PEI-GSCN WORKSHOP

Regulatory issues relating to the development and clinical application of pluripotent stem cells

November 10th, 2016
10:00 – 17:00

Hörsaal, Paul-Ehrlich-Institut, Langen

Pre-registration required
(the number of participants is limited)

Contact: GSCN Central Office, e-mail: gscn.office@mdc-berlin.de

This workshop provides an overview of regulatory aspects related to the development and translation of pluripotent stem cells, including iPS cells and human embryonic stem-cell derived progenitors towards clinical trials. It is the aim of the workshop to support the researchers organized in the German Stem Cell Network (GSCN) in the translation of these innovative products towards the first clinical trials, and also to provide a forum for exchange of information between researchers and clinicians of the network, PEI and the competent authorities of the Länder.

Preliminary Agenda

10:00 - 10:15	**Welcome and opening remarks** Zoltan Ivics (PEI), Daniel Besser (GSCN), Martina Schüßler-Lenz (PEI)
	Session 1: Introduction to the topic
10.15	Daniel Besser (GSCN) Background and current status of the GSCN Stem cell research in Germany – Where do we stand and what do we want to achieve?

10.30	Hartmut Krafft (PEI) What is needed for a Clinical Trial Authorization?
10.45	Egbert Flory (PEI) Overview regulatory framework and clinical trials with ES/iPS cells as advanced therapies medicinal products (ATMPs) in the EU
11.00	Peter Löser (RKI) Use of hESCs in clinical applications - legal issues in the frame of the Stem Cell Act
11.10	Burning Questions
11.20	**Coffee**
	Session 2: Quality aspects
11.45	Matthias Renner (PEI) Regulatory aspects of manufacturing and quality control of genetically-modified stem cell-based products (including considerations for CRISPR/Cas)
12.15	Andreas Kurtz (GSCN) Challenges in quality control of stem cell based products –experiences, GAITE (global alliance for iPS therapy) initiative, haplo-bank
12.30	Jürgen Scherer (PEI) GMP for ATMPs
12.45	Burning Questions 10 min
12:55	**Lunch**
	Session 3: Non-Clinical aspects
13.40	Egbert Flory (PEI) Regulatory aspects of non-clinical development
13.55	Gerald G. Schumann (PEI) Genome stability/instability in human iPS cells

14.10	Arne Hansen (Hamburg) 3D engineered heart tissue model and its potential in drug development and regenerative medicine
14.25	Burning Questions 10 min
	Session 4: Clinical aspects
14.35	Martina Schüßler-Lenz (PEI) Regulatory aspects of clinical trials with pluripotent stem cells
14.50	Ulrich Martin (Hannover) Clinical Translation of iPSC-based therapeutic concepts: challenges, hurdles and risks
15.05	Christelle Monville (INSERM) Pluripotent stem cells for eye diseases
15.35	**Panel discussion**
16:55 - 17:00	**Closing remarks and Outlook**