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.

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

WHO IT IS DESIGNED FOR

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

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**
08:45 - 09:30	**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 identity sterility and safety methods. • Review common strategies for identity. • Describe at what time points full analytical validations are required. Speaker: **Adrienne Mendoza, MHA** Senior Vice President, BioBridge Global & Chief Operating Officer, BBG Advanced Therapies, Texas, USA
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 Speaker: **Lindsay Davies, PhD** Co-founder, QVance, Sweden
10:15 - 10:30	**BREAK**

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10:30-11:15

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)

Speaker: **Anna Koptina, PhD**
Founder, Exellerium AB
Sweden

11:15-12:00	Panel Discussion **Case Study / Workshop**
12:00-13:15	**LUNCH**

13:15-14:00

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.

Speaker: **Melissa van Pel, PhD**
Head of Cell Therapy
NecstGen, the Netherlands

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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.

Speaker: **Margarida Serra, PhD**
Head of Stem and Immune Cells Bioengineering Lab / Bioengineering for Cell-based Therapies, iBET, Portugal

14:45-15:30	Panel Discussion **Case Study / Workshop**
15:30-15:45	**Wrap Up and Quiz**
15:45-17:00	**Networking Reception**

Planning Committee:

Wade Atkins
MS, MT (ASCP) SBB, CQA (ASQ)
Department of Transfusion Medicine at the Clinical Center of the National Institutes of Health, United States

Diane Kadidlo
BSc, MT (ASCP) SBB
University of Minnesota
United States

Lizette Caballero
BS, MT (ASCP)
The Janssen Pharmaceutical Companies of Johnson & Johnson,
United States

Emily Hopewell
PhD, CABP(H)
Indiana University School of Medicine
United States

Karen English
PhD
Maynooth University
Ireland

Lindsay Davies
BSc (Hons), PhD, FHEA
ISCT VP-Elect, Europe
QVance, Sweden