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Regulatory Affairs Expert/Specialist/Lead (European based)

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Company: Univercells

Location: Charleroi

Category: other-general

RESPONSIBILITIES

- Guidance to 2-3 customers on the regulatory requirements for approval of a first in human clinical study
- Writing of the IMPD and IB and submission of the clinical trial application packages in close collaboration with the customers and medicine agencies.
- Writing, submission, follow-up of Orphan Designation requests to the EMA and the FDA
- Writing, submission, follow-up of scientific advices/interact meetings requests to EMA and FDA

REQUIREMENTS:

- Master/PhD in Biology/Bio-Medical Sciences/Chemistry or Industry Pharmacist or Bioengineer.
- Well-organized, flexible, rigorous, dedicated. Team spirit.
- Fluency in English (oral, written); a good command in French and other European languages are a plus.
- Ideally a minimum 2 years in regulatory guidance and dossier writing in pre-marketing medicinal product development.

OUR OFFER:

We offer a long-term contract (CDI), a competitive salary package and the possibility of evolution in an international, dynamic, and fast-growing company.

Is it appealing to you? Are you a powerful thinker combined with an efficient doer? Apply now !

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