell therapy products using different approaches (case studies: mesoblast, CAR-T). • Define and discuss potency assay and functional assays.
14:45-15:30	Panel Discussion **Case Study / Workshop**
15:30-15:45	**Wrap Up and Quiz**
15:45-16:45	**Networking Reception**

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