Belgium Jobs Expertini®

Regulatory Affairs Specialist – Medical Devices

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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, technical file to Vigilance. We support from idea to commercialization. Do you want to support companies throughout the entire medical device regulatory lifecycle? Do you want to guide them through complex regulatory requirements? 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 – Medical Devices?

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 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 manufacturers to obtain and maintain a marketing authorization for their products.

You **provide regulatory advice to project teams** to ensure continued regulatory compliance and timely market release.

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

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

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

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

You **offer support during product launch** : reviewing marketing materials, product registration … After launch you are involved in post market surveillance tasks and handling of adverse events by assuming the PRRC role.

Who are we looking for?

You have a **master's degree in a scientific discipline** (Biomedical Sciences, Biomedical Engineering, Biochemical Engineering…) with **2-3 years** of experience in **regulatory affairs** related to **medical devices**

You have knowledge of **regulation for Medical Devices** (21 CFR 820 & EU MDR), **quality management system** (ISO 13485), technical standard applicable to medical devices and **software used for Medical Devices** (IEC 62304)

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.

A **true QbD'er** can be recognized 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 seriously.

What does QbD 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** : Joy in Partnership, going for the Extra mile to Get 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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