ISCT
INSTITUTE OF TRAINING & DEVELOPMENT

CELL THERAPY MANUFACTURING: STRATEGY & OPTIMIZATION

COURSE OVERVIEW

This **on-demand** course addresses critical areas within the cell manufacturing workflow where inconsistencies and challenges arise, with real-world case studies presented by leading academic and industry experts.

Participants will gain advanced knowledge in standardizing processes essential to cell product quality, including cryopreservation, product characterization, safety testing and knowledge to integrate new technologies into their current workflows.

WHO IT IS DESIGNED FOR

- Senior lab technologists, lab managers, and senior process development associates.
- Learners who have previously completed the Cell Product Handling & Regulatory 101 and Essentials of Cell Therapy Product Manufacturing, Qualification, and Validation on-demand courses.

DELIVERY METHOD

Online, on-demand

Four hours

ASCP

ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)- approved provider. This course consists of 4 CMLE credits.

International Society ISCT Cell & Gene Therapy®

www.isctglobal.education

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SESSION ONE: Cell Product Manufacturing Considerations: Characterization And Safety (361 vs 351 products)

Speaker:

Olive Sturtevant, MHP, MT(ASCP) SBB,SLS, CQA(ASQ)
Senior Administrative and Director of the Connell & O'Reilly Families, Cell Manipulation Core Facility
Dana-Farber Cancer Institute, United States

Learning Outcomes:

- Recall applicable regulatory requirements for performing critical assays on HCT/P products.
- Recognize at what time points full analytical validations are required
- Recall current characterization, sterility and safety methods
- Compendial, PCR, gene sequencing, fluorescence detection, or other
- Give examples of common challenges for CT products assays

SESSION TWO: Cell Product Manufacturing Considerations: Cryopreservation, Stability, Storage, And Product Tracking (361 vs 351 products)

Speakers:

Steve Oh, PhD
Independent Cell Therapy Leader, Singapore, and

Sita Somara, PhD, MBA
Drug Development and Regulatory Program
Soma Life Science Solutions, United States

Learning Outcomes:

- Understand the scientific and regulatory basis for cryopreservation and storage of cell therapy products. Includes techniques, stability considerations, and GMP infrastructure.
- Differentiate between Section 361 and Section 351 cell therapy product classifications and their regulatory implications.
- Emphasis on manipulation, use, and systemic effect
- Evaluate product tracking strategies including Chain of Identity (COI) and Chain of Custody (COC) in maintaining patient safety and product integrity With examples from autologous therapies like CAR-T

SESSION THREE: Adapting To Emerging Technologies: Key Considerations

Speaker:

Darin Sumstad, MLS(ASCP)
Technical Lead of Cell Therapy Clinical Laboratory
M Health, Fairview, University of Minnesota Medical Center, United States

Learning Outcomes:

- Describe internal techniques used to support product development and technology transfer.
- Evaluate culture assessment tools to optimize process performance.
- Assess scalability considerations and key manufacturing limitations.

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SESSION FOUR: Identifying And Mitigating Common Issues When Bringing On Industry-Sponsored Technologies

Speakers:

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

Diane Kadidlo, BSc, MT (ASCP) SBB
Director of Molecular and Cellular Therapeutics
University of Minnesota, United States

Learning Outcomes:

- Recognize and manage common issues that arise when on boarding products or services developed outside your organization
- Identify strategies to resolve issues encountered in the Cell Processing lab when dealing with external Sponsors
- Summarize how a Quality Agreement can be utilized to identify and address potential challenges between a transplant center and the Sponsor/manufacturer

SESSION FIVE: Designing A Sustainable And Robust Training Program: Approach And Competency Assessment

Speakers:

Cheryl Cox, MHA, MT(ASCP), CSSMBB
Director of Cell Therapy Core Operations
Moffitt Cancer Center, United States, and

Christina J Vaughan, MS, CABP
Manager of Cell Immunotherapy and Transduction (CIT) Facility
Indiana University School of Medicine, United States

Learning Outcomes:

- Understand the importance of a training/competency program within the Cell Therapy community.
- Recognize the Regulatory requirements and impact on the cell therapy facility.
- List the key components of a Cell Therapy Training/competency program

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Planning Committee:

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