

OCTOBER 21–25, 2019 PHILADELPHIA, PENNSYLVANIA, USA

CELL THERAPY TRAINING COURSE

a partnership between ASBMT & ISCT

The International Society for Cell and Gene Therapy (ISCT) and the American Society for Blood and Marrow Transplantation (ASBMT) are proud to present the third biennial ISCT-ASBMT Cell Therapy Training Course from Monday, October 21, 2019 to Friday, October 25, 2019 in Philadelphia, Pennsylvania, USA.

The expertise of the 2019 Program Faculty will be primarily in blood cell and gene therapy (stem cells and immunotherapy) but faculty with other relevant experience (e.g. ophthalmologic, neurologic, cardiovascular, dermatological, and other regenerative medicine applications) will be added as indicated by successful applications.

Applications open October 19, 2018 and will be accepted until January 31, 2019.

Tuition, travel, housing, and meal expenses will be paid 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) Didactic lectures
- (3) Visits to GMP facilities for cell products
- (4) Breakout sessions on select topics with real world examples
- (5) 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.
- ***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.

CELL THERAPY TRAINING COURSE

a partnership between ASBMT & ISCT

- **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**

2019 Planning Committee & Faculty

Co-Chairs

David DiGiusto, PhD
Chief Technical Officer
Semma Therapeutics
Cambridge, Massachusetts, USA

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

Planning Committee

Bruce Levine, PhD
Barbara and Edward Netter Professor
In Cancer Gene Therapy
University of Pennsylvania
Philadelphia, PA, United States

Colleen Delaney, MD, MSc
Chief Medical Officer
Nohla Therapeutics
Associate Member, Fred Hutchinson Cancer
Research Center
Seattle, WA, United States

Catherine Bollard, MBChB, MD
Professor of Pediatrics and Immunology
Children's National Health System
George Washington University
Washington, DC, United States

Gay Crooks, MBBS
Professor, Pathology and Laboratory
Medicine, Pediatrics
University of California Los Angeles
Los Angeles, CA, United States

Krishna Komanduri, MD
Professor of Medicine and Director
University of Miami Sylvester Cancer Center
Miami, FL, United States

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 the 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 and previous ASBMT Clinical Research Training Course Scholars are not eligible for the 2019 Course.

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. The candidates should have a cell therapy product that they plan to translate to the clinic. The proposal outline should be a total of 5 pages (excluding references) which includes: project title, specific aims, hypothesis, significance, innovation and brief research plan. Applicants must also 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.

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.

OCTOBER 21–25, 2019 PHILADELPHIA, PENNSYLVANIA, USA

CELL THERAPY TRAINING COURSE

a partnership between ASBMT & ISCT

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

1. **Sophie Bockhold** at ISCT (sophie@celltherapysociety.org)
2. **Anna Hawkshead** at ASBMT (ahawkshead@asbmt.org)

Subject: ISCT-ASBMT 2019 Cell Therapy Training Course Application