

Susan E Caldwell, PhD

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Summary

Work Experience: As a PhD scientist with medical research training, performed hands-on laboratory research for 10 years. From 1995 to 2005, as Senior Director, Director, or Associate Director, managed medical writers at four life-science companies. Since January 2005, maintained a medical writing consulting practice as principal writer and president of Biotech Ink, LLC.

Broad background in biotechnology, pharmaceutical, and medical device product development, with a strong publication record—a rare combination of medical knowledge, analytical skills, management experience, and medical writing expertise.

Experienced in all phases of drug, biologic, and medical device product development. Consult with clients regarding eCTD preclinical and clinical content, scope, organization, and format to ensure submission readiness. Write, edit, and review medical manuscripts, process development reports, manufacturing (CMC) documentation, medical conference minutes, full regulatory submissions (INDs, NDAs, BLAs, sBLAs, 5 eCTDs, and 2 combination drug/device submissions since 2005), clinical protocols, amendments, study reports, investigator brochures (IBs), slide sets, white papers, internal reports, web sites, and many other document types.

Clinical writing expertise includes the areas of cardiology, oncology, pediatric/adult neurology, ophthalmology, infectious diseases, allergy and immunology, and more. Examples include glioblastoma multiforme (GBM), multiple sclerosis (MS), analgesia, squamous cell carcinoma, non-small-cell lung cancer (NSCLC), human immunodeficiency virus (HIV) infection, atherosclerosis, chronic granulomatous disease (CGD), Crohn's disease, age-related macular degeneration (AMD), influenza, hepatitis B virus (HBV) infection, congestive heart failure (CHF), coronary artery disease (CAD), graft-versus-host disease (GVHD), artificial organs and a variety of other medical devices.

Academic Background: PhD in medical microbiology and immunology (emphasis in medical virology, immunology, and protein biochemistry). Postdoctoral laboratory researcher in human infectious diseases.

Publications and Presentations: Publications include numerous medical articles, book chapters, newsletters, and web content. Strong publication record in the peer-reviewed medical literature (samples available on request), and presentations at many medical conferences. Publish the *Biotech Ink Insider*, a free weekly newsletter for medical writers (see [archives](#)). Write for multiple internet sites (eg, see blog, [Biotech Ink Spots](#)).

References: Recommendations available for review on LinkedIn; additional references available on request.

Professional Experience

Medical Writer Consultant and President

Biotech Ink, LLC; Foster City, CA
Jan 2005-present

Advise clients on appropriate content, scope, organization, and format of materials for eCTD submissions and individual research reports and protocols. At all stages of document development, recommend strategies for optimal data presentation in regulatory submissions. Work with client to develop best strategy for document development, including the appropriate use of abbreviated clinical study reports, manuscript submissions, and other approaches. Fine-tune tables and figures to optimize for clear, concise content presentation to complement data analyses. Advise clients on document preparation decisions that enhance publication readiness. Provide comprehensive document review services to ensure high-quality document work products.

Medical writing: Provide clients with medical writing, reviewing, and editing services for many document types. Write manuscripts for peer-reviewed journals, abstracts, posters, white papers, brochures, newsletters, and slide sets. Regulatory documents include regulatory submissions (eCTDs as INDs, NDAs, and BLAs); clinical study protocols, amendments, reports (CSRs), and IBs; clinical data evaluations; drug safety documents, including serious adverse event (SAE) narratives; CMC, PK, and toxicology reports; GXP audit reports; literature reviews; and informed consent forms. Prepare documents for publication with Acrobat and ISIToolbox. Use EDMS software, including SharePoint and Open Text Document Management.

Medical writing infrastructure: As needed, form and supervise writers for companies that need writing support. Develop infrastructure documents (eg, SOPs, style guides, work practice documents, preflight checklists, and Word and PowerPoint templates). Develop eCTD submission templates that are fully ICH compliant.

Technical and other writing: Write technical documents for CMC and process sciences, including experimental design, data presentation, and data analysis. Draft and edit web site content.

Management: Form medical or scientific writing teams (including medical writers, medical copy editors, and proofreaders), and direct writers' work to ensure on-time and on-budget project completion.

Publishing: Write for and publish the Biotech Ink Insider, a free weekly newsletter for medical writers, editors, copywriters, and publishers.

Senior Associate, Medical Writing (Consultant)

Raland Technologies, Inc., Life Science Services & Solutions; Rochester, NY
Dec 2008-May 2009

Advised client on strategies for developing preclinical eCTD modules. Analyzed data and developed preclinical documents in support of NDA and MAA eCTD submissions for an oncology indication. Worked to ensure that (1) timelines for document development were met, (2) the scope of submission content was well defined, and (3) the publishing group was kept informed of writing issues. Collaborated with the preclinical department to ensure accurate identification of all legacy documents. Developed complete 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

Scios, Inc. (a Johnson & Johnson Company); Fremont, CA
Apr 2005-Jul 2005

Recommended use of clinical research data and other content to develop clear, concisely worded clinical study reports. Wrote, reviewed, and edited clinical documents pertaining to congestive heart failure (CHF). Provided medical writing services to support development of drug products, and revised clinical study documentation (protocol amendments, IBs, SAE and AE narratives, and CSRs).

Senior Director, Writing and Publishing

ICON Clinical Research, PLC; Redwood City, CA
Feb 2004-Jan 2005

Expanded medical writing and publishing services for a large clinical research organization. Directed activities of writers and an epublisher. Supported clients with manuscripts and documents for phase 1-4 clinical studies. Clinical disciplines included cardiovascular disease, oncology, infectious diseases, inflammatory diseases, and analgesia. Nonclinical areas included toxicology, PK, pharmacology, and CMC.

Medical writing: Wrote and reviewed regulatory documents for drugs, biologics, and medical devices, including clinical study protocols, amendments, and CSRs; IBs; SAE/AE narratives; informed consent forms; and two CTDs, two as drug-device combinations. Performed QC and reported on clinical, basic research, process sciences, and CMC documents. Wrote and edited abstracts, slides, posters, and manuscripts.

Technical and other writing: Developed process development and CMC documentation for two CTD submissions. Developed, reviewed, and edited web site content. Prepared and edited press releases.

Infrastructure: Developed processes and templates, style guide, and other materials to support medical writing; hired medical writers and epublishing manager; prepared budgets; mentored writers; acquired ISIToolbox and CoreDossier software for in-house publishing, and Documentum for document management.

Administration: Developed budgets, assigned project resources, and met timelines; interfaced with other departments to ensure input for medical writing projects; created slide kits and marketed medical writing services; advised senior management on status of projects, staffing changes, and other issues. Served on numerous management and project teams.

Publishing: Used ISIToolbox to publish parts of an eCTD and prepared CSRs for esubmissions (for example, hyperlinking, cross-referencing, and pagination across volumes); planned writing strategy for future esubmissions; worked with electronic publishing manager to publish a CTD and an eCTD.

Management: Directed 7 medical writers, 1 editor, 2 medical writing consultants, and 1 publisher.

Technical Writer Consultant

Touchstone Technologies, Inc.; Fremont, CA

Jun 2003-Sep 2003

Provided writing services to support development of computer validation plans for a large biotechnology company.

Director, Medical Writing

Abgenix, Inc.; Fremont, CA (Abgenix was sold to Amgen, Inc., in 2006)

Jun 2002-Jan 2004

Clinical disciplines included oncology (renal cell, NSCLC, colorectal, breast, pancreatic, and prostate), inflammatory diseases (GVHD, psoriasis, and COPD), and fully human monoclonal antibody technology.

Medical writing: Wrote and reviewed CSRs, protocols, IBs, drug safety narratives, manuscripts, style guide, slide kits, and summaries. Provided writing support for preclinical and clinical research, process development, and CMC. Developed abstracts, posters, and slides for FDA advisory board and other meetings.

Technical and other writing: Developed web content; drafted, reviewed, and edited press releases.

Infrastructure: Developed infrastructure documents (eg, SOPs, templates, and checklists) to support medical writing; helped implement Documentum (EDMS); member, Biosafety Committee.

Administration: Shepherded documents through review and approval; planned project schedules and ensured on-time and on-budget document completion; participated in budget and resource planning.

Publishing: Published CSRs for esubmissions (eg, hyperlinking, cross-referencing, paginating, and processing scanned documents for esubmissions) with Adobe Acrobat (full version) and ISIToolbox.

Management: Directed 4 medical writer consultants, 1 technical editor, and 1 word processor.

Director, Technical Writing; Associate Director, Medical Editing

Pharmacyclics, Inc; Sunnyvale, CA

Jan 1999-May 2002

Wrote documents for drug and medical device products. Clinical disciplines included oncology (brain metastases, squamous cell carcinoma, and GBM), cardiovascular disease (PAD and CAD), and ophthalmology (AMD).

Medical writing: Drafted and reviewed regulatory documents, including study protocols, amendments, SAE narratives, CSRs, IBs, PIs, PK reports, a mock NDA, and clinical development plans. Drafted manuscripts, slide kits, abstracts, posters. Generated reports for toxicology, PK, process development, and manufacturing projects.

Technical and other writing: Wrote and edited SOPs, working guidelines, MSDSs, and stability reports. Wrote, reviewed, and edited press releases. Developed intranet web site content.

Infrastructure: Formed medical writing group and hired medical writing consultants; informed management of medical writing project status; developed processes to facilitate document production; helped implement

Documentum (EDMS) and CoreDossier (electronic publishing software) systems; supervised Reference Manager database development and developed intranet web content.

Administration: Guided documents through review and approval; planned project schedules and ensured timely document completion; did budget and intradepartmental project planning.

Publishing: Collaborated to publish esubmission documents; authored and implemented writing strategy for publishing CSRs and esubmissions; ensured documents met publishing requirements.

Management: Directed 6 staff medical writers and 12 medical writer consultants.

Associate Director, Medical Writing

Berlex Laboratories; Richmond, CA (later merged with Bayer Healthcare)

Sep 1995-Jan 1999

Clinical areas of writing experience included multiple sclerosis, oncology (leukemia), and MRI contrast agents.

Medical writing: Wrote and edited Summary Basis for Approval, Integrated Safety Summary, Integrated Efficacy Summary, package insert, SAE narratives, IB, and supplemental BLA for Betaseron; drafted and reviewed manuscripts; wrote CSRs; developed abstracts and slides; generated CSRs for Phase 4 studies.

Technical and other writing: Developed CMC and process development documentation and stability study reports. Reviewed and edited press releases.

Infrastructure: Wrote, edited, reviewed, and approved SOPs for clinical research and working procedures for process development; ensured staff received continuing education; participated in implementation and configuration of Documentum (EDMS) and CoreDossier (epublishing software).

Administration: Planned project schedules and ensured timely document completion; participated in budget preparation; assigned timelines and directed medical writing project management activities.

Publishing: Published partly electronic BLA for Betaseron using manual methods combined with the use of CoreDossier, Adobe Acrobat, and Documentum.

Management: Directed 4 staff medical writers, 5 medical writer consultants, and 2 clinical administrators.

Partner

BioInformation Resources; Miami, FL

1993-1995

Owned and operated BioInformation Resources. Specialized in biomedical information research from online databases. Analyzed information and wrote reports. Performed competitive intelligence and market analysis; projected industry trends. Obtained patent and product liability data for lawsuits.

Senior Scientist

Baxter Diagnostics (a subsidiary of Baxter Healthcare, Inc.); Miami, FL

1991-1993

Wrote regulatory documents, including PMAs, for diagnostic devices. Wrote study protocols and final reports. Managed clinical studies; generated and analyzed data. Chaired meetings to manage clinical trials. Developed diagnostic assay for acute hepatitis A virus infection. Co-chaired Biosafety Committee; served on Management Safety Committee. Brought BL-3 containment laboratory into cGMP compliance, and supervised its operations. Wrote clinical, CMC, and SOP documents to support assay manufacture; directed assay manufacture. Supervised 2 technicians.

Scientist II; Scientist I

Genelabs Incorporated; Redwood City, CA (merged with GlaxoSmithKline in January 2009)

1987-1990

Directed phase 1 clinical trial support for GLQ223. Generated data in an IND for GLQ223, a drug with antiviral activity against HIV. Screened substances for antiviral activity. Wrote portions of patents, INDs, manuscripts for

publication, SOPs, and procedures. Coordinated phase 1 trial support between Medical Affairs, Pharmaceutical Development, QA and QC, and Regulatory Affairs. Presented data at meetings. Supervised 5 technicians and operations of a BL-3 containment laboratory. Served as Biosafety Officer. Education and Training

Education

Wake Forest University School of Medicine; Winston-Salem, NC
Department of Medicine, Section on Infectious Diseases
Postdoctoral Researcher, Human infectious diseases, 1983-1987

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

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

Training and Continuing Education

cGXP Training, Scios, Inc.(a Johnson & Johnson company), Fremont, CA, June 2005
FDA Inspection Training; Scios, Inc., Fremont, CA, May 2005
cGXP Training; ICON Clinical Research, Redwood City, CA, Jun 2004
Drug Information Association (DIA) Electronic Document Management Meeting; Philadelphia, PA, Feb 2004
ISIToolbox; Abgenix, Inc, Fremont, CA, Oct 2003
Medical/Technical Writing; DIA, Baltimore, MD, Oct 2002
cGXP Training; Abgenix, Inc., Fremont, CA, Jun 2002
Clinical Research (cGCP) Training; Pharmacyclics, Inc., Sunnyvale, CA, Nov 2001
ICH 2001: Understanding the Common Technical Document; DIA, San Diego, CA, Mar 2001
Preparing INDs & NDAs; Center for Professional Advancement, East Brunswick, NJ, May 2000
Medical and Technical Writing; DIA, Baltimore, MD, Apr 1997
Regulatory Training I and II; DIA, San Francisco, CA, Oct and Nov 1996
Information and Technology; DIA, Philadelphia, PA, Apr 1996
Medical Writing; DIA, Philadelphia, PA, Oct 1995

Professional Skills

Medical Writing Skills

Expert manuscript drafting, reviewing, and editing
Expert use of graphs, tables, and figures to develop concise, compelling data presentation
Thorough knowledge of FDA and ICH guidelines and regulations
Strong expertise with the American Medical Association Manual of Style
Advanced Microsoft Word and PowerPoint skills (including macros, styles, and templates)
Adept in document preparation techniques for e-publishing using Adobe Acrobat and ISIToolbox
Skilled in preparing oral presentations, slides, and posters for medical and scientific conferences
Extensive writing experience with process development and CMC (manufacturing) documentation.

Biomedical Research Skills

Medical and scientific data analysis and interpretation

Expert use of graphs, tables, and figures to develop concise, compelling data presentation

Presentation of research projects and results as PowerPoint slide sets and posters

Virus cultivation in cell culture (HIV, HTLV-1) and embryonated eggs (influenza, VSV, and Sendai virus)

Virus purification, cloning, fractionation, and replication experiments

Drug candidate screening methods for antiviral activity, including tissue and cell culture methods

Separation methods: centrifugation, SDS-PAGE, IEF, blots, and chromatography

In vitro metabolic radiolabeling, fluorography, autoradiography, and densitometry

Colorimetry, fluorometry, and fluorescence-activated cell sorter (FACS) experience

Computer Skills

Word processing (Word, WordPerfect)

Spreadsheets (Microsoft Excel, Lotus 1-2-3)

Presentations (Microsoft PowerPoint, Freelance)

Reference software (Reference Manager, Endnote)

Internet browsers (Explorer, Netscape, Opera, Safari, and Firefox)

Graphics (Adobe Acrobat, Photoshop, Paint Shop Pro Photo, and Illustrator)

Publishing and document management (LiveLink, CoreDossier, Documentum, QUMAS, Acrobat, ISIToolbox)

Extensive online database search experience (eg, Medline, Dialog, and Lexis-Nexis)

Professional Memberships

American Medical Writers Association (AMWA)

Bay Area Biotechnology Consultants Network (BABCN)

Drug Information Association (DIA)

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

Recognition and Awards

Biographee, Who's Who Registry of Outstanding Professionals (2006-2007)

Biographee, Who's Who in the World (2002)

Biographee, Who's Who in the World (1997-98)

Biographee, Who's Who in Medicine and Healthcare (1997-98)

Biographee, Who's Who in Medicine (1996)

Biographee, Who's Who Worldwide Registry, Platinum Edition (1992-93)

Biographee, Who's Who in Science and Engineering (1992-93)

Biographee, Who's Who of American Women (1989-1993)

Outstanding Performance Achievement Award (Genelabs Inc., 1989)

Scholarly Publications

- ROACH (nee' CALDWELL) SC and Lyles DS. 1980. Forces binding Sendai viral nucleocapsid and M proteins to cellular membranes. Abs Ann Mtg Amer Soc Microbiol, p 265.
- CALDWELL SE and Lyles DS. 1981. Interaction of Sendai virus proteins with the cytoplasmic surface of erythrocyte membranes following viral envelope fusion. *J Biol Chem* 256:4838-4842.
- Lyles DS, Bowen HA, and CALDWELL SE. 1981. Interaction of Sendai viral proteins with the cytoplasmic surface of cellular membranes. In: *The Replication of Negative Strand RNA Viruses*. DHL Bishop and RW Compans, eds. Elsevier North Holland, New York, pp 559-565.
- CALDWELL SE and Lyles DS. 1983. Vesicular stomatitis virus-induced hemolysis and fusion with erythrocyte membranes. *Fed Proc* 42:2140.
- CALDWELL SE 1985. Interactions of viral proteins with the cytoplasmic surface of cell membranes. PhD dissertation.
- CALDWELL SE and Lyles DS. 1986. Dissociation of newly synthesized Sendai viral proteins from the cytoplasmic surface of isolated plasma membranes of infected cells. *J Virol* 57:678-683.
- CALDWELL SE, McPhail LC, Bass DA, and McCall CE. 1986. Protein phosphorylation in human neutrophils (PMN) induced by phorbol myristate acetate (PMA) and formyl-met-leu-phe (fMLP). *Fed Proc* 45:1136.
- CALDWELL S, Torres M, Coates T, Bass D, McCall C, and McPhail L. 1986. Multiple protein abnormalities in Mo1-deficient human neutrophils (PMN). *J Cell Biol* 103:509a.
- Torres M, CALDWELL SE, Coates TD, Bass DA, McCall CE, and McPhail LC. 1986. MO1 deficiency and protein kinase C. *J Cell Biol* 103:509a.
- CALDWELL SE, Bass DA, Gerard C, and McCall CE. 1987. Alterations in protein phosphorylation in human neutrophils (PMN) induced by a protein kinase C inhibitor, C-I. *Fed Proc* 46:2068.
- CALDWELL SE, Bass DA, McPhail LC, and McCall CE. 1987. Phosphorylation of a 48 kd protein, defective in chronic granulomatous disease (CGD) neutrophils, is not required for activation of the respiratory burst. *Fed Proc* 46:1030.
- CALDWELL SE, Cassidy LF, McCall CE, and Abramson JS. 1987. Alterations in protein phosphorylation during influenza virus infection of neutrophils may induce depressed cellular end-stage functions. *Clin Res* 35:470A.
- CALDWELL SE, McCall CE, Hendricks CL, Leone PA, Bass DA, and McPhail LC. 1987. Cell-free phosphorylation of a 48 kd proteins and activation of NADPH oxidase is defective in neutrophils from a patient with chronic granulomatous disease: restoration with normal cytosol. *Clin Res* 35:655A.
- Wheeler JG, Cassidy LF, CALDWELL SE, Bass DA, and Abramson JS. 1987. Influenza A virus (IAV) may induce cytoskeleton dysfunction in polymorphonuclear leukocytes (PMNL) by depressing protein phosphorylation. *Pediatr Res* 21 (4, Part 2):320A.
- CALDWELL SE, McCall CE, Hendricks CL, Leone PA, Bass DA, and McPhail LC. 1988. Coregulation of NADPH oxidase activation and phosphorylation of a 48-kD protein(s) by a cytosolic factor defective in autosomal recessive chronic granulomatous disease. *J Clin Invest* 81:1485-1496.
- CALDWELL SE, Cassidy LF, and Abramson JS. 1988. Alterations in cell protein phosphorylation in human neutrophils exposed to influenza virus: a possible mechanism for depressed cellular end-stage functions. *J Immunol* 140:3560-3567.
- Lifson JD, Huang KM, CALDWELL SE, Wu P, Ng V, Crowe S, Daniels J, Gaston I, Deinhart T, Marsh J, Vennari J, Yeung H-W, and McGrath MS. 1989. GLQ223: a compound with anti-HIV activity in acute and chronic infection of T cells and macrophages. *UCLA Symposium on Molecular and Cellular Biology*, Feb 4-11, 1989.

- McGrath MS, Huang KM, CALDWELL SE, Gaston I, Luk K-C, Wu P, Ng VL, Crowe S, Daniels J, Marsh J, Deinhart T, Lekas PV, Vennari JC, Yeung H-W, and Lifson JD. 1989. GLQ223: An inhibitor of human immunodeficiency virus replication in acutely and chronically infected cells of lymphocyte and mononuclear phagocyte lineage. *Proc Natl Acad Sci, USA.* 86:2844-2848.
- CALDWELL SE, Abrams H, Kibort T, Shiba A, Ross B, Wang M, and Lifson J. 1990. Effects of GLQ223® on synthesis and accumulation of HIV and cellular proteins in acutely infected T cells in vitro. Sixth International Conference on AIDS, June 20-24, 1990.
- Luk K-C, CALDWELL S, and Lifson J. 1990. Effects of GLQ223® on HIV and cellular RNA species from acutely infected T cells. Sixth International Conference on AIDS, June 20-24, 1990.
- Shrader V, Christensen L, Kibort T, Wang M, CALDWELL S, Fry K, and Piatak M. 1990. Structure-function studies of alpha-trichosanthin through manipulation of a synthetic gene. Second International Symposium on Immunotoxins, June 14-16, 1990.
- McGrath MS, Luk KC, Abrams HD, Gaston I, Santulli S, CALDWELL SE, Piatak M, and Lifson JD. 1991. Antiviral studies with trichosanthin, a plant derived single chain ribosome inactivating protein. 202nd Meeting of the American Chemical Society, August 25-30, 1991.
- Chin B, Cortes G, Butler M, CALDWELL S, Edwards L, Delgado J, Hall J, Okonmah A, and Kirchick H. 1991. Detection of specific IgG and IgM antibodies in class capture formats using radial partition enzyme immunoassay (RPEIA). 4th Science and Technology Seminar, Baxter Healthcare Corporation.
- McGrath MS, Luk KC, Abrams HD, Gaston I, Santulli S, CALDWELL SE, Piatak M, and 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 and Writing Samples

Recommendations from seven colleagues are available on Susan Caldwell's LinkedIn profile.

References, sample regulatory documents, and samples of Susan's publications from the peer-reviewed medical literature are available on request.