

## Medical Writer Expert – Regulatory Affairs

We are looking for a Medical Writer Expert– Regulatory Affairs for our team of development, strategy and scientific writing expert unit. Someone who loves Science and wants to use their experience in a new challenging professional step.

### Main responsibilities:

The Medical Writer will be in charge of the timely and correct execution of projects according to defined timelines:

- Writing regulatory documents to support drug development (SA, PIP, ODD, IMPD, IB)
- Writing eCTD Dossier clinical/nonclinical documents (M2)
- Design of regulatory roadmaps
- Regulatory strategy for MAA
- Client and partner management: define milestones, planning and execution of tasks, manage timelines, project reporting
- Liaison with health authorities for drug development procedures
- Submission and management of applications through portals (CTIS, IRIS, ...)

### Requirements:

Educational Background: Scientific/biomedical background

Experience: Minimum of 5-7 years in a similar role working in regulatory writing in pharma sector, or spin-off /start up

Skills and Competencies:

Strong knowledge of regulatory affairs.

Excellent client-oriented communication skills and proactive mindset.

Advanced proficiency in IT tools (MS Office Suite).

Languages: Fluency in English (C1 or higher) is mandatory; Spanish is a significant advantage.

### Why working at Asphalion?



Permanent contract.



Flexible working schedule - Friday until 15.30h.



Homeoffice & Hybrid or Remote Model **(You can be located anywhere in Spain!)**



Wide variety of projects, new challenges and experiences.



Training and personal development program.



English lessons.



A professional, inclusive and high-performance work environment to develop your skills and grow your career. A great company culture built around Passion, Flexibility, Commitment, Quality & Companionship.



A highly & dynamic working environment with employees from more than 15 nationalities.



Our people and their well-being are our priority: Physical, psychological and emotional well-being programme.



Internal activities & RSC Activities



Equal Opportunity Employer