



**JOY A. CAVAGNARO, Ph.D., DABT, RAC**

### **Education**

- 1979                      Ph.D. (Biochemistry)  
University of North Carolina  
Chapel Hill, NC
- 1975                      B.S. (Biology)  
University of Miami  
Coral Gables, Florida

### **Academic Positions and Research Experience**

- 1976 – 1978              Teaching Assistant  
University of North Carolina / School of Medicine  
Chapel Hill, NC
- 1979 – 1980              National Toxicology Fellows  
Duke University / School of Medicine  
Durham, NC
- 1981 – 1982              Research Associate, Division of Pediatric Hematology-Oncology  
Boston University / School of Medicine  
Boston, MA
- 1982 – 1983              Research Assistant Professor, Division of Pediatric Hematology-Oncology  
Boston University / School of Medicine  
Boston, MA

*\*During tenure in Boston University, developed a patented system for primary in vitro immunization of human peripheral blood lymphocytes and their subsequent fusion to produce human-derived monoclonal antibodies.*

### **Credentials/ Certifications**

- 1997 - Appointed to Department of Health and Human Services Senior Biomedical Research Service
- 1986 – Diplomate American Board of Toxicology (recertified 1991, 1995, 1999)
- 1999– Regulatory Affairs Certificate (recertified 2002)
- 2003- NIH Human Participants Protection Education for Research Team

### **Patents**

U.S. Patent 696,546  
'Process for Producing Human Antibodies'

**Current Role**

1999 – Present                      Access BIO, L.C.  
Leesburg, VA  
***President and Founder***

Consultancy specializing in science-based regulatory strategies and development services to facilitate biomedical research, emerging technologies and product development, including vaccines, cellular and gene therapies, animal-based and plant-based bio-therapeutics, biotechnology-derived and tissue engineered products.

**Prior Experience**

1997 – 1999                      Human Genome Sciences, Inc.  
Rockville, MD  
***Vice President,  
Regulatory Affairs and Integrated Compliance***

Established the Regulatory Affairs Department, which included regulatory affairs and clinical data management data programming functions and assisted in identifying and developing new pre-clinical opportunities. Served as company spokesperson with the FDA and foreign agencies in all aspects of the regulatory process. Provided regulatory oversight for the pilot manufacturing facility start-up and commissioning, validation and expansion initiatives. Additional responsibilities included management of an Integrated Compliance Program, a unit formed in 1998, comprised of Quality Assurance (QA), Environmental Health & Safety (EH&S) function and the cross-functional Quality Systems Team (QST.) Provided oversight for development of the HGS EH&S Master Health and Safety Plan which was designed to enhance the management of corporate compliance activities.

1989 - 1997                      Food & Drug Administration  
Center for Biologics Evaluation and Research (CBER)  
Bethesda, MD  
***1996 – 1997                      Senior Pharmacologist & Director of Quality Assurance  
Office of the Center Director***

Responsible for inter-center and inter-national policy guidance for the preclinical development and safety assessment of biological projects. Spokesperson for CBER at local, and national and international meetings related to pharm/tox aspects of biologic product review. From 1990-1997 served as FDA safety topic lead for the International Conference on Harmonization of Technical requirements for Pharmaceuticals (ICH) initiative and as rapporteur for the ICH S6 guidance on preclinical safety evaluation of biotechnology-derived pharmaceuticals.

Monitored quality and consistency of CBER review activities and provided oversight for CBER technical committees created to support review activities. Ensured the accuracy of review and tracking of application data collected and reported by CBER. Chaired and Clinical Hold and Refuse to File Oversight Committees and served as Product Jurisdiction Liaison and center Ombudsman for resolution of review activity disputes unresolved at the division or office level between individuals or entities inside and outside of CBER. Additional responsibilities included supervising the regulatory information management system (RIMS) staff and the project manager of electronic submissions. Served as a member of the Intercenter Prescription Drug User Fee Application (PDUFA) Reauthorization Team In 1997 chaired the FDA Science Symposium. Served as CBER representative to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and chaired the Immunotoxicity Working Group.



and revenues for the laboratories under supervision. Interfaced with the FDA, EPA and other regulatory agencies to assist clients in meeting regulatory requirements. Chaired, Hazleton R&D committee.

**1983 – 1984**

***Staff Scientist  
Hybridoma Technology Services, Immunobiology Division***

Established an in vitro immunization capability as part of a comprehensive monoclonal antibody production contract service. Initiated research and development efforts for an Immunotoxicology Program. Member of Hazleton Laboratories Corporation Research and Development Committee.

**Selected Presentations**

“Enabling clinical development: Leveraging discovery research” – Keystone Symposium: Molecular Toxicology, Toxicogenomics and Associated Bioinformatics Applied to Drug Discovery, January 13, 2000, Sante Fe, NM.

“Alternative Approaches in Carcinogenicity Assessment of Biotechnology-Derived Medicinal Products: Gene Transfer Products” – DIA Meeting, May 15, 2001, Copenhagen, Denmark.

“Optimizing the preclinical development of (bio) pharmaceuticals: use of primates to predict immunotoxic risk” –Primate Models in Pharmaceutical Drug Development, 13<sup>th</sup> Primate Symposium sponsored by Covance, February 27, 2002, Munster, Germany.

Program Chair “Designing Preclinical Safety Evaluation Programs for Novel Therapies: What is the Question?” Preclinical Drug Development Improving Efficiency and Prediction to Proof of Concept, Barnett International, November 28-29, 2001, Philadelphia, PA.

“Regulatory oversight of gene transfer and GLP compliance: good science, good sense and the three R’s of preclinical testing,” Preclinical development of gene therapy vectors: from petri dish to Patient. – Comprehensive Reviewer Course on Clinical Gene Transfer ASGT’s 5<sup>th</sup> Annual Meeting, June 4, 2002, Boston, MA.

“The way toxicity evaluation of bio-pharmaceutical products should be conducted: ICH S6 guideline”, The role of toxicology in accelerating drug development and improving safety evaluation. - 29<sup>th</sup> Annual Meeting of the Japanese Society of Toxicology, June 20, 2002, Nagoya, Japan.

Program Co-chair: DIA Worldwide Preclinical Development of Biotechnology-Derived Products: The Science and the Regulation, Oct 21-22, 2002, Bethesda, MD.

“Nonclinical Safety Assessment of Biotechnology-derived Medicinal Products,” What you Need to Know about Optimal Transition from Animal to Man, DIA, Dec 4-5, 2002, Helsingor, Denmark.

Program Co-chair: “Discussion Forum: Development and Regulation of Cell-Based Therapies”, RAPS, March 20-21, London, UK.

“Putting in all Together- Writing the Label,” Nonclinical Toxicology in Support of Licensure of Gene Therapies, ASGT, March 13-14, 2003, Arlington, VA.

Invited Speaker Korean FDA: “Preclinical Safety Assessment of Cell Therapy and Related Products,” International Symposium on the Current Status of Gene and Cell Therapy, September 2-3, 2003, Seoul, Korea

“Developing Immunotoxicology Guidelines for (Bio) Pharmaceuticals: What is the Question?,” Immunotoxicology, Pharmaceutical Educations Associates, September 17, 2003, Rockville, MD

“The State of Vector Biodistribution: How we got here and what we have learned,” 7th Annual ASGT Meeting, June 2, 2004, Minneapolis, MN.

June 2005

“Product Comparability: From a “Regulatory Viewpoint”, 10<sup>th</sup> Annual Bio International Conference, June 7, 2004, San Francisco, CA.

Keynote Speaker: “From Bench to Bedside: How Scientist Move Novel Technologies for Test Tubes to Therapies”, Junior Science and Humanities Symposium Greater Washington Metropolitan Area 2005, January 6, 2005, Georgetown University, DC.

Moderator Breakout Session –Pharmacology and Toxicology Studies, FDA/DIA Workshop on Follow-on Protein Products, February 14-16, 2005, Arlington, VA.

Scientific Advisory Board and meeting Chairperson – “Do animal models of disease predict human risk better than normal volunteers” Integrative Preclinical Development for in Vivo and In Vitro Validation. Molecular Medicine Tri-Conference, April 10-22, 2005, San Francisco, CA.

Key Opinion Leaders Meeting for Adenovirus, GlaxoSmithKline, May 19-20, 2005, London, UK

“Optimizing Design and Analysis of Preclinical Development Programs,” 8<sup>th</sup> Annual Meeting American Society of Gene Therapy, June 2, 2005, St. Louis, MO.

### Selected Publications

J.A.Cavagnaro. 1992. Science-based approach to preclinical safety evaluation of biotechnology products. *Pharmaceutical Engineering*, 12 (No.3), 32-22.

J.A. Cavagnaro et al., 1995. Perspectives on the immunotoxicological evaluation of therapeutic products: assessment of safety. In *Methods in Immunotoxicology*, vol. 1, G.R. Burleson, H.H. Dean and A.E. Munson, Wiley-Liss, NY, pp37-49.

J.A. Cavagnaro. 1996. Safety Testing of Biotechnology Products. In *Comprehensive Toxicology, vol. 2, Toxicity Testing & Evaluation*, P.D. Williams and G.H. Hottendorf, Elsevier Science, pp. 291-298.

J. Cavagnaro. 1998. Influence of regulatory systems: A viewpoint of the US FDA process. In *Safety Evaluation of Biotechnology-derived Pharmaceuticals: Facilitating a Scientific approach*, S.A. Griffiths & C.E. Lumley, Kluwer Academic Publishers, UK, pp 31-38.

J.A. Cavagnaro. 2002. Preclinical safety evaluation of biotechnology-derived pharmaceuticals. *Nature Rev Drug Discov* 1: 469-75.

### Professional Affiliations

Chesapeake Research Review (CRR) IRB - independent central IRB- First independent IRB to receive PHRP and AAHRPP Accreditation (**Member since 2000- Co-Chair 2004 to present; Member Executive Committee and SAE Committee**)

Institute for OneWorld Health (a nonprofit pharmaceutical company), Saronyx, Tengion, CovX, Ribovax. BiogenIdec (PCDS), Sumitomo (Toxicology) (**Member – Scientific Advisory Boards**) BioPharmAnalysis, LLC, Pharmaceutical Diligence Consultants, New York, NY (**Associate**)

Biotechnology Industry Organization (Bio); Virginia Biotechnology Association (VABio)  
Association of Clinical Research Professionals (ACRP)  
American Society of Gene Therapy (ASGT)  
International Society for Cellular Therapy (ISCT, formerly ISHAGE)  
Society of Toxicology (SOT); National Capital Area Chapter society of Toxicology (NCAC-SOT)  
Regulatory Affairs Professional Society (RAPS)  
FDA Alumni Association (FDAAA) –**Charter Member; Member Centennial Committee**

### Professional Appointments

- 2003 NIH Scientific Review Program – **Chairperson Review Committee** -In Vitro and Animal Models for Emerging Diseases and Biodefense
- 2004 **US Proposal Reviewer** for International Science and Technology Center (ISTC) and Science and Technology Center in Ukraine (STCU) Project-CRDF Proposal Evaluation Form for Science -Harmonization of the Conditions Perform Pre-Clinical Trails According to the Russian and US Standards
- 2002- Present National Gene Vector Laboratory **Steering Committee**
- 2002- Present American Society of Gene Therapy **Industry Liaison Committee** (2002-2005) **Clinical and Regulatory Affairs Committee** (2005-2008)
- 1998 – Present Society of Toxicology  
**Education Committee (2001-2004); Chair Subcommittee for Minority Initiatives (2002-2003), Chair Committee on Public Communications (1997-1999)**
- 1995 – Present National Capital Area Chapter of the Society of Toxicology  
**President (1999-2000), Vice President (1998-1999)**
- 1996 – Present Regulatory Affairs Professional Society (RAPS)  
**Chair of the Board (2001-2002), President (2000-2001)**
- 1999 – 2002 **(Bio Industry Organization Rep)** to the Nonclinical Sciences Subcommittee of the FDA CDER/ Research Advisory Committee for Pharmaceutical Science
- 2000 – Present Bio Organization  
Member Regulatory Affairs Committee (RAC); RAC Lead Work Group and Preclinical Safety Expert Working Group (**BioSafe-Committee Chair**)
- 2005- Present Drug Information Association (DIA) – (**North America Chairperson** – Biotechnology SIAC)

### Selected Awards and Honors

- Letter of Commendation (1996)** From the Secretary of Health and Human Services for special tasks related to emergency preparedness planning for the 1996 Centennial Olympic Games
- FDA Group Award (1996)** For outstanding contributions regarding tissue engineered medical products for developing a strategy to evaluate associated safety and efficacy issues.
- FDA Award of Merit (1994)** For outstanding effort in the rapid approval of DNase for the treatment of cystic fibrosis.
- FDA Award of Merit (1993)** For outstanding leadership, which led to the FDA’s ability to harmonize with the international community its pre-clinical reproductive and developmental toxicity guidelines.
- FDA Commendable Service Award (1992)** For outstanding leadership in design and review of pre-clinical studies of cytokine and growth factor products.

### Additional Training

“Biotechnology: Strategies for Value Creation” - Kellogg Graduate School of Management Executive Program, March 13-16, 2002, Chicago, IL.

“Advances in Tissue Engineering” – Rice University, August 14-17, 2002, Houston, TX.

“The State of Bioethics: from Seminal Works to Contemporary Explorations” –Georgetown University’s Kennedy Institute of Ethics, April 5-7, 2002, Washington, D.C.

“Bio-Pharmaceuticals for the 21<sup>st</sup> Century: Responsibility, Sustainability & Public Trust”- Fordham University Center for Ethics Education, January 10-11, 2005, NYC, NY.

### Personal Data

Place of Birth- Boston, MA. Married (1977), 3 children.

Community Service: Coach Virginia Special Olympics –Volleyball, Basketball, Swimming