https://www.biolink360.com/job/lab-tech-operator-for-jon-2/

Senior Medical Writer-REMOTE

Hiring organization
BioLink 360

Employment Type
Full-time, Contractor

Industry
Medical Device/Pharma

Job Location
San Francisco, CA
Remote work from: Massachusetts

Date posted
June 4, 2022

Description

Job Category: Research & Development
Reports to: VP of Clinical Development
Job Type: Full time
Contract or Direct Hire
Location: REMOTE Based
Pay Rate: Depends on Experience
Company Type: Pharma, 600 Employees globally with HQ in Boston.
Product Category: Diagnostic imaging agents, Oncology Biopharma

The person in this role will provide a wide range of medical writing services for multiple ongoing R&D projects and programs. The main areas of responsibility include:
• Writes and edits pre-clinical and/or clinical reports, summarizing data from pre-clinical and/or clinical studies.
• Prepares clinical reports, summary documents, package inserts and other documents that may be submitted to the Food and Drug Administration and other regulatory agencies.
• Prepares scientific manuscripts, abstracts and posters.
• Supports clinical research associates and medical doctors in clinical protocol development.

Responsibilities

• Write and prepare clinical and regulatory documents including complex integrated clinical statistical reports, protocol synopses, protocols, protocols amendments, informed consent, annual reports, and investigators brochures.
• Actively participate in multiple ongoing projects and, or programs on clinical work teams that drive the pipeline products through the regulatory process.
• Lead the process of critical reviews of these documents and incorporating multiple reviews into successive drafts.
• Manage all medical writing activities associated with an individual study or product, collaborating across matrixed organizations. Coordinate and prioritize multiple projects in a fast-paced environment, aligning work activities to meet multiple competing project timelines.
• Manage and coordinate work with external medical writing and publication vendors.
• Maintain current knowledge of and ensure all functional work team activities are conducted in compliance with the full range of related internal and external systems, technology, regulatory requirements and related policies and procedures.

Qualifications

• BA/BS Degree in a scientific discipline
• 4-6 years of biopharmaceutical industry experience including 3 years of clinical and regulatory writing, in all phases of pre-clinical and clinical development and regulatory submissions and approvals