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Job offers

(July 2021)

Drug Development and Regulation (DDR, www.ddrmedic.com) is a company providing strategic and operational, independent and global consulting services focused on Drugs and Medical Device Development and Regulation in both EU and US. DDR works across all drug development fields –Quality, Nonclinical, Clinical and Regulatory– and support products both in pre- and post-authorization.

DDR is located in Barcelona, London and Amsterdam and the positions will be located either at any of our offices or can be home/remote based

DDR has currently open positions (preferably full-time) for

1. Director Regulatory
2. Regulatory Officers for Drugs or Medical Devices
3. Project Manager

Regulatory Officers for Drugs will be assigned to the Drugs Department and Regulatory Officers for Medical Devices will be assigned to the Medical Device Department. They will work within functional teams for each project.

Please check job offers at:
https://www.ddrmedic.com/careers/

Applicants should submit a curriculum vitae and a motivation letter to: info@ddrmedic.com before September 10th 2021
(email subject should include "Job offer application" + name of the position).

Regulatory Officers

Experience in international drugs and/or medical device, In Vitro Diagnostic development and regulatory processes.

The responsibilities will be:

- Managing, supervising and executing projects if assigned as Project Team Leader (PTL)
- Provide support to the PTL when assigned as Project Team Manager
- Activities related to the assigned projects including but not limited to:
  - Search of bibliography and databases
  - Analysis of data
  - Writing reports and other documents
  - Conducting strategic reports (i.e. gap analysis, road maps)
  - Prepare presentations
  - Manage operational interactions with regulatory authorities
  - Other to be defined on a project-by-project basis
- Interacting with clients
- Ensure high quality documents from the content, formatting and English point of view
- Provide weekly detailed progress reports
- Identify problems and propose solutions and contribute to internal brainstorming sessions regarding ongoing projects and organization
- Contribute to internal training sessions
- Interact with the Project Manager
- Contribute to the work of the Business Development Manager
- Report to the Director Regulatory

It is requested:

- BS/MS degree or similar in human health related discipline
- Experience in drug and/or medical devices development and international regulatory processes
- Expertise on Quality, Nonclinical and/or Clinical drug/medical device/In Vitro Diagnostic development
- Work effectively and productively
- Strong interpersonal, communication and presentation skills
- Very high sense of integrity and confidentiality
- Excellent written and verbal communication skills in English
- Comply with all corporate governance requirements
- Able to get fully integrated in a dynamic, up to dated and intellectually challenging team

- Previous experience in regulatory procedures at the EMA and/or FDA and/or any of the Member States' regulatory agencies is a plus for drugs and at Notify Bodies for medical devices and/or In Vitro Diagnostics

What we offer:

- Preferably full-time contract and permanent position, but option for part-time
- Salary according to experience
- Access to training programs
- Potential additional advantages according to performance
- Be part of an international and highly competitive team, mainly focused on innovative projects of pharma, biotechnology and/or medical devices companies, where >80% of them are from international locations