



## **ISCT Process Development & Manufacturing (PDM) Commercialization Subcommittee ESP Leadership Development Program**

### PDM Subcommittee Scope:

The PDM Subcommittee aims to establish and communicate best practices in process and product development as it relates to Therapeutic cell-based products, and to assess emerging cell processing technologies and forecast their impact on the commercialization process.

#### *PDM Scope inclusions:*

Cell manufacturing for therapeutic applications

- Allogeneic and autologous approaches
- Supply chain
- Upstream
- Downstream
- Fill/finish
- Cryopreservation/bio preservation
- Product Characterization, Analytical Procedures and specification setting
- Qualification and Validation of Analytical Procedures and Manufacturing Processes
- Cost of goods considerations

All forms of therapeutic platforms where living cells are a major component of the final product including adult primary and stem cells, hES/iPS derived cells, cell-based cancer immunotherapies, (e.g. T-cells, DCs), cell-based gene therapies, and engineered tissues.

### Current and 2022 Committee Initiatives:

As a member of the ISCT PDM Subcommittee, the ESP member will be acutely involved in the Committee's initiatives. The following are the Committees current identified plans for 2021:

- **White Paper Publication** – A potential output of the recently formed PDM working group focused on CGT particulate assessment.
- **Webinars & Webinar Transcription** – The PDM Committee plans to host up to 3 webinars in 2021 with supporting summary abstracts to be used to promote the PDM's webinar archive.
- **PDM Educational Suite Oversight** – In a light of the ISCT website revamp in early 2021, the PDM Subcommittee will be responsible for compiling and monitoring resources to be housed in the ISCT Educational suite.

- **Annual Meeting Support** – The PDM Committee will be assist in the production of sessions at the ISCT 2021 Annual Meeting.

ESP Member Responsibilities and Opportunities:

The PDM Subcommittee is looking for ESPs who are driven, enthusiastic and adaptable. We ask that applicants are available for up to 3 hours monthly to assist the Committee in executing its objectives.

The ESP member of the PRM Committee will assist in the execution the Committee's identified initiatives. Support may include, but not limited to:

- **Speaker outreach** –Webinar speaker/panelist confirmation.
- **Resource outsourcing** – Spearhead the curation of the PDM resources for the ISCT Educational Suite on the ISCT webpage.
- **Writing and Editing support** – Provide writing and editing assistance for the Committees publication initiatives. This is the most important role of the PDM ESP member.
- **Current Events** – Provide relevant and fact checked current event topics for discussion on monthly teleconferences.
- **Topic-Focused Working Groups** - In 2022, The PDM Committee will introduce 3-4 specialized working groups. ESP members will have the opportunity to participate in a working group of their choosing.

Attendance to monthly Committee teleconferences is mandatory. The ESP will work closely with the Committee's Co-Chairs and ISCT Head Office liaison

The term of the PDM Subcommittee ESP seat is 2 years.