Welcome

Dear Colleagues, Dear Partners
in Research and Industry,

It is a great pleasure for us and for REGENERATE – European Network for Regenerative Medicine EEIG to invite you in the name of three European Universities Krems, Amsterdam and Leipzig to our first Industrial Workshop

„Current problems on Regulatory Approval of ATMP in Europe“

to be held, June 25, 2010 in Berlin. The increasing amount of clinical trials in Regenerative Medicine in the European Harmonization of Regulatory aspects is resulting in a Europeanwide debate involving scientists, clinicians and industry. In our one day workshop we want to focus on the necessary regulatory approval of ATMP in Europe elucidating the legislative background and translational problems for the clinical use in the discussion with different regulatory bodies in Europe.

REGENERATE partners from different memberstates and their regulatory authorities will discuss practical problems in translation of regenerative medicine approaches under the new regulations. The Network hopes that this exchange will facilitate the development in this innovative field for the benefit of European patients.

We kindly want all of you to participate in this discussion, in the constructive and open atmosphere of the centrally located Langenbeck-Virchow house in beautiful Berlin on June 25th , 2010.

Sincerely

Hans Jörg Meisel Kai Pinkernell

on behalf of the Universities Krems, Amsterdam and Leipzig

Organizer

regenerate

Co-Organizers

BioRegio STERN

GRM
DEUTSCHE GESELLSCHAFT FÜR REGENERATIVE MEDIZIN e.V.

TRM Leipzig

Supported by

Bergmannstrost
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SHARING EXPERTISE

TETEC
Tissue Engineering Technologies AG

Vrije Universiteit Amsterdam
Donau-Universität Krems
Universität Leipzig

Regenerate - European Network for Regenerative Medicine

„Current problems on Regulatory Approval of ATMP in Europe“

June, 25th 2010
Berlin

DONAU UNIVERSITÄT KREMS

VU university medical center

UNIVERSITÄT LEIPZIG

Programm

10:00 – 10:15 **Welcome Address**
HJ Meisel K. Pinkernell

10:15 – 10:30 + discussion
Route to EU market access for Advanced therapies medicinal products: legal and regulatory requirements
P. Celis

10:40 – 11:55 + discussion
Cells as medicinal products -scientific requirements of the development
P. Salmikangas

12:05 – 12:20 + discussion
Current problems on ethical and regulating issues with cell and tissue banking
F. Emmrich

12:30 – 12:45 + discussion
EU-Regulation 2007/1394/EC – benefit or obstacle for the marketing approval of Advanced Therapy Medicinal Products
C. Herbst S. Mach

13:00 – 14:00 Lunch

14:00 – 14:15 + discussion
Product innovation and development under changing regulations
K. Pinkernell

14:25 – 14:40 + discussion
Practical consequences of the 15th Novel of the German Pharmaceuticals Act ("AMG") for Novel Advanced Therapies Medicinal Products (ATMPs)
H. Joseph

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14:50 – 15:05 + discussion
Interface of Tissue Directive and ATMP Regulation – interpretation and implementation
H. Kurz

15:15 – 15:30 + discussion
The Implementation of the European Regulation on ATMPs into German law
J. Reinhardt

15:40 – 15:55 + discussion
Assessment of cell therapy studies in the Netherlands
G. Koeter P. Vossebeld

16:10 – 16:25 + discussion
Preparing a protocol of a ATMP POC study: an example from manipulated immune cells
U. Mansmann

16:35 – 16:50 + discussion
Clinical Trial Support – the Network of Coordinating Centers for Clinical Trials
I. Bruns S. Sell

17:05– 17:20
Summary and conclusion
HJ Meisel K. Pinkernell

Venue
Langenbeck-Virchow-Haus
Luisenstraße 58/59, 10117 Berlin (Mitte)
Room „Rudolf Virchow“, 2nd floor

Registration
Please register at the Administrative Office of Regenerate until **June, 15th 2010**

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Tel.: 0049- (0)345 132 7404

Speaker Panel

Dr. P. Celis
CAT – European Medicines Agency, London, (GB)

Prof. Dr. F. Emmrich
Fraunhofer Institute for Immunology and Cell Therapy, Translational Center for Regenerative Medicine Leipzig, (D)

Dr. C. Herbst & S. Mach
Lawyer Herbst/Bröcker,
Berlin, (D), Section Regulatory &IPR Regenerate

Dr. H. Joseph
Tetec AG Reutlingen, (D)

Dr. G. Koeter & P. Vossebeld
Central Committee of Research inv. Human Subjects – CCMO, Den Haag, (NL)

Dr. H. Kurz
Federal Ministry of Health, Subunit Blood, Tissue and Inspection, Deputy Head Pharmaceuticals and Medical Devices Vienna, (A)

Prof. Dr. U. Mansmann
Institute of Biostatistics and Epidemiology
University Munich, (D)

Prof. Dr. med. HJ Meisel
BG-Clinic Bergmannstrost Halle (D),
CEO Regenerate

I. Bruns & S. Sell
Coordinating Centres for Clinical Trials,
Cologne/Duesseldorf (D)

Dr. K. Pinkernell
Miltenyi Biotec GmbH Bergisch Gladbach (D), Industrial Platform Regenerate

Dr. J. Reinhardt
Paul-Ehrlich-Institute, Division of Medical Biotechnology, Langen, (D)

Ass. Prof. P. Salmikangas
Finnish Medicines Agency Helsinki, Finland
CAT-European Medicines Agency, London, (GB)