

AGENDA

ELN-Workshop: Regulatory requirements for the clinical development of cell therapeutics and biologicals

Monday, February 1, 2010

15.00 – 18.00 h

Congress Center Rosengarten Mannheim
Franz Xaver Richter

Part 1: Stem Cell Transplantation

Chair: M. Mansmann (München), P. Dreger (Heidelberg)

Presentations:

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| 15:00 | Welcome
<i>U. Mansmann (München), P. Dreger (Heidelberg)</i> |
| 15:10 | Regulatory aspects (PEI)
<i>Dr. Thomas Hinz (Langen)</i> |
| 15:30 | Problems in the development of national and international non-commercial clinical IITs: Report on a finally successful handling.
<i>D. Niederwieser (Leipzig)</i> |
| 15:45 | Problems in the finalizing of an IMPD: Transplantation of manipulated stem cells.
<i>R. Buhmann (München)</i> |
| 16:00-16:45 | Round Table (Panel and audience)
Discussants: Bethge, Bornhäuser, Buhmann, Dreger, Gökbuget, Hinz, Mansmann, Niederwieser |

Teil 2: Cell therapeutics and biologicals und Biologicals

Chair: M. Mansmann (München), A. Ho (Heidelberg)

Presentation:

- 17:00 Regulatory aspects (PEI)
Dr. Thomas Hinz (Langen)
- 17:20 Autologous transfer of heat shock protein (HSP) 70-activated NK cells in high-risk patients with locally advanced soft tissue sarcoma
V. Milani (München)
- 17:35 Round Table (Panel and audience)
Discussants: Gökbuget, Ho, Mansmann, Milani, Hinz
- 18:15-18:30 Consequences and next steps: Contributing to a Guideline
Mansmann, Ho, Dreger, Niederwieser, Hinz