James E. Mullally, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices, Office of In Vitro Diagnostic Devices and Radiological Health, CDRH
US Food and Drug Administration
James.Mullally@fda.hhs.gov

Dr. James Mullally has worked at FDA for 3.5 years as a scientific reviewer in the Division of Chemistry and Toxicology Devices (DCTD) in the Office of In Vitro Diagnostic Devices and Radiological Health, Center for Devices and Radiological Health. His responsibilities include review of premarket submissions and pre-submissions for the chemistry, toxicology, renal/cardiology, and diabetes device branches within DCTD. He also reviews Investigational Device Exemption (IDE) applications for clinical studies, as well as post-market compliance cases. He serves as the DCTD product specialist for both device instrumentation and device software for premarket submissions, and he has represented FDA as an expert panelist for software used in diabetes devices. Prior to joining FDA, Dr. Mullally worked at Meso Scale Discovery as a Field Application Scientist, assisting clients in the development of custom immunoassays. Dr. Mullally received his Ph.D. in Medicinal Chemistry from the University of Utah, School of Pharmacy and received his postdoctoral training at Emory University, School of Medicine and Johns Hopkins University, School of Medicine, and he is an author of several scientific publications.