

Project Title: All Inclusive Topical Drug Bioequivalence and Bioavailability Summit

Principal Investigator: Audra Stinchcomb, PhD

Project Activities during Reporting Period (March 2013 – May 2013):

The University of Maryland School of Pharmacy hosted a conference co-sponsored by the [Center of Excellence in Regulatory Science and Innovation \(CERSI\)](#) and the American Association of Pharmaceutical Scientists that spotlighted topical drug bioequivalence and bioavailability. The conference offered a collegial, open forum that allowed the world's leading researchers, regulators, and industry professionals to learn from one another and work towards developing new approaches in the fields of topical drug bioequivalence and bioavailability.

Organized by **Audra Stinchcomb, PhD**, professor in PSC at the School of Pharmacy, the All-Inclusive Topical Drug Bioequivalence and Bioavailability Summit was the first conference in this series. It was held on May 21, and addressed methods for evaluating topical drug bioavailability and bioequivalence, and provided a follow-up discussion on the results from the Product Quality Research Institute (PQRI) workshop held at the US Pharmacopeia Meeting Center in Rockville, Md., on March 11-13.

“This conference brought world-class researchers representing academia, government, and industry together to discuss the advances that have been made in the field of dermal drug delivery,” says Stinchcomb. “We reviewed the results of the latest PQRI workshop and built upon those findings by offering new perspectives and potential methods to evaluate topical drug bioequivalence and bioavailability.”

This conference featured two panel discussions. Its speakers included Ethan Stier, RPh, PhD, pharmacologist and deputy director of the Division of Bioequivalence II in the Office of Generic Drugs at the FDA; Ken Miller, PhD, senior vice president of research and development at IGI Laboratories in Buena, NJ; Richard H. Guy, PhD, professor of pharmaceutical sciences at the University of Bath, who also delivered a presentation to students in the PSC Graduate Program earlier that week; Ken Walter, PhD, chief executive officer of An-eX in Taunton, UK; and Thomas J. Franz, MD, an independent consultant and inventor of the Franz diffusion cell.