



John E. Humphries, M.D.
Senior Clinical Consultant

John E. Humphries, MD, joined Biologics Consulting Group, Inc., as a Senior Clinical Consultant on January 31, 2008.

Dr. Humphries received an AB in German and Biology from Middlebury College in 1980; an MD from the Johns Hopkins School of Medicine in 1984; completed an internship and residency in Internal Medicine at the Johns Hopkins University School of Medicine in 1987; and subsequently completed a Hematology Fellowship at the University of Virginia School of Medicine in 1990. From 1990-1993, Dr. Humphries was involved in NIH-funded basic research on fibrinolysis at the University of Virginia while serving clinically as Instructor then Assistant Professor in the Departments of Internal Medicine (Division of Hematology/Oncology) and Pathology. Within the Pathology Department Dr. Humphries served as Associate Director of the Special Coagulation Laboratory. In 1997, he was promoted to Associate Professor at the University of Virginia in 1997. Dr. Humphries joined Bayer Pharmaceuticals, Biologics Division, in 1998 as Associate Director, Scientific Studies, responsible for all US phase IV activities. In 1999 he joined the International Clinical Development Group as Director for International Clinical Projects with responsibility for international trials of alpha-1-antitrypsin, antithrombin III, plasmin and albumin. Later, as Director of Global Clinical Strategy starting in 2001, strategic development of intravenous immunoglobulin was added to his responsibility for development of the above proteins. From 2005-2008 Dr. Humphries served as Vice President of Drug Development at Biolex Therapeutics, in Pittsboro, North Carolina, making transgenic protein therapeutics in Lemna (duckweed) with strategic and operational responsibility

for preclinical, toxicological and clinical development for all products in development, including a controlled-release interferon alfa and recombinant plasmin.

Dr. Humphries has acquired diverse skills and competencies during his 20+ year professional career. While at the University of Virginia, he was an accomplished researcher, educator and clinician with over 40 peer-reviewed journal publications, focused in the field of hemostasis, thrombosis and fibrinolysis. While at Bayer he was involved in the clinical development and regulatory interactions with FDA and EMEA on a transgenic alpha-1-antitrypsin, was responsible for early clinical development of a plasma-derived plasmin, clinical strategy for development of intravenous immunoglobulin in neurologic disorders and clinical strategy for new indications for plasma-derived antithrombin III. During his years at Bayer served on the PPTA (Plasma Protein Therapeutics Committee) subcommittee on Albumin, with responsibility of phase IV studies of albumin. While at Biolex he produced the toxicology and clinical sections of regulatory submissions for the controlled-release interferon for the treatment of chronic hepatitis C and for recombinant plasmin for the management of thrombotic disorders.

As a Senior Clinical Consultant with Biologics Consulting Group, Inc. Dr. Humphries will utilize his research and clinical expertise to assist clients in the following aspects of drug development and commercialization:

Technical

- Global development planning for drugs and biologics, focusing on clinical aspects
- Strategic and operational input to streamline dossier development and maintenance throughout the product lifecycle
- Assistance in writing various sections of pre-IND and IND submissions
- Assistance with the planning and conduct of clinical trials, including liaison, and medical monitoring
- Preparation for FDA, FDA Advisory Committee and International Regulatory Agency meetings.

Managerial

- Project and product lifecycle management approaches
- Assistance with due diligence activities, including potential mergers, acquisitions, in-licensing, and out-licensing

Marketing Initiatives

- Assistance with strategic and operational initiatives involving governmental or other agencies and/or advisory groups