Kalpana Shankar, PhD

Freelance Medical Writer

3C Medical Writing, LLC

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Summary

- Advanced scientific writing and editing skills, as evidenced by authoring continuing medical education materials, abstracts, manuscripts, news pieces, posters, and more.
- Adept at articulating complex scientific information through simple and effective writing techniques and PowerPoint slide decks to diverse stakeholders including contract research Organizations (CRO), US FDA staff, medical communication companies, medical education agencies, hospital care providers and university students.
- Authored an NSF-SBIR grant proposal for a start-up biotechnology company. Also assisted with authoring 3 grant proposals to the Department of Energy, National Institutes of Health, and the National Science Foundation during doctoral and post-doctoral career over the course of 3 years, resulting in $350,000 in research funding. Proficiency in ChemDraw software led to co-authoring a book chapter.
- Demonstrated project management, problem-solving skills, and self-driven initiatives in complex scientific environments resulting in innovative solutions, process improvement and regulatory compliance within the biopharmaceutical, compounding and CRO industry.
- Experience driven organizational skills and the ability to meet project deadlines on time, as demonstrated by managing 9 high profile compounded admixture projects in tandem that led to concurrent sales of 8 admixtures over 3 quarters thereby delivering profit for the company.

Work Experience

2020 – Present: Owner & Freelance Medical Writer at 3C Medical Writing, LLC

2020 – Present: Subcontractor for Nascent Medical, LLC

- Providing clear, concise, and compelling medical and scientific writing.
- Write and edit the following types of documents (not limited to):
    - Research manuscripts
    - Scientific platforms
    - PowerPoint slide decks

    - Abstracts and posters
    - News articles
    - Grant proposals
- Annotating and fact-checking of medical and scientific documents

2017 – 2019: R&D Project Manager (PM) & Quality Auditor, Prompt Praxis Laboratories, Vernon Hills, IL

- Researched and developed familiarity with FDA.gov, clinicaltrials.gov, Code of Federal Regulations Title 21, and PubMed and authored the Introduction, Regulatory Background, Pharmacological Class, and Proposed Clinical Indication sections of a pre-IND oncology package in the pre-clinical phase which resulted in a complete and compliant document.
- Authored an Empower uPLC software work instructions technical document for a team that comprised 6 quality assurance reviewers to review chromatography data that led to minimal errors during the review process.
- Exceptional eye for detail as evidenced by auditing of analytical batch level testing data, R&D data, ELN's, method validation protocols, stability study reports and technical documents per client specifications and SOP's.

2014 – 2016: R&D PM & Study Director, AmerisourceBergan-PharMEDium Services, Lake Forest, IL

- Oversaw 9 high-profile projects concurrently ($500K+ total budget) and performed tasks included stability protocol design, monitoring, advising, and reviewing stability data and reports from external contract research organizations (CRO's) from inception to completion leading to 8 successful product launches.
- Recipient of the PharMEDium's Certified Quality Auditory certificate resulted in auditing of 4 external CRO's to determine compliance with internal, ICH and cGMP/GLP regulatory guidelines.
- Assisted senior management in generating the 483 Response to the FDA (for 15 drugs). Provided customer support by responding to hospital questions about admixture stability or storage conditions.

2013 – 2014: Senior Project Coordinator, AbbVie, North Chicago, IL

- Audited the work of 100 chemists at 6 CRO's based in Asia and Europe to ensure quality standards.
- Coordinated CRO shipments (200 compounds), created a standardized 12-point checklist and performed monthly reviews of chemists' Electronic Lab notebooks – increased average pass rate per CRO from 10 users to 20 and introduced processes to ensure accurate/timely registration of +70 organic compounds in a chemistry database.

2009 – 2011: Post-Doctoral Researcher, University of North Texas, Denton, TX

- Devised a methodology for synthesizing gold nanoparticles electrochemically in an environmentally friendly green medium.
- Assisted with writing 2 grant proposals to NIH and NSF over the course of 2 years, resulting in $200,000 in research grant funding.
- Mentoring 2 undergraduate students resulted in their successful completion of the thesis defense. Reviewed and edited the master's thesis of 2 graduate students.

Education

2008: PhD, Chemistry, Tulane University, New Orleans, LA
(Research/Teaching Assistant - taught 15 labs, 120 students over four semesters)
2002: MSc, Chemistry, University of Madras, (Tamil Nadu, India)
1999: BSc, Chemistry, University of Madras, (Tamil Nadu, India)

Skills, Tools & Leadership

Medical/Scientific writing	SharePoint	Project Management
Annotating and fact-checking	MS office suite	Organizing & Leading meetings
Quality Control/Quality Assurance	Adobe Acrobat	Document Control & Development
Data Presentation	End Note	Team Collaboration
	Chemdraw	Effective use of search engines

Certificates and Trainings

- PharMEDium's Certified Quality Auditor Certificate
- Reviewing Data Electronically with Empower 3 Software
- Coursera Certificate for Drug Discovery authorized by University of California, San Diego
- Coursera Certificate for Drug Development authorized by University of California, San Diego

Affiliations

- Member, American Medical Writers Association
- Member, American Chemical Society
- Member, Cheeky Scientist Association (CSA) & Medical Writing Organization (affiliated to CSA)