

## Regulatory Affairs Manager

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Company: Univercells

Location: Charleroi

Category: other-general

### RESPONSIBILITIES

- Guidance to some customers on the regulatory requirements
- Writing, preparation of dossier for regulatory submissions like ANDA, Type B/C, BLA, Breakthrough Designation, Interact/fastrack,...
- Writing and submission of the pre-IND and/or IND, in close collaboration with the customers and FDA.
- Writing, submission, follow-up of Orphan Designation (ODD) requests to the FDA
- Writing, submission, follow-up of briefing documents/interact meetings requests to FDA
- Liaise and negotiate with global authorities or FDA authorities

### 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). Any other languages are a plus.
- Ideally a minimum 5 years in regulatory guidance and dossier writing in pre-marketing medicinal product development.
- Very strong know-how of FDA requirement and legislation.

### OUR OFFER:

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

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