Sam Raney, PhD
U.S. Food & Drug Administration

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 30 years of experience in skin research, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, serves on multiple expert committees and panels in the U.S. Pharmacopeia. He is the Acting Associate Director for Science in the FDA's Office of Research and Standards, and serves as the Chief Scientific Advisor for topical product bioequivalence issues in FDA's Office of Generic Drugs. Dr. Raney holds a Bachelor's Degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

PANEL SESSION: FDA Regulatory Updates for Topical Drug Products

Moderator: Sam Raney, PhD

The session would consist of 3 brief (10 minute) presentations followed by a brief panel discussion. The session will encompass a description of FDA's various role in researching and regulating products applied to the skin, including cosmetics, personal care products, drugs and devices. The session will also review how FDA funded research helps the U.S. public, focusing on examples whereby patient access to generic topical products is enhanced by the development of more efficient bioequivalence approaches for topical dermatological products. Furthermore, the session will discuss the results and insights from FDA-funded research that have elucidated how the components, composition and arrangement of matter in semisolid dosage forms modulates the rate and extent to which drug is delivered into the skin. Finally, the FDA presenters will offer their perspectives, comments, and reflections about the topics and discussions throughout the 2 days of the meeting.