



Curriculum Vitae

Reginald D. Neal
rneal@bcg-usa.com
(202) 294-8543
Senior Consultant
Biologics Consulting Group, Inc.
Washington, DC

SUMMARY OF EXPERTISE

- 27 years experience working for the U.S. federal government, including the Department of Health and Human Services/U.S. Food and Drug Administration, Department of Agricultural, Department of the Navy, Department of Commerce, and Department of Interior/ U.S. Fish and Wildlife Service
- 8 years field inspection/investigational experience
- 10 years compliance experience with the Center for Biologics Evaluations and Research (FDA)
- Overseas work experience in 7 countries

EXPERIENCE

Biologics Consulting Group, Inc, Senior Consultant
Washington, DC (Mar. 2006 to present)

U.S. Food and Drug Administration, Center for Biologics Evaluation and Research Office of Compliance and Biologics Quality, Division of Manufacturing and Products Quality, Consumer Safety Officer, Rockville, MD (1999 to Feb 2006)

- Responsible for performing reviews of biologics license applications (BLA's) and supplements
- Involved in biological counter terrorism initiatives to include recognition in the 2003 Public Health Achievement Award as a member of the Bio-Terrorism Site Visit Team
- Responsible for planning and conducting internal and industry meetings
- Inspectional team lead for pre-licensing and prior approval inspections
- Recognized as cGMP expert for aseptic processing
- Evaluated industry responses to violations of the FD & C Act and/or the PHS Act
- Responsible for Supervisory management details to include guidance and support of approximately 9 reviewers on all technical and cGMP issues related to biological products; received a recognition award in 2003 for exemplary performance as Acting Branch Chief during Branch Chief's absence



U.S. Food and Drug Administration, Center for Biologics Evaluation and Research Office of Compliance and Biologics Quality, Division of Surveillance and Inspections, *Consumer Safety Officer*, Rockville, MD (1997-1999)

- Responsible for Source Plasma Inspection Compliance Program (CP) and related field guidance documents
- Coordinated the revision of Compliance Programs and related field guidance documents between the FDA, Office of Regulatory Affairs, FDA Office of Enforcement, CBER, Office of Blood Research and Review, and CBER, Office of Compliance Biologics Quality
- Respond to field inquiries concerning Source Plasma and Blood Bank inspectional issues
- Coordinate CBER initiated field lead inspections
- Responsible for tracking and data entry of reportable adverse events

U.S. Food and Drug Administration, Center for Biologics Evaluation and Research Office of Compliance and Biologics Quality, Division of Surveillance and Inspections, *Consumer Safety Officer*, Rockville, MD, (1995-1997)

- Issue assignments for audits of clinical trials
- Bioresearch monitoring committee member for new BLA's
- Drafted warning letters for concurrence and approval by the Director of the Office of Compliance

U.S. Food and Drug Administration, Office of Regulatory Affairs, Investigations Branch, *Consumer Safety Officer*, New Orleans, LA (1988-1995)

- Performed wide range of inspectional and investigational assignments
- Types of assignments included bioresearch monitoring audits, drug inspections, Good Laboratory Practice (GLP) inspections/audits, biologics inspections, device manufacturing inspections, food inspections, and interstate travel sanitation inspections
- Special assignments included tissue residue follow-up, undercover investigations of AIDS-related therapy promotions, undercover investigation of dietary supplements, suspect product tampering investigations, investigation of illegal sale of unapproved aquaculture drugs, and food-borne illness investigations
- Participated in assignments with the Office of Criminal Investigations
- Program monitor for fumonisin sampling program and health fraud coordinator

U.S. Department of Agriculture, Food and Feed Safety Research Unit, *Physical Science Technician*, New Orleans, LA (1985-1988)

- Conducted research on mycotoxins and mycotoxin contaminated agricultural commodities
- Performed sample preparations for extraction of biologically-active compounds and conducted sample analyses by various procedures to include thin-layer chromatography, HPLC, and spectrophotometry



U.S. Department of the Navy, U.S. Naval Oceanographic Office, Operations Branch,
Hydrographic Division, *Physical Scientist*, Bay Saint Louis, MS (1982-1985)

- Responsible for analysis of state-of-the-art technology in hydrographic survey methods
- Performed 50% of work assignments abroad; assisted foreign governments in the execution and quality control of hydrographic and geodetic surveys of ports, harbors and coastal areas
- Overseas assignments included Egypt, Greece, Singapore, the Philippines, Haiti, Italy, and Somalia

U.S. Department of Commerce, National Oceanic and Atmospheric Administration, *Physical Scientist*, Rockville, MD (1979-1980)

- Responsible for the acquisition and retrieval of oceanic data

U.S. Department of Commerce, National Oceanic and Atmospheric Administration
Office in Rockville, MD; Studies and Work at Texas A&M, *Biologist*, College Station, TX;
1978--1979

- Student trainee for completion of graduate studies in oceanography

U.S. Fish and Wildlife Service, Office of Law Enforcement, *Clerk*
Washington, DC (1977-1978)

- Responsible for issuing and record keeping of violation codes, correspondence with law enforcement agents nationwide, and for research and interpretation of investigative reports
- Responded to requests made by staff specialists from 13 field offices nationwide

EDUCATION

Graduate Studies in Marine Science; 1980-1982

Jackson State University, Jackson, MS

Graduate Studies in Phycology; 1980

Duke University, Beaufort, NC

Marine Research Center, Satellite Campus

Graduate Studies in Oceanography; 1978-1979

Texas A&M University, College Station, TX

Experiment in International Living; Summer 1974

Foreign /Student Exchange Cross Cultural Experience

Kenya, Africa

Bachelor of Science, Zoology; 1977

Howard University, Washington DC

Major in Zoology, minor in Chemistry