

PEI-GSCN WORKSHOP

Regulatory issues relating to the development and clinical application of MSCs

November 6th, 2017

09:30 – 16:40

Max Delbrück Center, Communications Center (house C83), Axon 2, Berlin
[Travel Directions](https://www.mdc-berlin.de/directions): <https://www.mdc-berlin.de/directions>

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 mesenchymal stem/stroma cells 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 as well as to provide a forum for exchange of information between researchers and clinicians of the GSCN, PEI and the competent authorities of the federal states (Bundesländer).

Agenda

09:30 - 09:45	Welcome and opening remarks <i>Zoltán Ivics</i> , Paul Ehrlich Institute (PEI, Langen) and <i>Daniel Besser</i> , German Stem Cell Network (GSCN, Berlin)
	Session 1: Introduction to the topic Chairs: <i>Zoltán Ivics</i> and <i>Daniel Besser</i>
09:45	<i>Hans-Dieter Volk</i> , Berlin-Brandenburg Center for Regenerative Therapies (BCRT) Background and current status of application of MSCs in Germany and activities at BCRT
10:15	<i>Egbert Flory</i> , PEI (Langen) Overview regulatory framework and clinical trials with MSCs as advanced therapy medicinal products (ATMPs) in the EU

10:45	Burning Questions
11:00	Coffee
	Session 2: Quality and non-clinical aspects Chairs: <i>Zoltán Ivics</i> and <i>Daniel Besser</i>
11:20	<i>Oleg Krut</i> , PEI (Langen) Microbial safety of MSC-based products
11:50	<i>Zami Aberman</i> , PluriStem Therapeutics (Haifa, Israel) How to match a MSC derived product to its target indication?
12:20	<i>Heidrun Holland</i> , Saxonian Incubator for Clinical Translation and Faculty of Medicine, University of Leipzig Genetic stability of MSC-based products
12:50	Burning Questions
13:00	Lunch
	Session 3: Clinical aspects I Chairs: <i>Egbert Flory</i> and <i>Hans-Dieter Volk</i>
14:00	<i>Dirk Strunk</i> , Paracelsus Private Medical University of Salzburg (PMU, Austria) No identical MSC: Human stromal progenitors from non-skeletal sources display limited chondrogenic potential – implications for clinical trials
14:30	<i>Wilfried Dalemans</i> , TiGenix NV (Leuven, Belgium) Key learnings from developing two cell therapy products from A to Z
15:00	Burning Questions
15:10	Coffee Break
	Session 4: Clinical aspects II Chairs: <i>Egbert Flory</i> and <i>Hans-Dieter Volk</i>
15:30	<i>Felix Hermann</i> , apceth GmbH & Co. KG, Munich Bringing cell-based therapies to the clinic: A company view
16:00	Panel discussion
16:30 - 16:40	Closing remarks and Outlook