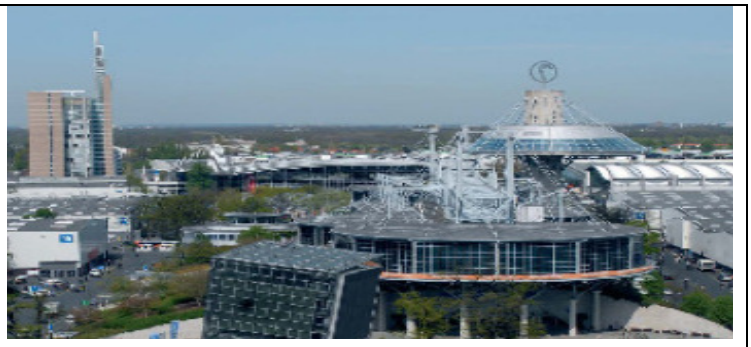
EUROPEAN ASSOCIATION OF PHARMA BIOTECHNOLOGY

EAPB **Special Interest Group Regulatory Aspects for Biopharmaceuticals** **October 4, 2010**	 **Venue: Messe, Hannover / Room 18**

Monday, October 4th, 2010

13:30 – 13:45 **Introduction: SIG Regulatory Aspects in Biopharmaceutical Development and Manufacture**

Speaker: Dr. Karoline Bechtold-Peters, Boehringer Ingelheim, Biberach, Germany

Topic 1: Practice of Quality by Design Approaches

13:45 – 14:30 **Targeted development of biosimilar pharmaceutical products**

Thomas Stangler, Sandoz Biopharmaceuticals, Kundl, Austria

14:30 – 15:15 **New Variation Regulation 1234/2008 – classification and procedures**

Maren von Fritschen, PharmaLex, Berlin, Germany

15:15 – 15:30 **Coffee Break**

Topic 2: Aggregates and Particulate matter in Biopharmaceuticals

15:30 – 16:15 **The US perspective on aggregates and subvisible/visible particles – review from recent Breckenridge conference on aggregates and immunogenicity**

Karoline Bechtold-Peters, Boehringer Ingelheim, Biberach, Germany

16:15 -17:00 **Immunogenicity of Therapeutic Proteins**

Brigitte Brake, BfArM, Bonn

17:00 – 17:30 **Discussion**

Participants are encouraged to forward short case studies and questions which will be discussed within the SIG group

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Aim & Scope of the Special Interest Group

In contrast to many other sciences, the biopharmaceuticals sciences are heavily impacted by national and international regulations so that developers and manufacturers of biopharmaceutical drug substances and drug products need profound knowledge of the current drug regulations in the field as well as of current regulatory opinions. On the other hand, drug regulations must consider what is scientifically feasible and sensible. This balance is achieved the best by frequent exchanges between industry, academia and regulatory bodies. The SIG **Regulatory Aspects for Biopharmaceuticals** wants to give this exchange room and targets at taking up current hot topics in presentations and discussion forums.

The aim of this workshop is to bring together experts on regulation and experts from academia and industry in order to share experiences and discuss different opinions on two selected current hot topics: "Quality by Design" and "Subvisible Particles".

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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