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

REGULATORY ASSISTANT

The Role:

CLIN-r+ now has an exciting opportunity for a contractor Regulatory Assistant to join our team. Are you a wizard at compiling gap assessment or Technical Documents (Dossier)? Is your super power to easily spot gaps in Technical Documents and knowing how to remediate them? 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.

This role will be in the Regulatory Affairs team primarily to supporting interesting MedTech and Invitro Diagnostic transitions to EU MDR/IVDR. 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 EU MDR regulatory requirements, GSPR checklist, Classification and conformity routres.

Or

- 3 - 5 year's industry experience in regulatory affaits in the healthcare industry or in a related area such as quality, regulatory, clinical research, or product support.
- Experience with FDA & international regulations, requirements & guidance associated with CE marking document preparations, submissions & reporting preferred.
- Action-Oriented, Approachability, Building Effective Teams, Business Acumen, Career Ambition, Composure, Courage (Managerial), Customer Focus, Decision Quality, Informing, Integrity & Trust, Interpersonal Savvy, Planning.
- Microsoft Office proficient with experience working within MS Teams.
- Background or experience in MedTech, Clinical Affairs or Regulatory Affairs would be beneficial.

Key Responsibilities:

- Do Gap analysis of clients existing files 510K, EU MDD/IVDD or TGA dossier to use towards EU MDR/IVDR.
- Draft the technical documents using our technical documentation templates.
- Transcribe the information from the current submission documents to the appropriate sections of the new technical document.
- Review individual document content relative to current practice.
- Identify any additional gaps in coverage of the EU MDR requirements and communicate with the responsible teams the remediation needed.
- Know submissions process and advise on this.
- Be able to respond to NB questions and deficiencies, and the client responses.

No agency applications please.