

## Curriculum Vitae



**John J. Jessop, Ph.D., M.P.H.**

**[jjessop@bcg-usa.com](mailto:jjessop@bcg-usa.com)**

Director, Pharmacology/Toxicology

Biologics Consulting Group, Inc.

P (540) 776-0680

F (540) 776-0681

### **SUMMARY OF EXPERTISE**

**20 years with the U.S. Food and Drug Administration, 2 years with a private pharmaceutical company and 8+ years as a pharmaceutical consultant**

#### **FDA**

- Expertise in the drug and biologics regulatory review process (IND, NDA/BLA)
- Pharmacologist/toxicologist with extensive experience in Preclinical Pharmacology and Toxicology review of both biological products and drugs
- Expert in the development of monoclonal antibodies
- Extensive experience in the development of prophylactic and therapeutic vaccines
- Authoring of policy/guidance documents at the FDA (monoclonal antibodies, electronic submissions; immunotoxicology)
- Participated in standard FDA Meetings (pre-IND, end of Phase 2, pre-BLA, etc.)
- Inspection of pharmaceutical manufacturers for GLP and GMP compliance
- Principal investigator for toxicology studies in compliance with the U.S. GLPs
- Doctorate in Pharmacology with minor in Immunology; therefore understands immunological principles as relates to development of biologics
- Directed basic research at CBER (National Institutes of Health campus) in immunopharmacology (monocytes, interleukin-1, cytokine release)

#### **Pharmaceutical Company**

- Director of all regulatory activities and preparation of FDA submissions (IND, NDA/BLA, Information Amendments, Annual Reports, etc.) required for development of NCEs (drugs and biological products) to market and required to support marketed products
- Served as core regulatory affairs representative on product teams tasked with global development of drugs and biologics
- Excellent knowledge and understanding of both the FDA and industry perspectives pertaining to the drug and biologics development process
- Helped with development of toxicology program for biologics



## DETAILED EXPERTISE

Dr. John Jessop joined the Biologics Consulting Group in August 1999, after **20 years experience with the FDA and two years experience with a private pharmaceutical company.** His previous position was as Director, U.S. Regulatory Affairs with Purdue Pharma, L.P. in Norwalk, CT. Dr. Jessop is a pharmacologist/toxicologist with a strong and unique background in the regulatory review and preclinical development of biologics and drugs. His doctorate is in Pharmacology (Georgetown University), with a specialty in immunopharmacology, and therefore he is also familiar with the principles of immunology. He has expertise in both pharmacology-toxicology and product review of biological products from his work experience at FDA/CBER. He also has experience as a pharmacology-toxicology reviewer of drugs in FDA/CDER. He served on a number of CBER and CDER committees, including the CDER Information Technology Committee (Electronic Submissions). He has co-authored a number of FDA Guidance and “Points-to-Consider” Documents, including a document providing guidance on the development of monoclonal antibodies as therapeutics and one outlining appropriate immunotoxicological testing of drugs. While at the FDA he also carried out GLP inspections of pharmaceutical companies and conducted toxicology research in compliance with the U.S. GLPs. Finally, he has worked for both the FDA and as a Director, Regulatory Affairs for the pharmaceutical industry. As the Director, Regulatory Affairs, he was responsible for directing all regulatory aspects of NCE development (both biologics and drugs) as well as providing regulatory support for marketed products. Therefore, he is familiar with the important regulatory issues from the perspective of both the FDA and the pharmaceutical industry. While working for the Biologics Consulting Group, he has added to his extensive experience and expertise in the development of vaccines. He has worked on projects at all different stages of development (pre-IND, IND, BLA) for the full spectrum of biologics (vaccines, cell and gene therapy products, blood products) and biologic therapeutics (monoclonal antibodies, cytokines, therapeutic proteins), as well as a number of drugs (small molecules). He has also written pre-IND, IND, and BLA documents as well as CTDs for many products, including monoclonal antibodies, gene therapy products and vaccines, among others. He has worked on projects involving the Animal Rule on a number of occasions, and has routinely carried out GLP audits. He has also continued to attend various meetings (DIA, RAPS, SOT, ACT) in order to maintain the most current regulatory information. Finally, he has written a book chapter and an article on the subject of preclinical pharmacology-toxicology development of biologics and drugs.

## EXPERIENCE

**Biologics Consulting Group, Inc.,** *Director, Pharmacology/Toxicology*  
Roanoke, VA (Aug. 1999 - present)

- Responsible for the scientific, regulatory and preclinical pharm/tox review, planning and analysis of a wide range of biologics and biological therapeutic products at all stages of development, from pre-IND through post-marketing
- Provide a full line of pharm/tox consulting services, including regulatory, scientific and pharm/tox guidance and support, develop product- and facility-related regulatory documents for submission, review SOPs, review pharm/tox packages, interface with toxicology CROs,



plan/review preclinical pharm/tox programs and protocols, do GLP audits and analysis of toxicology study results

- Provide a unique perspective in that I have CBER experience with both product and pharm/tox review
- Knowledge of both pharmacology and immunology; provides a unique understanding of the biologics, mainly designed to interact with the immune system
- Years experience as a pharm/tox reviewer at CDER, allow me to offer pharm/tox expertise in the development of drugs as well as biological products.
  - This experience is especially important in light of the recent transfer of the CBER therapeutic biological products to CDER.
- With experience as the Director, Regulatory Affairs in a pharmaceutical company, I have an excellent understanding of the drug development process and issues important to the FDA as well as to the industry.
  - This level of experience allows me to plan optimal pharm/tox programs on a case-by-case basis for the various biologics, therapeutic biologics and drugs as well as to develop regulatory documents (pre-IND, IND, BLA, CTD) that provide the information required by the FDA in a clear and concise manner.
- Current in my knowledge of the role of pharmacology/toxicology in product development through continuing participation in scientific and regulatory meetings.
- Developed extensive experience and expertise in the pharm/tox requirements for development of vaccines
- Wrote an article and a book chapter on the subject of preclinical pharmacology-toxicology development of biologics. Recent experience includes:
  - Plan appropriate pharm/tox programs and specific study protocols for vaccines, gene therapy products, monoclonal antibodies, cytokines, and others.
  - Write and/or review pre-IND, IND, BLA and CTD pharm/tox sections for gene therapy products, vaccines, monoclonal antibodies and other biologics.
  - Participate in the development of counter-bioterrorism vaccines utilizing the Animal Rule.
  - Obtain cost estimates and interface with various toxicology CROs in the planning and completion of pivotal GLP toxicology studies.

**Purdue Pharma, L.P., Director, U.S. Regulatory Affairs**

Norwalk, CT (Nov. 1997 - Aug. 1999)

- Directed all regulatory activities and provided regulatory guidance associated with the development of NCEs (biological products and drugs) and support of marketed products.
- Directed the preparation and filing of all FDA submissions, including IND, NDA, amendments, protocols, etc. related to development of NCEs and support of approved products.
- Acted as liaison with the FDA for all meetings, teleconferences, and other FDA communications.
- Directed company efforts to globalize development of NCEs.
- Provided expert consultation on pharm/tox issues related to biological products and drugs.
- Provided expert consultation regarding manufacturing issues related to biological products.



**FDA/CDER/ODE1**, Division of Neuropharmacological Drug Products, *Senior Regulatory Pharmacologist*

Bethesda, MD (Apr. 1994 - Nov. 1997)

- Senior pharmacology/toxicology reviewer of INDs/NDAs; also expertise in immunotoxicology.
- CDER committees:
  1. Chairman, Information Technology Committee; co-author guidance for format and content of electronic submission of pharmacology/toxicology information contained in INDs/ NDAs.
  2. Immunotoxicology Committee; co-authored guidance document for the review of drug products with respect to immunotoxicology issues.

**FDA/CBER/OTRR, DARP**, Hybridoma and Hematological Products Branch, *Senior Regulatory Pharmacologist*

Bethesda, MD (April 1993 - April 1994)

- Scientific reviewer of INDs/PLAs for biologicals in the areas of product-related issues and pharmacology/toxicology; expert in the pharmacology of monoclonal antibody therapies.
- Co-authored “Points to Consider for Use of Monoclonal Antibodies as Therapeutics” guidance document.
- Speaker at professional meetings: regulation of monoclonal antibodies as therapeutics.

**FDA/CBER**, Division of Hematology, Laboratory of Cell Biology, *Senior Scientist, Immunopharmacology*

Bethesda, MD (Oct. 1988 - Apr. 1993)

- Regulatory: scientific review (product-related issues and pharmacology/toxicology) of IND/PLAs for new biological therapies, with emphasis on monoclonal antibody therapies.
- Scientific: principle investigator; original basic research in the areas of immunopharmacology (mechanisms of monocyte function, interleukin1 release and potential pharmacological intervention) and neuroimmunology (effects of opioids and opioid peptides on immune function).

**FDA/CFSAN**, Division of Toxicology, *Research Scientist, Pharmacology*

Bethesda, MD (Aug. 1980 - Oct. 1988)

- Principal investigator:
  - 1) GLP studies examining toxic effects of food additives and contaminants on immune system.
  - 2) Studies to examine effects of various stressors (animal housing, light-dark cycle, water deprivation, foot-shock) and opioid peptide release on immune function.

**FDA/Bureau of Foods**, Division of Microbiology, *Researcher, Microbiology*

Bethesda, MD (Aug. 1978 - Aug. 1980)

- Developed Defect Action Level guidelines for regulation of microbial and insect contamination of various food products.
- Implemented studies identifying microbial and insect-related food contaminants and evaluating the health significance of these contaminants.



**FDA/Baltimore District**, Washington Resident Post, *Consumer Safety Officer*  
Bethesda, MD (Sept. 1977 - Aug. 1978)

- Responsible for inspection of facilities regulated by the Food and Drug Administration for compliance with the Federal Food, Drug and Cosmetic Act, including pharmaceutical companies (GLP & GMP), blood banks, and food manufacturing facilities.

#### **EDUCATION**

Ph.D., Georgetown University School of Medicine; Pharmacology/Immunopharmacology (1986)

M.P.H., Tulane University School of Public Health; Public Health (1977)

B.S., State University of New York, Brockport; Biology (1973)

#### **HONORS AND AWARDS**

Commissioned Officer, U.S. Public Health Service

Achievement Medal-CBER, received April, 1995

PHS Unit Commendation-CBER, received January, 1993

PHS Citation Award - CBER, received May, 1991

#### **PROFESSIONAL SOCIETIES**

- Regulatory Affairs Professional Society (RAPS)
- Drug Information Association (DIA)
- American College of Toxicology (ACT)

#### **FDA REGULATORY COMMITTEES**

- **Product Licensing Application (PLA) Committees** within CBER to review and formulate recommendations for regulation of new biological products.
- **New Drug Application (NDA) Committees** within CDER to review and formulate recommendations for regulation of neuropharmacological drugs.

#### **FDA SPECIAL COMMITTEES**

- **Chairman, CDER Information Technology Committee:** develop policy regarding format and content of electronic IND/NDA submissions.
- **CDER Immunotoxicology Committee:** co-authored internal guidance document for review of IND/NDAs with respect to immunotoxicology issues; Center advisory committee on immunotoxicology issues.
- **Chairman, CDER PTCC (Pharmacology-Toxicology Coordinating Committee)-GRP (Good Review Practice) Committee:** co-authored Pharmacology and Safety Pharmacology sections of Good Review Practice document.
- **"FIRST Initiative" Committee:** develop internal Agency searchable database of electronic toxicology reviews from all the Centers within the FDA.
- **CBER Sepsis Committee:** formulate guidance for regulation of biological products for treating sepsis.



### **FDA “OTHER REGULATORY ACTIVITIES”**

- **Formulation of Agency Policy:**
  1. Co-author of the guidance document entitled "Points-to-Consider for Use of Monoclonal Antibodies as Therapeutics".
  2. Develop policy for utilization of monoclonal antibodies to prepare purified blood factors.
- **Author of Intercenter Agreement:** authored guidance document for CBER and CDRH for regulation of antibody test kits to evaluate immunogenicity of biologics.
- **Invited speaker:** International Business Communications (IBC) Symposium on "Commercializing Human Monoclonal Antibodies", February 7-8, 1994, San Diego, California.

### **RECENT REGULATORY/SCIENTIFIC MEETINGS**

- Society of Toxicology, ToxExpo '07, Charlotte, NC (March 2007)
- American College of Toxicology Annual Meeting, Indian Wells, CA (November 2006)
- BIO 2006, Chicago, IL (April 2006)
- American College of Toxicology Annual Meeting, Williamsburg, VA (November 2005)
- Annual DIA Meeting, Washington, D.C. (June 2005)
- DIA/FDA Meeting, "Follow-On Proteins", Crystal City, VA. (February 2005)
- Annual RAPS Meeting, Washington, D.C. (October 2004)
- Annual DIA Meeting, San Antonio, TX. (July 2003)
- ASGT Meeting, "Clinical Gene Transfer Review Course" and "6th Annual ASGT (Gene Therapy) Meeting", Washington, D.C. (June 2003)
- SOT Meeting, "Workshop on Nonclinical Safety Evaluation of Preventive Vaccines", Crystal City, VA. (Dec. 2002)
- "SOT Workshop on Nonclinical Safety Evaluation of Preventive Vaccines", Marriott Crystal City, Crystal City, VA (December 2002)
- DIA Worldwide Clinical Meeting, "Worldwide Preclinical Development of Biotechnology-Derived Products", Bethesda, M.D. (October 2002)
- "DIA Meeting: Worldwide Preclinical Development of Biotechnology-derived Products", Bethesda Hyatt Regency, Bethesda, MD (October 2002)
- "PDA/FDA Joint Regulatory Conference: Emerging Global Regulatory Issues", Hyatt Regency Washington on Capitol Hill, Washington, DC (September 2001)
- "Safety Considerations in the Use of AAV Vectors in Gene Transfer in Clinical Trials", Doubletree Hotel, Rockville, MD (March 2001)

### **REGULATORY ARTICLES AUTHORED AND PRESENTATIONS**

- Presentation on “Unique Aspects of the Safety Evaluation of Biologic Cancer Agents”, Berlin, Germany, 2005.
- Presentation on “Preclinical Pharmacology/Toxicology Development of Biologics and Drugs” for the Tri-State SBIR Forum Meeting, Roanoke, VA, 2005.
- FDA Regulatory Affairs, A Guide for Prescription Drugs, Medical Devices and Biologics. *Chapter 6. Biologics*, James G. Kenimer and John J. Jessop. Eds. D. Pisano and D. Mantus, CRC Press, Boca Raton, FLA, 2004.
- Jessop, J. The IND (Investigational New Drug) Application: Is Our Product Safe to Administer in the Clinic? *GOR Vol. 5:2, 41-43, 2003.*