TRAINING THE NEXT GENERATION OF CGT PROFESSIONALS

The Global Leader in CGT Workforce Development
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ISCT Vision and Mission

The Global Leader Focused on Advancing Cell and Gene Therapy since 1992.

ISCT has over 3,600 Cell and Gene Therapy (CGT) experts from over 60 countries who work in leading regulatory agencies, academic institutions, and industries to create the perfect collaborative environment for advancing clinical translation. ISCT drives the advancement of research into a standard of care.

Our Vision
To improve lives through safe and effective cell and gene therapies.

Our Mission
To drive clinical translation of cell and gene therapies worldwide.

Our Values
- Promote innovation in translational research.
- Strive for excellence in everything we do.
- Respect and support diversity and inclusivity.
- Uphold the highest ethical standards.
- Serve our members and advocate for our society.
Setting Standards in Cell and Gene Therapy

ISCT plays a critical role in the development and guidance of the CGT sector through training, collaboration, and standards setting. ISCT has co-founded FACT and JACIE to ensure that best practices are carried out consistently and reproducibly across the industry.

ISCT Co-Founded FACT and JACIE Accreditation Bodies

The Foundation for Accreditation of Cellular Therapy (FACT) was established in 1996 to set standards for high-quality medical and laboratory practice in cellular therapies. The Joint Accreditation Committee-ISCT & EBMT (JACIE) was established in 1988 to oversee the laboratory assessment and accreditation in the hematopoietic stem cell (HSC) transplantation field.
ISCT Institute of Training and Development

The Global Leader in CGT Workforce Development

ISCT Institute of Training and Development is the Global Leader in CGT Workforce Development. Our programs are developed based on ISCT’s translation-focused framework to address the training needs in critical topics across scientific research, pre-clinical, biomanufacturing, regulatory, safety, and patient access.

With over 3,600 global CGT KOLs and SMEs, a deep leadership bench in early translation and strategic partnerships with global regulatory, scientific, and industries, ISCT delivers comprehensive, accredited training programs for professionals to learn, collaborate and lead the CGT field!

ISCT collaborates closely with the following organizations:
Global Accreditation and Instructional Design

ISCT Institute of Training and Development is the Global Leader in CGT Workforce Development. ISCT acknowledges students have diverse learning experiences and styles. Our multi-modal teaching and assessment approach effectively transfers knowledge and evaluates learner success. Our programs are developed using A.D.D.I.E. instructional design strategy and delivered using globally accepted training best practices.

Our course content is curated and developed by international subject matter experts and key opinion leaders working across academia, industry and regulatory. Our courses are certified by ANSI/ANAB, one of the leading international accreditation bodies.

The Institute of Training and Development Program Advisory Board implements a 360° approach to review feedback from learners, trainers and the CGT community to ensure content and assessments are continuously updated in line with recent developments in the rapidly growing cell and gene therapy field.
Current Constraints in the CGT Sector

Scott Gottlieb, FDA Commissioner, estimated that the FDA will approve up to 20 CGT products annually by 2025.¹ The US Department of Education indicated that biomanufacturing’s current education and workforce systems are lagging behind.² Without significant investments towards workforce development and training, the US could result in 2.4 million unfilled jobs in the manufacturing sector by 2028.³

We are Ready for the Challenge:

ISCT is investing in robust education, training, and mentoring programs to standardize knowledge and techniques used in clinical translation across the globe. Our programs are developed with you in mind, addressing current gaps and future training requirements for developing CGT leaders.

Why Choose Our Programs?

- Comprehensive: Focused on critical topics across all translation stages.
- Global: Represents more than 3,600 CGT experts from over 60 countries.
- Relevant: Curriculum developed by SMEs within the CGT field.
- Easy of Access: On-demand, live-virtual and in-person training format.

Queenie Jang, BSc (Pharmacy), MBA
CEO, ISCT

“As part of ISCT’s continued commitment to alleviate the current skills gap within the advanced therapies sector, we have created the ISCT Institute of Training and Development, specially designed for professionals working in the CGT space. Through a number of strategic partnerships, we are delighted to be able to offer internationally recognized training for all learners.”

Bruce Levine, PhD
Barbara and Edward Netter Professor in Cancer Gene Therapy at the University of Pennsylvania
Chair, ISCT Strategic Advisory Council and Immediate Past President

“My passion for ISCT stems from the fact that in my career, no other society has played as integral a role in my professional development.”

² US, Department of Education: Advanced Manufacturing: Jobs of the Future, July 28, 2021
Clinical CGT Training Programs
Clinical Cell Therapy Leadership Micro Course

Designed for:
Fellow-in-Training or Junior Faculty members working in BMT and CGT fields.

Course Overview:
Experience a condensed and targeted learning opportunity with our Clinical Cell Therapy Leadership Training Micro Course, a specialized program aiming to distill the latest knowledge offered by international CGT Subject Matter Experts and Key Opinion Leaders.

Format:
• 10 hours of on-demand learning at your own pace

Learning Outcome:
• Gain a comprehensive understanding of key concepts and practices in clinical cell therapy leadership, distilled from expert-led lectures and discussions.
• Enhance skills in critical areas specific to roles within the cell and gene therapy field, fostering immediate application of knowledge.
• Develop strategies to apply insights and innovations in clinical cell therapy leadership to drive advancements in professional practice and industry impact.

Key Topics:
• Clinical trial design & conduct
• Pre-clinical development
• Study design, conduct and analysis
• IND development
• Manufacturing best practices
• Release testing procedures
• Quality systems & regulatory
• Correlatives studies
• Team science & research ethics
• Routes to commercialization

Upon course completion, you will receive:
• Certificates of course completion from ISCT.
• ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of 10 CMLE credits.
Clinical Cell Therapy Leadership Training Program

Designed for:
*Fellow-in-Training or Junior Faculty member working in the BMT or CGT field.*

Course Overview:
Developed by Global CGT KOLs and SMEs working in the CGT fields, the Clinical Cell Therapy Leadership Training Program is designed to develop future CGT leaders. The combination of training, mentoring and networking provided in this course is a one-of-a-kind opportunity for CGT professionals to further their advancement and influence in their fields.

Format:
- Five-day in-person at one of the CGT Training Centers of Excellence.

Key Topics:
- Clinical trial design & conduct.
- Pre-clinical development.
- IND development.
- Manufacturing best practices.
- Release testing procedures.
- Quality systems & regulatory.
- Correlatives studies.
- Team science & research ethics.

Previously hosted at the following CGT Centers of Excellence:
Cell Therapies for Autoimmune Diseases: MSCs for Clinical Applications

Designed for:
Students exploring MSC characteristics and clinical applications, researchers studying MSC therapeutic uses, and professionals working in EU ATMPs and MSC applications in clinical trials.

Course Outline:
Designed for clinicians, researchers, and pharmacists looking to advance their knowledge in the clinical applications of using Mesenchymal Stem Cells for treating autoimmune diseases.

Format:
- 8 hours of on-demand learning at your own pace.

Learning Outcome:
- Have a basic understanding of MSC biology.
- Know the statistical considerations for clinical trial design when using MSC to treat auto-immune diseases.
- Understand the process behind the production, regulation, and quality of MSC cell products.
- Have an understanding of the clinical applications of MSCs for auto-immune diseases.
- Understand the key principles for developing clinical trials.

Key Topics:
Designed for healthcare professionals seeking comprehensive knowledge on the therapeutic applications of Mesenchymal Stem Cells (MSCs) in various autoimmune diseases.

- MSC biology, regulatory requirements, and statistical approaches for clinical applications.
- ATMP framework in Europe.
- Applications and mechanisms of MSCs for CGT auto-immune diseases

Upon course completion, you will receive:
- A certificate of course completion from ISCT
- ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider.
  This course consists of 8 CMLE credits
Master’s Degree in European Manufacturing of ATMPs

Designed for:
Professionals in Europe working in GMP facilities producing Advanced Therapy Medicinal Products (ATMPs) for human use.

Course Overview:
The Master’s Degree in European Manufacturing of ATMPs is ideal for Europeans who are either working or planning to work in GMP facilities producing ATMPs for human use. Developed by Andalusian Network for the design and translation of Advanced Therapies (And&tAT) and the University of Granada, the Specialization Degree and the Master’s Degree in Manufacturing of ATMPs curricula comprised of twelve on-demand modules, case studies, online debate and discussions with peers and instructors.

In addition, the Master’s Degree in European Manufacturing of ATMPs includes a 3-week practical training at a GMP training facility at Linea IAVANTE’s (Fundación Progreso y Salud) in Granada, Spain.

Format:
Specialized degree:
• Approximately 1.5 years consisting of 12 on-demand modules and live-virtual discussions.

Master’s degree:
• Approximately 2 years consisting of 12 on-demand modules, live-virtual discussions and a 3 weeks in-person training at a GMP laboratory.

Scholarships are made possible in part by an educational grant from:

Hear from Past Participants:

Katja Sirlvo, MSc.(Pharm)
Kuopio Center for Gene and Cell Therapy, Finland

“The practical sessions in the GMP facilities allowed us to put theory into practice and bonded with SMEs and other ATMPs professionals.”

Organized by:
International Society of Cell & Gene Therapy®
Junta de Andalucía
Universidad de Granada
Harmonized Laboratory & Manufacturing Practices Training Programs
Cell Product Handling & Regulatory 101

**Designed for:**
Laboratory Professionals including, Lab Assistants, Operations Managers, Quality Control and Quality Assurance staff working in the CGT field.

**Course Outline:**
Designed to onboard professionals new to the CGT field, this course covers the fundamental knowledge important for working in Cell and Gene Therapy (CGT) labs—including cell collection, sample processing, storage, distribution, quality control and regulatory requirements.

**Format:**
- 3 hours each course of on-demand learning at your own pace.

**Learning Outcome:**
- Apply best practices for sample collection, processing and storage.
- Understand the QA and Regulatory requirements for CGT products.

**Key Topics:**
- Collections.
- Processing and QC.
- Quality assurance/regulatory.
- Product storage, distribution & logistics.

**Upon course completion, you will receive:**
- Certificates of course completion from ISCT.
- ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of three CMLE credits.
Essentials of Cell Therapy Product Manufacturing, Qualification and Validation

Course Outline:
Designed for experienced CGT staff and lab managers, this course provides a concise overview for professionals looking to learn the essentials of cell product development, qualification, validation, stability, and regulatory submissions.

Format:
• 3 hours each course of on-demand learning at your own pace.

Learning Outcome:
• Understand the workflow for developing a CAR-T program.
• Know the critical path and steps to translate process development into GMP production.

Key Topics:
• Developing a CAR-T program.
• Developing a validated assay that will please the FDA.
• Role of manufacturing in regulatory submissions.
• Cryopreservation and stability.

Upon course completion, you will receive:
• Certificates of course completion from ISCT.
• ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of three CMLE credits.
The Principles and Applications of Cell Therapy Biomanufacturing, Characterization, and Regulatory

Designed for:
Graduate students and professionals looking to learn the fundamentals of CGT manufacturing.

Course Outline:
Learn fundamentals and best practices on CGT biomanufacturing, product characterizations, and regulatory-quality framework through on-demand modules and live-virtual discussions.

Format:
• 16 hours total over 9 weeks, including:
  • 12 hours of on-demand learning at your own pace.
  • 4 hours of live-virtual discussions with Global CGT experts.

Learning Outcome:
• Understand the therapeutic cell manufacturing approach and applications.
• Develop knowledge in cell-based therapies and biomanufacturing.
• Understand the current landscape and gaps in the CGT industry.
• Learn from CGT experts in academic, clinical, regulatory and industry sectors.

Key Topics:
• Stem cell and immune cell engineering and therapies.
• Quality assurance and regulatory framework.
• Cell bioprocessing and manufacturing.
• Cell product characterization and importance of standards.

Upon course completion, you will receive:
• An electronic copy of the course materials.
• Certificates of course completion from ISCT-CMaT.

97% LEARNERS AGREED CONTENT WAS RELEVANT
90% OF LEARNERS RECOMMEND
250+ GLOBAL LEARNERS IN THE LAST 18 MONTHS

This course has been accepted by the ANSI National Accreditation Board’s Certificate Accreditation Program (CAP). ISCT is an ANAB-approved provider. This course consists of 16 CE credit hours.
Hands-on Laboratory Bootcamp for Cell Therapy Biomanufacturing

**Designed for:**
*Those seeking hands-on training experience working in GLP/GMP laboratory*

**Course Outline:**
This five-day experiential, hands-on training course teaches your techniques central to cell and gene therapy manufacturing. Learn to work under GLP/GMP-like laboratory operations and safety best practices. Gain practical skills and confidence with aseptic techniques, small- to large-scale cell manufacturing, product characterization, and documentation.

**Format:**
- Five-day in-person at Georgia Tech, Atlanta, USA.

**Learning Outcome:**
- Understand the conditions to culture and maintain high-quality therapeutic cells.
- Perform key steps to initiate, maintain, and expand cells in culture.
- Understand key steps in the downstream processing of human cells, including harvesting and cryopreservation.
- Evaluate the quality and sterility of cell products.
- Apply GLP/GMP-like guidelines to document cell products.

**Key Topics:**
- Recognize key components of the updated Hazard Communication Standard (HCS) under the Globally Harmonized System (GHS).
- Best practices for small- and large-scale cell manufacturing.
- Fundamentals of working in GLP/GMP-like labs.
- Setting up cell manufacturing bioreactors.
- Analytical techniques, product evaluation and characterization.
- GLP/GMP documentations.

**Upon course completion, you will receive:**
- An electronic copy of the course materials.
- Certificates of course completion from ISCT-CMaT and CMLE.

This course has been accepted by the ANSI National Accreditation Board’s Certificate Accreditation Program (CAP). ISCT is an ANAB-approved provider. This course consists of 30 CE credits.
Methods and Analytical Processes for Cell and Gene Therapy Bioprocessing

**Designed for:**
Research Scientists, Lab Professionals including Bioprocessing Technicians, Quality Control Analysts, Manufacturing Associates and Laboratory Technicians.

**Course Outline:**
Enhance your skills in assay development and standardization of bioprocessing methods through this intensive three- and half-day lab training course, led by industry experts. Gain hands-on experience with immune and stem cells, transfections, and downstream analytical methods to enhance your skills in translational processes and regulatory compliance.

**Format:**
- Three and half day in-person at Patheon Pharma Services, San Diego, USA.

**Learning Outcome:**
- Knowledge of key considerations for developing cell therapy processes and preparing for translation to GMP manufacturing.
- Framework for how to evaluate and implement new and emerging equipment and technologies in the CGT arena.
- Insight into standardization, foundational methods, and analytical assay establishment approaches.
- Develop and deploy a framework for standardized immune- and stem-cell workflows.
- Hands-on training in critical parts of gene modification of primary and stem cells.

**Key Topics:**
Focus on translational services and biomanufacturing:
- Bioprocessing equipment evaluation and compatibility
- Gene editing and characterization
- Introduction to flow cytometry and data analysis
- Assay development with consideration of ISO-Standards and ICH-Q2(R2) Guidance

**Upon course completion, you will receive:**
- Course Booklet
- Certificates of course completion from ISCT.
- ISCT is an ASCP Continuing Medical Laboratory Education (CMLE)-approved provider. This course consists of 24 CMLE credits.

*Education Partner:*
patheon by Thermo Fisher Scientific
European Advanced Cell Therapy Manufacturing and Regulatory

**Designed for:**

*Professionals seeking to learn more about ATMP regulation, cell therapy, gene therapy, and tissue engineering.*

**Course Outline:**

This course is based on the Manufacturing of ATMPs Master’s Degree program at the University of Granada. You will learn the fundamentals of ATMPs development and regulations for cell and gene therapy and tissue engineering in Europe.

**Format:**

- Six self-paced e-learning modules.

**Learning Outcome:**

- Understand the conditions for ATMP production.
- Know the characterization and QC parameters for manufacturing CGT products.
- Know the regulatory process for ATMPs.
- Describe the Good Manufacturing Practice (GMP) as applied to ATMPs.
- Summarize the structure of an IMPD.

**Key Topics:**

- Cell and gene therapy manufacturing methods.
- Quality assurance.
- Product development pathways.
- GMP compliance.
- Investigational Medicinal Product Dossier (IMPD) writing.
- Biosafety.

**Upon course completion, you will receive:**

- Certificates of course completion from Andalusian Network.

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*This course has been accepted by the ANSI National Accreditation Board's Certificate Accreditation Program (CAP). ISCT is an ANAB-approved provider. This course consists of 6 CE credits.*
Standards Training Programs
The Implementation of ISO Cell Counting Standards Training Course

**Designed for:**
Laboratory and regulatory professionals in biomanufacturing, tissue engineering, and medical laboratories.

**Course Outline:**
The ISCT-SCB ISO Cell Counting Standards training is designed to teach you how to implement:

- ISO 20391 –1:2018 Biotechnology – Cell Counting – Part I: General Guidance on Cell Counting Methods and

Guided by subject matter expertise who developed these Standards, you will have the knowledge and confidence in implementing the Cell Counting Standards to improve the quality and comparability of your cell counting process for regulatory review.

**Format:**
- 12 hours on-demand.

**Learning Outcome:**
- Learn how to implement ISO 20391 (Part 1 and 2).
- Determination of best-fit methods and equipment for your cell counting needs.
- Understand the goals and importance of an experimental design for the cell counting measurement process.
- Know how to properly report your cell counting process for use in regulatory review.

**Key Topics:**
- Understand the scope, requirements, and limitations of ISO 20391 (Part 1 and 2).
- The impact of ISO 20391 (Part 1 and 2) on meeting regulatory requirements.

**Upon course completion, you will receive:**
- SCB certificate of course completion.
- An electronic version of the course booklet.
CGT Career Development Programs
Early-Stage Professional Mentoring Program

**Designed for:**
*Professionals who’ve graduated less than 10 years of their terminal degree or with less than 10 years of working experience in the CGT field.*

**Course Outline:**
Developed by the ISCT-ESP committee, the ESP mentoring program is ideal for early-stage CGT professionals to become successful in their careers. The mentee is matched with a CGT mentor in the same discipline for personalized teaching and support.

The ESP mentoring program is eight months long, consisting of virtual meetings to discuss topics related to the CGT field, followed by an in-person session at the ISCT annual meeting.

**Format:**
- Eight months.
- Monthly live-virtual meeting.
- One in-person meeting at the ISCT annual meeting.

**Values:**
- Personalized mentoring from CGT experts.
- Connect with a global network of professionals across 5 expertise areas.
- Attend drop-in events with ISCT CGT leaders.
- Attend Town Hall meetings with the mentoring community.

**Hear from Past ESP Mentees:**

**Lucilia Mouriès, PhD**
Health & Environmental Science Institute, USA

“The mentoring program created a safe space for mentee to ask questions and for guidance. The program has allowed me to engage with other mentors and mentees around the globe - creating a long-lasting relationships!”

**Lorena Braid, PhD**
Aurora Biosolutions Inc, Canada

“The program was extremely valuable to my development as a professional in the CGT field, and gave me important confidence to pursue my path. ISCT has played an important role in my career development journey.”
Early-Stage Professional Leadership Development Program

**Designed for:**

CGT professionals with less than 10 years of working experience in the same field and are interested in serving on one of the ISCT Committees to advance the CGT field.

**Course Outline:**

The ESP Leadership Development program offers early-stage professionals a unique opportunity to serve on one of the ISCT committees to develop leadership skills, collaborate with global CGT experts on key projects and advance the field of CGT therapy.

**Format:**

- Two-year term at one of the ISCT committees.

**Values:**

- Listed as one of the Authors in one review and position paper.
- Act as a facilitator in one of our committee meetings.
- Act as a Chair for one of the Plenary sessions at an international conference.
- Develop skills in organizing various educational sessions.
- Network with Global KOLs and SMEs.
Education Materials
Education Materials

Something for everyone!
Open access and members-exclusive content provide quick access to CGT’s current affairs, expert views, educational content, and forums to keep CGT professional current and foster global collaborations.

ISCT resources
• Publications
• Webinars
• Guide documents (coming soon)
• Cytotherapy journal
• Telegraft hub - News and Community
• Laboratory Life Line discussion forum

FACT resources:
• FACT Quality Management Series
• FACT standards
• Inspector resources
• Tutorials and webinars

JACIE resources:
• Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy – The JACIE Guide
• EBMT handbook
• EBMT Nurses handbook
• Webinars and e-learning
Education Partnerships & Sponsorships
Let ISCT be Your Beacon for Training & Development

Professionals trust ISCT to support their learning. ISCT’s global recognition, achievements, translation-focused framework and over 3,600 CGT experts globally means we have accredited programs suitable for professionals at all levels. There is no time better than now to become an ISCT member.

Together, we can improve lives through safe and effective cell and gene therapies.

Participating institutions, biotech, pharm and regulatory agencies include:

- Stanford Medicine
- HSA
- Signature Biologics
- Kite, a Gilead Company
- UCSF
- NUS
- Tessa Therapeutics
- Actris
- Penn
- Agency for Science, Technology and Research, Singapore
- A vectas
- Terumo
- University Kebangsaan Malaysia
- FDA
- SeerPharma
- ThermoFisher Scientific
- Chula
- Takeda
- AstraZeneca
- Sartorius
Sponsorship Opportunity

Be Part of the Legacy in Advancing the Cell and Gene Therapy Sector

Partner with the ISCT Institute of Training and Development to support the development of CGT professionals worldwide for a sustainable cell and gene therapy field.

Benefits of Sponsorship:

- Showcase your organization as a solution provider in the CGT product development pipeline.
- Network and create lasting relationships with current and future leaders in CGT.
- Increase visibility and maximize brand awareness with a relevant and targeted audience.
- Demonstrate Corporate Social Responsibility by participating in a critical program that addresses the workforce development crisis.

Sponsorship Opportunities:

**Thought Leadership:** Showcase your organization’s expertise in the CGT sector. Partner with the ISCT Institute of Training and Development to curate a training course or feature a speaker on one of our expert panels.

**Brand Recognition:** Demonstrate Corporate Social responsibilities by supporting vital training opportunities to address skills gaps in the sector.

**Scholarship:** Increase access to essential training to develop the next generation of CGT leaders by sponsoring a scholar to attend an ISCT training course of your choice.

ISCT is proud to partner with the following organizations to deliver specialized training and development programs globally.

Create a tailored package to suit your needs contact Raymond Lam at raymond@isctglobal.org
Contact Us

Not seeing what you need?
ISCT offers customized programs to meet your specific training needs. Custom training courses are available in various formats and topics.

Please contact Raymond Lam at raymond@isctglobal.org for more information.
TRAINING THE NEXT GENERATION OF CGT PROFESSIONALS

The Global Leader in CGT Workforce Development