ISCT
INSTITUTE OF TRAINING
& DEVELOPMENT

TRAINING THE NEXT GENERATION OF CGT PROFESSIONALS

The Global Leader in CGT Workforce Development

ISCT

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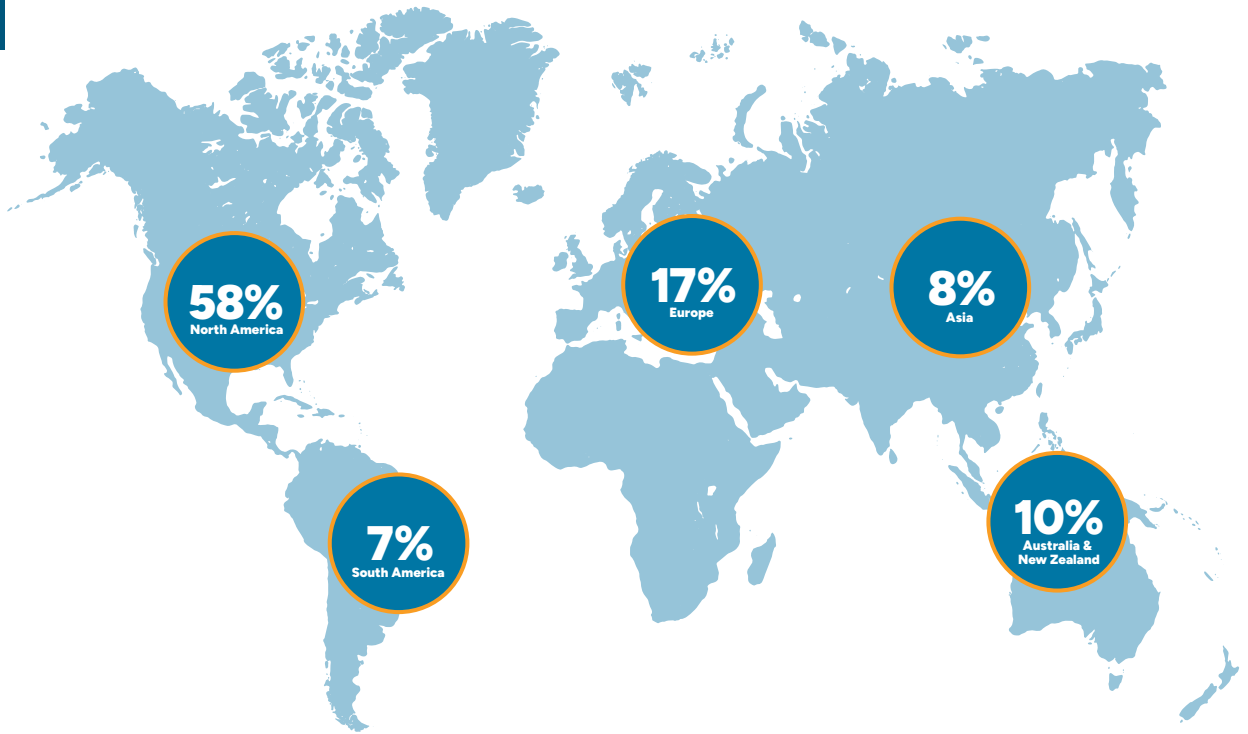
About ISCT

ISCT Vision and Mission

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

ISCT has over 3,000 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 3,000 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:

usp

European Commission

FDA

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

World Health Organization

ISO

Global Accreditation and Instructional Design

ISCT Institute of Training and Development is the Global Leader in CGT Workforce Development. Our programs are developed using A.D.D.I.E. instructional design strategy and delivered using industry training best practices.

Our programs are certified by one of the leading international accreditation bodies, the Gold Standard in the Quality of Content and Learning Experiences.

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 3,000 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."

[1] *https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics*
[2] *US, Department of Education: Advanced Manufacturing: Jobs of the Future, July 28, 2021*
[3] *Deloitte: 2018 skills gap in manufacturing study. https://www2.deloitte.com/us/en/pages/manufacturing/articles/future-ofmanufacturing-skills-gap-study.html*

Clinical CGT Training Programs

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:

Baylor College of Medicine

FRED HUTCH CURES START HERE®

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Making Cancer History®

Penn Medicine

Texas Children's Hospital®

International Society ISCT Cell & Gene Therapy®

ASTCT® American Society for Transplantation and Cellular Therapy

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.

Hear from Past Participants:

Katja Slrvlo, *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."

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

Miltenyi Biotec

Organized by:

International Society ISCT Cell & Gene Therapy®

Junta de Andalucía

UNIVERSIDAD DE GRANADA

Cell Therapies for Autoimmune Diseases: MSCs for Clinical Applications

Designed for:

Clinicians and clinicians-in-training, researchers, and pharmacists looking to increase knowledge on the use of MSCs from lab to clinical application for CGT in auto-immune diseases.

Course Outline:

This 1.5-day training course is designed to teach you the applications of MSCs for treating auto-immune diseases, including rheumatic, immune-neurological, and gastrointestinal diseases as well as the European ATMP framework.

You will also gain an understanding of the regulatory requirements for using MSCs in clinical applications, specifically on the study design, conduct, analysis and recommendations for developing clinical trials.

Format:

- 1.5 day, in-person at Hôpital Saint-Louis AP-HP, Paris, France

Learning Outcome:

- 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.
- Understand the key principles for developing clinical trials.

Key Topics:

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

Upon course completion, you will receive:

- ISCT certificate of course completion.

Host institution:

Hôpital Saint-Louis AP-HP

Course sponsored by:

FamiCord®

EBAH

This course has been accepted by the European Board for Accreditation in Hematology (EBAH). This course consists of 12 CME credits.

Harmonized Laboratory & Manufacturing Practices Training Programs

The Principles and Applications of Cell Therapy Biomanufacturing, Characterization, and Regulatory

Designed for:

Graduate students and professional 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.
- 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 bio-processing 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

150+ GLOBAL LEARNERS IN THE LAST 12 MONTHS

International Society ISCT Cell & Gene Therapy®

CMaT Cell Manufacturing Technologies

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:

Graduated students and professionals seeking hands-on training experience working in GLP/GMP-like 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.

International Society ISCT Cell & Gene Therapy®

CMaT Cell Manufacturing Technologies

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.

Lab Professional Training Series

Designed for:

Laboratory Technologists, Lab Assistants, QC, QA staff and Operations Managers working in the CGT field

Course Outline:

This on-demand training course provides technologists and laboratory professionals with fundamental training in cell product manufacturing, including collections, QC/QA, regulatory, distribution logistics, devices and insights into working with industry partners.

Tailored to the specific needs of laboratory professionals, choose between two tracks based on your expertise and interest.

1. Cell Product Handling & Regulatory 101

2. Essentials of Cell Therapy Product Manufacturing, Qualification and Validation

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

Key Topics:

- Processing and QC.
- QA and regulatory.
- Product storage, distribution and logistics.
- Cell Therapy Manufacturing - Bench to Bedside
- Process development & validation.
- Role of manufacturing in regulatory submissions.
- Manufacturing devices and operations.
- Immunotherapy: Working with industry.

Upon course completion, you will receive:

- Certificates of course completion from ISCT.

ISCT is an ASCP-approved provider. This course consists of 3 CMLE credits.

European Advanced Cell Therapy Manufacturing and Regulatory

Designed for:

Professionals looking to learn the fundamentals of Advanced Therapy Medicinal Products (ATMPs) development and regulations in Europe.

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.

International Society ISCT Cell & Gene Therapy®

andalusian network For the design & translation of advanced therapies

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 Cell Counting Standards Course

Designed for:

CDMO, cell manufacturing Lab Technologists,. QA, RA and Lab Operations Managers.

Course Outline:

This course was developed by the Subject Matter Experts (SMEs), including NIST, FDA, and device manufacturers, who created the ISO 20391 (Part 1 and 2) Standards. You will learn to implement ISO Cell Counting Standards and the use of consensus standards in the regulatory process to improve the quality and comparability of your cell counting process; thus may help shorten 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:

- Implementation of ISO Cell Counting Standards Part 1 & 2.
- 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.
- An electronic copy of ISO 20391-1:2018 and ISO 20391-2:2019 Standards.

International Society ISCT Cell & Gene Therapy®

STANDARDS COORDINATING BODY REGENERATIVE MEDICINE

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 s 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 3,000 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:

Join forces with ISCT to develop the future leaders of CGT!

With our synergistic approach with global CGT KOLs and SMEs combined with expertise in learning management systems, we can develop future leaders and create a sustainable CGT field together.

Contact **Raymond Lam** at **raymond@isctglobal.org** for training partnership opportunities.

Give back to the CGT community!

Support training the next generation of CGT leaders by sponsoring ISCT programs.

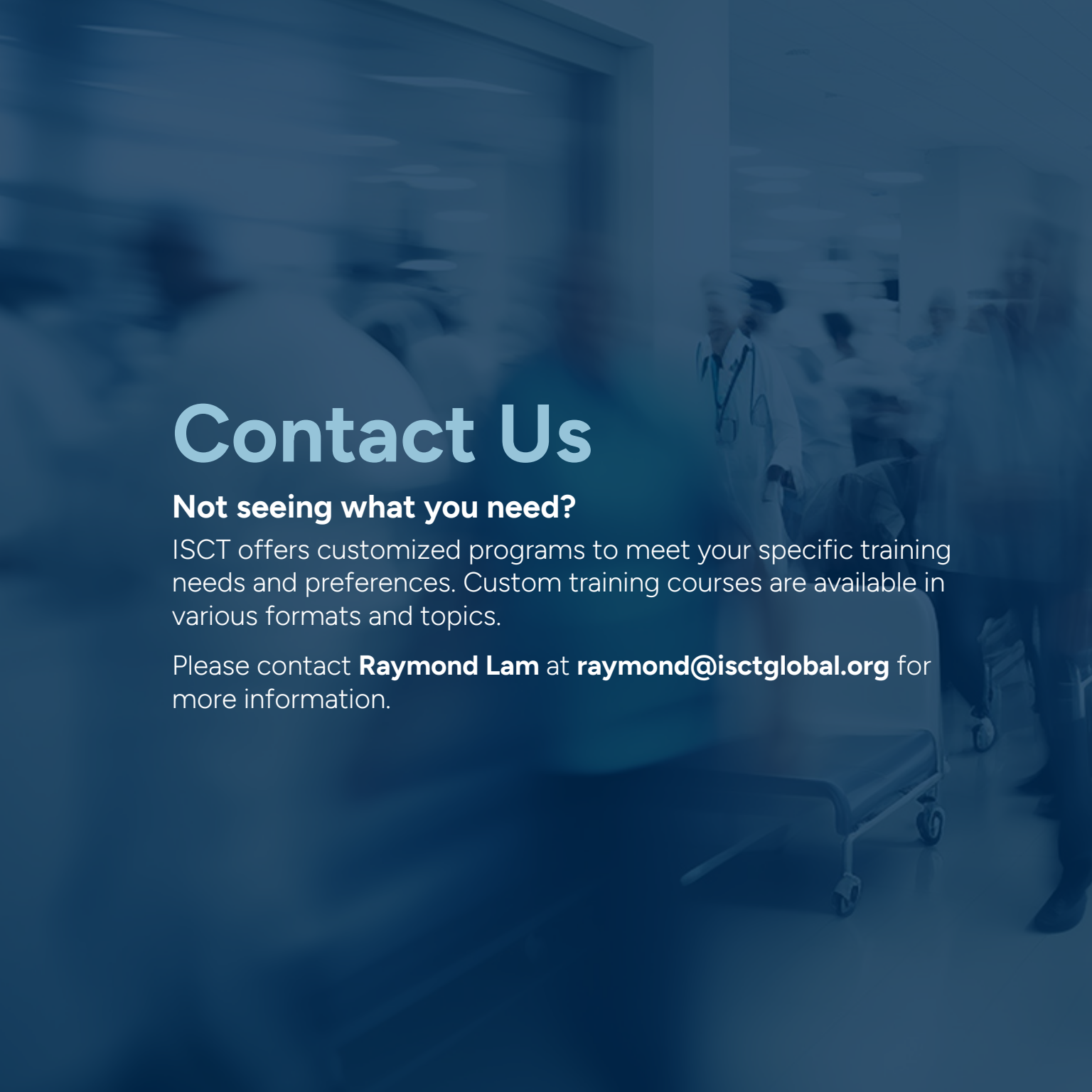
Sponsor benefits:

- 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.

Contact Simone Stickland at simone@isctglobal.org for more information about ISCT sponsorship packages.

Past sponsors include:

ASTCT American Society for Transplantation and Cellular Therapy
BD
BIOLIFE SOLUTIONS cell and gene therapy tools
bluebirdbio
CBMTG
Cell Medica
CellGenix
emily whitehead foundation
FRESENIUS KABI
International Society ISCT Cell & Gene Therapy®
JUNO THERAPEUTICS
Kite A GILEAD Company
LEGEND BIOTECH
Lonza
NOHLA THERAPEUTICS
NOVARTIS
Penn Medicine
SANFORD RESEARCH
semma THERAPEUTICS
Takeda
TERUMO
ThermoFisher SCIENTIFIC
TMUNITY



Contact Us

Not seeing what you need?

ISCT offers customized programs to meet your specific training needs and preferences. Custom training courses are available in various formats and topics.

Please contact **Raymond Lam** at **raymond@isctglobal.org** for more information.

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