

Roberta Connelly, MS, ELS

Professional Strengths

Over 10 years of experience writing regulatory documents and clinical publications

- Preparing regulatory documents for submission: protocols, investigator brochures, statistical analysis plans, clinical study reports (phases 1 – 4), summaries of safety and efficacy, briefing documents, package inserts, and responses to questions from regulatory authorities
- Summarizing clinical advisory board and data safety monitoring board (DSMB) discussions
- Working closely with investigators and sponsors to develop clinical manuscripts and to create abstracts, slides, and posters for professional meetings

Strong scientific background and skills in data analysis

- Solid understanding of oncology; microbiology; and chronic immune/inflammatory diseases such as cystic fibrosis, multiple sclerosis, HIV/AIDS, and rheumatoid arthritis
- Participated in evaluations of case report forms and patient data listings to identify potential data collection and programming issues
- Skilled in conducting online searches and in screening, evaluating, and summarizing pertinent literature

Proficient in managing projects

- Highly organized and adept at planning, coordinating, and completing detailed projects
- Reputation for delivering high-quality results on time

Experience

Freelance Medical Writer and Editor, Puget Sound region, WA, 1998 – present

Specializing in regulatory documents and clinical publications.

Therapeutic areas include chronic inflammatory diseases, hemostasis, microbiology, and oncology.

Bristol-Myers Squibb Pharmaceutical Research Institute, Seattle, WA, 1990 – 1997

Held 3 increasingly responsible research scientist positions.

Research topics included vaccine development targeting viral oncoproteins, interactions of HIV gp120 with cellular proteins, and modulation of T-cell responses.

Louisiana State University Medical Center, New Orleans, LA, 1989 – 1990

Research associate in the Department of Biochemistry and Molecular Biology.

Studied intracellular glucocorticoid receptor regulation.

Genetic Systems Corporation, Seattle, WA, 1984 – 1988

Held 4 increasingly responsible positions culminating in Project Leader, Research & Development.

Developed and optimized monoclonal antibody-based immunoassays, coordinated their transfer into production, assisted in the regulatory approval process, and provided customer support.

Education and Credentials

- Editor in the Life Sciences (ELS) awarded by the Board of Editors in the Life Sciences (BELS)
- Multidisciplinary certificate (pharmaceutical/research), American Medical Writers Association (AMWA)
- Certificate in Technical Writing and Editing, University of Washington, Seattle, WA
- MS, Pathobiology, University of Washington
- BS, Microbiology and Immunology, University of Washington

Active Participation in AMWA Programs

- Panelist in an interactive forum: "Medical Writing Genres: Finding or Expanding Your Niche" (providing perspective on regulatory writing) 2009
- Co-presenter: "The Fine Art of Project Management: Keep Your Writing Projects on Track" 2009