

OCTOBER 21–25, 2019 PHILADELPHIA, PENNSYLVANIA, USA

CELL THERAPY TRAINING COURSE

a partnership between ASBMT & ISCT

Cell Therapy Training Course Background Information

The International Society for Cell & Gene Therapy (ISCT) and the American Society for Blood and Marrow Transplantation (ASBMT) are proud to present the 3rd ISCT-ASBMT Cell Therapy Training Course (CTTC) in October 2019. The course aims to address the 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 spans a full week of intensive teaching, collaboration, and networking amongst the Scholars and Faculty. Covering the full spectrum of the cell and gene therapy field from research through development, the CTTC seeks to expose Scholars to those topics that may not have been part of their formal education. As space is limited in the CTTC, and fully funded by ISCT, ASBMT and our generous Industry sponsors, there is an intense competition for the limited number of Scholar opportunities. Twelve International Scholars, are selected for the CTTC, based on their experience and the strength of their project proposals. We believe that these Scholars represent the future of our field and that the investment in their training will provide dividends throughout their careers. As part of the CTTC, Scholars have access to ISCT and ASBMT Leadership, allowing for interactions that may not otherwise be possible in the limited scope of a Conference or Seminar speaker.

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 *(subject to change per course dependent on faculty expertise)*:

- **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

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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.
- **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**

Eligibility and Application (subject to change for 2019)

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 future courses. Unsuccessful applicants from the previous Training Courses are encouraged to re-apply for future courses.

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To apply, applicants must the following (4) items: *(subject to change/confirmation for 2019)*

- (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.

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.

It is anticipated that applications for the 2019 Cell Therapy Training Course will open in mid-October 2018. Please watch <https://www.celltherapysociety.org/page/CTTC2019> for up to date information.