



**PQRI Workshop on the
Evaluation of New and Generic Topical Drug Products - Current Challenges in
Bioequivalence, Quality, and Novel Assessment Technologies**

Co-sponsored with AAPS, FIP and USP

U.S. Pharmacopeia Meeting Center

Rockville, Maryland

March 11-13, 2013

Goals and Objectives:

1. Develop a science based regulatory approach for development and evaluation of topical drug products – product quality, performance and bioequivalence (BE) determination.
2. Review the current approaches and novel technologies for determining bioequivalence of topical drug products.
3. Identify and suggest the methodology(ies) that may be used by the regulatory agencies to assess bioequivalence as part of registration dossiers.
4. Evaluation of product uniformity and stability and impact on bioequivalence of commercial products.
5. Determine the value of *in-vitro* drug release in semisolid dosage forms development and in assessment of product quality and BE.
6. Develop a summary report of the workshop discussions and recommendations.

Planning Committee members:

[Avraham \(Avi\) Yacobi, Ph.D.](#), DOLE Pharma LLC, **Co-Chair**

[Vinod P. Shah, Ph.D.](#), Pharmaceutical Consultant, **Co-Chair**

[Derek Ganes, Ph.D.](#), Independent Consultant

[Isadore Kanfer, Ph.D.](#), Rhodes University

[Majella E. Lane, Ph.D.](#), University College London School of Pharmacy

[Robert Lionberger](#), U.S. Food and Drug Administration

[Guang Wei Lu, Ph.D.](#), Allergan

[Russell J. Rackley, Ph.D.](#), Mylan Pharmaceuticals Inc.

[Chinmay G. Shukla](#), Ph.D., U.S. Food and Drug Administration

Clarence Ueda, Pharm.D.,Ph.D., University of Nebraska Medical Center

March 11, 2013

7:30 am – 5:00 pm

Registration

8:30 am – 12:30 pm

Session I: Regulatory Approaches

8:30 am

Welcome and Introduction

Moderators

[Vinod P. Shah, Ph.D.](#)

Pharmaceutical Consultant

[Avraham Yacobi, Ph.D.](#)

DOLE Pharma LLC

8:45 am

[Regulatory Challenges and Standards for BE Evaluation of Topical Drug Products](#)

[Vinod P. Shah, Ph.D.](#)

Pharmaceutical Consultant

9:15 am

[Current Approaches and Guidelines for BE of Topical Drug Products in the U.S. and Canada](#)

[Derek A. Ganes, Ph.D.](#)

Independent Consultant

9:45 am

Clinical Studies in BE Evaluation: FDA Perspective

Susan Walker, M.D. , *Invited*

U.S. Food and Drug Administration

10:15 am – 10:30 am

Coffee Break

10:30 am

[Clinical Studies in BE Evaluation of Generic Products](#)

[Brenda Gierhart, M.D.](#)

U.S. Food and Drug Administration

11:00 am

[Challenges with Clinical Endpoints in Designing BE Studies](#)

[Howard Maibach, M.D.](#)

University of California-San Francisco

11:30 am

[Role of Pharmacometrics in Evaluation of Topical Drugs \(PBPK Dermal Modeling: Drug Transport Across the Skin\)](#)

[Gerald B. Kasting](#)

University of Cincinnati

12:00 noon

[Present Experience and Challenges with the Use of Pharmacodynamics Evaluation of BE of Glucocorticoids – Industry Perspective](#)

[Lindsey Katz](#)

Biostudy Solutions LLC

12:30 pm

Question and Answer Session

1:00 pm

Lunch Break

2:00 pm – 3:30 pm

Session 2: Dermatopharmacokinetics

Moderators

Kailas Thakker, Ph.D.

Tergus Pharma, LLC

[Majella E. Lane, Ph.D.](#)

University College London School of Pharmacy

2:00 pm

[Experience with the Use of DPK](#)

[Lynn Kennard Pershing, Ph.D.](#)

Consultant, Akesis

2:30 pm

[FDA's Experience and Concern in Evaluation of DPK Data](#)

Dennis Bashaw, Pharm.D.

U.S. Food and Drug Administration

3:00 pm

Dermatopharmacokinetics (DPK) in BE Determination of Topical Products – Potential and Limitations

[Majella E. Lane, Ph.D.](#)

University College London School of Pharmacy

3:30 pm -3:45 pm

Coffee Break

3:45 pm – 5:30 pm

Session 3: Quality of Topical Drug Products

Moderators

Kailas Thakker, Ph.D.

Tergus Pharma, LLC

[Majella E. Lane, Ph.D.](#)

University College London School of Pharmacy

3:45 pm

[Scientific Approaches to Assess Quality and Performance of Topical Products](#)

[Avi Yacobi, Ph.D.](#)

Dole Pharma LLC

4:15 pm

[Evaluation of In-vitro Release Methodologies in Product Development of Topical Products](#)

Kailas Thakker, Ph.D.

Tergus Pharma, LLC

4:45 pm

[Quality by Design \(QbD\) for Topical Dermatologic Products](#)

Andre Raw, Ph.D.

U.S. Food and Drug Administration

5:15 pm

Question and Answer Session

6:00 pm – 7:00 pm

Networking Reception

March 12, 2013

8:30 am – 1:00 pm

Session 4: New Methodologies to Evaluate Topical Products

Moderators

[Robert Lionberger, Ph.D.](#)

U.S. Food and Drug Administration

[Russell J. Rackley, Ph.D.](#)

Mylan Pharmaceuticals Inc.

8:30 am

[Regulatory Approaches for New Drugs: BA/ BE of Topical Drug Products](#)

Dennis Bashaw, Pharm.D.

U.S. Food and Drug Administration

9:00 am

[Approaches in Evaluation of BE of Topical Products: FDA's Perspective](#)

[Robert Lionberger, Ph.D.](#)

U.S. Food and Drug Administration

9:30 am

[New Approaches and Optimization of Methods for BE Assessment of Topical Drug Products](#)

[Isadore Kanfer, Ph.D.](#)

Rhodes University

10:00 am – 10:15 am

Coffee Break

10:15 am

[Potential of Microdialysis in Evaluation of Topical Drug Products – An Opportunity for Bioequivalence Determination of Topical Products](#)

[Eva M. Benfeldt, Ph.D., M.D.](#)

University of Copenhagen

11:00 am

[Development of Pilosebaceous Gland-targeted Drug Products and Potential Impact on BE Testing](#)

[Guang Wei Lu, Ph.D.](#)

Allergan

11:30 am

[Generic Industry Perspectives on BE Testing of Topical Drug Products](#)

[Russell J. Rackley, Ph.D.](#)

Mylan Pharmaceuticals Inc.

12:00 noon

Question and Answer Session

12:30 pm – 1:30 pm

Lunch Break

1:30 pm – 5:15 pm

Breakout Sessions

(Each breakout session will last 45 minutes and will be repeated 5 times)

Please Note: The afternoon break will be set up for you to help yourself throughout the afternoon any time after 3:00 pm

A. Clinical endpoint BE studies (variability, CR products)

Moderators: [Derek Ganes](#), [Brenda Gierhart](#)

B. BE Studies Using Pharmacodynamics and Pharmacokinetic Methodologies (Data processing)

Moderators: [Majella Lane](#) and [Barbara Davit](#)

C. In-vitro Release Methodologies – Applications

Moderators: [Tapash Ghosh](#) and [Kailas Thakker](#)

D. Alternative New Techniques to Assess BE Including In vitro Method

Moderators: [Robert Lionberger](#) and [Russ Rackley](#)

E. Modeling and Simulations, Pharmacometrics

Moderators: [Chinmay Shukla](#) and [Gerald Kasting](#)

March 13, 2013

8:30 am – 12:30 pm

Session 5: Regulatory Approaches

Moderators

[Barbara Davit, Ph.D.](#)

U.S. Food and Drug Administration

[Derek Ganes, Ph.D.](#)

Independent Consultant

8:30 am

Summary of Break-out Sessions

8:30 am- Breakout Session A

8:45 am- Breakout Session B

9:00 am- Breakout Session C

9:15 am- Breakout Session D

9:30 am- Breakout Session E

9:45 am

[An Investigator's Perspective on Practical Issues and Challenges in Conducting Clinical Endpoint Studies](#)

[Elizabeta Zovko, M.D.](#)

Forest Research Institute

10:15 am

[Regulatory Approaches for Generic Drugs: BE of Topical Drug Products](#)

[Barbara Davit, Ph.D.](#)

U.S. Food and Drug Administration

10:45 am

Coffee Break

11:00 am

[Practical Applications to Evaluate Topical Drug Products in Patients](#)

[Nathalie Wagner, M. Sc.](#)

Galderma R & D

11:30 am

[Challenges of Assessing Bioequivalence of Topical Pharmaceutical Products](#)

[Robert Lionberger, Ph.D.](#)

OGD Science Staff

12:00 pm

Combination Techniques That Can Assure BE of Topical Drug Products

[Avraham Yacobi, Ph.D.](#)

DOLE Pharma LLC

12:30 pm

Question and Answer Session

12:45 pm

Conclusions –

[Vinod P. Shah, Ph.D.](#)

Pharmaceutical Consultant

[Avraham Yacobi, Ph.D.](#)

DOLE Pharma LLC

March 13, 2013 in the afternoon

1:30 pm – 4:30 pm

Planning Committee/Faculty Members ONLY– Summary Report