INTERNATIONAL SOCIETY FOR CELL & GENE THERAPY

Established in 1992, ISCT is the global society fostering cell and gene therapy translation to the clinic. The society is comprised of over 2,400 cell therapy experts across five geographic regions and from over 60 countries. ISCT members are part of a global community of peers, thought leaders and organizations invested in cell therapy translation.

ISCT leads the field in the translational aspects of developing cell-based therapeutics, advancing scientific research into innovative treatments for patients. ISCT has built a unique collaborative environment that advances three key areas of clinical translation: Academia, Regulatory and Commercialization. This has been achieved through long-term strategic relationships with global regulatory agencies, academic institutions, and industry partners internationally.

MORE INFO: WWW.ISCTGLOBAL.ORG

ISCT has co-founded two accreditation bodies:

Foundation for the Accreditation of Cellular Therapy (FACT), in partnership with the American Society for Transplantation and Cellular Therapy

Joint Accreditation Committee – ISCT & EBMT (JACIE), in partnership with the European Society for Blood and Marrow Transplantation

MISSION:
To improve lives through safe and effective cell and gene therapies.

VISION:
To drive clinical translation of cell and gene therapies worldwide.

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

Cytotherapy, the official journal of ISCT, is a leading publication in the Cell and Gene Therapy sector, with a growing impact factor at 4.218

ISCT Membership continues to maintain a consistent upwards trajectory across the globe

OVERVIEW
LEADERSHIP
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ISCT is led by a range of global champions, delivering expertise across the translational spectrum to lead their peers in a common mission to advance the field. These leaders blaze trails, contributing towards each of the society’s pillars of value. ISCT leaders are highly influential within their areas of expertise, and have been elected or nominated by virtue of significant achievements that have helped advance the field.
Dr. Bruce Levine, Barbara and Edward Netter Professor in Cancer Gene Therapy, is the Founding Director of the Clinical Cell and Vaccine Production Facility (CVPF) in the Department of Pathology and Laboratory Medicine and the Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania.

Dr. Levine has overseen the production, testing and release of 3,100 cellular products administered to over 1,300 patients in clinical trials since 1996. He is co-inventor of the first FDA approved gene therapy (Kymriah), chimeric antigen receptor T cells for leukemia and lymphoma, licensed to Novartis. Dr. Levine is also co-inventor on 27 issued US patents and co-author of >180 manuscripts and book chapters with a Google Scholar citation h-index of 89. He is a Co-Founder of Tmunity Therapeutics, a spinout of the University of Pennsylvania.

Dr. Levine is President of the International Society for Cell & Gene Therapy and serves on the Board of Directors of the Alliance for Regenerative Medicine. He has been interviewed by the NY Times, Wall Street Journal, Washington Post, NPR, Time Magazine, National Geographic, Forbes, Bloomberg, BBC, and other international media outlets.
John Rasko, AO, MBBS, PhD, FRCPA, FRACP, FAHMS
Immediate Past President, 2020-2022

John Rasko is a clinical haematologist, pathologist and scientist with an international reputation in gene and stem cell therapy, experimental haematology and molecular biology. In over 160 publications he has contributed to the understanding of stem cells and blood cell development, gene transfer technologies, cancer causation and treatment, human genetic diseases and non-coding RNAs.

Professor Rasko is an Australian pioneer in the application of adult stem cells and genetic therapy. Since 1999 he has directed the Department of Cell and Molecular Therapies at Royal Prince Alfred Hospital and the Gene and Stem Cell Therapy Program at the Centenary Institute, University of Sydney.

Professor Rasko’s contributions to scientific organizations include co-founding (2000) and past-President (2003-5) of the Australasian Gene & Cell Therapy Society; Vice President (2008-12) and President (2018-20), International Society for Cell & Gene Therapy. He is a founding Fellow of the Australian Academy of Health and Medical Sciences. He is the recipient of national (RCPA, RACP, ASBMB) and international awards in recognition of his commitment to excellence in medical research, including appointment as an Officer of the Order of Australia.
Jacques Galipeau, MD, FRCP(C)
President-Elect, 2020-2022

Internationally recognized expert and educator in clinical applications
Clinical leader in cell therapy standards and applications for Mesenchymal Stromal Cells
Developer of fusion engineered cytokines known as fusokines

Jacques Galipeau, M.D., FRCP(C), is the Don and Marilyn Anderson Professor of Oncology within the Department of Medicine and UW Carbone Comprehensive Cancer Center at the University of Wisconsin in Madison, and is Associate Dean for Therapeutics Development at the University of Wisconsin School of Medicine & Public Health.

Dr. Galipeau has an NIH-funded research program in the study and use of mesenchymal stromal cells as an immunotherapy of illnesses including cancer and immune disease. He is an internationally recognized expert in translational development of cell therapies and the sponsor of a series of FDA-sanctioned clinical trials examining the use of autologous marrow-derived mesenchymal stromal cells for immune disorders, including Crohn's disease and graft vs host disease. He has also developed the field of fusion engineered cytokines known as fusokines, as a novel pharmaceutical means of treating immune disorders and cancer.

Dr. Galipeau is the director of the University of Wisconsin Advanced Cell Therapy Program whose mission is to develop personalized cell therapies for immune and malignant disorders and to promote and deploy first-in-human clinical trials of UW cell therapy innovations to improve outcomes for children and adults.
Ms. Jang is a senior executive with over 25 years of business leadership and management experience in the biomedical / pharmaceutical industry in both private and public companies. As CEO and Chair; Executive Management Committee of ISCT, International Society for Cell & Gene Therapy, Ms. Jang leads a global organization of innovators and KOLs in academia, regulatory and industry which serves to catalyze harmonized clinical translation of cell and gene therapies to the clinic worldwide.

Through her extensive business leadership and management experience in the biomedical/pharmaceutical industry in both private and public companies, Ms. Jang has led the emergence of ISCT as the leading global cell therapy society focused in regulatory, commercial and academic thought leadership.

Prior to her CEO role with ISCT, Ms. Jang was Officer and VP of Corporate and Business Development at Conjuchem Biotechnologies Inc. through the Conjuchem IPO, and executed multiple licensing agreements leveraging the company’s proprietary peptide technology platform. In the pharmaceutical industry, her leadership roles included; VP Strategy and Marketing with Sanofi in North America, senior Marketing and Business Development management roles with DuPont and GSK.
Daniel J. Weiss, MD, PhD
Chief Scientific Officer

Internationally recognized leader in ex vivo lung regeneration & cell-based therapies for lung diseases
Clinical practitioner with history of benchmark publications
Founder of the UVM Stem Cells and Cell Therapies in Lung Biology Conference

Daniel J. Weiss, MD, PhD, is Professor of Medicine and Professor of Cell and Molecular Biology at the University of Vermont. Dr. Weiss is recognized internationally as a leader in the area of ‘ex vivo’ lung regeneration and in cell-based therapies for lung diseases, with a longstanding interest in lung repair and regeneration after injury, notably gene and cell therapy approaches for lung diseases.

Recent published work in cell therapy approaches for lung diseases has included several benchmark publications that have included the first ever trial of cell therapy for emphysema. Dr. Weiss also instituted a biennial meeting held at the University of Vermont, Stem Cells and Cell Therapies in Lung Biology and Diseases, that is widely viewed by the NIH, FDA, and non-profit Respiratory Disease Foundations as the major meeting in the field.

As Chief Scientific Officer of ISCT, Dr. Weiss oversees the strategic positioning and movements of the scientific committees and working groups of the Society, in addition to representing the interests of the scientific committees on the Board of Directors.
Karen Nichols is VP, Regulatory CMC and Quality, at Vertex Cell and Gene Therapies. Prior to this, she was VP, Regulatory and Quality, at Magenta Therapeutics.

Prior to this, Ms. Nichols spent over 30 combined years at Magenta Therapeutics, PerkinElmer, Genzyme Corporation, Immunogen, Inc. and Wyeth Pharmaceuticals, in various leadership positions in Regulatory Affairs, Quality Operations and Corporate Compliance.

As Chief Regulatory Officer of ISCT and Chair of the North America Legal and Regulatory Affairs Committee, Ms. Nichols oversees the annual FDA Cell Therapy Liaison Meeting, the ISCT Global Regulatory Perspectives initiative, and regulatory advocacy on behalf of the Society.

She completed her undergraduate studies at the State University of New York in Biology, followed by a JD from Suffolk University. She is registered with the Massachusetts bar and the US Patent and Trademark Office as a patent attorney.
Dr. Ting joined Athersys in 2001 as a Senior Scientist and has risen through the ranks over his nineteen-year tenure at the Company, where he currently serves as Vice President of Regenerative Medicine and Head of Cardiopulmonary Programs.

With more than thirty years of experience in cell and stem cell biology, Dr. Ting has developed expertise in translational clinical studies with adult stem cell therapies and has been responsible for all stages of the development of MultiStem® from the bench to the bedside. Dr. Ting manages all programs in the cardiovascular and pulmonary areas at the Company, as well as the evaluation of potential new uses for the cell therapy product. Dr. Ting serves on several regenerative medicine society committees including the International Society for Cell Therapy and the Alliance for Regenerative Medicine.

From 1995 to 2001, Dr. Ting was a Principal Investigator and Head of the Screening for Novel Inhibitors group at the Institute of Molecular and Cell Biology (IMCB) at the National University of Singapore, where he established a multi-disciplinary group that focused on the identification of therapeutic targets and the development and implementation of high-throughput screens.
The ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell & Gene Therapies is comprised of prominent experts in the cell and gene therapy field, spanning academia, industry, and regulation.

The Task Force strives to characterize unproven and unethical cell and gene interventions, and to promote safe and effective practices worldwide.

**Reference Guide – Talking About Unproven Cell-Based Interventions**

**List of Cell/Tissue/Gene products with marketing authorization**
With the goal of building consensus within the cell and gene therapy sector, ISCT has developed several programs that help to build bilateral communications between regulatory bodies and industry/community stakeholders, and continues to provide consultation and support to regulatory bodies seeking advocacy from the field around the globe.

**Regulatory Consultation and Support (Click each title to learn more)**

ISCT provides consultation and support to regulatory bodies seeking advocacy from the field around the globe, including:

- United States Food & Drug Administration (FDA)
- Health Canada
- Australian Therapeutic Goods Administration (TGA)
- European Medicines Agency (EMA)
- World Health Organization (WHO)
- International Organization for Standardization (ISO)

### FDA Cell Therapy Liaison Meeting (CTLM)

Since 2004, ISCT has been the host coordinating up to 17 global stakeholder organizations in the annual FDA Cell Therapy Liaison Meeting (CTLM). These closed meetings enable the cell and gene therapy community to inform the FDA of specific concerns, challenges and recent developments to advance the regulatory field.

### Health Canada Cell Therapy Stakeholder Group (CTSG)

The CTSG bilateral meeting, chaired by ISCT, was initiated for manufacturers in the field to interact directly with Canadian regulatory authorities. Since 2014, the Biologics and Radiopharmaceutical Drugs Directorate has met with national stakeholder organizations through CTSG meetings.

### International Organization for Standardization (ISO)

ISCT is a Category A Liaison to the International Organization for Standardization and participates actively in ongoing CGT standards development.
ISCT Annual Meetings target core issues in Cell and Gene Therapy translation, drawing professionals from across industry, academia, and regulatory spheres with the purpose of building consensus that advances the field.
“Book-ending plenary sessions on COVID-19 set the scene for a lot of the discussions this meeting around developing a robust supply chain, clinical trial protocol or manufacturing process...”

“The ISCT has long been fighting against unproven cell and gene products and services from rogue actors looking to profit from ill-informed and sometimes desperate patients.”

“To explore how outsourcing can prove beneficial for cell and gene therapy (CGT) development, Pharmaceutical Technology spoke with Miguel Forte, chief commercialization officer, ISCT, CEO of Bone Therapeutics...”
Since 2017, ISCT has worked with Image Box Communications to manage its media strategy, and to cultivate media-based relationships and outreach within the cell and gene therapy sector.

For media and press queries about ISCT, please contact:

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