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

Stanford MEDICINE
School of Medicine

Laboratory for Cell and Gene Medicine

International Society
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Scan this QR code to learn more and register

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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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