



EUROPEAN ASSOCIATION OF  
PHARMA BIOTECHNOLOGY

**EAPB**

**Special Interest Group  
Regenerative Medicine**

**October 4, 2010**



**Venue: Messe, Hannover / Room 17**

**Monday, October 4th, 2010**

- 13:30 – 13:45    **Introduction: SIG Regenerative Medicine - targets**  
Speaker: Dr. Joachim Nöller, Translational Centre for Regenerative Medicine, Leipzig, Germany
- 13:45 – 14:30    **Scientific Advice –essential for Small and Medium sized Enterprises and academia in Europe?**  
Dr. Jens Reinhardt, Paul Ehrlich Institute, Langen, Germany
- 14:30 – 15:15    **"Do´s and Don´t s during Scientific Advise"**  
Dr. Gabriele Dallmann, Pharmatching GmbH, Freiburg, Germany
- 15:15 – 15:45    **Coffee Break**
- 15:45 – 16:30    **Challenges in the Non-Clinical Development of Cell Based Therapies**  
Dr. Monika Chabicovsky, MC Toxicology Consulting, Vienna, Austria
- 16:30 – 17:00    **Questions and answers – open discussion, brainstorming about focus for next SIG meeting**



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## **Aim & Scope of the Special Interest Group**

Advanced Therapy Medicinal Products (ATMPs) are tightly regulated by the European Medicines Agency (EMA) with the intention to ensure the safety, efficacy as well as the good quality of the products. A well defined risk evaluation in order to cover the whole development process and not only quality or safety risks should be set-up. For example, tumorigenicity, genome stability, biodistribution are now among the top issues during non-clinical and clinical development and need to be addressed for stem cell-based products early. A key point is hereby an efficient communication with the regulators as early as possible to avoid detours or even worst failures. So the scientific advice became a very powerful tool to find the right way through the jungle of guidelines, reflection papers, regulations and the expectation of the regulators.

The aim of this workshop is to bring together experts on regulation and developers from academia and industry in order to share experiences and handy tips for the process of scientific advice by regulatory agencies and for the development of cell-based products in Europe.

## **Language**

English will be the language of the Special Interest Group.

## **Registration**

Members of the Special Interest Group are requested to become personal members of the European Association of Pharma Biotechnology, EAPB, in order to attend this workshop with a registration fee of 50 Euro. For non-members the registration fee will be 150 Euro for the workshop, which will be not refundable upon cancellation. The payment has to be made within 14 days after registration or the registration will be cancelled.

## **Contacts for Special Interest Group**

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## **Contact for Membership**

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