ISCT ACADEMY OF TRAINING & DEVELOPMENT

CELL PRODUCT HANDLING & REGULATORY 101



COURSE OVERVIEW

TheCellProduct Handling& Regulatory 101 is a three-hour, on-demand course developed for professionals new to the cell and gene therapy field.

This course covers the fundamental knowledge important for working in Cell and Gene Therapy (CGT) labs—including cell collection, sample processing, storage, distribution, quality control and regulatory requirements.

WHO IT IS DESIGNED FOR

Technologists withlessthan3yearofcell processing lab experience

DELIVERY METHOD

- Online, on-demand
- Three hours

UPON COMPLETION, YOU WILL RECEIVE:

Certificate of course completion from ISCT

ANAB ANSI National Accreditation Board ACCREDITED ANSI/ASTM E2659 CERTIFICATE ISSUER

3 CMLE Credit Hours

ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of 3 CMLE credits.

International Society ISCT Cell & Gene Therapy®

www.isctglobal.org/workforce-development

Scan this QR code for more information about the course

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SESSION ONE: Collections

Speaker:

Federico Rodriguez Quezada, SBB, MLS (ASCP)
UF Health Shands BMT Program

Learning Outcomes:

- List the standard methods for collecting human cell sources
- Recognize the frequency of progenitors given different modes of collection
- Explain the different types of allogeneic donors in cell therapy
- Classify donors based on their medical eligibility and suitability
- Describe the basic screening and testing requirements for HCT/P establishments

SESSION TWO: Processing & Quality Control

Speaker:

Darin Sumstad, MLS (ASCP)
Health Fairview University of Minnesota Medical Center

Learning Outcomes:

- Describe the requirements, techniques and considerations for processing HPC
- List the scope and requirements for performing QC testing on an HPC product
- Name common methods to remove red blood cells from HPC product

SESSION THREE: Quality Assurance / Regulatory

Speaker:

Wade Atkins, MS, MT (ASCP), SBB, CQA (ASQ)
NIH Clinical Center Department of Transfusion Medicine (DTM)

Learning Outcomes:

- Describe the regulatory requirements for HTC/P products
- Recognize the GTP product release criteria and framework
- Describe nonconformities & deviations: Communication & Roles

SESSION FOUR: Product Storage, Distribution & Logistics

Speaker:

Ljiljana Vasovic, MD
Weill Cornell Medicine

Learning Outcomes:

- State the areas to examine when inspecting for cellular therapy products upon receipt
- Recognize the basic requirements for storing HCT/P products
- Identify the cellular therapy product shipping and transportation best practices
- List the information required for an inventory control system