

infarAMA, founded in 2008 through a merge of Infarmed and RA-MAnagement, is a Contract Research Organisation active in regulatory affairs, quality assurance and translations all over the world and for a broad range of products.

We are currently looking for a (m/f):

REGULATORY AFFAIRS OFFICER

Job description

- Review of and scientific support for registration dossiers.
- Creation, verification and adaptation of product information.
- Management of DCP/MRP procedures (full responsibility both for RMS and CMS).
- Electronic submission (NeeS/eCTD) of registration dossiers and their updates (renewals/PSUR cycles) or variations.
- Life cycle management for the client portfolios (follow-up dossier, correspondence with authorities and manufacturers, approvals).

Required Profile

- Scientific degree (pharmacist or biomedical science or equivalent by experience) - official recognitions (QP/PV/RIP) are an asset.
- 1 to 3 years experience in a comparable function in pharmaceutical industry.
- Detailed knowledge of the rules governing medicinal products in the European Union.
- Strong knowledge of current software;
- Outstanding personal and communication skills (verbal and written), ideally trilingual (NL/FR/EN), knowledge of other languages is an asset
- Able to function within a quickly changing working environment with a high stress level and continuous time pressure.
- No reluctance to travel on an occasional basis.

At infarAMA we provide a dynamic and supportive working environment and a range of development challenges and opportunities. We also offer competitive benefits and compensation packages.

Contact

Contact the office manager by email office.manager@infarama.be or by phone 011/31 26 16.