Greenleaf Health

Robert J. Meyer, M.D.

Principal, Drug and Biological Products

BACKGROUND	• 30 years of regulatory and academic leadership
SPECIALTY	• Drugs and biological products
EXPERIENCE	• Director of the Virginia Center for Translational and Regulatory Sciences at UVA • Head of Global Regulatory Strategy, Policy & Safety at Merck Research Laboratories • Director of the Office of Drug Evaluation II within CDER

As a Principal of Greenleaf's Drug and Biologics group, Dr. Robert Meyer contributes a rich knowledge, gained through 30 years of regulatory and academic leadership, of the important issues facing the pharmaceutical sector today. Bob was previously the Director of the Virginia Center for Translational and Regulatory Sciences (VCTRS) at the University of Virginia (UVA) School of Medicine and continues as an Associate Professor of Public Health Sciences at UVA.

At the VCTRS, Bob led the development of a new regulatory science curriculum and served as a faculty expert in drug/biologic regulation, clinical development and study design, and commercial discovery and development, providing insight to support the regulatory success of medical research with transformational potential. Before joining UVA in 2013, Bob headed worldwide regulatory and pharmacovigilance activities at Merck Research Laboratories (MRL), most recently as Vice President, Global Regulatory Strategy, Policy, and Safety. He was also a member of MRL's Early Stage and Late Stage Development Review Committees and Safety Review Committee. Bob serves currently as a non-executive Director on the Board of Chimerix Inc., and did so for Translate BIO until its acquisition by Sanofi.

Prior to his academic and corporate experience, Bob had a notable career at the U.S. Food and Drug Administration (FDA), including five years (2002-2007) as the Director of the Office of Drug Evaluation II within the Center for Drug Evaluation and Research (CDER), with oversight of pulmonary and allergy, metabolic and endocrine, analgesic and anesthetic, and rheumatologic drug products. The rest of his tenure at the FDA was spent in CDER's Division of Pulmonary and Allergy Drug Products, which he directed from 1999 to 2002 after positions as a medical reviewer and team leader. He chaired the Pre-Market Risk Assessment guidance development for CDER and participated in several Prescription Drug User Fee Act (PDUFA) negotiations on behalf of both the FDA and the Pharmaceutical Research and Manufacturers of America (PhRMA).

During his tenure at Merck, Bob chaired the Regulatory Affairs Coordinating Committee for PhRMA. While at the FDA, he served on the third expert panel for the National Heart, Lung, and Blood Institute's National Asthma Education and Prevention Program (NAEPP EPR3). Bob also served on the Board of Directors for the Reagan-Udall Foundation and an elected term as a Medical Science Trustee for the United States Pharmacopeia Board (2015-2020). A recognized expert on environmental impacts of medical aerosols, Bob has contributed his expertise to the United Nations Environmental Program (UNEP) Technical Options Committee on Medical Aerosols beginning in 1998.

Bob received his medical degree from the University of Connecticut School of Medicine and completed his residency with the University of Connecticut School of Medicine at the VA Medical Center in Newington, CT, serving as Chief Medical Resident from 1987-88. At the Oregon Health Sciences University in Portland (1991-94), he was an academic pulmonologist and critical care specialist, helping to establish the medical service for the Lung/Heart-Lung Transplantation team. He has also served as a volunteer staff physician in pulmonary medicine at the National Naval Medical Center in Bethesda, MD.