



HANDS-ON LABORATORY BOOTCAMP FOR CELL THERAPY BIOMANUFACTURING

March 23-27, 2026 • Stanford LCGM, California, USA

COURSE OVERVIEW

This 5-day expert-guided hands-on lab training provides participants with a comprehensive overview of cell therapy manufacturing processes within GMP-compliant environments. Over the week, participants will gain both theoretical knowledge and hands-on experience in key areas including aseptic techniques, cleanroom operations, T-cell expansion, transduction, QC testing, product harvest, release criteria, and documentation practices.

WHO IT IS DESIGNED FOR

Graduated students and Industry professionals seeking hands-on training experience working in GLP and GMP laboratory.



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

KEY LEARNING TOPICS INCLUDE:

- Understand the principles of Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP).
- Learn the workflow for cell product handling, processing, and release, including QC and safety testing.
- Practice aseptic techniques, sample handling, flow cytometry, and transduction procedures in a controlled environment.
- Review and analyze batch records, deviations, and CAPA processes to ensure compliance and quality.
- Develop competency in product harvest, cryopreservation, and formulation for downstream assays and release.

DELIVERY METHOD



Hands-on Lab Training



Five-day hands-on training course



Laboratory for Cell and Gene Medicine
Stanford School of Medicine
855 California Avenue, Palo Alto, CA 94304 USA



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ISCT
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DAY ONE

08:00–08:10	Check-In, Registration and Coffee
08:10 – 08:20	Welcome and Introduction • Ice-breaker session. • Course overview and expectations.
09:00 - 10:00	Lecture Introduction to Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP) for Cell Therapy Manufacturing Learning Objectives: • Explain core principles and best practices in cell therapy manufacturing. • Describe the purpose and essential elements of GDP and GMP. • Develop a basic understanding of GLP & GMP standards. • Report using GMP best practices. • Learn to track samples, reagents, and data. • Recognize the impact of non-compliance and identify strategies to mitigation risks.
10:00 - 10:10	BREAK
10:15 - 11:45	Lab Training Laboratory Operations and Safety Best Practices Learning Objectives: • 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.
11:45-13:00	SPONSORED LUNCH & LEARN: Biolife Solutions

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Lab Training

Aseptic Media Preparation for T-Cell Culture Initiation and Expansion in GMP Settings

Learning Objectives:

13:00 - 16:00

- Demonstrate proper aseptic techniques for preparing materials and reagents needed for T-cell thawing, counting, and culture initiation.
- Perform accurate cell counts and cell viability to support decision-making during culture set-up.
- Initiate and activate T-cell cultures using cell manufacturing equipment.
- Apply best practices to thaw cryopreserved T cells for culture initiation.

16:00 - 16:15

BREAK

Lecture

Data Management and Reporting

Learning Objectives:

16:15 - 17:00

- Describe key principles of data management in GMP cell therapy operations
- Identify best practices for data capture, storage and retrieval in manufacturing workflows.
- Recognize common data integrity issues and implement strategies to mitigate errors or non-compliance.

17:00 - 17:30

WRAP UP

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DAY TWO

Lecture

Cell Product Handling and Processing Workflows: Considerations and Best Fit

Learning Objectives:

- Summarize key facility and equipment requirements for full-scale GMP operations and cell product manufacturing.
- Recognize and explain key considerations when selecting equipment for cell bioprocessing and manufacturing methods.
- Understand the framework and parameters used to assess equipment suitability within a workflow.
- Describe critical requirements and fail-safe mechanisms for equipment in GMP operations
- Identify the best-fit equipment for a given workflow or application.

09:00 - 10:00

10:00 - 10:15

BREAK

Facility Tour

Understanding GMP Infrastructure and Workflow

Learning Objectives:

- Describe key facility features and requirements for GMP-compliant cell therapy operations— including HVAC, environmental controls, reagent storage, quarantine space and material handling practices requirements.
- Identify critical workflow areas and their role in supporting GMP-compliant cell therapy manufacturing.

10:15 - 11:15

Lecture

Cleanroom Setup and Operations Best Practices for GMP Cell Therapy Manufacturing

Learning Objectives:

- Explain the purpose of Impact assessments and the use of SLIA form for GMP equipment.
- Summarize CRN Requirements to bring equipment into cleanrooms (IQOQ, SLIA, 21CFR Compliance).

11:15 - 12:00

12:00 - 13:15

SPONSORED LUNCH & LEARN: Scale Ready

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Lab Training

Cell Product Manufacturing Workflow

Learning Objectives:

13:00 - 16:15

- Apply GMP laboratory safety and operational best practices during cell manufacturing equipment setup and operations
- Analyze cell culture systems to select appropriate platforms for small- and large-scale cell manufacturing applications.
- Evaluate post-thaw cell quality and perform cell culture observation and scale up using the G-Rex system.

16:15 - 17:00

Reporting

- Demonstrate knowledge of documentation using GLP/GMP best practices.

17:00 - 17:30

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DAY THREE

Lecture

Cleanroom Operations: Forms, Campaign Initiation, and Workflow Overview

Learning Objectives:

- Identify required forms and documentation for initiating a cleanroom manufacturing campaign.
- Explain the step-by-step workflow process for campaign execution in a GMP cleanroom.
- Recognize critical compliance checkpoints to ensure sterility, safety, and regulatory compliance.

09:00 - 09:30

09:30 - 09:45

BREAK

Lab Training

Aseptic Qualification

Learning Objectives:

- Prepare and use kit materials required for cleanroom operations.
- Perform aseptic qualifications in GMP compliant cleanroom environment
- Demonstrate hands-on aseptic techniques in a GMP-compliant environment.
- Identify required manufacturing and QC documentations and compliance requirements.
- Apply best practices for safe and compliant operations in GMP cleanroom setting.

09:45 - 13:00

13:00 - 14:00

SPONSORED LUNCH & LEARN: QIAGEN

Lab Training

Cell Product Handling, Transduction and QC Testing

Learning Objectives:

- Perform T cell transduction using viral method.
- Evaluate T-cell transduction efficiency.
- Conduct QC testing to assess product quality.

14:00 - 17:15

17:15 - 17:30

Reporting

- Demonstrate knowledge of documentation using GLP/GMP best practices.

17:30 - 17:45

WRAP UP

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DAY FOUR

Lecture

Cell Therapy Product Release Requirements and Best Practices

Learning Objectives:

- Explain the steps involved in product harvest and final formulation for cell therapy products.
- Describe the steps required to prepare samples for release testing and the purpose of various QC assays.
- Explain the principles of flow cytometry.
- Interpret release criteria in ensuring safe and compliant product release.

09:00 - 09:45

09:45 - 10:00

BREAK

Lab Training

Cell Product Harvest, Formulate and Cryopreservation

Learning Objectives:

- Perform final product harvest and formulate for downstream assays.
- Carry out cryopreservation procedures to preserve cell products for storage or transport.

10:00 - 13:00

13:00 - 14:00

LUNCH

Lab Training

Cell Product Characterization and Release Assays

Learning Objectives:

- Prepare samples for flow cytometry analysis, including proper staining, compensation, and reporting.
- Perform product safety testing, including sterility, mycoplasma and endotoxin testing.
- Understand the interpretation of release criteria to support decision-making for product release.

14:00 - 16:30

16:30 - 17:00

Reporting

- Demonstrate knowledge of documentation using GLP/GMP best practices.

17:00 - 17:30

WRAP UP

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DAY FIVE

Lecture

Preparing a Manufacturing Batch Record and Release Criteria

Learning Objectives:

- Review mock batch records and identify GDP errors, including process deviations and out-of-specification issues.
- Understand batch record formatting and execution in compliance with GMP and GDP guidelines.
- Perform root cause analysis for deviation and process errors.
- Propose corrective and preventive actions (CAPA) based on findings from investigations.
- Document deviations, investigations and CAPA plans according to GDP and QA requirements.

09:00 - 11:30

11:30- 12:30

LUNCH

12:30 - 14:30

Open Lab Session

Review and Practice

14:30 - 15:00

Reporting

15:00 - 15:30

WRAP UP: Assessment and course feedback

15:30 - 17:00

Networking Reception