

**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):

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### **REGULATORY AFFAIRS MANAGER**

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The RA Manager will take a key responsibility within the organisation, effectively managing the RA function of the business, implementing the regulatory objectives of the business and responding to legislative change.

#### **Key responsibilities**

- Take the lead in CP/DCP/MRP/NP registration procedures.
- Ensure regulatory maintenance and compliance for assigned products/portfolio of clients, pharmaceutical companies.
- Establish, maintain and develop the expertise domains (regulatory affairs, pharmacovigilance, medical information and quality assurance) to enable products, services, strategies and policies to meet required standards.
- Lead and manage the RA Officers team.

#### **Required profile**

- Scientific degree (pharmacist or biomedical science or equivalent by experience) - official recognitions (QP/PV/RIP) are an asset.
- Detailed knowledge of the rules governing medicinal products in the European Union (regulatory affairs, pharmacovigilance, medical information and quality assurance).
- Proven experience in a comparable function in the pharmaceutical industry.
- Exceptional interpersonal and communication skills, ideally trilingual (NL/FR/EN), knowledge of other languages is an asset.
- Strong knowledge of current software.
- Able to function within a quickly changing working environment with a high stress level and continuous time pressure.

***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**

Please contact our Office Manager by mail at [office.manager@infarama.be](mailto:office.manager@infarama.be) or by phone 011/31 26 16, Stationsstraat 27, B-3570 Alken, BELGIUM.