Elena M. Rodriguez, PhD

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PROFESSIONAL SUMMARY

Senior Medical Writer with over 8 years of experience in regulatory and clinical writing for oncology and immunology. Proven track record of producing high-quality CSRs and manuscripts for Top 10 pharmaceutical companies. Adept at transforming complex datasets into clear, compliant documents while meeting strict project timelines.

WORK EXPERIENCE

Senior Regulatory Medical Writer | Biogen Therapeutics | Cambridge, MA
May 2020 - Present

- Lead author for pivotal Phase III Clinical Study Reports (CSRs) in the neurology therapeutic area.
- Coordinate the assembly of Common Technical Document (CTD) summaries for FDA and EMA submissions.
- Collaborate with biostatisticians and clinicians to interpret complex data from neurodegenerative disease trials.
- Managed the end-to-end production of 5 successful Investigator Brochures for early-stage pipeline assets.
- Streamlined the internal peer-review process, reducing document prep time by 15%.

Medical Writer | Scientific Comm Solutions | New York, NY
Aug 2017 - Apr 2020

- Developed high-quality manuscripts, abstracts, and posters for publication in journals like JAMA and The Lancet.
- Facilitated publication planning meetings with Key Opinion Leaders (KOLs) and pharmaceutical sponsors.
- Conducted comprehensive systematic literature reviews to support product value propositions.
- Ensured 100% compliance with GPP3 and ICMJE guidelines across all projects.

Postdoctoral Research Fellow / Technical Writer | Mass General Research | Boston, MA
Jun 2015 - Jul 2017

- Wrote and edited grant proposals resulting in over $2M in NIH funding.
- Authored 8 peer-reviewed primary research articles in cellular biology.
- Managed the documentation for Institutional Review Board (IRB) approvals and protocol amendments.

EDUCATION

Harvard University | Doctor of Philosophy | Molecular Biology
Sep 2010 - May 2015

University of Michigan | Bachelor of Science | Biochemistry
Sep 2006 - May 2010

SKILLS

Clinical Study Reports (CSR), Investigator Brochures (IB), Module 2.7 Clinical Summary, Literature Reviews (SLR), Protocol Design, Pharmacovigilance Reporting, Cross-functional Collaboration, Attention to Detail, Time Management, Analytical Thinking, Peer Reviewing, Stakeholder Management, ICH-GCP Guidelines, AMA Style Manual, Veeva Vault, EndNote / Zotero, MedDRA Coding, GraphPad Prism

CERTIFICATIONS

Medical Writer Certified (MWC) | American Medical Writers Association (2019)
Essential Skills Certificate | AMWA (2017)

LANGUAGES

English (Native)
Spanish (Professional Working (C1))

ACTIVITIES

AMWA Chapter Member
Active contributor to the New England chapter of the American Medical Writers Association.

Journal Peer Reviewer
Ad hoc reviewer for the Journal of Biomedical Communication.