

Teresa T. Jarrett, PhD

SUMMARY:

Highly skilled regulatory medical writer providing medical writing, project management, and consulting services within the pharmaceutical, biotechnology, and CRO industries. Able to deliver the highest quality regulatory documents for global submissions within specified timelines. Key strengths include exceptional writing skills, attention to detail, and the ability to concisely and accurately interpret and summarize complex clinical data.

EDUCATION:

Ph.D., Pharmacology (Cardiovascular and Autonomic), 1985
Howard University, College of Medicine, Washington, DC

B.S., Biology (Minor in Chemistry), 1976
Tennessee State University, Nashville, TN

CAREER ACHIEVEMENTS OVERVIEW:

(See Professional Experience section for further details)

- 16 years experience as a regulatory medical writer including 3 years experience as Manager of Medical Writing
- Former FDA scientist (8 years) and Scientific Affairs Manager (7 years)
- Successfully prepared Phase I-IV CSRs, protocols, protocol amendments, protocol synopses, informed consents, SAE narratives, NDA summary documents (ISE, ISS, ISI), CTD Module 2 clinical summaries, IND nonclinical and clinical sections (Pharm/Tox, PHE, IB), 505(b)(2) applications, manuscripts, and posters
- Prepared Pre-IND and Pre-NDA Meeting Briefing documents
- Prepared all sections of full INDs and NDAs
- Prepared CMC modules (Module 2.3 - QOS and Module 3 - Quality) in CTD format for several IND and IMPD submissions
- Prepared CMC updates for IND amendments
- Provided team leadership, project management, protocol development, and medical writing support for an extensive array of clinical documents for US government-sponsored global vaccine and infectious disease clinical trials
- Consistently produced well-written, comprehensive, 1st draft document versions with minimal editorial revisions required
- Demonstrated exceptional ability to critically evaluate, interpret, and summarize complex clinical data
- Developed protocol templates and boilerplate text allowing faster and more consistent protocol preparation
- Developed processes for writing and reviewing clinical study reports and protocols
- Experienced with diverse client style guides and templates
- Provided individual and department training on medical writing topics and basic pharmacology

PROFESSIONAL EXPERIENCE:

2006 – Present, Regulatory Writing Solutions, LLC, Wilmington, NC

Owner and Regulatory Medical Writing Consultant

A full range of regulatory medical writing and project management services are offered to clients in the pharmaceutical, biotechnology, and CRO industries. Partnerships are developed with clients to facilitate and expedite global clinical and regulatory submissions. Services include writing, editing, review, and project management. Regulatory documentation prepared includes, but is not limited to, clinical study reports, protocols, informed consents, Investigator's Brochures, IND annual safety reports, CMC sections, SAE narratives, INDs, IMPDs, CTAs, NDAs (CTD format), 505(b)(2) applications, and FDA meeting briefing documents.

1999 – 2006, PPD Inc, Wilmington, NC

Senior Medical Writer

Prepared regulatory documents for multiple pharmaceutical and biotechnology companies, including clinical study reports (Phase I - IV), protocols, protocol amendments, SAE narratives, informed consents, manuscripts, Investigator's Brochures, IND annual safety reports, IND sections, integrated summaries of efficacy, safety, and immunogenicity, and other NDA sections. Mentored junior level medical writers.

Responsible for overall project management (budgets, timelines, resourcing, coordination, team and sponsor meetings, contract details) and project review meeting updates. Using scientific expertise, provided senior review of documents prepared by other medical writers.

Supported US government-sponsored (NIH/NIAID/DMID) global vaccine and infectious diseases clinical trials through review, revision, and development of an extensive array of clinical documents. Provided team leadership and project management for all medical writing services.

Manager, Medical Writing

Managed the activities of a team of medical writers and directed all medical writing programs in the Wilmington office. Managed the preparation of regulatory documents and other medical writing products. Assigned projects and ensured the timely completion of projects. Developed and trained medical writers in writing skills. Reviewed (scientific, clinical, and quality control) all documents prepared by medical writers prior to submission to client, serving as a resource for interpretation of clinical efficacy and safety data, and for questions relating to study design, adverse event reporting, laboratory test results, and other clinical test results.

Budgeted, forecasted, and planned for the medical writing department and trained medical writers in the management of budgets, resources, timelines, billing approval, contract negotiation, and sponsor contact. Attended developmental team meetings and negotiated timelines and expenditures for medical writing department. Budgeted and forecasted project-related costs and set timelines for completion of projects. Tracked and evaluated the profitability and timeliness of medical writing programs and medical writing tasks. Wrote and reviewed departmental procedures and standard operating procedures and ensured compliance with these procedures.

Gave marketing presentations to potential clients on the capabilities of the medical writing group in order to recruit medical writing projects. Prepared time and cost estimates and proposals for future medical writing projects.

1997 – 1998, Consultant Medical Writer

Independent Contractor

Consulted on medical writing projects and prepared documents (integrated summary of efficacy, clinical pharmacology, summary volume, expert opinion reports) for regulatory submissions.

1994 –1996, Procter and Gamble Pharmaceuticals, Cincinnati, OH

Medical Writer, Regulatory Services

Prepared final clinical study reports for cardiac and bone studies (Phase I to III). Edited investigator's brochures; prepared, updated, and managed global documentation standards (writer's guides and electronic templates); and trained project teams on documentation standards.

1987 – 1994, the former Hoechst-Roussel Pharmaceuticals, Inc, Somerville, NJ

Manager, Scientific Affairs

Established and developed the image of HRPI among the medical, pharmaceutical, and scientific communities in Ohio, West Virginia, Indiana, and Kentucky through 1) relationships with top medical professionals and their associates in major medical institutions, 2) presentation of scientific and technical information to the medical community on marketed products, 3) grant awards to qualified physicians, and 4) medical and pharmacy education programs. Identified potential investigators for preclinical and clinical (Phase I-IV) studies and helped identify licensing opportunities. Primary areas of focus included anti-infectives, peripheral vascular disease, Alzheimer's disease, oncology, diabetes, dermatology, cardiology, and hypertension.

1980 – 1987, US Food and Drug Administration, Washington, DC

Junior Staff Fellow/Pharmacologist, 1985 – 1987, Center for Food Safety and Applied Nutrition, Division of Toxicology, Drug Metabolism Branch in Beltsville, MD

Pharmacologist, 1983 – 1985, Center for Drugs and Biologics, Division of Drug Biology, Drug Pharmacology Branch

Biologist, 1980 – 1983, Center for Drug and Biologics, Division of Drug Biology, Drug Pharmacology Branch

PROFESSIONAL DEVELOPMENT:

- Extensive training in medical writing, biostatistics, clinical research, and drug development topics
- Additional post-graduate training in pharmacokinetics
- Training in current Good Manufacturing Practices (cGMP)
- Management and leadership training

PROFESSIONAL AFFILIATIONS:

American Medical Writers Association
Drug Information Association