

RITA C. TOMLIN

CAREER SUMMARY

A senior Medical Writer with 10 years of writing experience, including 4 years medical writing management experience, in the biopharmaceutical industry. Specializing in regulatory writing including the writing and editing of CSRs, protocols, IBs, and sections of regulatory submissions (e.g., IND, NDA, BLA, End of Phase 2, annual reports). Experience with submissions in eCTD format. Expertise in organizing and presenting data as strong scientific arguments.

EXPERIENCE

Owner – Freelance Medical Writer

August 2007 – Present

Tomlin Consulting

San Diego, CA

- Projects to date have included writing protocols, an Investigator Brochure (IB), and Informed Consent Forms (ICFs); updating an IB; template integration and customization; and a Clinical Study Report (CSR) quality control (QC) review.
- Indications have included eosinophilic esophagitis, anaphylaxis, and gastroenteritis.

Faculty – Part-time

Starting Fall 2007

San Diego State University

San Diego, CA

- Teach one 500-level course in scientific writing
- Required course for science majors applying for graduate studies in the sciences

Manager, Medical Writing

October 2005 – August 2007

Pacira Pharmaceuticals, Inc. (formerly SkyePharma Inc.)

San Diego, CA

- Indication: Analgesia (extended-release bupivacaine)
- Recruit and train contract writers, CRO writers, freelance writers, support personnel
- Manage, write, and edit CSRs, IBs, protocols, posters, slide decks, and clinical sections of regulatory submissions (i.e., Investigational New Drug [IND], Investigational Medicinal Product Dossier [IMPD], end of Phase 2 summary, electronic Common Technical Document [eCTD]) and journal articles
- Create and maintain processes and templates: style guide, document templates (i.e., protocol, CSR, IB, poster, informed consent, study start-up forms), Standard Operating Procedures (SOPs) (i.e., document review and approval processes, document storage and version control, QC forms and check lists) and monitor adherence to these processes
- Write and edit clinical documents and SOPs; assist scientists with preclinical sections of IB and submissions
- Ensure documents are of the highest quality: clear, accurate, and complete
- Ensure processes for producing documents are effective and efficient
- Foster teamwork and represent department interests on clinical development and study management teams
- Attend and conduct relevant continuing in-house and external education and professional development courses

Manager, Medical Writing

Biogen Idec Inc.

April 2003 – Sept 2005

San Diego, CA

- Primary Indications: rheumatoid arthritis (Rituxan), chronic lymphocytic leukemia
- Supervised 3 in-house writers in their continuing education, career growth, and production of clinical documents
- Managed and assisted in the development of IND and Biological License Application (BLA) documentation; researched, wrote, reviewed, and interpreted preclinical and clinical data for multiple indications
- Managed the production of CSRs, IBs, annual reports, protocols, abstracts, posters, and journal articles for multiple indications
- Ensured documents were of the highest quality: clear, accurate, and complete
- Ensured processes for producing documents were effective and efficient
- Fostered teamwork and represented department interests on clinical development and study management teams
- Recruited, trained, and mentored internal personnel
- Created templates and work instructions to document essential processes and procedures and monitor adherence to these instructions
- Attended and conducted relevant continuing education and professional development courses

Senior Medical Writer

Santarus, Inc.

October 2002 – March 2003

San Diego, CA

Principle task – establish a Medical Writing Department in a start up company

- Indication: Gastrointestinal (omeprazole)
- Coordinated with Clinical Research, Biostatistics, and Data Management Departments to formalize the production of document productions, the organization of electronic files, and the flow of data
- Managed document timelines; wrote Phase II and III reports and protocols
- Developed Style Guide Manual, CSR template, and protocol template
- Wrote SOPs associated with medical writing (e.g., protocol content, CSR content, QC review of documents, document review, and approval procedures)
- Participated in planning and developing templates and procedures for New Drug Application (NDA) using CTD format
- Coordinated with Information Technology, Publishing, and Regulatory Affairs Departments to establish processes for creating and submitting the company's first CTD
- Edited CTD sections, reports, and protocols written by physicians and scientists
- Hired and manage contract medical writers
- Conducted MicroSoft Word training for Publishing Group and other staff, as needed

Senior Medical Writer

Neurocrine Biosciences, Inc.

March 2001 – Sept 2002

San Diego, CA

- Primary Indications: Glioblastoma, endocrinology (GnRH)
- Managed and wrote protocols, CSRs, IBs, posters, and abstracts for 6 compounds
- Participated in clinical study design on project teams
- Communicated with scientists to interpret data from preclinical and clinical studies
- Prepared Phase I through III CSRs in accordance with ICH Guidelines
- Set up systems to track and manage documents
- Initiated Medical Writing Internship Program and mentored intern/entry level writer
- Led project team in developing Style Guide Manual and Writer's Guide Manual

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Medical Writer III

Pfizer Global R & D (formerly Agouron Pharmaceuticals, Inc.)

January 2000 – March 2001

La Jolla, CA

- Indication: HIV (Virocept)
- Established procedures to transfer responsibility for Phase I CSRs from the Pharmacokinetics (PK) Department to the Medical Writing Department to improve the quality and consistency of Phase I CSRs.
 - Developed protocol template and CSR prototype
 - Initiated working relationship between PK and Medical Writing Departments
 - Collaborated with Data Management to standardize Phase 1 tables and listings
 - Wrote Phase I CSRs
- Reviewed and edited all Phase I protocols
- Managed 4 contract medical writers
- Managed timelines for approximately 50 Phase I CSRs
- Contributing author for Integrated Summary of Efficacy and edited Item 6 (Pharmacokinetic section) of a large supplemental NDA for a new indication

Medical Writer

Phoenix International Life Sciences, Inc. (CRO)

December 1997 – December 1999

Cincinnati, OH

- Participated in designing of Phase I trials
- Wrote and edited Phase I protocols and CSRs
- Designed and edited case report forms
- Designed and edited scientific presentations and posters with scientists

Clinic Coordinator

Phoenix International Life Sciences, Inc. (CRO)

April 1996 – December 1997

Cincinnati, OH

- Managed the implementation and conduct of 18 Phase I clinical trials and 2 radiolabel (ADME) studies
- Designed source documents to accurately and completely captured study data
- Anticipated and resolved logistical issues
- Scheduled study staff and facilities for each clinical trial
- Monitored and assisted with daily study procedures
- Reviewed study documentation and case report forms for accuracy and completeness

Medical Technologist

University of Cincinnati Hospital, St. Elizabeth's Hospital

1985 – 1996

Cincinnati, OH

- Performed clinical laboratory testing in the Hematology, Coagulation, and Clinical Chemistry Departments; prepared blood and blood products for transfusion
- Lectured in clinical chemistry for the Medical Technologist Internship Program

Education

- Bachelor's of Science in Medical Technology 1985
University of Nebraska at Omaha
- Graduate Certificate in Technical/Scientific Writing 2004
San Diego State University
- Master's of Arts in Rhetoric and Writing Studies 2007
San Diego State University

Professional Affiliations

- American Medical Writers Association (AMWA) since 1998
 - Core Curriculum Workshop Leader, Understanding and Reporting Routine Laboratory Results, AMWA Annual Conference, presented annually since 2004
- Phi Kappa Phi Honor Society since 2006
- Association of Teachers of Technical Writing (ATTW) since 2006

Publications

Tomlin RC. Online FDA Regulations: Implications for Medical Writers. Technical Communications Quarterly. (peer-reviewed journal; publication pending).

Military Experience

- Captain, Army National Guard, 1978-1988, Personnel and Medical Supply Officer
- ROTC, 1983-1984, University of Nebraska at Omaha