

## Curriculum Vitae



**Holli S. Vaughan, MS, RAC**

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Associate

Biologics Consulting Group, Inc.

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### **EXPERIENCE**

#### **Biologics Consulting Group, Inc., Associate**

Alexandria, VA

(Mar. 2000 - present)

- Serves as a project manager for FDA submissions
  - Including INDs, BLAs and ODDs
  - Familiar with FDA policies and procedures at CDER/CBER
  - Has assisted clients with Establishment Registration and Drug Listing
  - Familiar with legacy IND format (following form 1571) and CTD format
  - Can provide document formatting assistance for Word files
  - Readies documents for printing or electronic submission
- Provides regular support to US Agent clients with regard to IND and BLA maintenance

#### **Pharma Pacific Pty. Ltd, Manager, Regulatory Affairs**

Arlington, VA.

(Oct. 1993 - Mar. 2000)

- Responsible for all regulatory activities in the Americas for Australian-based bio-pharmaceutical company.
  - Planned and prepared regulatory submissions and documents, drafted and edited protocols and final reports, researched and wrote scientific literature reviews, created standard operating procedures for key regulatory and clinical functions.
  - Ensured data quality and integrity. Participated in a due diligence preclinical review.
- Managed all aspects of research development projects.
  - Directly involved with product development strategies and planning.
  - Coordinated the design, initiation and completion of preclinical and clinical studies.
  - Worked with a wide range of professionals including manufacturing, marketing and business development personnel, independent consultants, clinical research organizations, principal investigators, scientific review committees and peer review boards.



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- Budgeted and executed service agreements with selected principal investigators, academic institutions and contract research laboratories.
- Researched Latin American regulatory requirements and processes, and potential commercial partners for business development evaluation.
- Presented research and program updates to upper management, consultants, investigators and international commercial partners on a frequent basis.

**FIDIA Pharmaceutical Corporation, Regulatory Affairs Associate**

Washington, DC

(Dec. 1992 - Sept. 1993)

- Wrote and prepared protocol and information amendments, safety reports and annual progress reports for Investigational New Drug (IND) applications, Investigational Device Exemptions and Pre-market Approval applications. Assisted physicians with preparing Sponsor-Investigator INDs.
- Worked with microbiologists and manufacturing personnel in formulating responses to regulator inquiries.
- Supervised and coordinated the labeling and packaging of investigational drug supplies.

**Social & Scientific Systems, Inc., Regulatory Affairs Section Leader**

Rockville, MD

(May 1991 - Dec. 1992)

- Provided regulatory advisement to the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and related contractors for the initiation and completion of all NIAID-sponsored clinical trials.
- Supervised four regulatory professionals, conducted quality assurance reviews of all regulatory submissions and assisted with departmental management issues.

**Anaquest, Inc., International Regulatory Affairs Assistant**

Murray Hill, NJ.

(May 1988 - Apr. 1991)

- Prepared and submitted regulatory submissions into 14 foreign countries for marketed and/or investigational pharmaceutical products.
- Facilitated the regulatory process by liaising with foreign governmental authorities, consultants and all company departments.

**EDUCATION**

M.S., Johns Hopkins University; Interdisciplinary Scientific Studies, Biology; (1995)

B.S., Mary Washington College; Biology; (1988)

**CONTINUING EDUCATION**

Mar. 1999 Clinical Statistics for Non-Statisticians Training Course

Oct. 1997 A Joint [FDA](#) and [DIA](#) Project Management Training Workshop

Nov. 1995 Regulatory Policy Issues in the Development and Manufacture of Biopharmaceuticals and Other Biotechnology Derived Products



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May 1995      Conducting Successful Negotiations in Regulatory Affairs Workshop  
Oct. 1994      Biologics Approval and Compliance Workshop

**CERTIFICATION**

2001            Regulatory Affairs Certification (RAC)

**PROFESSIONAL SOCIETIES**

Regulatory Affairs Professional Society (RAPS)

**HONORS AND AWARDS**

2009            BCG special appreciation peer award for electronic submission work