Mei-Ling Zhou

Principal Medical Writer

San Diego, CA (858) 555-0167 meiling.zhou@email.com linkedin.com/in/meilingzhou

SUMMARY

Principal medical writer with 13 years of experience leading regulatory writing for neurology and rare disease programs. Directs submission documents from protocol through NDA and MAA, sets writing standards and templates, and leads teams of up to 8 writers. Strong organizational skills and attention to detail, with fluent use of MS Word, Excel and PowerPoint.

EXPERIENCE

Principal Medical Writer

03/2021 - Present

Torrey Pines Neuroscience

San Diego, CA

Biopharma company with 2 approved neurology drugs and 6 clinical programs.

- Lead regulatory writing for **2** NDA and 1 MAA submissions, all filed on the planned date.
- Manage 8 medical writers and 2 contract vendors with a $1.6M annual writing budget.
- Develop MS Word templates and a style guide that cut CSR drafting time by 25%.
- Represent medical writing on submission teams and present plans to the VP of regulatory affairs.
- Build Excel resource forecasts that matched writer capacity to 40 planned documents a year.

Senior Medical Writer

08/2016 - 02/2021

Pacific Rare Disease Therapeutics

Carlsbad, CA

Rare disease biotech running global Phase II-III trials.

- Authored 10 clinical study reports, 3 investigator brochures and 2 pediatric study plans.
- Wrote the clinical overview for a breakthrough therapy designation request that was granted.
- Trained 5 writers on lean CSR writing and data interpretation.
- Coordinated reviews with 6 functions, holding each document to 3 review rounds or fewer.

Medical Writer

06/2013 - 07/2016

La Jolla Clinical Research Organization

La Jolla, CA

Contract research organization focused on early-phase trials.

- Wrote protocols and clinical study reports for 15 Phase I studies.
- Prepared PowerPoint data summaries for 20 sponsor safety review meetings.
- Drafted informed consent forms and patient diaries for 9 first-in-human studies.

SKILLS

- **Regulatory Writing**
- **Clinical Study Reports**
- **NDA and MAA Submissions**
- **Investigator Brochures**
- **Protocols**
- **Style Guides**
- **MS Word**
- **Excel**
- **PowerPoint**
- **Organizational Skills**

EDUCATION

Doctor of Philosophy

University of California, San Diego

Neuroscience

La Jolla, CA

06/2013