Brenda Sue Gierhart, M.D., Medical Officer, Division of Clinical Review (DCR), Office of Generic Drugs (OGD), CDER, FDA

During her past five years in the OGD, Dr. Gierhart has been the primary author of approximately 170 product-specific bioequivalence Draft Guidances, with the majority for topical drug products. She has been with the FDA since 1999, previously serving as Primary Reviewer or Team Leader within the Office of New Drug (OND) Divisions of Reproductive and Urologic Products (DRUP), Metabolic and Endocrine Products (DMEP) and Medical Imaging and Radiopharmaceutical Drug Products (DMIRDP). From 1998-1999, Dr. Gierhart was a Clinical Research Physician-Consultant at Eli Lilly & Company. From 1971 to 1998, she delivered direct patient care in multiple positions within the health care industry: Obstetrician-Gynecologist, RN, LPN and Nurse's Aide. She is a board certified Obstetrician-Gynecologist, received a Diploma of Pharmaceutical Medicine from the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom in 2001 and graduated from the Johns Hopkins School of Medicine in 1981.