Dr. Brian J. Ledwith is Head of Nonclinical Safety for Alexion Pharmaceuticals. Prior to joining Alexion in May of 2016, he was Executive Director and head of Program Development in Safety Assessment at Merck Research Laboratories (known as MSD outside of North America). In this role, he oversaw Safety Assessment support to all discovery and development teams, including nonclinical strategies, pipeline management, regulatory submissions, and due diligence of in-licensing projects. Dr. Ledwith also served as the Global Product Development Team Leader for Merck's GARDASIL 9, GARDASIL, and ROTATEQ vaccines from 2011 to 2013. He led his teams through the first BLA filing of GARDASIL 9, the first filing of a 2-Dose regimen of GARDASIL, and initiation of clinical development of a thermostable formulation of ROTATEQ. Dr. Ledwith has been an invited expert to the WHO, FDA, EMEA, and CHMP Gene Therapy Experts Group. He was a contributing author on the WHO Guideline for Nonclinical Evaluation of Vaccines. Dr. Ledwith has a B.S. in Chemistry from The College of William and Mary, Williamsburg, VA; a Ph.D. in Biochemistry from The Medical College of Virginia, Richmond, VA; and an MBA from The Wharton School, University of Pennsylvania, Philadelphia, PA.