Novellas Healthcare
Qualified people. Better results.

Being a specialist in international healthcare recruitment, Novellas Healthcare offers plenty of possibilities to **develop your career in the healthcare industry** and to grow personally and professionally. Do you want to take the next step in your healthcare career? Then check our our newest **Regulatory vacancies** below!

Pharmaceutical Affairs Manager - Flanders Area

Our client is an international pharmaceutical company active in Specialty/Critical Care with interesting Bio Similars products.

- You assume the end responsibility for registrations, licenses and patient leaflets to guarantee continuity of the products in the market
- You play a supporting role in the analysis of the business development opportunities, explicitly based on your knowledge of pricing and reimbursement procedures

- You have a Master in Pharmaceutical Sciences, and a specialization as Industrial Pharmacist
- You are certified as Qualified Person
- You have a first relevant experience within the pharmaceutical industry and in regulatory affairs role
- You are fluent in Dutch/English/French

Benelux Regulatory Manager - Diabetes - Benelux Area

- Manage legal / RA questions concerning the products
- Manage questions from local health authorities
- Manage product documentation
- Lead public procurement processes
- Advising role concerning strategies and regulatory requirement
- Review advertising and promotional materials for regulatory compliance
- Strengthen Regulatory Affairs in the DNA of the organization

- Master's degree in Science preferably in Life Sciences or Regulatory Affairs or Master's degree in Law
- Trilingual: Dutch, French, English
- Experience in the pharmaceutical, biopharmaceutical, medical, or similar industries is preferred (preferably medical devices: IVDs)
- 5 years of exposure to governmental regulations, HTA processes, compliance initiatives, value dossier submission

Regulatory Affairs Manager - Medical Devices – Benelux

- You ensure the application and compliance regulations relating to Medical Devices and Pharmaceutical Products distributed in the Benelux
- You guarantee the implementation of the regulatory measures relating to Medical Devices and Pharmaceutical Products
- You endorse the role of Responsible Person for the distribution and promotion of pharmaceutical products in Belgium
- Ensure product monitoring and follow-up complaints Processing processes related to product quality with Benelux production units including materio / pharmaco vigilance, recalls and FSCA activities etc
- Supporting customer disputes with the lawyers, and other relevant internal and external departments
- Ensure regulatory and normative surveillance in connection with Belgian medical device regulation
- Being represent for the Quality Management system in Belgium

- Master in Pharmacy
- Minimum 5 years experience in a similar position in the field of medical devices
- Knowledge of the regulations regarding medical devices + a basic knowledge of regulations in pharmaceutical products
- Knowledge on Material Vigilance / Pharmacovigilance
- Bilingual NL/FR with a professional proficiency of English (reading, writing, speaking)

More info? Check out our website http://www.novellashealthcare.com or contact us at 02/456 00 00.