Vikram Sinha, Director, Division of Pharmacometrics, USFDA

Vikram Sinha, Ph.D., is the Director, Division of Pharmacometric at the USFDA. In his current role, Vikram leads the Pharmacometrics Division. The Division plays a critical role in understanding the impact of variability in response to drugs and relates it to assessing benefit and risk. He leads a multidisciplinary team of quantitative clinical pharmacologists, statisticians, engineers, and data management experts. Within CDER, pharmacometric work is conducted with the intent to aid the decision to approve and label the drug product. There is particular attention on providing a consulting function on drug dosing for patients and advice on trial design decisions by sponsors. Previously, Vikram was at Eli Lilly, where he was scientific lead for global pharmacokinetics/pharmacodynamics and pharmacometrics. At Lilly, he was accountable for developing quantitative translational strategies, clinical plans, and regulatory strategies in the area of clinical pharmacology. He has 16 years of experience in the pharmaceutical industry. He has made notable contributions to the general scientific community through teaching, publications, and engagement with industry/government consortia dedicated to advancing innovation in the area of drug discovery and development. Vikram earned a bachelor's degree in pharmacy and a doctorate degree in pharmaceutical sciences from the University of Arizona. He completed post-doctoral training at the University of Nebraska Medical Center.