

SPEAKERS

Prof. Marc Brown, PhD

CSO
MedPharm Ltd

Susan Ciotti, PhD

Director of Formulations
NanoBio Corp

Emma Guttman-Yassky, MD, PhD

Professor of Dermatology and Immunology
Vice Chair for Research, Department of Dermatology
Icahn School of Medicine at Mount Sinai

Hans Hofland, PhD

VP Research and Nonclinical Development
Dermira Inc.

Robert Houlden

Formulation Manager
Formulytica Pty. Ltd.

Betsy Hughes-Formella, PhD

Independent Consultant
Dermatological Product Development

Piyush Jain, PhD

Topical Formulation Scientist
Dermatology TAU, R&D
GlaxoSmithKline

Frank Kayser

Senior VP Chemistry, Integrated Programs
BioDuro

Ernst Kriehuber, MD

Director, Dermatology and Immune Mediated Diseases
Novartis Institutes for BioMedical Research

Jon Lenn, PhD

VP, US Operations
MedPharm Ltd

Shamarez Ali Mohammed, PhD

Associate Director, Research and Development
Dr. Reddy's Laboratories Inc.

Vijendra Nalamothu, PhD

CEO & Co-Founder
Tergus Pharma

Deborah G. Nguyen, PhD

Senior Director of R&D, Organovo Inc.
Organovo Inc.

Mark Prausnitz, PhD

Regents' Professor and J. Erskine Love Jr. Chair
Chemical and Biomedical Engineering Georgia Tech

Deepak K Rajpal, PhD

Director, Computational Biology
Target Sciences GlaxoSmithKline

Sam Raney, PhD

Scientific Lead for Topical & Transdermal Drug Products
Division of Therapeutic Performances
Office of Research & Standards
US. Food and Drug Administration, Office of Generic Drugs

David Rubenstein, MD, PhD

VP, Discovery & Preclinical Development
Dermatology TA, R&D
GlaxoSmithKline

Leandro Santos

Head, Topical Drug Delivery & Early DMPK
Dermatology TAU, R&D
GlaxoSmithKline

Frank Sinner, PhD

Director HEALTH - Institute of Biomedicine and
Health Sciences
Joanneum Research Forschungsgesellschaft

Susan J. Walker, MD, FAAD

Past Director, Division of Dermatology and
Dental Products, FDA
Susan J. Walker Consulting, LLC

INFORMATION

Venue	Bethesda Marriott Hotel 5151 Pooks Hill Road MA 20814 Bethesda, Maryland/USA
Date	May 11-12, 2017
Fees	Mid registration fee before May 11, 2017 1,350 \$ per person On-site registration fee 1,500 \$ per person
Accommodation	Room blocks available within the online registration

CONTACT AND FURTHER INFORMATION

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7th AGAH DERMATOLOGICAL PRODUCT

DEVELOPMENT WORKSHOP

MAY 11 - 12, 2017

Bethesda, Maryland/USA

INVITATION

An International Workshop on De-Risking Strategies from Candidate Selection to Regulatory Approval

The workshop will address key issues and challenges in the evolving landscape of topical drug development. Practical and effective approaches to de-risk topical drug development of new drugs as well as generics will be covered including candidate selection, formulation issues, approaches for determination of PK/PD and paths through to marketing authorization.

Scientific Committee

- Marc Brown, MedPharm
- Hans Hofland, Dermira
- Betsy Hughes-Formella, Independent Consultant
- Piyush Jain, GlaxoSmithKline
- Leandro Santos, GlaxoSmithKline
- Vijendra Nalamothu, Tergus Pharma
- Frank Sinner, Joanneum Research

Day 1 · THURSDAY MAY 11, 2017

08:45 Welcome and introduction on behalf of the AGAH
Betsy Hughes-Formella
Workshop Chair and Regent AGAH

CANDIDATE SELECTION

Session 1

Moderator: Leandro Santos, GlaxoSmithKline

09:00 Selection of drug development candidates for dermatology
Frank Kayser, BioDuro

09:30 Immune-mediated dermatological indications: lessons from clinical transcriptomics
Deepak K. Rajpal, GlaxoSmithKline

10:00 Bioprinted three-dimensional (3D) human tissues for toxicology and disease modeling
Deborah G. Nguyen, Organovo Inc.

10:30 Break

Session 2

Moderator: Hans Hofland, Dermira

10:45 Topical formulation development of new chemical entities
Robert Houlden, Formulytica Pty. Ltd.

11:15 Clinical and tissue biomarkers as predictors of therapeutic response
Emma Guttman-Yassky, Icahn School of Medicine at Mount Sinai

11:45 Discussion

12:00 Break

DERMAL DOSAGE FORM DEVELOPMENT AND CHARACTERIZATION: IMPACT OF VEHICLE AND EMERGING NEW TECHNOLOGIES

Session 3

Moderator: Piyush Jain, GlaxoSmithKline

13:30 Nanotechnology in topicals: screening and identification of nanoemulsion formulations as an effective topical therapy
Susan Ciotti, NanoBio Corp

14:00 Microneedle technologies to enhance drug delivery targeted to the skin
Mark Prausnitz, Georgia Tech

14:30 Strategies for de-risking dermal formulation development
Marc Brown, MedPharm Ltd.

15:00 Break

Session 4

Moderator: Marc Brown, MedPharm Ltd.

15:15 Characterization of topical dosage forms: the utility of predictive data to identify potential risks during and post clinical development
Piyush Jain, GlaxoSmithKline

15:45 Impact of vehicle on performance and safety: usage of the early development data to de-risk clinical formulations
Vijendra Nalamothu, Tergus Pharma

16:15 Discussion

16:30 End of day 1

19:00 Workshop Dinner

Day 2 · FRIDAY MAY 12, 2017

DERMAL PHARMACOKINETICS AND PHARMACODYNAMICS: KEY ROLE FOR EFFECTIVE DEVELOPMENT OF DERMALLY ACTING DRUGS

Session 5

Moderator: Marc Brown, MedPharm Ltd.

09:00 How dermal drug development would look like today if reliable dermal PK and PD methods could be used
Ernst Kriehuber, Novartis Institutes for BioMedical Research

09:35 Innovative dermal PK and PD: approaches using ex-vivo human skin
Jon Lenn, MedPharm Ltd.

10:10 Innovative dermal PK and PD: in vivo Proof-of-Mechanism to clinical dermal bioequivalence using Open Flow Microperfusion
Frank Sinner, Joanneum Research Forschungsgesellschaft

10:45 Break

Session 6

Moderator: Frank Sinner, Joanneum Research

11:00 Cutaneous pharmacokinetics and pharmacodynamics for the 21st century
Sam Raney, U.S. Food and Drug Administration

11:35 Discussion

12:00 Break

STRATEGIES FOR DE-RISKING TOPICAL PRODUCT DEVELOPMENT

Session 7

Moderator: Betsy Hughes-Formella, Independent Consultant

13:30 Opinions on the current status of the field: what big pharma does best, the obstacles, how things could be improved
David Rubenstein, GlaxoSmithKline

14:00 Case studies of success from a small pharma innovator
Hans Hofland, Dermira Inc.

14:30 Case studies of success from a generics company
Shamarez Ali Mohammed, Dr. Reddy's Laboratories

15:00 Break

Session 8

Moderator: Hans Hofland, Dermira

15:15 Strategic placement of clinical trials through proof-of-concept: comparison of key factors across regions
Betsy Hughes-Formella, Independent Consultant

15:45 Regulatory strategy: building the plan to include innovation
Susan J. Walker, Susan J Walker Consulting, LLC

16:15 Round table discussion

16:45 Closing remarks

16:50 End of day 2