

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.

SPEAKERS

Mohamed Baccouche, PhD

IPMB GmbH, Institute for Regulatory Affairs and Pharmaceutical Sciences

Eva Benfeldt, MD, PhD

Department of Dermatology, University of Copenhagen

Gordon Dow, Pharm D

Founder and Chief Technical Officer,
Dow Pharmaceutical Sciences, Inc.

Joachim Fluhr, MD

Medical Director, bioskin GmbH

Betsy Hughes-Formella, PhD

Director Business Development and Consulting,
bioskin GmbH

Andria Langenberg, MD, FAAD, FACP

Vice President, Clinical Development, Neosil, Inc.

Segundo Mariz, BA, MD

Medical Assessor, MHRA

Linda Mutter, PhD, DABT

Regulatory Affairs, Director Non-Clinical,
Dow Pharmaceutical Sciences, Inc.

Mira Pavlovic, MD

Vice-Chair Scientific Advice Working Party EMEA,
Efficacy Working Party, EMEA,
Scientific Advice Coordinator, AFSSAPS

Torsten Reum, MD

Dept. of Scientific Service/Clinical Trials, BfArM

Susanne Theile-Ochel, MD

Dept. of Scientific Service/Clinical Trials, BfArM

Jonathan Wilkin, MD

Pharmaceutical Industry Consultant and
retired Founding Director of the FDA's
Dermatology and Dental Products Division

PROGRAM COMMITTEE

Betsy Hughes-Formella, PhD

Andrea Schmidt, PhD

Susanne Stauske, MS

bioskin GmbH, Hamburg



Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

WORKSHOP

DERMATOLOGICAL PRODUCT DEVELOPMENT

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

CONTACT

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MAY 29 + 30, 2008
NOVOTEL HAMBURG ALSTER

Luebecker Strasse 3
22087 Hamburg, Germany

PROGRAM

THURSDAY MAY 29, 2008

- 08:30 Registration
- 08:45 Welcome and Introduction
Betsy Hughes-Formella, bioskin GmbH, Germany

Morning Session:

Formulation and Preclinic

- 09:00 Formulating dermatologicals for regulatory, clinical and commercial success
Gordon Dow, Dow Pharmaceutical Sciences, Inc., USA
- 09:40 In vitro skin penetration – an essential tool for formulation of dermatological products
Gordon Dow, Dow Pharmaceutical Sciences, Inc., USA
- 10:20 Preclinical testing: Special features, guidelines and FDA requirements
Linda Mutter, Dow Pharmaceutical Sciences, Inc., USA
- 11:00 Discussion
- 11:15 Coffee Break

Phase I and II

- 11:30 Phase I testing: From tradition to rational test design
Betsy Hughes-Formella, bioskin GmbH, Germany
- 12:10 Strategies for effective phase I and phase II development
Jonathan Wilkin, retired founding director of the FDA's Dermatology and Dental Products Division, USA
- 12:50 Discussion
- 13:10 Lunch break

Afternoon Session:

- 14:40 **Impact of pediatric legislation**
Mohamed Baccouche, IPMB GmbH, Germany
- 15:20 **Endpoint measures in dermatology**
Andria Langenberg, Neosil, Inc., USA
- 16:00 Discussion
- 16:15 Coffee Break
- Cutaneous PK: Tools for the future**
- 16:30 Tape stripping and microdialysis sampling
Eva Benfeldt, Department of Dermatology, University of Copenhagen, Denmark
- 17:10 In vivo Raman Spectroscopy: New approach for cutaneous PK?
Joachim Fluhr, bioskin GmbH, Germany
- 17:50 Discussion
- 18:00 End of workshop day 1**
- 20:00 Dinner

FRIDAY MAY 30, 2008

Morning Session:

- Requirements for clinical trial applications in Germany**
- 09:00 Preclinical safety assessment of topical products in clinical trial applications
Torsten Reum, BfArM, Germany
- 09:40 Clinical assessment of topical products in clinical trial applications
Susanne Theile-Ochel, BfArM, Germany
- 10:20 Discussion
- 10:40 Coffee Break

Topical drugs: Clinical requirements (part I)

- 11:00 AFSSAPS perspective
Mira Pavlovic, Vice-Chair Scientific Advice Working Party EMEA, Efficacy Working Party, EMEA, Scientific Advice Coordinator AFSSAPS, France
- 11:40 MHRA perspective
Segundo Mariz, MHRA, UK

12:20 Lunch

Afternoon Session

Topical drugs: Clinical requirements (part II)

- 14:00 FDA perspective
Jonathan Wilkin, retired founding director of the FDA's Dermatology and Dental Products Division, USA
- 14:40 **Round-table discussion: Regulatory requirements**
- 15:10 Coffee Break
- 15:30 **Strategies for effective FDA meetings**
Jonathan Wilkin, retired founding director of the FDA's Dermatology and Dental Products Division, USA
- 16:10 Discussion
- 16:30 End of workshop**