Manufacturing and Testing of Pluripotent Stem Cell Therapies
June 5-6, 2018 – Los Angeles, CA

FULL AGENDA

Program Highlights Include

- **Lessons Learned in Stem Cell Manufacturing**
- **Navigating the International Regulatory Landscape**
- **Quality Control in Stem Cell Manufacturing**
- **Safety Testing for Pluripotent Stem Cells**
- **Global Storage and Shipment of Cell Therapeutics**

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LESSONS LEARNED in STEM CELL MANUFACTURING: Chaired by Robert Deans (BlueRock Therapeutics) and Thorsten Gorba (IQVIA)

How have leading pluripotent stem cell developers tackled their manufacturing challenges for FDA allowed clinical trials?

Learn about the challenges product developers have experienced using pluripotent stem cells in manufacturing. Developers will provide their perspectives on the major lessons learned over the last ten years including knowledge gained in the transition from one cell substrate type to another for the same indication. We will also compare how the challenge of manufacturing scale up and demonstration of product consistency has been tackled. A major emphasis will be the key differences between autologous and allogenic products, in terms of their development and standardization.

NAVIGATING the REGULATORY LANDSCAPE: Chaired by Kathryn Zoon (NIH Emeritus)

How can we position our stem cell products for the global market?

A panel of representatives from national regulatory bodies including the USFDA, are being convened to identify existing guidance for pluripotent stem cell-based products and discuss what guidance and standards, including physical reference materials, are needed in this area and the broader field of cell-based medicines. This session will provide a perspective on regulatory trends in Europe, North America and Asia.

PUTTING QUALITY in QUALITY-CONTROL: Chaired by Kathy Francissen (Genentech) and Steven Oh (USFDA)

How do I demonstrate my product meets critical quality attributes?

What is the expectation for product consistency at different levels of manufacturing, from raw materials to final product testing of cell-based products? Approaches for demonstrating product consistency and comparability will be discussed by our expert panel. Industry case studies describing critical quality attributes (CQAs) and the analytical tools required to establish the most appropriate and robust CQAs will be described. The panel will also consider the applicability of clinical data in early experiences in the assessment of biologicals.

ASSESSMENT of PRODUCT SAFETY: Chairs, Mercedes Serabian (USFDA) and Yoji Sato (Japanese National Institute for Health Sciences)

What are current safety tests for pluripotent stem cells?

This session will seek to give an understanding of the regulatory perspective on tumorigenicity testing, compare experiences from industry in establishing suitable preclinical testing, and review output from regulatory science programs to develop appropriate assays for biodistribution and tumorigenicity.

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