

## REGULATORY AFFAIRS OFFICER – LIFE SCIENCES

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Company: TMC

Location: Belgium

Category: other-general

You manage the regulatory activities for a diverse range of products, including but not limited to: prepare, submit and follow-up regulatory submissions (BLA, CTD, NDA,...), assess post-approval changes, manage responses to the Board of Health, review of packaging/inserts...

You collaborate closely with the Regulatory Affairs team and other departments.

You act as the primary liaison with regulatory authorities and notified bodies.

You act as a point of contact for regulatory audits, inspections and related processes.

You are responsible for the regulatory impact assessment of changes and their implementation.

You provide regulatory guidance for Research and Development (R&D) projects.

### **| What do we expect from you?**

You have a Master's degree in Life Sciences.

Experience with CMC is a plus.

Relevant experience within Regulatory Affairs management and regulatory submissions is a plus.

You have an eye for detail.

You have strong communication, writing and organization skills.

Fluent in Dutch and English

### **| What can you expect from TMC?**

TMC is an international high-tech consultancy company that brings expertise to its clients in order to support them with the realization of their technological challenges. As such, TMC is operating as an expert center at the disposition of its clients and we help them to be more competitive in an ever more global and faster changing technological world.

At TMC we believe that people are the driving force behind technological innovation. That is why we want to create the best possible conditions for tech talents to thrive in. We offer you a challenging and stimulating work environment in which you can be the director of your own career.

As an Employeneur you are part of our TMC family. Next to our outstanding technical expertise, fun and engagement are meaningful parts of our culture.

### **| Why choose for Employeneurship?**

We are truly unique thanks to our Employeneurship model which is a true innovation for the High Technology consulting business. It is the business relationship of the 21st century for high skilled technical professionals. It is built around 5 main pillars:

You will have a permanent employment contract, offering you stability and security

You will get to know your market value and have a share in the profit your work generates thanks to the individual profit sharing

We will support you with one-on-one coaching and training designed to help you develop your entrepreneurial skills

The competence cells structure provides you with a strong meaningful and relevant network

The entrepreneurial lab: a playground for new ideas and a potential launching for start-ups

TMC is an equal opportunity employer and values diversity. We do not discriminate on the basis of race, religion, color, national origin, gender, sexual orientation, age, marital status, veteran status, or disability status.

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