PhaRA

PHARMACEUTICAL REGULATORY AFFAIRS

Join our team if you have
an eye for detail
an ear for understanding client needs
a sense for urgency
a heart and talent for regulatory affairs

Vacancy

Regulatory Affairs Manager Benelux

(more than 2 years of experience)

About us

PhaRA is a leading consultancy firm in EU Regulatory Affairs located in the Benelux. Focusing exclusively on regulatory affairs, PhaRA offers in-depth expertise and skills covering a broad range of RA activities throughout product development and life cycle for chemical entities and biologicals. PhaRA is the content provider of Clarivate's Belgian RA related documents. Established in 2002, our renowned PhaRA team has an impressive track record of successful registrations and projects. Our consultants highly value the broad range of roles and projects they can take on, as well as the variable client settings in which they can operate. Talent development and know-how sharing is at the heart of our strategy, acknowledging needs for personal flexibility and ambitions.

For more information, visit www.phara.eu.

We are seeking to strengthen our team with an enthusiastic, motivated, hands-on Regulatory Affairs Manager with more than 2 years of experience in RA at Benelux level.

Your job

Depending on your level of experience, you will, for our clients:

- Manage a product or portfolio and interact with national competent authorities on regulatory submissions in Benelux countries.
- Advise the European regulatory affairs groups on local regulatory intelligence information and contribute as appropriate to the European regulatory strategies.
- Interact with colleagues from European headquarters at client companies with regards to the collection of information necessary for submissions and address questions from competent authorities.
- Be responsible for the preparation, submission and follow-up of marketing authorization applications, variations, risk minimisation activities (RMA), compassionate use (CU) and medical need programs (MNP), in line with national Benelux regulatory requirements, scientific principles, and company policies and procedures.
- Contribute to regulatory affairs project planning and co-ordination as well as to product information (labelling) activities.
- Assess material for publicity and information purposes in the Benelux territories.
- Contribute to the maintenance of quality systems and SOP writing.

In a nutshell, you continuously develop your RA experience, live your passion in RA, and strive to become an RA expert with keen interest in Benelux RA. Consultancy allows you to deal with a large variety of projects and to learn quickly.

Your background

- Master in pharmaceutical sciences or equivalent with a few years (min. 2) of industry experience in Regulatory Affairs in a pharma or biotech environment.
- Qualification as a Responsible Person for Information and Publicity (RIP) is an asset.
- Proficient oral and written Dutch, French and English language skills; German is a plus.

Your strengths and mindset

- A highly motivated, dynamic person and team player who can operate in a flexible and often virtual working environment.
- Accurate, proactive, reliable, hands-on, and quality output driven.
- Proven ability to maintain product portfolio overview, meet deadlines and set priorities.
- Clear and effective written and oral communication skills.
- A pleasant personality with effective interpersonal skills.
- Ability to foster relationships with internal and external stakeholders (such as RA colleagues, medical affairs, commercial, market access, supply, pharmacovigilance, and competent authorities).
- Diligent to work in compliance with regulatory legislation and Quality Assurance systems.
- Ability to adapt to different client company cultures and customer-minded attitude.

Our offer

- You are part of a young, diverse and unique team with an informal culture where expertise sharing is paramount.
- A competitive salary and extra benefits.
- A varied job where you can take on different kind of projects in a broad range of therapeutic areas and procedures (national, MRP/DCP, CP).
- A clear commitment to invest in expanding your knowledge and personal growth.

Working conditions

The PhaRA office is located in Antwerp, Belgium. Excellent accessibility by public transport (literally 5 minutes' walk from Antwerp Central Station).

To us, working from home was common before covid-19 and we are fully equipped to continue to do so. We nevertheless believe in the benefits of real-life contact and face-to-face knowledge-sharing, learning and mentoring. Of course, respecting all necessary precautions and government instructions comes first.

Normally, your job requires regular commutes to clients and/or partially working from a client's premise.

APPLY HERE

LOVE, LIVE AND BREATHE REGULATORY AFFAIRS