

## Professional Experience

### PharmaNet, Inc., Washington, DC

*Executive Director, PharmaNet Consulting* 2005 – Present

- Provide regulatory consultation for in-house clinical projects and stand-alone regulatory projects
- Provide regulatory consultative input into the creation of clinical development plans
- Prepare (or review) scientific technical documents in support of clinical trials or marketing applications in compliance with appropriate guidelines/regulations
- Maintain proficiency regarding all applicable regulatory guidelines
- Develop client-relationships, in conjunction with business development, to market regulatory consulting

### Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration Rockville, MD

*Acting Director* 1999 – 2000, 2003 – 2004

- Managed and directed regulatory activities including IND and BLA submissions and supplements, and lot-release testing for products within the responsibility of the Office of Vaccines Research and Review (OVRR), including viral, bacterial, parasitic vaccines, and allergenic products
- Represented the OVRR and CBER to organizations and government agencies, both national and international

*Deputy Director* 1995 – 2004

- Provided assistance to the Director in the management and direction of the office
- Served as Director in the Directors' absence

*Associate Director, Research* 1993 – 2004

- Provided direction and oversight for the research program
- Presented the research program to organizations and government agencies, both national and international

### Biophysics Laboratory, Division of Biochemistry and Biophysics, CBER, (formerly Bureau of Biologics), FDA Bethesda, MD

*Chief* 1982 – 1995

- Managed and directed research and regulatory activities for the Biophysics Laboratory
- Developed physical and chemical methods to characterize bacterial vaccines including; nuclear magnetic resonance spectroscopy and laser light scattering
- Provided CMC review for IND and license submissions for bacterial vaccines

*Research Chemist* 1977 – 1982

- Conducted research on the characterization of bacterial polysaccharidase by physical and chemical methods emphasizing nuclear magnetic resonance spectroscopy
- Provided CMC review for IND and license submissions for bacterial vaccines

**National Institute of Child Health and Human Development National Institutes of Health, Bethesda, MD**

Senior Staff Fellow

1976 – 1977

Staff Fellow

1975 – 1976

- Developed nuclear magnetic resonance spectroscopic methods for studying protein structure and function

## Education

**Princeton University, Princeton, NJ**

PhD – Chemistry

**Manhattan College, New York, NY**

BS – Biology

**Lund Institute of Technology, Lund, Sweden**

Post – Doctoral (Physical Chemistry)

## Professional Memberships

- American Chemical Society
- International Association of Biological Standardization
- Sigma Xi
- Member, Scientific Advisory Board, Keystone Symposia, 1996 – 2004
- Member, World Health Organization, Expert Committee on Biological Standards, 2000 – 2005
- Expert Consultant, World Health Organization, Consultation on TSEs (2003)
- Expert Consultant, World Health Organization, Consultation on Cell Substrates (2002)
- World Health Organization, Expert Working Group on Haemophilus influenzae type b Conjugate Vaccines, (1997 and 1998)
- World Health Organization, Expert Working Group on Harmonization of Antigen Content & Potency Measurements of DT Containing Vaccines, (1999 and 2002)
- World Health Organization, Consultant on Rotavirus Vaccines, 2000
- World Health Organization, Consultant on Epidemic control of Group A Meningococcal Meningitis, 1996
- Member, Scientific Meeting Committee, International Association of Biologicals, 1998 – Present
- Member, Interagency Group, National Vaccine Program Office, 1993 – 2004
- Ex Officio Member, Advisory Committee on Immunization Practices, 1999 – 2000
- Ex Officio Member, National Vaccine Advisory Committee, 1999 – 2000
- Member, Steering Committee, NIH In Vivo NMR Center, (1985 – 1995)
- Chair, Protocol Review Committee, NIH In Vivo NMR Center (1985 – 1995)
- Adjunct Professor (previous appointments); The Catholic University of America, American University, Georgetown University
- Member, NIH Study Section: Biophysical Chemistry, 1989 –1993
- Ad hoc Member, NIH Study Sections: i.) Experimental Therapeutics, ii.) National Cooperative Drug Discovery Group for HIV
- Member, NIH Reviewers Reserve, 1993 – Present
- Co-chair, Working Group to Develop the PHS's "Vaccine Safety Action Plan," 1998

## Awards

- Outstanding Service Award, "As a member of the CBER COOP Development Plan" (2004)
- Outstanding Service Award, "As a member of the CBER COOP Development Plan" (2004)
- Award of Merit "As a member of the Defense Team for the St. Louis University Litigation (2004)
- Center Director's Distinguished Service Award. "For outstanding contributions to assuring the safety of vaccines and tireless efforts to communicate with concerned members of the community regarding vaccine safety." (2003)
- Center for Biologics Evaluation and Research Public Health Achievement Award. "For exceptional effort in risk assessment and public communication regarding vaccines manufactured in the presence of bovine-derived materials from countries where bovine encephalopathy exists." (2001)
- FDA Group Recognition Award, "For helping avert a major influenza virus vaccine shortage and helping PHS agencies, health practitioners, and the general public cope with delayed availability." (2001)
- FDA Group Recognition Award, "For helping avert a major influenza virus vaccine shortage and helping PHS agencies, health practitioners, and the general public cope with delayed availability." (2001)
- Group Recognition Award, "For contributions to the training of Team Biologics. Investigators in preparation for the transfer of the biennial inspection responsibility from CBER to the Field." (2000)
- Commendable Service Award (group award), "as a member of FDA Expert Working Group for Q6B: Specifications" (1997)
- Commissioners Special Citation (group award), "For rapidly determining the significance to the Public Health and for efficiently coordinating an interagency response to the recall of influenza vaccine" (1997)
- FDA Group Recognition Award, "For outstanding efforts in preparation of a guidance document on product comparability to ensure the continued improvement and availability of biological products" (1997)
- CBER Public Health Achievement Award, Viral Vaccine Safety Taskforce. "For demonstrating exceptional and collaborative efforts, which brought honor to CBER, the Public Health Service and the Department of Health and Human Service" (1996)
- FDA Award of Merit, "For outstanding management of the Office of Vaccines Research and Review National Vaccine Program and other research programs" (1996)
- FDA Commendable Service Award, "For Sustained excellence in research and administration." (1988).
- FDA Group Recognition Award, "For exemplary efforts furthering the goals of increasing career opportunities for FDA scientists, engineers and statisticians working in fields related to regulatory review activities. (1989)
- Grant recipient (\$100,000), NIH Intramural AIDS Targeted Research, 1988 – 1989
- Grant Recipient (\$100,000), NIH Intramural AIDS Targeted Research, 1986 - 1987

## Bibliography

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