Grant Whitaker

SENIOR MEDICAL WRITER

Princeton, NJ
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Certificates

Regulatory Affairs Certification (RAC-Drugs)
Regulatory Affairs Professionals Society
09/2023

Skills

Clinical Study Reports
Investigator Brochures
Clinical Research
Document Management Systems
Veeva Vault • Adobe Acrobat
Microsoft Word • Excel
PowerPoint
Project Management Skills

Summary

Senior medical writer with 8 years of experience in clinical research for immunology and cardiovascular programs. Leads clinical study reports, investigator brochures and submission summaries, and manages files in document management systems such as Veeva Vault. Brings project management skills, analytical skills and strong presentation skills to cross-functional teams.

Experience

Senior Medical Writer 02/2022 - Present
Raritan Biotherapeutics Princeton, NJ
Mid-size biopharma company with 5 programs in Phase II-III.

- Lead writing of **14** clinical study reports and 4 investigator brochures across 2 programs.
- Author Module 2.5 and 2.7 summaries for a BLA submission accepted without writing queries.
- Negotiate timelines with biostatistics and clinical leads, delivering 95% of drafts on schedule.
- Mentor 3 medical writers on CSR structure, data review and comment resolution.
- Manage reviews in Veeva Vault and Adobe Acrobat, cutting comment cycles from 3 rounds to 2.

Medical Writer II 06/2019 - 01/2022
Garden State Clinical Services East Brunswick, NJ
Contract research organization specializing in cardiovascular trials.

- Wrote protocols and clinical study reports for 11 Phase I-III studies.
- Built Excel trackers of document status for 6 sponsors and their reviewers.
- Drafted annual safety reports and DSURs for 3 investigational products.
- Presented report timelines in PowerPoint at weekly sponsor calls.

Associate Medical Writer 07/2018 - 05/2019
Mercer Medical Communications Lawrenceville, NJ
Medical communications agency serving pharma clients.

- Prepared slide decks and abstracts for 12 congress presentations.
- Checked references and data in 30 manuscripts before client review.
- Wrote plain-language summaries of 8 published trials for patient advocacy groups.

Education

Doctor of Philosophy 05/2018
Rutgers University New Brunswick, NJ
Pharmacology