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 - ENGINEERING VALIDATIONS

The Role:

CLIN-r+ now has an exciting opportunity for a contractor Technical Writer to join our team. Are you a wizard at writing testing protocols or validation reports. Do you have experience in Medical device validations? 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 availability and as the contractor masters our workflow more hours can be allocated as you need.

This role will be in the Subject expert team primarily supporting interesting MedTech, Invitro Diagnostic and Health Economic projects. You'll work with subject matter experts and consultants with documentation, but 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 industry and knowledge of evaluation report regulatory requirements, validation evidence generation, and document creation

Or

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

Or

- Microbiologist or Scientist in a Bio-Lab.
- Regulatory Affairs background or Laboratory Scientist looking to step into this kind of position.
- Educated to degree level in engineering, regulatory, pharmacology, biomedical engineering, or related subject.
- Ideally experience of CE marking validations.

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 and regulatory requirements to formulate a validation plan and report structure to show conformity.
- Supporting validations engineers and testing house to review/write/summarise validation plans and reports.
- Strong technical writing skills
- Preparing, writing, editing, and reviewing engineering validations and regulatory documents.
- Knowledge and understanding of proposed and current global regulations and guidance and the ability to relay the impact of such regulations and guidance internally and with our team.
- Ensures documents are produced in accordance with procedures, internal and external guidelines.
- Knowledge of ISO standards and conformity assessments (EU MDR, MDSAP and FDA) to CE mark.

No agency applications please.

CLIN R+