

Decus Biomedical, LLC

Bonnie H. Wu, R.A.C. (US and EU)

Summary of Qualifications

- Certification in Regulatory Affairs (RAC, US and EU)
- Experience in US FDA and EU regulatory guidelines
- Experience in regulatory process in medical device and pharmaceutical settings
- Strong technical writing, proof reading, and editing skills
- Highly organized and attentive to detail

Summary of Professional Experience

iScience Interventional Corporation, Menlo Park, CA (Jan 2007 – June 2008)

Regulatory Affairs Associate

- Prepare regulatory documents for submission to international authorities, such as CE marking technical file, Investigational Device and Device License Applications to Health Canada.
- Maintain regulatory calendar and file regulatory related documents. Ensure the timely and accurate completion of regulatory projects and submissions.
- Prepare submission of clinical study protocols and amendments. Perform on-site monitoring duties of clinical trials and collect clinical data.
- Collaborate with clinical affairs team to develop clinical data management strategies for long-term clinical studies.

Schering-Plough Biopharma, Palo Alto, CA (March 1996 – June 2004)

Principal Scientist/Project Manager

- Coordinated an oncology preclinical project under a cross-functional team environment. Interfaced with scientific teams, legal, and regulatory departments.
- Assisted in developing and maintaining positive relationships with clinical product development team through oral and written communications regarding pre-submission strategy planning, timeline development, and testing requirements.
- Reviewed data and compiled preclinical study reports for IND submissions.
- Made scientific presentations at project reviews.

Sugen, Inc. (Pfizer), South San Francisco, CA (June 1993 – March 1996)

Research Associate

- Developed and maintained standardized assay protocols.
- Developed in vitro screening assays to characterize chemical compounds as therapeutic candidates.

Certification

Regulatory Affairs Certificate, United States (2006) and EU (2008)

Summary of Academic Experience

On-Site English, Palo Alto, CA (2001 - 2004)

Lessons in "Technical Writing Skills"

Miami University, Oxford, OH (May 1993)

M.S., Biochemistry

South China Institute of Technology, Guangzhou, China (July 1990)

B.S., Food Engineering

Summary of Publication

- Extensive knowledge of Microsoft Office Suite (Word, Excel, and PowerPoint)
- Experience with Adobe Acrobat Professional