

The Central Afdeling voor Fractioniering / Département Central de Fractionnement bvba-sprl (CAF-DCF bvba-sprl) is a Belgian biopharmaceutical company specialized in commercializing medicines derived from blood plasma. The company belongs to a French biopharmaceutical group ranked among top players in Europe in its field. State-of-the-art medicines proposed by the company to hospitals in Belgium are covering fields like intensive-care as well as hemophilia and auto-immune diseases. Main office of the company is located in Brussels. For its activities in Belgium, the company is currently looking for a (m/f):

**Regulatory Affairs Officer - Part-time (50% of a FTE)**  
**Accuracy – Quality oriented – Problem solving – Procedure/process focus**

**Main tasks and responsibilities:**

- You will prepare license submissions & variations
- You are involved in labelling activities (creation of new labeling, follow-up of changes, alignment with existing regulations)
- You will support the Responsible person for pharmaceutical information to ensure compliance of promotional material with applicable laws & guidelines
- You will act as a Deputy Safety Officer for Vigilance activities/handling of PV data
- You will manage internal & external queries
- You manage internal and external queries on a daily basis
- You help the Regulatory Affairs Manager in the completion of RA administrative tasks
- You provide assistance in preparing Module 1 documents (Cover letter, Application Form, SPC, PIL, Labelling)
- You request and track submission related documents (in particular GMP Certificates)
- You contribute in the life-cycle management of registered products.

**Profile:**

- Master in pharmaceutical sciences or a university background in life sciences with relevant working experience.
- You acquired at least 2 years practical experience with Regulatory Affairs.
- You are analytical by nature, set priorities quickly, and have the sense of planning and organization.
- You show flexibility to work in a changing and complex environment.
- You are able to work independently and demonstrate good interpersonal skills.
- You report quickly and accurately (oral and written) in English, Dutch and French.
- You have a strong interest in IT environment and conversant with MS Office applications as well as validated systems.

**Offer:**

This position will provide the possibility to work autonomously within RA, a changing and positive work environment, tools and support to grow your career, plenty of opportunities to develop your skills, a competitive benefits package and facilities.

Report to: RA Manager                      Interactions: all departments of the company

**Please send your application (Resume + cover letter) at [recrutement@lfb.fr](mailto:recrutement@lfb.fr)**