Susan E. Caldwell, PhD

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Summary

Work Experience: Deep background in regulatory medical writing and biotechnology product development, and a strong publication record in the peer-reviewed medical literature—an unusual combination of medical writing expertise, analytical skills, management experience, and medical knowledge. Experienced in all phases of drug, biologic, and medical device product development, with emphasis on clinical development. Manage medical writing groups, mentor and develop junior writers, and build medical writing infrastructure.

Writing Experience: Write, edit, and review ICH-compliant US and international regulatory submissions (numerous INDs, NDAs, sNDAs, BLAs, sBLAs, 6 eCTDs, 2 combination drug/device submissions, and 1 CTA); clinical study protocols and amendments; clinical study reports (CSRs); serious adverse event (SAE) and adverse event (AE) narratives; briefing packages; investigator brochures (IBs); process development and manufacturing/CMC documentation; manuscripts, slides, brochures, and white papers; SOPs and templates; internal reports; and web site content.

- Clinical writing experience includes oncology; pediatric and adult neurology; infectious diseases; immunology, allergy, and inflammation; cardiovascular disease; ophthalmology; drug, biologic, and medical device manufacturing (CMC); and more.
- Example indications include acute myeloid leukemia (AML), age-related macular degeneration (AMD), analgesia, anemia, atherosclerosis, chronic granulomatous disease (CGD), chronic kidney disease (CKD), congestive heart failure (CHF), coronary artery disease (CAD), Crohn disease, glioblastoma multiforme (GBM), graft-versus-host disease (GVHD), hepatitis B (HBV) and C virus (HCV) infections, HIV/AIDS, infant epilepsy, influenza virus infection, multiple sclerosis (MS), multiple myeloma, myelofibrosis (MF) and myeloproliferative diseases (MPDs), non-Hodgkin lymphoma (NHL), non-small-cell lung cancer (NSCLC), pancreatic cancer, phenylketonuria (PKU), polycythemia vera (PV), renal failure, squamous cell carcinoma (SCC), and others. Experienced with light-activated drugs and other combination drug-device products.
- Headed medical writing groups at 4 biotechnology companies and 1 clinical research organization (CRO). Strong experience developing quality review processes for clinical and regulatory documents. Very comfortable with staffing, training, mentoring, and managing medical writing departments. Extensive medical writing project management experience.
- Broad drug, biologic, and medical device product development experience, from discovery and preclinical through clinical research, postmarketing, process development, and manufacturing/CMC.

Major Accomplishments: Two major submissions that were approved by FDA: (1) Led medical writing team in developing an NDA/eCTD submission for Kyprolis™, approved in July 2012; (2) was lead writer on the team at Berlex Laboratories that prepared an sBLA for Betaseron®, approved by the FDA.

Academic Background and Early Work Experience: PhD in medical microbiology and immunology; postdoctoral laboratory experience in human infectious diseases at Wake Forest School of Medicine, Winston-Salem, NC. Early work experience as laboratory scientist at Genelabs Inc. (Redwood City, CA; acquired by Glaxo in 2008) and Baxter Healthcare (Dade Diagnostics Division; Miami, FL).

Publications and Presentations: Publications in peer-reviewed journal articles, book chapters, news-letters, and web content. Strong publication record in the peer-reviewed journals and presentations at medical conferences (see Scholarly Publications). Published the Biotech Ink Insider newsletter for medical writers. Author and publish a medical writing blog, Biotech Ink Spots.

Professional Experience

Medical Writer Consultant and President
Biotech Ink, LLC; Mercer Island, WA
Jan 2005 to present

Medical writing: Provide clients with medical writing, reviewing, and editing services. Write manuscripts for peer-reviewed journals, abstracts, posters, white papers, medical literature reviews, brochures, newsletters, and slide sets. Regulatory documents include regulatory submissions (eCTDs as INDs, NDAs, sNDA, BLAs, sBLAs, and a CTA); clinical study protocols, amendments, CSRs, and IBs; data evaluations; drug safety documents, including serious adverse event (SAE) narratives; CMC, PK, and toxicology reports; GXP audit reports; and informed consent forms (ICFs).

Document development: In all areas of product development, advise clients on appropriate content, scope, organization, and format of materials. Recommend strategies for data presentation. Provide comprehensive document review services to ensure highest-quality work products.

Medical writing infrastructure: Hire, supervise, and mentor writers for companies needing writing support. Develop documents (eg, style guides, work-practice documents, preflight checklists, and Word templates) that support infrastructure.

Technical and other writing: Write technical documents for CMC/manufacturing and process development.
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Management: Provide project management services for medical writing projects. Create medical or scientific writing teams (including medical writers, editors, and proofreaders) and direct their work.

Publishing: Prepare documents for publication with Adobe Acrobat and ISIToolbox. From Oct 2008 to June 2013, published Biotech Ink Insider. Publish Biotech Ink Spots, a medical writing blog.

Examples of Consulting Positions

> Medical Writer Consultant
> Jul 2012 to Feb 2013
> Sutter Health and Palo Alto Medical Foundation; Mountain View, CA
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> Developed medical marketing brochures and web site content for patient and physician audiences. Collaborated with physicians, directors, analysts, and other program participants to create content that was accurate, educational, and persuasive. Provided project management oversight.
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> Medical Writer Consultant
> May 2012 to Nov 2012
> Fibrogen, Inc.; San Francisco, CA
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> In collaboration with multidisciplinary submission team, wrote, edited, and reviewed documents for an international regulatory submission (CTA) for an anemia indication in patients with chronic kidney disease (CKD). Wrote abstracts for submission and slides for presentation at medical conferences in collaboration with contributing authors.
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> Interim Senior Director (Consultant), Medical Writing
> Mar 2011 to Mar 2012
> Consultant, Medical Writing Development
> Mar 2012 to Jun 2012
> Onyx Pharmaceuticals, Inc.; South San Francisco, CA

Wrote, edited, and reviewed regulatory documents. Provided guidance for hiring, resourcing, project planning, and infrastructure development. Worked with project managers to develop timelines. Implemented QC function for clinical documents. Provided mentoring to medical writing staff. Led medical writers to develop NDA submission for Kyprolis™ (carfilzomib); the drug was approved in July 2012. Other documents included CSRs and a peer-reviewed manuscript. In collaboration with project management, biometrics, preclinical research, and other departments, worked with writers to remove obstacles and facilitate completion of high-quality, on-time documents.

Senior Associate, Medical Writing (Consultant)
Raland Technologies, Inc., Life Science Services & Solutions; Rochester, NY
Dec 2008 to May 2009

Advised client on strategies for developing preclinical eCTD modules. Analyzed data and developed preclinical documents supporting NDA and MAA eCTD submissions for an oncology indication. Developed library of ICH-compliant preclinical templates for Module 2 in the eCTD and regulatory style guide for use with eCTD document development.

Medical Writer Consultant
Gilead Sciences; Foster City, CA
Jan 2008 to Jan 2009

Wrote, edited, and reviewed clinical study reports, briefing package, and other clinical documents for inclusion in regulatory submissions. Chaired document review meetings.

Medical Writer Consultant
Questcor Pharmaceuticals, Inc. (acquired by Mallinckrodt); Union City, CA
August 2005 to Feb 2006

Led medical writers to develop supplemental NDA (sNDA) for an infant epilepsy indication. Wrote, edited, and reviewed documents in collaboration with regulatory personnel; directed other writers' activities. Performed QC on regulatory documents.

Medical Writer Consultant
Scios, Inc. (a Johnson & Johnson Company); Fremont, CA
Apr 2005 to Jul 2005

Wrote, reviewed, and edited clinical documents for congestive heart failure (CHF). Provided medical writing services supporting drug products, and revised clinical study documents (protocol amendments, IBs, SAE and AE narratives, and CSRs).

Director, Medical Writing
CTI BioPharma Corp.; Seattle, WA
Jun 2013 to Feb 2015

Medical writing: Wrote, edited, and reviewed manuscripts for peer-reviewed journals, abstracts, posters, slides, and oral presentations. Represented Medical Writing on the Publication Committee. Wrote, reviewed, and edited clinical and regulatory documents, including an NDA; IND annual reports; clinical study protocols and amendments; clinical study reports (CSRs); investigator brochures (IBs); statistical analysis plans (SAPs); drug safety documents, including DSURs and serious adverse event (SAE) narratives; pharmacokinetic/pharmacodynamic and toxicology reports; and informed consent forms (ICFs). Responsible for regulatory submissions to the US, EU, and Japan.

Document development: Provided guidance on appropriate content, scope, organization, and format of materials for regulatory submissions, reports, and protocols. Recommended strategies for data

presentation. Developed and fine-tuned tables and figures to optimize for clear presentation. Provided comprehensive document reviews to ensure highest-quality work products.

Medical writing infrastructure: Recruited, hired, supervised, and mentored in-house and contract medical writers. Developed documents to support infrastructure (eg, SOPs, style guides, work-practice documents, preflight checklists, and ICH-compliant Word templates). Worked with Legal and Finance to negotiate consultants' contracts and develop budgets.

Management: Provided project management oversight for regulatory submissions and other medical writing projects. Collaborated with project managers. Directed work by contract writers and medical writing staff to ensure on-time and on-budget project completion.

Publishing: Prepared documents for publication with Adobe Acrobat and ISIToolbox. Collaborated with publisher to ensure highest-quality published clinical and regulatory documents.

Senior Director, Writing and Publishing
ICON Clinical Research, PLC; Redwood City, CA
Feb 2004 to Jan 2005

Expanded medical writing and publishing services for a large CRO. Developed manuscripts and documents for phase 1 to 4 clinical studies. Clinical disciplines included cardiovascular disease, oncology, infectious and inflammatory diseases, and analgesia. Nonclinical areas included toxicology, PK, pharmacology, and CMC.

Medical writing: Wrote regulatory documents for drugs, biologics, and medical devices, including clinical study protocols, amendments, and CSRs; IBs; SAE/AE narratives; briefing packages; ICFs; and CTDs. Performed QC on clinical, research, process sciences, and CMC documents. Wrote abstracts, slides, posters, and manuscripts.

Technical and other writing: Developed process development and CMC documentation for 2 CTDs.

Infrastructure: Developed processes and templates, style guide, and other materials to support medical writing; hired medical writers and publishing manager; prepared budgets; mentored writers; acquired ISIToolbox, Documentum, and CoreDossier.

Administration: Developed budgets and allocated project resources; worked with others to ensure input for medical writing projects; advised senior management on projects, staffing changes, and other issues. Served on several management and project teams.

Publishing: Used ISIToolbox to publish an eCTD and CSRs (eg, hyperlinking, cross-referencing, and pagination); planned writing strategy for future submissions; worked with publisher to publish 2 CTDs.

Early Medical Writing Positions (details available on request):

Director, Medical Writing
Abgenix, Inc.; Fremont, CA (sold to Amgen, Inc., in 2006)
Jun 2002 to Jan 2004

Director, Technical Writing; Associate Director, Medical Editing
Pharmacyclics, Inc.; Sunnyvale, CA
Jan 1999 to May 2002

Associate Director, Medical Writing
Berlex Laboratories; Richmond, CA (merged with Bayer Healthcare)
Sep 1995 to Jan 1999

Education

Wake Forest School of Medicine; Winston-Salem, NC: Dept. of Internal Medicine/Infectious Diseases
Postdoctoral Researcher, Infectious Diseases, 1983-1987

Wake Forest School of Medicine; Winston-Salem, NC: Graduate School, Microbiology/Immunology
Major: Medical virology Minor: Protein biochemistry
PhD Medical microbiology and Immunology, 1985

University of Tennessee, Knoxville, TN
BA Biology major with honors, 1978

Speaking Engagements

- Writing in Bio-Medicine: Regulatory Medical Writing. Silicon Valley Communicators Chapter of the Society for Technical Communication; Santa Clara, CA; April 26, 2007.
- Regulatory Writing—Skills and Thrills, American Medical Writers Association (AMWA) Northern California Chapter Meeting; San Francisco; May 8, 2006.
- Medical Writing in Biotechnology. Career Fair, Technical and Professional Writing Department, San Francisco State University; San Francisco; May 1, 2006.
- The Employer's Perspective on Freelance Medical Writing. Bay Area Biomedical Consultants Network (BABCN) Meeting; Millbrae, CA; May 25, 2005.

Scholarly Publications

Authored or coauthored 26 peer-reviewed publications from 1980 to 2015, including 3 book chapters. Presented below are the 3 most recent publications. A complete bibliography is available on LinkedIn, or on request. Full publication samples are available at http://tinyurl.com/mvly4r or on request.

1. Verstovsek S, Dean JP, Cernohous P, Komrokji R, Seymour JF, Mesa R, Campbell MS, CALDWELL S, Wang L, Myint H. Pacritinib, a Dual JAK2/FLT3 Inhibitor: An Integrated Efficacy and Safety Analysis of Phase II Trial Data in Patients with Primary and Secondary Myelofibrosis (MF) and Platelet Counts ≤ 100,000/µl. American Society of Hematology Meeting, December 7-10, 2013.
2. Myint H, Campbell M, CALDWELL SE, Wang L, Toal M, Singer JW. An Integrated Efficacy and Safety Analysis of Phase 1/2 Studies of Tosedostat, a Novel Aminopeptidase Inhibitor, as Monotherapy for Hematological Malignancies. Society of Hematologic Oncology Annual Meeting, September 18-21, 2013.
3. McGrath MS, Luk KC, Abrams HD, Gaston I, Santulli S, CALDWELL SE, Piatak M, Lifson JD. 1992. Antiviral studies with trichosanthin, a plant derived single chain ribosome inactivating protein. In: Natural Products as Antiviral Agents, CK Chu and H Cutler, eds. Plenum Press, New York, pp 171-193.

References

Recommendations are on Susan's LinkedIn profile and on request.