ORGANISATION

Attendance Fees

450 € Non-Members

300 € Member of the AGAH, DGPharMed 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. Registration fees are charged and collected on behalf of AGAH e.V. All bookings are subject to change.

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ACCOMMODATION

We have reserved a limited room contingent in the Park Hotel Bad Homburg. If you need an accommodation please use the enclosed registration form.

WORKSHOP VENUE

Park Hotel Bad Homburg
Kaiser-Friedrich-Promenade 53 - 55
61348 Bad Homburg v. d. Höhe
Web: www.parkhotel-bad-homburg.de

REGISTRATION & ORGANISATION

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May we please ask you to use the registration form:

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Erfurt, Germany

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Oberursel, Germany

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  Hexal AG, Holzkirchen, Germany

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AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

AGAH WORKSHOP

BEYOND THE GUIDELINES

Workshop in designing

and conducting pharmacokinetic

and bioavailability/bioequivalence trials

16 MAY 2013, BAD HOMBURG (GERMANY)

RATIONALE FOR THE WORKSHOP

Pharmaceutical development of more sophisticated medicinal products with known active ingredients often desires tailor-made solutions instead of conventional PK and BA/BE studies. Drugs, which can only be investigated in the patient population, locally applied, locally acting drug products as well as non-typical routes of application, are examples to be addressed in this workshop.

This workshop is intended to provide experience-based insight into concepts and approaches for projects which cannot simply be solved by taking international guidelines as "cook-book" model. The examples discussed in the presentations shall serve as prototypes for individualized solutions applicable to comparable or analogous design requirements.

Proof of validity and acceptance by authorities are the relevant obstacles to be overcome.

K. Breithaupt-Grögler
AGAH President

I. Klingmann
Past President

PROGRAMME

08:30 Registration

Morning Session

Pharmacodynamic endpoints as surrogate for clinical efficacy assessment

09:00 **How to substitute efficacy/safety studies by PD analysis in locally applied / locally acting drugs**
Successful examples and problems in selecting appropriate pharmacodynamic surrogate end-points for abridged generic or hybrid applica-tions
H. Blume, Oberursel, Germany

09:30 **Validation of pharmacodynamic methods and endpoints**
Challenges, strategies and solutions depending on the type of endpoint
B. Schug, Oberursel, Germany

10:00 **Clinical development program for demon-strating therapeutic equivalence between inhaled products**
Abridged application in the indications asthma and COPD against the background of the cur-rent European regulations
M. Klein, München, Germany

10:30 Break

Bioequivalence of non-oral modified release formulations

11:00 **BE assessment of transdermal patches**
Pharmaceutical development and in vivo study characterising relevant quality parameters
U. Becker, Langenfeld, Germany

11:30 **Patch adhesion and local tolerability of Transdermal Delivery Systems**
Requirements according to the new draft EMA guideline
J. Schriever, Bonn, Germany

12:00 **Implants and vaginally administered devices**
Which study design and PK/PD characteristics may be appropriate for assessing therapeutic equivalence?
H. Blume, Oberursel, Germany

12:30 Lunch Break

PROGRAMME

Afternoon Session

Pharmacokinetic and BA/BE studies in the patient population

13:30 **Protocol development, definition of in/ex criteria and clinical conduct of BA/BE studies in patients**
Challenges and solutions, e.g. in case of oncological, HIV or psychiatric patients
F. Donath, Erfurt, Germany
B. Schug, Oberursel, Germany

14:00 **Investigation of highly variable drugs in a patient population**
Replicate design studies and differing requirements in the E.U. and the U.S.A.
U. Thyroff-Friesinger, Holzkirchen, Germany

14:30 **Pharmacokinetic and bioanalytical issues in patient studies**
Impact of (multiple) concomitant medications and other adjuvant therapies used by patients enrolled into BE studies
C. Schulte Beckhausen, Oberursel, Germany

15:00 Break

15:30 **Biostatistical issues and equivalence testing in patient populations**
Single- and/or multi-centre studies; continuous recruitment; group and centre effects; inter- and intra-individual variabilities in the context of crossover and/or parallel group design; adequate and prospectively planned handling of missing values for PK-evaluation
Omitted

“Blue Sky” beyond the guideline

16:00 **Development of formulations with added value**
Scientific rationale and concepts for scientific characterisation of medicinal products with known active ingredients
H. Blume, Oberursel, Germany