

ISCT Process and Product (PPD) Commercialization Subcommittee

ESP Leadership Development Program – Role Description

PPD Subcommittee Scope:

The <u>PPD Subcommittee</u> 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.

PPD Scope inclusions:

Cell manufacturing for therapeutic applications

- Allogeneic and autologous approaches
- Supply chain
- Upstream
- Downstream
- Fill/finish
- Cryopreservation/biopreservation
- 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 2021 Committee Initiatives:

As a member of the ISCT PPD 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 PPD working group focused on CGT particulate assessment.
- Webinars & Webinar Transcription The PPD Committee plans to host up to 3
 webinars in 2021 with supporting summary abstracts to be used to promote the PPD's
 webinar archive.
- **PPD Educational Suite Oversite** In a light of the ISCT website revamp in early 2021, the PPD Subcommittee will be responsible for compiling and monitoring resources to be housed in the ISCT Educational suite.
- Annual Meeting Support The PPD Committee will be assist in the production of sessions at the ISCT 2021 Annual Meeting.

- **Bioprocessing Summit 2021 –** The PPD Committee participate annually at the Bioprocessing Summit through hosted sessions.

ESP Member Responsibilities and Opportunities:

The PPD 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 PPD 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 PPD 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 PPD ESP member.
- Current Events Provide relevant and fact checked current event topics for discussion on monthly teleconferences.

Attendance to monthly Committee teleconferences is mandatory. The ESP will work closely with the Committee's Co-Chairs, Dominic Clarke (HemaCare) and John Fink (Pall) and ISCT Head Office liaison, Simone Stickland, and

The term of the PPD Subcommittee ESP seat is 1 year, with the option to renew.