REGISTRATION RATES

Early registration until April 30

850 € for Non-Member
550 € for AGAH Member

Registration after April 30

1000 € for Non-Member
700 € for AGAH Member

LOCATION

Empire Riverside Hotel
Bernhard-Nocht-Straße 97
20359 Hamburg, Germany

REGISTRATION

Intercom Dresden GmbH
Diana Berthold
Zellescher Weg 3
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ROOM RESERVATIONS

Room reservations are possible at conference rates at several hotels. Reservations can be made using the registration form.

ORGANIZING COMMITTEE

Betsy Hughes-Formella, PhD
bioskin GmbH, Hamburg, Germany

Ulrike Ebert, MD
Intendis GmbH, Berlin, Germany

SPEAKERS

Daniel Bucks, PhD
Director of Skin Biology & Drug Delivery,
Dow Pharmaceutical Sciences, Inc., Petaluma, CA, USA

Sandra Johannsen, DVM, PhD, ERT
Global Preclinical Development, Intendis GmbH, Berlin, Germany

Walter Wigger-Alberti, MD
Managing Director, bioskin GmbH, Hamburg, Germany

Professor Andrew Finlay
Department of Dermatology, Cardiff University; Cardiff, UK

Frank Sinner, PhD
Deputy Head of Institute of Medical Technologies and Health Management, Joanneum Research,
Graz, Austria

Klaus Rose, MD
Principle Consultant, Granzer Regulatory Consulting and Services, Munich, Germany

Elke Röhrdanz, PhD, ERT
Preclinical Assessor, BfArM, Bonn, Germany

Michelle Carpenter, JD, RAC
Regulatory and Clinical Affairs, Dow Pharmaceutical Sciences, Inc., Petaluma, CA, USA

Charles Bon, MS
President, Biostudy Solutions, LLC,
Wilmington, NC, USA

Segundo Mariz, MD
Medical Assessor, MHRA, London, England

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

2-DAY WORKSHOP

DERMATOLOGICAL PRODUCT DEVELOPMENT

An International Workshop on Strategy and Regulatory Requirements from Formulation through Clinical Development

May 27 - 28, 2010

HAMBURG, GERMANY

PROGRAM

In this workshop many of the key issues and challenges involved in the successful development of dermatologicals will be addressed. Practical guidance will be given as well as discussion of strategies and regulatory requirements. Time for questions and discussion will encourage interaction among participants and experts.

Day 1 Thursday May 27

9:00 Welcome and introduction
Betsy Hughes-Formella, bioskin GmbH, Hamburg, Germany

Formulation and In-Vitro Penetration

9:10 Science and art of dermatological formulations: Pathway to success
Speaker from Dow Pharmaceutical Sciences, Inc., Petaluma, CA, USA

9:55 Effective use of in vitro skin penetration studies in topical formulation development
Daniel Bucks, Dow Pharmaceutical Sciences, Inc., Petaluma, CA, USA

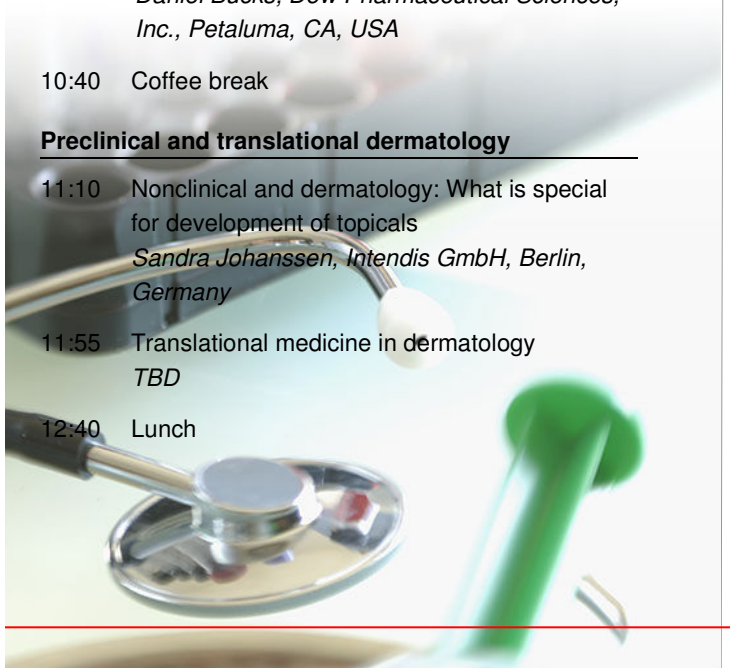
10:40 Coffee break

Preclinical and translational dermatology

11:10 Nonclinical and dermatology: What is special for development of topicals
Sandra Johanssen, Intendis GmbH, Berlin, Germany

11:55 Translational medicine in dermatology
TBD

12:40 Lunch



Phase I and QoL

14:00 Irritation and sensitization testing from a dermatologist's perspective
Walter Wigger-Alberti, bioskin GmbH, Hamburg, Germany

14:45 Quality of life assessments in dermatology
Professor Andrew Finlay, Cardiff, UK

15:30 Coffee break

Innovation and methodology

16:00 A review of imaging techniques and analysis methodologies for the clinical research pursuit
Speaker from Canfield Scientific

16:45 DermAxess®: Access to continuous in-vivo sampling in skin for realistic probes
Frank Sinner, Joanneum Research, Graz, Austria

17:30 End of presentations day 1

19:00 Dinner

Day 2 Friday May 28

Pediatric development and generics

9:00 EU & US regulatory requirements for pediatric development: Update 2010 & the specific challenges of dermatological products
Klaus Rose, Granzer Regulatory Consulting and Services, Munich, Germany

9:45 The vasoconstriction assay for BE of topical corticosteroids: A retrospective look 5 years after introduction of the US FDA guidance.
Charles Bon, Biostudy Solutions, LLC, Wilmington NC, USA

10:30 Coffee break

Preclinical requirements and FDA strategy

11:00 Preclinical requirements for clinical trials of dermatological products - a regulator's view
Elke Röhrdanz, BfArM, Bonn, Germany

11:45 Tips for successful FDA negotiations and hot topics for development of dermatological products in the US
Michelle Carpenter, Dow Pharmaceutical Sciences, Inc., Petaluma, CA, USA

12:30 Lunch

Regulatory requirements

13:45 Clinical requirements for approval of topical drugs from regulator's view
Regulatory speakers from several European agencies including Segundo Mariz from the MHRA

15:15 Coffee break

16:00 Regulatory round table with all speakers from day 2

17:15 End of the workshop