

ORGANISATION

Attendance Fees

450 € Non-Members

300 € Member of the AGAH, other VKliPha societies (DGPharMed or DGKliPha) or junior scientist up to the age of 30

The participation fee is per person. Please note, according to § 4, para. 22, German Turnover-Tax Law registration and workshop fees are exempt from VAT, charged and collected on behalf of AGAH e.V. All bookings are subject to change.

CONTACT

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ACCOMMODATION

We have reserved a limited room contingent in the GSI for the period of October 10 – 11, 2012. If you need an accommodation please use the enclosed accommodation form.

WORKSHOP VENUE

GSI - Gustav Stresemann Institut Bonn

Langer Grabenweg 68

53175 Bonn

Web: www.gsi-bonn.de

PROGRAMME COMMITTEE

Graham Bailey

Janssen Pharmaceutica, Beerse, Belgium

Christine Klipping

Dinox BV Female Health Research, Groningen
The Netherlands

Stephanie Plassmann

PreClinical Safety (PCS) Consultants, MuttENZ, Switzerland

Hildegard Sourgens

Consultant, Munich, Germany

Diane Stannard

Huntingdon Life Sciences, Eye, Great Britain

Chris Willoughby

Huntingdon Life Sciences, Eye, Great Britain

REGISTRATION & ORGANISATION

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May we please ask you to use the registration form.



AGAH WORKSHOP

REPRODUCTIVE TOXICITY

What can we predict
from reproductive toxicity studies
in animals to mitigate human risk?

11TH OCTOBER 2012, BONN

RATIONALE FOR THE WORKSHOP

What are reproductive toxicity findings of clinical relevance? How can those be identified? What is their likely impact on clinical drug development? How can we deal with such findings in the IMPD/IB and the informed consent? What is their likely impact on a pediatric investigational plan (PIP)?

Reproductive toxicity findings, their interpretation and impact on drug development are addressed in a recent Guidance for Industry issued in 2011 by the US FDA (*Reproductive and developmental toxicities – integrating study results to assess concerns*).

Reproductive toxicity findings from all animal studies as required by ICH S5 and juvenile toxicity studies will be addressed in the workshop, in view of the above questions and the new FDA guidance.

Therefore, this AGAH workshop, conducted by experts in the field, is the ideal opportunity for all colleagues involved in drug development (e.g. phase I/II units, translational medicine, regulatory affairs) to obtain up to date information on recent developments in this area and discuss their practical implications.

K. Breithaupt-Grögler
AGAH President

I. Klingmann
Past President

PROGRAMME

08:30 Registration

Morning session

Chair: Christine Klipping, Groningen, The Netherlands
Hildegard Sourgens, Munich, Germany

09:00 Concept of reproductive toxicology in preclinical safety
Chris Willoughby, Eye, Great Britain

09:30 Study for effects on embryo-fetal development, including case history
Graham Bailey, Beerse, Belgium

10:30 Study of Fertility and Early Embryonic Development to Implantation, including case history
Chris Willoughby, Eye, Great Britain

11:15 Break

11:30 Study for effects on pre- and postnatal development, including case history
Stephanie Plassmann, Muttenz, Switzerland

12:15 Juvenile toxicity studies, including case history
Diane Stannard, Eye, Great Britain

13:00 Break

PROGRAMME

Afternoon Session

Chair: Lutz Wiesner, BfArM, Bonn, Germany
NN, tbc

13:45 FDA Guidance for Industry Reproductive and Developmental Toxicities — Integrating Study Results to Assess Concerns – A critical appraisal
Stephanie Plassmann, Muttenz, Switzerland
Graham Bailey, Beerse, Belgium

14:30 Workshop break-out session to review data sets for the 4 study types
Graham Bailey, Beerse, Belgium
Stephanie Plassmann, Muttenz, Switzerland
Diane Stannard, Eye, Great Britain
Chris Willoughby, Eye Great Britain

15:30 Break

15:45 Workshop feedback session
Graham Bailey, Beerse, Belgium
Stephanie Plassmann, Muttenz, Switzerland
Diane Stannard, Eye, Great Britain
Chris Willoughby, Eye Great Britain

16:15 Open floor Q & A session
Graham Bailey, Beerse, Belgium
Christine Klipping, Groningen, The Netherlands
Stephanie Plassmann, Muttenz, Switzerland
Hildegard Sourgens, Munich, Germany
Diane Stannard, Eye, Great Britain
Lutz Wiesner, BfArM, Bonn, Germany
Chris Willoughby, Eye Great Britain

16:50 Close out summary
Hildegard Sourgens, Munich, Germany

17:00 End of Workshop