An exciting career in a fast growing industry with flexibility on worklife balance

With remote working

Manage your own time and schedule your hours

Join CLIN-r+ as a

TECHNICAL WRITER - BIOCOMPATIBILITY ASSESSMENT

The Role:

CLIN-r+ now has an exciting opportunity for a contractor Technical Writer to join our team. Are you a wizard at reviewing Biocompatibility tests and writing testing plans (BEP) to testing laboratories. Do you have experience in Medical device validations Or biocompatibility evaluations? Are your more than comfortable following ISO standards to create reports to show compliance? Do you desire working from home and setting your own hours? Then we want to speak to you.

The role is **fully remote** so the ideal candidate must have mastered remote working and have a home office set up that can deal with reviewing multiple documents. The role initially requires a minimum of 10 hours a week initial availability and as the contractor masters our workflow more hours can be allocated as you need.

This role will be in the Subject Matter Expert team primarily to support interesting MedTech, Invitro Diagnostic device projects. You'll work with subject matter experts and consultants with documentation, but the right candidate will also be an important part of the wider team and there is potential for further development.

Please state your availability on your application.

Essential Skills & Experience:

- 2+ years of experience within the medical device/pharma/cosmetics industry and knowledge of evaluation report regulatory requirements, evidence generation, and document creation

Or

- 3 - 5 year's industry experience in technical writing in the Laboratory industry or academia or in a related area such as life science, quality, regulatory, clinical research, or product support.

Suitable background

- Microbiologist or Scientist in a Bio-Lab. Ideally experience of GCMS.
- Regulatory Affairs background or Laboratory Scientist looking to step into this kind of position.
- Educated to degree level in a Chemistry, Toxicology, Pharmacology, or related subject.

Or

- Experience with FDA and international regulations, requirements and guidance associated with clinical regulatory document preparations, submissions and reporting preferred

Key Responsibilities:

- Reviewing ISO standards (10993 or 18562) and regulatory requirements (example FDA Docket Number: FDA-2013-D-0350) to formulate a biological evaluation plan and report structure to show conformity.
- Supporting medical device/pharma/cosmetic manufacturers, toxicology labs or toxicologist to write evaluation plans and reports.
- Strong technical writing skills
- Preparing, writing, editing, & reviewing regulatory documents.
- Knowledge & understanding of proposed and current global regulations & guidance & the ability to relay the impact of such regulations and guidance internally & with our team.
- Ensures documents are produced in accordance with procedures, internal and external guidelines.
- Knowledge of ISO 10993, 18562, FDA-2013-D-0350 or GSPR checklist.

No agency applications please.

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