ISCT
INSTITUTE OF TRAINING & DEVELOPMENT

HANDS-ON LABORATORY BOOTCAMP FOR CELL THERAPY BIOMANUFACTURING

March 1 - 5, 2027 • 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.

ASCP

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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International Society ISCT Cell & Gene Therapy®

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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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13:00 - 16:00	Lab Training **Aseptic Media Preparation for T-Cell Culture Initiation and Expansion in GMP Settings** Learning Objectives: • 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**
16:15 - 17:00	Lecture **Data Management and Reporting** Learning Objectives: • 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

09:00 - 10:00	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.
10:00 - 10:15	**BREAK**
10:15 - 11:15	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.
11:15 - 12:00	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).
12:00 - 13:15	**SPONSORED LUNCH & LEARN: Scale Ready**

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13:00 - 16:15	Lab Training **Cell Product Manufacturing Workflow** Learning Objectives: • 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	**WRAP UP**

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DAY THREE

09:00 - 09:30	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.
09:30 - 09:45	**BREAK**
09:45 - 13:00	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.
13:00 - 14:00	**SPONSORED LUNCH & LEARN: QIAGEN**
14:00 - 17:15	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.
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

09:00 - 09:45	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.
09:45 - 10:00	**BREAK**
10:00 - 13:00	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.
13:00 - 14:00	**LUNCH**
14:00 - 16:30	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, such as sterility, mycoplasma and endotoxin testing. • Understand the interpretation of release criteria to support decision-making for product release.
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

09:00 - 11:30	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.
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**

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