

OCTOBER 23 - 27, 2017 SEATTLE, WASHINGTON, USA

CELL THERAPY TRAINING COURSE

a partnership between ASBMT & ISCT

The International Society for Cellular Therapy (ISCT) and the American Society for Blood and Marrow Transplantation (ASBMT) are proud to present the second ISCT-ASBMT Cell Therapy Training Course from Monday, October 23, 2017 to Friday, October 27, 2017 in Seattle, Washington, USA.

The expertise of the 2017 Program Faculty will be primarily in Hematopoietic Stem Cells and Immunotherapy.

Applications open December 16, 2016 and will be accepted until **March 15, 2017**.

Tuition, travel, housing, and meal expenses will be paid by ISCT, ASBMT, and corporate sponsors for up to 12 scholars to attend the course. Participants will be competitively selected. Preference will be given to fellows and faculty with no more than two years of BMT and Cellular Therapy experience following training or a faculty appointment. See "Eligibility and Application" for more information.

Objectives and Curriculum

The ISCT and ASBMT Boards of Directors created the course because of concerns that there is an unfulfilled need for cell therapy training covering the process of translational research to cell manufacturing and clinical trials in cellular therapy including regulatory components.

The course has four elements:

- (1) A proposal for a cell product by the scholar presented at the beginning of the course, to be refined in small group discussion with faculty, and presented as a final version at the end of the course
- (2) Visits to GMP facilities for cell products
- (3) Didactic lectures
- (4) Informal discussions with Faculty

The course aims to cover:

- **Development of Investigational New Drug [IND]** – Applications and the chemistry, manufacturing and control documentation required to support them. This will include collation of pre-clinical data, preparation of SOPs & worksheets, development of release criteria, establishment of quality indicators, validation of procedures, training of staff, and pre-clinical Pharm/Tox studies. Emphasis on Toxicology/Tumorigenicity study design and interpretation.

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- **Translating concept into a GMP product** – Translational research design and execution. Full scale engineering runs and final process qualification, developing QA and QC programs.
- **Development of Manufacturing and Testing Procedures to Provide Clinical Products and the Accompanying Documentation for the Trial Including** – cGMP infrastructure, inventory management, environmental monitoring, cleaning & changeover, production monitoring, coordination of product testing, competency & proficiency testing, SOP creation, review & revision, performing audits, review quality indicators, developing stability testing.
- **Product Release and Follow-up** – Assembling batch/manufacturing records, collate test results, Issuing certificate of analysis, perform audits, controlled GMP storage, release for administration, product follow-up and recall.
- **Protocol Development** – Inclusion of correlative studies.
- **Infusion Cell Therapy Products** – Pre-infusion conditioning, monitoring infusion reactions, patient follow-up.
- **Clinical Trial Design** – Including research subject eligibility and recruitment, biostatistics, clinical trial conduct, regulatory approvals, monitoring adverse effects, long-term follow-up (correlative studies), research ethics.
- **Team Science** – Approaches to forming and sustaining a multi-disciplinary translational research team. Collaboration between laboratory and clinic, communication, strategies for pursuing and developing a successful career in cell therapy.
- **Viral Vector Development and Characterization**

2017 Planning Committee & Faculty

Co-Chairs

David DiGiusto, PhD

Executive Director
Stem Cell and Cellular Therapeutics
Operations
Stanford Healthcare
Stanford, CA, USA

John Barrett, MD

Chief
Stem Cell Allotransplantation Section
Hematology Branch
National Heart, Lung and Blood Institute
Bethesda, MD, USA

Planning Committee

Colleen Delaney, MD, MSc

Chief Medical Officer, Nohla Therapeutics
Associate Member, Fred Hutchinson Cancer
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Associate Professor, University of Washington
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Shelly Heimfeld, PhD

Director, SCCA Cellular Therapy Laboratory
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Helen Heslop, MD, DSc (Hon)
Professor of Medicine and Pediatrics
Interim Director, Center for Cell and Gene
Therapy, Baylor College of Medicine
Houston, TX, USA

Lizabeth Cardwell, MT(ASCP), MBA, RAC
Principal Consultant
Compliance Consulting
Seattle, WA, USA

The Course Faculty will be established investigators from both local and non-local institutions. Faculty members will participate over multiple days to share expertise and mentor the Course Scholars.

Eligibility and Application

This program is open to all geographic regions. Geographical scholar representation will be six from North America (USA/Canada/Mexico) and six international scholars outside of North America.

An applicant must be a Fellow-in-Training or have a Junior Faculty position and **must be an ISCT and/or ASBMT member and sponsored by an ISCT and/or ASBMT member**. To join ISCT and/or ASBMT, please visit www.celltherapysociety.org and/or www.asbmt.org.

For purposes of this program, "Junior Faculty" is defined as two years or less teaching in the BMT and Cellular Therapy field. Other applicants may be considered based on perceived need and potential benefits from the course.

Previous ISCT-ASBMT Cell Therapy Training Course Scholars are not eligible for the 2017 Course. Unsuccessful applicants from the 2015 Training Course are encouraged to apply for 2017.

To apply, please submit the following (4) items:

- (1) A 1-2 page letter of application (maximum 1,000 words, Arial, font size 10). The letter should provide the applicant's background, training, interest in cellular therapy and clinical research, and career goals. Particular attention and weighting will be placed on the applicant's reasons for attending the course.
- (2) A detailed proposal for a translational research project in cell therapy to be further refined at the course. Applicants must provide the name of a mentor from their own institution with whom to work in implementation of the project after the course.
- (3) A current curriculum vitae (CV), preferably in the NIH Biographical Sketch format.
- (4) A 1 page letter of recommendation from the applicant's mentor. This should include a description of the resources (facilities, infrastructure and funding) available to the candidate to complete the proposed clinical investigation.

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Applicant selection will be based on criteria including, but not limited to:

- (1) Applicant training, productivity and experience as indicated in the curriculum vitae, letter of application and letter of recommendation.
- (2) Proposed project significance, feasibility, and likelihood of completion, with due consideration to the quality of mentor supervision available and the resources (facilities infrastructure and funding) available to support the project in the future.
- (3) Commitment to a career in clinical translational research as outlined in the letter of application.
- (4) All other considerations being equal, regional representation.

E-mail Applications and Attachments to *either* ISCT or ASBMT:

1. **John Wheler** at ISCT (john@celltherapysociety.org)
2. **Maureen Knight** at ASBMT (maureenknight@execadmin.com)

Subject: ISCT-ASBMT 2017 Cell Therapy Training Course Application

Successful Applications

In addition to participating in the 2017 Cell Therapy Training Course, the successful Scholars will be encouraged to write a position piece to be published in a 2018 edition of *Cytotherapy*®, the Official Journal of ISCT, *Cytotherapy*.