



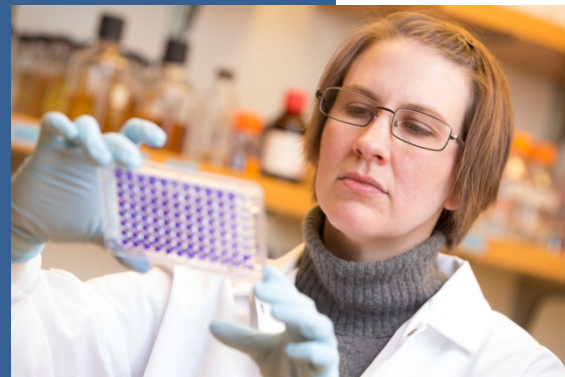
# All-Inclusive Topical Drug Bioequivalence and Bioavailability Summit

Mark your calendars for the All-Inclusive Topical Drug Bioequivalence and Bioavailability Summit, co-sponsored by the University of Maryland Center for Excellence in Regulatory Science and Innovation (M-CERSI) and the American Association of Pharmaceutical Scientists (AAPS).

The All-Inclusive Topical Drug Bioequivalence and Bioavailability Summit will be held on **Tuesday, May 21, 2013**, at the University of Maryland School of Pharmacy, located at 20 North Pine Street in Baltimore, MD.

This one-day conference is open to the public. Its goal is to address methods for evaluating topical drug bioavailability and bioequivalence, as well as follow up on the results from the Product Quality Research Institute workshop held at the US Pharmacopeia Meeting Center in Rockville, MD, on March 11-13, 2013.

For more information, please visit [www.pharmacy.umaryland.edu/topicalbioequivalence](http://www.pharmacy.umaryland.edu/topicalbioequivalence).



Registering by mail? Please detach this form and submit it with your check. All participants can also register online at [www.pharmacy.umaryland.edu/topicalbioequivalence](http://www.pharmacy.umaryland.edu/topicalbioequivalence), which accepts credit cards.



## All-Inclusive Topical Drug Bioequivalence and Bioavailability Summit Mail-In Registration

Please make check payable to **UMBF/CERSI** and mail to:

University of Maryland School of Pharmacy  
Attn: Sharese Essien  
20 Penn Street  
HSF II, Room 518  
Baltimore, MD 21201

Please provide the following information:

Name \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Email \_\_\_\_\_

Title and Company/School/Agency \_\_\_\_\_

Please indicate highest degree obtained:

- High School       Master's Degree
- Bachelor's Degree       Doctorate

Please indicate which category best describes you:

- Faculty, Staff, Student from the University of Maryland Baltimore or College Park Campus (FREE)
- M-CERSI Industrial Consortia Members (FREE)
- Federal Government Employees (FREE)
- Other Participant (\$50.00)

# CONFERENCE AGENDA

## May 21, 2013

**9:25-9:30 a.m.**

### Welcome

Audra Stinchcomb, PhD  
Professor of Pharmaceutical Sciences  
University of Maryland School of Pharmacy

**9:30-10:00 a.m.**

### “Current FDA Perspective”

Ethan Stier, RPh, PhD  
Pharmacologist  
Deputy Director, Division of Bioequivalence II  
Office of Generic Drugs  
Food and Drug Administration (FDA)

**10:00-10:30 a.m.**

### “Current Generic Pharma Perspective”

Ken Miller, PhD  
Senior Vice President, Research & Development  
IGI Laboratories (Buena, NJ)

**10:30-11:00 a.m.**

### “Dermatopharmacokinetics and Tape Stripping the Stratum Corneum: Origins and Problems”

Richard H. Guy, PhD  
Professor of Pharmaceutical Sciences  
University of Bath

**11:00-12:00 p.m.**

### Discussion

- What were the conclusions from the USP meeting?
- What actions are companies taking to proceed with ANDAs and NDAs?
- Has the FDA changed any guidances?
- Will guidances be changed in the future?

**12:00-1:00 p.m.**

Lunch is Provided

**1:00-1:30 p.m.**

### “Dermatopharmacokinetics and Tape Stripping the Stratum Corneum: State-of-the-Art and Potential”

Annette L. Bunge, PhD  
Professor Emeritus  
Colorado School of Mines

**1:30-2:00 p.m.**

### “In Vitro Permeation Studies and Bioequivalence”

Ken Walters, PhD  
Chief Executive Officer  
An-eX (Taunton, UK)

**2:00-2:30 p.m.**

### “Comprehensive Approach to Topical Bioequivalence”

Thomas J. Franz, MD  
Dermtech International (San Diego, CA)

**2:30-2:45 p.m.**

Break

**2:45-4:30 p.m.**

### Panel and Audience Discussion

- What research is needed?