



Lawrence X. Yu, Ph. D.

Dr. Lawrence X. Yu is currently the Director for Science in the Office of Generic Drugs, FDA. He is also an adjunct Professor of Pharmaceutical Engineering at the University of Michigan and an adjunct Associate Professor of Pharmaceutical Sciences at the University of Maryland and the University of Tennessee. Prior to joining the FDA, Dr. Yu had worked in the Pharmaceutical R&D Departments of both Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, Division Director, and Office Director for Science. Dr. Yu's research interests have centered on the *in silico* prediction of oral drug delivery. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, *GastroPLUS*<sup>TM</sup> which is being widely used in the pharmaceutical industry. He has made significant contributions to the advancement of quality and bioequivalence regulatory policies, including those relating to pharmaceutical solid polymorphism, drug substance and drug product impurities, the Biopharmaceutics Classification System, food effect testing, and the concept of bioequivalence. A fellow of the American Association of Pharmaceutical Scientists, Dr. Yu has authored or co-authored over 200 papers, patent, book chapters, abstracts, and invited presentations.