

## **Roth PharmaReg LLC**

**John Roth, Ph.D.**

Dr. John Roth is a regulatory strategic leader with more than 25 years of experience in the development and implementation of US and Global regulatory strategies for small molecule and biologic products across all phases of drug development. He has direct experience in gaining approvals for BLAs, NDAs and sNDAs, as well as IND submissions, FDA and Global Health Authority Meetings, Formal Dispute Resolution procedures, Orphan Drug development and expedited approval pathways including Breakthrough Therapy, Fast Track and Priority Review designations. His therapeutic areas of expertise include Endocrine and Metabolic, Infectious Disease, Immunology and Inflammation, and Rare Disease and Rare Blood Disorders.

John previously was Associate Vice President at Sanofi-Aventis where he served as the Regulatory Therapeutic Area Head for Diabetes, and for Rare Disease and Rare Blood Disorders. Prior to that, he was Vice-President of Regulatory Affairs overseeing Infectious Disease at The Medicines Company. Earlier in his career, he held various US and Global Regulatory Affairs positions at Eli Lilly and Company, Roche and Bristol-Myers Squibb.

John received his Bachelor of Science degree from Albright College and his Ph.D. in Biochemistry from the University of Maryland at College Park.