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

March 11-13, 2013
U.S. Pharmacopeia Meeting Center
Rockville, MD 20852

Cosponsored with
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., Independent Consultant, Co-Chair
Vinod P. Shah, Ph.D., Pharmaceutical Consultant, Co-Chair
Derek Ganes, Ph.D., Independent Consultant
Isadore Kanfer, Ph.D., Rhodes University
Majella 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

PROGRAM AGENDA

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.
Independent Consultant

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 Ganes, Ph.D.
Independent Consultant

9:45 am
Clinical studies in BE evaluation: FDA Perspective
Susan Walker, M.D.
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
Linda Forsyth
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
Charles Bon
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
  Clarence Ueda, Pharm.D., Ph.D.
  University of Nebraska Medical Center
  Majella Lane, Ph.D.
  University College London School of Pharmacy

2:00 pm
Experience with the Use of DPK
Lynn Pershing, Ph.D.
Independent Consultant

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 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
  Clarence Ueda, Pharm.D., Ph.D.
  University of Nebraska Medical Center
  Majella Lane, Ph.D.
  University College London School of Pharmacy

3:45 pm
Scientific Approaches to Assess Quality and Performance of Topical Products
Clarence Ueda, Pharm.D., Ph.D.
University of Nebraska Medical Center

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
Regulatory Applications of In-vitro Release Methodologies to Establish Quality Profile
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 - 10:30 am
Coffee Break

10:30 am
Potential of Microdialysis in Evaluation of Topical Drug Products—An Opportunity for Bioequivalence Determination of Topical Products
Eva Benfeldt, M.D.
University of Denmark
11:00 am
PhARMA Perspectives on BE Testing of Topical Drug Products
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 pm
Question and Answer Session

12:30 pm – 1:30 pm
Lunch Break

1:30 pm – 5:15 pm
SESSION 5: 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 end-point BE studies (variability, CR products)
   Moderators: Derek Ganes and Linda Forsyth

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

PQRI Workshop on Evaluation of New and Generic Topical Drug Products
**PQRI MISSION STATEMENT**

The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality and development.

By virtue of its diverse membership, PQRI provides a unique forum to focus critical thinking, conduct research, exchange information, and propose methodology or guidance to pharmaceutical companies, regulators, and standard setting organizations.

**PQRI MEMBER ORGANIZATIONS**

**AAPS**
American Association of Pharmaceutical Scientists

**CHPA**
Consumer Healthcare Products Association

**FDA/CDER**
U.S. Food and Drug Administration, Center for Drug Evaluation and Research

**HC**
Health Canada

**IPEC-Americas**
International Pharmaceutical Excipients Council of the Americas

**USP**
United States Pharmacopeia

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**VENUE AND REGISTRATION**
The workshop is being held at the U.S. Pharmacopeia Meeting Center in Rockville, Maryland. Hotel accommodations can be made at either the Bethesda North Marriott or the Hilton Executive Hotel/Meeting Center both of which are in Rockville, Maryland. Both hotels will honor your request to utilize the USP Corporate rate of $194/$191 respectively for your accommodations.

Registration for the workshop can be made by going to the SignMeUp website at [www.signmeup.com/85131](http://www.signmeup.com/85131).

For additional information, please contact Vicki Penn at PennV@pqri.org or by phone at 703-248-4719.