

John J. Jessop, Ph.D., M.P.H.
Director, Pharmacology/Toxicology



John Jessop, Ph.D., M.P.H., joined BCG as Director, Pharmacology/Toxicology in August of 1999. Dr. Jessop is a pharmacologist (Ph.D., Georgetown University School of Medicine, Washington, D.C.) who brings to the firm 20 years of experience with the U.S. Food and Drug Administration (FDA) plus two years experience with a pharmaceutical company.

As a senior regulatory toxicologist in CBER, he reviewed license applications, supplements and INDs as both a product reviewer (monoclonal antibodies) and as a preclinical pharmacology/toxicology reviewer (monoclonal antibodies, cytokines and hematological growth factors). Dr. Jessop also co-authored policy/guidance documents on the FDA perspective for the regulation of monoclonal antibodies as therapeutic products and the pharmacology of monoclonal antibodies and represented the FDA as an invited speaker on these issues at scientific and regulatory meetings. He also has training and research experience in immunology, which provide for an excellent understanding of the biologics, mainly designed to interact with the immune system.

As a senior regulatory toxicologist in CDER, he was a pharm/tox reviewer of INDs and NDAs in the Division of Neuropharmacological Drug Products. He also chaired the Information Technology Committee for Pharmacology/Toxicology, where he co-authored a guidance document for format and content of electronic submissions. Additional experience with the FDA includes that of study director for toxicology studies carried out under the GLPs and an assignment as an FDA Investigator/Inspector, responsible for inspection of various industry facilities for compliance with the Federal Food, Drug and Cosmetic Act.

During his tenure with a private pharmaceutical company, Dr. Jessop served as Director, Regulatory Affairs, where he was responsible for directing all regulatory activities and preparing FDA submissions associated with the development of biologics and drug NCEs, as well as providing regulatory support for marketed products. He served as the core regulatory member of



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product teams, responsible for global development and registration efforts for NCEs. He also provided expert advice on appropriate pharmacology/toxicology programs to support development of biologics and drugs.

Dr. Jessop's extensive experience in the regulation of therapeutic biological products, his expertise in the pharmacology/toxicology of both therapeutic biological products and drugs, and his extensive experience in the drug and biologics development process from both the FDA and industry perspective, significantly enhance the expertise of the Biologics Consulting Group.