Belgium Jobs Expertini®

Regulatory Affairs Specialist – ATMP

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Company: Regulatory affairs

Location: Antwerp

Category: other-general

QbD

Belgium

Regulatory affairs

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At QbD our RA Services go from regulatory strategy, clinical, CTD registration dossier writing, eCTD compilation and submission to competent authorities to Vigilance. We support from idea to commercialization. Do you want to ensure the organization's compliance with the regulations and laws regarding ATMP's? Do you want to guide them through complex regulatory requirements and guidelines? This all in an efficient and pragmatic way? Then apply now and maybe soon you will be part of our **RA Division** !

What do we expect from you as a Regulatory Affairs Specialist – ATMP?

You guarantee that the regulatory requirements regarding**(inter)national regulation and international standards** are met.

You keep track of the**ever-changing regulation** in all the regions in which a company wishes to develop, manufacture, register and distribute its products and evaluate the impact on the business.

You align the operation of the departments with the realization of approved strategy, objectives and budget.

You advice the clients to obtain and maintain a marketing authorization for their products.

You **provide regulatory advice to project teams** to ensure continued regulatory compliance from the early development phase till the registration of the medicinal product and post approval changes on non-clinical and quality related aspects of drug development and manufacturing in collaboration clinical experts.

You advise on the regulatory and scientific restraints and requirements, while collecting and evaluating scientific data.

As CMC writer, you generate the quality related sections of the IMPD/IND and/or MAA/NDA/BLA.

Ensure that the content of non-clinical documents is appropriate, meets regulatory expectations and enables approval of regulatory submissions

You supervise the exchange and presentation of the registration documents to Notify Body or competent authority.

Prepare briefing packages for agency meetings (scientific advice, oral explanation, EoP2) and conduct such meetings together with the client

You work with **supra-national/international, national, and local regulatory agencies** (FAGG and EMA or FDA).

You **train** people on ATMP regulation and all its related aspects such as submission procedures.

Who are we looking for?

You hold a **master's degree in a scientific discipline** (Pharmaceutical Sciences, Biotechnology, Biomedical Sciences, Biomedical Engineering, Biochemical Engineering…) with **2-3 years** of experience in **regulatory affairs and/or CMC writing and/or non-clinical development activities** related to **ATMPs**

You have a good understanding and interpretation of the **regulation for ATMP**( ) and ATMP Classification (and Part IV of Annex I to),), GMP requirements for Advanced Therapy Medicinal Products (Eudralex GMP part IV) and the technical standard applicable to ATMP (Guideline on the minimum quality and non-clinical data for certification of ATMPs)

You have experience in the preparation of regulatory documentation related to CTA, MAA, IND, BLA/NDA, more specific with regulatory CMC writing and knowledge of in non-clinical and regulatory requirements for all stages of ATMP drug development from pre-clinical to Phase III or commercial. You have knowledge of the relevant national and international legislation, procedural regulations and technical regulations.

As a consultant you feel comfortable taking care of the early stage considerations and the development of regulatory plans.

You are a skilled CMC writer, developing compliant Module 3 with appropriate level of detail to ensure that the content of CMC work-packages and documentation are phase appropriate, meet regulatory expectations and enable approval of regulatory submissions

A **true QbD'er** can be recognised by the following qualities: **Resilient**: Your strong and positive attitude helps you overcome any challenge. **Hungry for knowledge**: You are always open to learning. **No BS mentality**: You can be straightforward in a respectful way. **Innovative**: You are constantly looking for new and better solutions. **(Not too) serious**: your job is serious, but you don't take yourself too serious.

What does QbD Group offer you?

An attractive and complete salary package:

A monthly wage, car, fuel card, (super fast) bicycle, insurance package, meal vouchers, etc.

But most of all…

We offer **sustainable careers** and **meaningful connections**

We are a **knowledge-based** company

You'll work for an **award-winning** company: Best Managed Company (Deloitte award), Baanbrekende Werkgever, …

Our promise to you:

As an **ambitious and pioneering company**, we want to offer you the **best possible environment to thrive** within the life sciences.

Moreover, we aim to create a **joyful community** where you dare to be and can be yourself.

Because the best way to grow is by **growing together as unique individuals**.

In short … We stand for **JPEG J** oy in **P** artnership, going for **E**he xtra mile to **G** et things done!

Interested?

Send us your CV and motivation letter and who knows, we might welcome you soon in our QbD family!

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