

Gelderloos Medical Writing, LLC

Julie A Gelderloos, PhD

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Overview

- A professional medical writer with over 20 years of experience in the pharmaceutical and device industries
- Wrote Phase 1, 2, and 3 clinical study reports, clinical sections of CTD/NDA/BLA documents, investigator brochures, annual reports, FDA meeting packages, and SOPs for pharmaceutical companies
- Wrote PMA sections, CERs, and literature reviews for medical device companies
- Authored and edited many journal manuscripts, meeting abstracts, and podium presentations
- PhD in molecular biology with extensive laboratory research experience in field of cellular signal transduction
- Highly skilled at analysis, interpretation, and critical evaluation of data
- Very effective at fostering productive working relationships
- Knowledge expertise in oncology, ophthalmology, neurology, and immunology
- Able to successfully meet deadlines and manage multiple projects simultaneously

Professional Experience

Consultant, MEDICAL WRITER, Jan 2002 – Present

GELDERLOOS MEDICAL WRITING, LLC

Medical writing consultant available to write and/or edit all types of clinical and regulatory documents including IND, CTD, NDA, BLA, PMA, and MAA sections, CERs, clinical study reports, investigator brochures, annual reports, journal manuscripts, meeting abstracts, and podium presentations. Experienced in writing SOPs, document templates, and training modules for sales forces.

MEDICAL WRITER, March 2001 – Dec 2003

ALLOS THERAPEUTICS INC, DEPT OF REGULATORY AFFAIRS

Westminster, CO

Responsible for writing Phase 1 and 2 clinical study reports, investigator brochures, annual reports, FDA meeting packages, and other regulatory documents. Wrote meeting abstracts and journal manuscripts based on clinical study results. Wrote Clinical Overview of CTD/NDA and contributed to writing of safety and efficacy summary sections. Worked with clinical, statistical, and regulatory departments to ensure all reported information was organized and summarized effectively. Ensured all documents accurately reflected study results, coincided with Allos R&D strategies, met regulatory requirements, and adhered to ICH guidelines.

PRINCIPAL MEDICAL WRITER, May 2000 – Dec 2000

ALLERGAN, GLOBAL MEDICAL AFFAIRS AND CLINICAL SERVICES

Irvine, CA

Responsible for writing clinical study reports for Phase 3 clinical research studies in support of regulatory submissions of drugs/biologics worldwide. Contributed to writing of clinical summary sections of NDAs/BLAs. Worked closely with Medical Writing Project Manager in planning and organizing medical writing projects.

SR MEDICAL WRITER, April 1998 – May 2000

ALLERGAN SURGICAL, MEDICAL RESEARCH COMMUNICATIONS DEPT Irvine, CA
Responsible for creating scientific communications based on clinical studies of Allergan Surgical devices (intraocular lenses). Duties included writing/editing peer-reviewed journal articles, slide presentations, and literature reviews.

BIOMEDICAL WRITER, 1997 – April 1998

THE WAYNE HUGHES INSTITUTE Glendale, CA / St. Paul, MN
Responsible for writing/editing journal articles and literature reviews, plus newsletter and web site pieces related to molecular biology/cancer research.

POSTDOCTORAL RESEARCH ASSOCIATE, 1996 – 1997

Molecular, Cellular, and Developmental Biology Dept University of Colorado Boulder, CO

POSTDOCTORAL FELLOW, 1994 – 1996

Basic Research Division National Jewish Center for Medicine Denver, CO

RESEARCH FELLOW, 1989 – 1994

Cellular and Developmental Biology Program University at Stony Brook Stony Brook, NY

Education **PhD Cellular and Developmental Biology, 1994** University at Stony Brook
Stony Brook, NY

BS in Biology, Cum Laude, 1989 Hope College
Holland, MI

Authored Publications

1. **Gelderloos JA**, Anderson SM. Over-expression of protein tyrosine phosphatase 1 (PTP1) alters IL-3- dependent growth and tyrosine phosphorylation. *Oncogene* 1996; 13:2367-78.
2. Bazenet CE, **Gelderloos JA**, Kazlauskas A. Phosphorylation of tyrosine 720 in the platelet-derived growth factor alpha receptor is required for binding of Grb2 and SHP-2 but not for activation of Ras or cell proliferation. *Mol Cell Biol* 1996; 16:6926-36.
3. **Gelderloos JA**, Witcher L, Cowin P, et al. Plakoglobin, the other ARM of vertebrates. In: Klymkowsky M, Cowin P, eds. *Cytoskeletal-Membrane Interactions and Signal Transduction*. Austin: Lands Bioscience, 1997.
4. **Gelderloos JA**, Rosenkranz S, Bazenet C, et al. A role for Src in signal relay by the platelet-derived growth factor alpha receptor. *J Biol Chem* 1998; 273:5908-15.
5. Rosenkranz S, DeMali KA, **Gelderloos JA**, et al. Identification of the receptor-associated signaling enzymes that are required for platelet-derived growth factor-AA-dependent chemotaxis and DNA synthesis. *J Biol Chem* 1999; 274:28335-43.

Have also served as author's editor for several published manuscripts.