ISCT
INSTITUTE OF TRAINING & DEVELOPMENT

METHODS AND ANALYTICAL PROCESSES FOR CELL AND GENE BIOPROCESSING

ISCT Training Course at Patheon

COURSE OVERVIEW

Gain hands-onpractical experience working with immune and stem cells, perform high-efficiency transfections, and optimize downstream analytical methods to ensure product quality and consistency. This course equips you with the knowledge and technical competencies to accelerate innovations and meet the demands of the rapidly evolving cell and gene therapy industry.

WHO IT IS DESIGNED FOR

Research scientists, lab technologists, and cell and gene therapy (CGT) professionals looking to enhance their skills in assay development and standardization of bioprocessing methods.

AS PART OF THIS COURSE, YOU WILL RECEIVE:

- A course booklet
- CMLE certificate upon completion

DELIVERY METHOD

In-person, lecture and lab training

10421 Wateridge Circle - Suites 150 & 250, San Diego, California 92121, USA

3.5 day intensive course

24 CMLE Credit Hours

ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of 24 CMLE credits.

patheon
by Thermo Fisher Scientific

International Society ISCT Cell & Gene Therapy®

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DAY 1

08:00–08:30	**Registration & Check-In**
08:30–09:00	**Introduction and Orientation**
09:00–09:30	**LECTURE: BLOOD BORNE PATHOGENS** ***Learning Objectives:*** • Understand the training and lab safety requirements for working in the laboratory. • Apply laboratory best practices for operating laboratory equipment and working with biological samples.
09:30–11:00	**LECTURE: CONSIDERATION FOR BIOPROCESSING EQUIPMENT FOR CELL THERAPY MANUFACTURING** ***Learning Objectives:*** • Share key considerations when researching equipment to use in bioprocessing methods. • Understand the framework and parameters to assess the suitability of equipment in a workflow. • Identify best fit equipment for use in intended workflow or application.
11:00–12:30	**LECTURE: CELL MODIFICATION CONSIDERATIONS** ***Learning Objectives:*** • Select best fit equipment for intended application. • Considerations for gene delivery (sequence design, reagent preparation, enhancers, equipment settings). • Methods for analysis (flow cytometry and polymerase chain reaction (PCR)).
12:30–13:30	**Networking, Lunch & Learn** *Presenters:YvetteTanheco&Alexey Bersenev*
13:30–15:00	**LAB TRAINING: CELL AND REAGENT PREPARATION** ***Learning Objectives:*** • Perform cell isolation and cell activation steps. • Prepare reagents and cells for gene editing using electroporation.

DAY 1

15:00–16:00

Group 1

LAB TRAINING: NONVIRAL GENE MODIFICATION - CRITICAL PARAMETER TESTING

Learning Objectives:

- Know the principles of gene editing of cells using electroporation.
- Perform electroporation to deliver DNA/RNA/Protein into cells.
- Know the critical parameters to optimize transfection efficiencies.

Group 2

LAB TRAINING: NONVIRAL GENE MODIFICATION - LARGE SCALE MODIFICATION

Learning Objectives:

- Understand large-scale options for non-viral modification.
- Evaluate platforms using metrics learned in previous lecture.
- Compare various options for scale of electroporation and select optimal system based on input and output requirements.

17:00–17:30	**Wrap Up**
17:00–19:00	**Networking Event**

DAY 2

08:30–09:00	**Review Day 1**
09:00–10:30	**LAB TRAINING: BIOPROCESSING EQUIPMENT COMPATIBILITY & CONSUMABLES** ***Learning Objectives:*** • Set up bioprocessing equipment using the correct consumable and modules. • Identify the proper use of consumables and reagents. • Compatibility of consumables and reagents. • Perform integrity checks and understand key considerations for maintaining sample/product sterility.
10:30–12:00	**LECTURE: INTRODUCTION TO FLOW CYTOMETRY** ***Learning Objectives:*** • Know the principles and workflow for performing flow cytometry. • Design flow cytometry experiment using the proper antibodies and fluorophores. • Know the key areas to look at when troubleshooting a flow cytometer and flow cytometry data.
12:00–13:00	**Networking, Lunch & Learn** *Presenter: Ashley Krull*
13:00–15:30	**LAB SESSION: FLOW CYTOMETRY BASICS** ***Learning Objectives:*** • Set up flow cytometer for a characterization. • Perform flow cytometry staining on gene-edited samples using the correct panel of antibodies. • Collect flow cytometry data on samples from gene editing experiment.
15:30–17:00	**DATA ANALYSIS: ANALYSIS OF GENE-EDITED FLOW DATA** ***Learning Objectives:*** • Introduction to flow cytometry data analysis. • Flow cytometry data presentation.
17:00–17:30	**Wrap Up**

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DAY 3

08:30–09:00	**Review Day 2**
09:00–10:30	**LECTURE: PCR PLATFORM AND ANALYTICS STANDARDIZATION** ***Learning Objectives:*** • Understand the use of ICH-Q2(R2) Guidelines. Know the purpose of • analytical target profile. Attain a comprehensive understanding of the PCR • method establishment principles. Know the key considerations when choosing PCR platforms. Identify key areas when establishing standards • and controls. •
10:30–12:00	**LAB SESSION: QUANTITATIVE (q) AND DIGITAL (d) PCR (qPCR/dPCR)** ***Learning Objectives:*** • Perform basic assay qualification. • Set up instrument and perform PCR assays on samples.
12:00–13:00	**Networking, Lunch & Learn** *Presenters: Sumona Sarkar & Holly Young*
13:00–15:00	**LECTURE: AI/ML APPLICATIONS IN BIOTECHNOLOGY AND CGT** ***Learning Objectives:*** • Understand the differences between different types of artificial intelligence a n a ly s is . • Learn how AI can be applied to cell and gene therapy processes. • Compare AI platforms and methods for generating a useful model for specific applications.
15:00–17:00	**LAB SESSION: APPLICATION OF MACHINE LEARNING MODEL TO EXPERIMENTAL DATA** ***Learning Objectives:*** • Understand how to use AI software. • Apply various analysis techniques to data generated in lab to develop and test a model. • Learn how to optimize the model and how machine learning software can be applied to results from different processes.
17:00–17:30	**Wrap Up**

DAY 4

08:30–09:00	**Review Day 3**
09:00–10:30	**DATA ANALYSIS: PCR DATA ANALYSIS** ***Learning Objectives:*** • Introduction to data analysis for qPCR/dPCR results • PCR data presentation
10:30–12:00	**LECTURE: EMERGING TECHNOLOGIES AND CURRENT TRENDS IN CGT** ***Learning Objectives:*** • Learn about recent advances in cell and gene therapy • Understand relevant regulatory developments • Discuss overall trends in the field
12:00–13:00	**Boxed Lunch To-Go, Wrap Up**