Belgium Jobs Expertini®

SR Associate Regulatory Affairs

Apply Now

Company: House of Talents

Location: Brussels

Category: other-general

Introduction

For our client in Zaventem we are looking for a SR. Associate Regulatory Affairs s who will
provide regulatory guidance and support for regional and global veterinary biological maintenance teams and
development project teams.

Job description

The Sr Associate Regulatory Affairs will first start supporting product-maintenance activities (such as renewals,
manufacturing-related variations and geographical expansions) and then progressively help/support
development projects (new claims, new products); ultimately, the person will help ensuring that these products
are developed, registered, and maintained in full compliance with EU, non-EU European, and/or relevant AfME
national competent authority requirements.

This person will liaise closely with other Zaventem regulatory and clinical staff to facilitate these activities consistent
with the manufacturing plans, company operating plan and project portfolio. The candidate will also liaise with
EUAfME, CLAR and APAC regulatory staff to support other global registration and

product maintenance
activities where appropriate.
The candidate will liaise with VMRA Regulatory Chemistry Manufacturing and Control (CMC), Laboratory Sciences, Global Biological Research, Global Therapeutic Research, Commercial
Development, Global Manufacturing, Project Management, and other partner groups to drive regulatory
activities consistent with approved Company objectives.

Key responsibilities:

Assemble renewal and variation dossiers for biological veterinary products and coordinate/support subsequent responses to Authority questions. Liaise directly with licensing authorities as needed to achieve objectives.

Help assemble new authorization dossiers and help coordinate/support responses to Authority questions.

Provide regulatory support for geographic expansion, especially in those cases where geographic expansion activities are concurrent with EU authorisation activities.

Serve as regulatory representative on assigned teams responsible for maintaining and geographically expanding veterinary biological products.

Help develop and implement the regulatory strategy for assigned teams, with guidance and mentoring from the manager of the biological team.

Help provide regulatory support and advice regarding Global Manufacturing initiatives and Commercial market enhancements.

Help liaise with US and CLAR/APAC regulatory staff to facilitate global registration activities where appropriate.

Profile

A Master of Science (MS) or similar advanced degree in biology or other related science (Pharmacology, Microbiology, Veterinary Science, etc.). A PhD in a relevant discipline or a Veterinary Medicinal Doctor degree is an asset, but not mandatory.

A minimum of 3 years of practical experience with veterinary medicinal products (VMPs) or

human medicines, preferably in regulatory affairs, compliance, or a related area.

General understanding of EU (and/or national) legislation applicable to marketing authorization of VMPs or human medicines, as well as EU (and/or national) regulatory bodies and authorization processes.

General understanding of the veterinary or human medicinal product development process, including early and late-stage development activities.

Knowledge in the production and testing of biological veterinary/human medicinal products is an asset, especially in terms of CMC section requirements and assembly.

A strong work ethic. Well-developed verbal and written communication skills, and a demonstrated ability to multi-task and work in a team environment

Offer

Depending on your experience you can count on a competitive salary complemented by a comprehensive package of fringe benefits. You are allowed to work two days a week from home.

Apply Now

11. **SR Associate Regulatory Affairs Phoenixjobs Jobs Brussels Phoenixjobs ↗**
12. **SR Associate Regulatory Affairs Christmasjobs Jobs Brussels Christmasjobs ↗**
13. **SR Associate Regulatory Affairs Statisticsjobs Jobs Brussels Statisticsjobs ↗**
14. **SR Associate Regulatory Affairs Jobspro Jobs Brussels Jobspro ↗**
15. **SR Associate Regulatory Affairs Nyjobscareer Jobs Brussels Nyjobscareer ↗**
16. **SR Associate Regulatory Affairs Searcheuropeanjobs Jobs Brussels Searcheuropeanjobs ↗**
17. **SR Associate Regulatory Affairs Findfulltimejobs Jobs Brussels Findfulltimejobs ↗**
18. **SR Associate Regulatory Affairs Nzjobs Jobs Brussels Nzjobs ↗**
19. **Sr associate regulatory affairs Jobs Brussels ↗**
20. **AMP Version of Sr associate regulatory affairs ↗**
21. **Sr associate regulatory affairs Brussels Jobs ↗**
22. **Sr associate regulatory affairs Jobs Brussels ↗**
23. **Sr associate regulatory affairs Job Search ↗**
24. **Sr associate regulatory affairs Search ↗**
25. **Sr associate regulatory affairs Find Jobs ↗**