ISCT
INSTITUTE OF TRAINING & DEVELOPMENT

HANDS-ON LABORATORY BOOTCAMP FOR CELL THERAPY BIOMANUFACTURING

A Global Partnership with ISCT & CMaT

COURSE OVERVIEW

This five-day expert guided hands-on laboratory training course is designed to train you on laboratory techniques and best practices essential to cell bioprocessing GMP labs. You will be working in a GMP- like lab to initiate, maintain, scale up, and cryopreserve adherent and suspension cells using aseptic techniques and under GMP guidelines. You will learn the entire cell product manufacturing workflow and perform cell product safety and characterization assays.

WHO IT IS DESIGNED FOR

Graduatedstudents andIndustryprofessionals seeking hands-on training experience working in GLP andGMPlaboratory.

DELIVERY METHOD

In-person

Marcus Center for Therapeutic Cell Characterization and Manufacturing
Georgia Institute of Technology
345 Ferst Drive, Atlanta, Georgia 30332
United States

Five-day hands-on training program

UPON COMPLETION, YOU WILL RECEIVE:

- Course materials including lab protocols
- Certificates of course completion from ISCT-CMaT and CMLE

30 CMLE Credit Hours

ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of 30 CMLE credits.

CMaT Cell Manufacturing Technologies

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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DAY ONE

7 hours

- Introduction to the Laboratory Environment (3 hrs)
- Data Management and Reporting (3 hrs)

Learning Outcomes:

- Apply laboratory safety, PPE, and ergonomics for working in GLP and GMP labs
- Apply GLP protocols when handling and reporting spills and injuries
- Apply GLP operations standards while working in the lab
- Apply proper aseptic techniques when handling biohazard materials in the lab
- Operate essential laboratory equipment (pipettes, biological safety cabinets, centrifuge, etc.)
- Prepare reports using GLP best practices
- Track and document samples, reagents and data for reporting

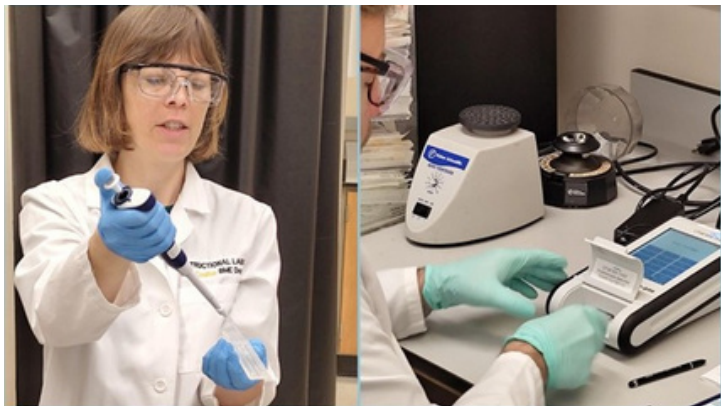
DAY TWO

7 hours

- CellProduct Safety Testing (3 hrs)
- Mammalian Cell Culture (3 hrs)

Learning Outcomes:

- Perform sterility, mycoplasma, and endotoxin testing
- Perform cell counting using manual and automated cell counters
- Evaluate post-thaw mammalian cells quality, such as cell viability and recovery
- Set up mammalian cell culture (e.g. T cells and MSCs)
- Document procedures and results using GLP practices



Dive deep into product safety testing, focusing on Endotoxin and Mycoplasma

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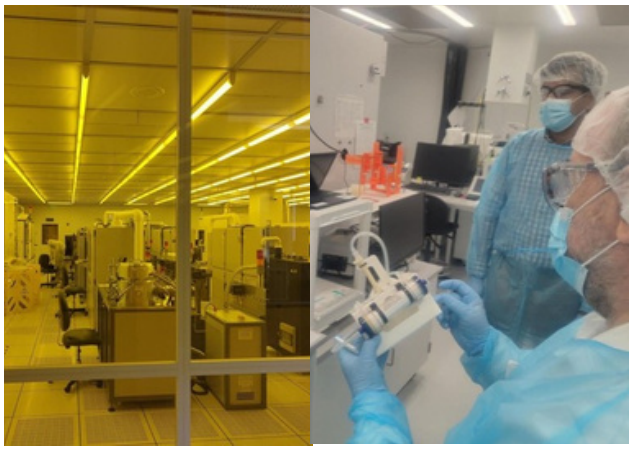
DAY THREE

7 hours

- Maintain Cell Culture (3 hrs)
- Harvest and Cyropreservation (3 hrs)

Learning Outcomes:

- Evaluate MSCs and T cells morphology under the microscope
- Maintain and passage T cells and MSCs
- Perform cell counting and viability assessment
- Calculate optimal cell seeding densities to expand T cells and MSCs
- Harvest and cryopreserve T cells and MSCs



Perform cell culture scale up and learn about the cell manufacturing workflow at the Marcus Center for Therapeutic Cell Characterization and Manufacturing

DAY FOUR

7 hours

- Cell Product Manufacturing Workflow (3 hrs)
- Cell Manufacturing (3 hrs)

Learning Outcomes:

- Apply GMP laboratory safety and operations best practices
- Analyze the cell culture systems to use for small and large scale cell manufacturing (e.g., PBS, wave, hollow fiber, Terumo, quantum bioreactors)
- Perform cell culture scale up using vertical-wheel bioreactors

Passaging cells in GMP lab for cell culture scale up

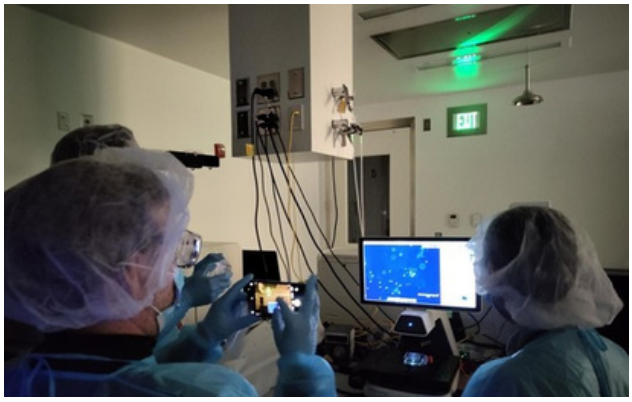
DAY FIVE

7 hours

- CellProduct Characterization Assays (7 hrs)

Learning Outcomes:

- Perform BCA assay and cellular metabolites monitoring
- Perform ELISA, apoptosis, flow cytometry and fluorescence microscopy to evaluate cell product characteristics
- Perform data collection and analysis



Observe cell interactions using DAPI and cell tracker staining under fluorescence microscopy