### ele<del>\/</del>ed



Amsterdam, Netherlands

Are you passionate about user-centric solutions? Do you thrive in a dynamic and fast-paced environment? Are you an expert in CER writing or clinical affairs? If yes, we have a great opportunity for you!

Come and join the leading experts developing, manufacturing and delivering self-care medical devices. This company is focused on innovating and developing new solutions to safely empower their users in self-care treatment and prevention. You'll enjoy a flat hierarchy (no top down management here!) where you will have the freedom to stretch beyond your job description, work collaboratively across the business and develop new skills whilst honing your existing ones. Although this company is not a political and large corporation, they provide their products to some of the biggest and best pharmaceutical brands in the world.

# THE OPPORTUNITY

You will have the opportunity to join the team as a Clinical Specialist/CER Writer where you will have autonomy and directly impact the products from a clinical perspective. As well as writing CERs, you will also be responsible for defining clinical strategy, writing clinical protocols and also overseeing the clinical trials. With the Medical Device Regulation in full force, you will ensure that all reports and data (existing & new) are kept compliant with the relevant regulations and highlight important information in cross-functional meetings. This is also an opportunity to experience new and exciting markets as the company continues to expand globally.

### ele<del>\/</del>ed



#### YOUR RESPONSIBILITIES:

- Develop and review documents, presentations and processes specific to the study and create study reports for the clinical parts of regulatory submissions
- Coordinate cross functional teams and liaise with CROs throughout clinical trials in order to ensure alignment and compliance to the company's goals and necessary regulations
- Prepare, organise and interpret clinical data
- Develop and guide clinical strategy for the company for various projects as they arise
- Manage relevant timelines required by the internal teams and external bodies from a clinical perspective
- Write CERs, clinical protocols, clinical data reports and more





### YOUR QUALIFICATIONS:

- 4+ years experience writing CERs OR clinical strategy for studies in the medical device, pharmaceutical or other **relevant** industry
- Minimum Master's degree or equivalent in science or health related field
- Fluent speaking, reading and writing in English

## Interested in further conversation?

Please send your CV to <u>kristina@elemed.eu</u> to arrange a confidential career discussion.







