Taking immunogenicity assessment of therapeutic proteins to the next level
Thursday 10th June – Friday 11th June, 2010 – Paul-Ehrlich-Institut, Langen, Germany

CHAIRPERSON:
Christian K Schneider
Head of Division EU-Co-operation/Microbiology, PEI, Co-opted CHMP Member, BMWP and CAT Chairman, EMEA

PARTICIPANTS:
Maximum of 150 delegates from regulatory agencies, academia and industry.

CONFERENCE OBJECTIVE:
To enhance dialogue on the application of guidance on minimising risks associated with undesirable immunogenicity of therapeutic proteins, and how unwanted immunogenicity may have to be interpreted in a product-specific manner.

CONFERENCE VISION:
To take the discussion to the next level: how immunogenicity should be assessed from a regulatory point of view, what is its impact on benefit/risk and in which direction future regulatory guidance may have to go. The meeting should benefit from the presence of regulators, industry members and other experts from Europe and beyond.

Confirmed speakers include world-leading experts:
- Paul Chamberlain (NDA, bioLOGICA)
- Roy Jefferis (University of Birmingham)
- Daniel Kramer (Merck Serono)
- Harald Kropshofer (Hoffmann La-Roche)
- Anthony Mire-Sluis (Amgen)
- Tom Platts-Mills (Vanderbilt University School)
- Jack Ragheb (FDA)
- Amy Rosenberg (FDA)
- Huub Schellekens (Utrecht University)
- Christian K Schneider (PEI)
- Philippe Stas (EIP, Algonomics NV)
- Meena Subramanyam (Biogen Idec)
- Robin Thorpe (NIBSC)
- Jean-Hugues Trouvin (AFSSAPS)
- Martina Weise (BfArM)

Program addresses key topics:
- EU perspective on immunogenicity assessment
- Update on regulatory approaches – comparability exercise and biosimilars
- Identification of clinical risk – what can we learn from case studies?
- Reflections on immunogenicity assessment – pathogenesis of unwanted immune responses
- Panel discussion – next steps on immunogenicity assessment

For more details and to register visit www.ifpma.org/IABS-PEI-2010 or contact IABS at iabs@iabs.org or PEI at immunogenicity@pei.de