OFERTA DE EMPLEO

QA/RA Consultant MD/IVD and MDSW

Asuntos regulatorios, calidad y evaluación clínica · 1 vacante · Teletrabajo 100%

About CMG MedDev

CMG MedDev is a consulting company in regulatory, quality and clinical evaluation for medical devices, in virtro diagnostics and medical software.

What are we looking for?

Weare looking for senior specialist in MD/ IVD/MDSW/ MDAI (**please only people based in SPAIN) with m**ore than **6 years of experience**, as part of manufacturer or consultancy company

(***Please don´t submmit the applcation if you do not meet this requirement.***
If you have less than 6 years of experience with QMS and TD, please do not apply for this position. Thank you.)

· With demonstrable knowledge and experience in the following areas: ISO 13485, IEC 62304, ISO 62366, ISO 14971, development and implementation of QMS, TD and MDSW specific documents.
· With demonstrable knowledge and experience in MDR 2017/745 IVDR 2017/746, valuable in FDA
· Experience to develop CEP, CDP , CER, PEP , PER, PMPF and PMCF
· Knowledge of preparing applications for approval of clinical studies and research to the AEMPS
· Knowledge in the preclinical area, such as biocompatibility, EMC safety, or analytical performance will be valued
· Experience in literature searches and in guiding teams in their execution must be demonstrated

What we offer
Permanent contract, salary according to the employee's skills and competence and the requirements of the position.
· Team attendance at congresses and learning forums.
· Continuous training.
· Workingin an organization of 10 employees, close, with direct relationship with the CEO, a person of recognized prestige and knowledge in the sector; and working in a team.
· 100% remote working mode. The company provides you with the necessary tools for its development. (only puntual travel)
· Pleasant working environment.

Responsibilities

Be autonomous in the leadership and execution of projects to obtain CE marking of products and to define regulatory strategies.
· Report weekly to your superior on the progress of the projects.
· Suuport team about CE mark doubst and spcecific requirements for product
· Establishthe most suitable regulatory strategy for the customer.
· Developmentof the customer's QMS documents and support in their implementation.
· Development TD of the product.
· Interactions with NB.

· Periodic meetings with client for the progress of each project and for the resolution of doubts or explanation of concepts.
· Developmentof presentations for congresses.
· Internal and external Training

Do you like what we propose?
Do you want to be part of this selection process?

Send us your CV to the following emails

- carmen.martin@cmgmeddev.com
- luisfe.burrieza@cmgmeddev.com