ISCT
INSTITUTE OF TRAINING & DEVELOPMENT

iPSC CULTURE AND APPLICATIONS IN CELL AND GENE THERAPY

COURSE OVERVIEW

This comprehensive course provides a deep dive into the process of reprogramming somatic cells into induced pluripotent stem cells (iPSCs) and their application in cell therapies. Participants will gain a solid foundation in the key steps and considerations involved in iPSC generation, including an understanding of viral and non-viral reprogramming methods, quality control measures, and the necessary morphological assessments of iPSC colonies. The course will also explore Quality by Design (QbD) approaches to optimize iPSC culture for cell therapy applications, emphasizing key in-process parameters and factors that influence pluripotency and iPSC quality.

In the later modules, the course will discuss the development of iPSC-derived therapeutic products, particularly focusing on the advantages and challenges of using iPSCs in allogeneic cell therapies. This includes insights into the differences between iPSCs and immune cell types in therapy manufacturing workflows, as well as regulatory considerations and risk assessments in clinical applications. Throughout the course, participants will engage in self-paced learning along with interactive live-virtual discussions, guided by leading global experts in the field, to ensure a thorough understanding of the fundamental concepts and practical applications of iPSCs in advanced research and therapeutic development.

WHO IT IS DESIGNED FOR

This courseis tailoredfor professionals eager to advance their knowledge in induced pluripotent stem cell (iPSC) technology, particularly its applications in regenerative medicine and cell therapies. It is ideal for CGT (Cell and Gene Therapy) professionals, clinical researchers, and those involved in the development of therapies and products derived from iPSCs. Whether you are new to the field or seeking to deepen your expertise, this course offers a comprehensive understanding of the latest advancements and best practices in iPSC technology.

DELIVERY METHOD

2 hours,
self-paced, on-demand modules

1 hour,
live-virtual expert panel discussions

Course access duration:

6 months of structured learning

UPON COMPLETION, YOU WILL RECEIVE:

Certificate of course completion fromISCT

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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MODULE 1: Reprogramming Somatic Cells to iPSCs

Speaker: Lise Munsie, PhD, BlueRock Therapeutics, Canada

In this module, you will gain a comprehensive understanding of the process of reprogramming somatic cells into induced pluripotent stem cells (iPSCs), a fundamental technique in regenerative medicine. You'll learn about the critical steps involved in this transformative process, from the initial isolation of somatic cells to their conversion into pluripotent stem cells.

Key topics include:

- **Reprogramming Techniques:** Detailed insights into the viral and non-viral methods of reprogramming, and the advantages and challenges associated with each approach.
- **Workflow Considerations:** Discover the key factors that influence the reprogramming process, based on the starting material used, and how to optimize the workflow for successful iPSC generation.
- **Morphological Features:** Learn to identify the specific morphological traits of iPSC colonies that indicate they are ready for selection and differentiation.
- **Undifferentiated vs. Differentiated iPSCs:** Understand the distinguishing characteristics of undifferentiated and differentiated iPSC colonies, crucial for ensuring quality control during culturing.
- **Quality Evaluation:** Explore the essential assays and techniques used to assess the quality and pluripotency of iPSCs, ensuring they meet the required standards for both research and clinical applications.

MODULE 2: Quality by Design (QbD) in Culturing iPSCs for Cell Therapy

Speaker: Shin Kawamata, MD, PhD, Cyto-Facto, Japan

This module focuses on the integration of Quality by Design (QbD) principles into the culturing process of iPSCs for use in cell therapies. You will gain deep insights into how these cells can be manufactured under rigorous quality control standards, optimizing their potency and safety for therapeutic applications.

Key topics include:

- **Functional Characteristics of iPSCs:** Understand the unique attributes of iPSCs that make them an ideal starting material for cell therapies, including their ability to self-renew and differentiate into a wide range of cell types.
- **Influencing Factors:** Delve into the factors that affect pluripotency and quality, including culture conditions, genetic stability, and the impact of different reprogramming methods.
- **Comparison of Manufacturing Processes:** Learn about traditional manufacturing techniques for cell production versus modern QbD-based automated processes, and how automation enhances scalability, reproducibility, and quality.
- **In-Process Monitoring:** Discover the critical in-process parameters needed to monitor iPSC quality during manufacturing, such as cell viability, differentiation potential, and genomic integrity, to ensure they meet the high standards required for clinical use.

MODULE 3: Development of Multi-Engineered, iPSC-Derived Therapeutic Products

Speaker:BrunoMarques, PhD, Century Therapeutics, UnitedStates

This module addresses the complexities and innovative strategies involved in the development of iPSC-derived therapeutic products. As regenerative medicine moves toward more personalized and allogeneic cell-based therapies, iPSCs play a crucial role.

Key topics include:

- **Allogeneic Cell Therapy Manufacturing:** Understand the significant advantages of using iPSCs for allogeneic therapies, such as their ability to be derived from a single donor source and the potential for reducing immune rejection.
- **iPSCs vs. Immune Cells:** Learn why iPSCs offer a broader range of therapeutic potential compared to traditional immune cell therapies, including their ability to differentiate into various cell types that can be used for treating a wide range of diseases.
- **Manufacturing Workflow Differences:** Gain insights into the differences between iPSC-based and immune cell-based therapeutic manufacturing processes, from the initial cell isolation to final product production and quality control.
- **Challenges and Risk Assessments:** Understand the key challenges and risks associated with using iPSCs in therapeutic applications, such as genomic instability, differentiation efficiency, and the need for specialized culture conditions.
- **Regulatory Considerations:** Learn about the regulatory landscape for iPSC-derived therapies, including the challenges of clinical translation, safety concerns, and the evolving standards for cell-based products.
- **iPSC Differentiation for Therapy Development**: Explore how iPSC differentiation processes are used to create therapeutic products, from generating specialized cells for disease modeling to developing functional tissues for transplant or regenerative therapies.

MODULE 4: Expert Panel Discussion and Q&A

A live-virtual session for you to ask questions to Module 1-3 speakers in real-time.

Panelists: *Shin Kawamata, MD, PhD, Cyto-Facto, Japan*
Bruno Marques, PhD, Century Therapeutics, United States
Lise Munsie, PhD, BlueRock Therapeutics, Canada