GlyCardial Diagnostics	Human resources	
Job offer 2019/02	rrhh@glycardial.com	93 4020259

About us

GlyCardial Diagnostics is a spin-off company of the IR-Hospital de la Santa Creu i Sant Pau and the Spanish National Research Council (CSIC) focused on the development of a novel in vitro diagnostic device (IVD) for myocardial ischemia. The technology is based on the detection of Apo J-Glyc in blood as a biomarker for the early diagnosis of cardiac ischemia and the prediction of patient's evolution after an ischemic event.

The company was incorporated in September 2017, closed its first funding round of 2.4M€ in October 2017 and has recently received 1.9M€ from the SME Instrument H2020 funding program.

We are a small company willing to incorporate enthusiastic professionals that aim to be part of a disruptive project and to develop together with the company.

Job offer description

We are looking for an expert in Regulatory affairs and Quality assurance to design, implement and oversee the regulatory roadmap and the quality management system needed at each stage within the company.

Job requirements

Education

- University degree in Health Sciences
- MSc in RAQA (Regulatory Affairs and Quality Assurance)

Knowledge

- Good knowledge of international IVD regulations (including EU directive and regulation and US regulation), of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP)
- Computer skills: Office, database management
- High English level (demonstrable)

Experience

- Up to 3 years of previous related experience in IVD development and biomarker validation studies

Competences

- High level of commitment and working capacity
- Methodical and organised
- Attention to detail and good problem-solving skills
- High planning and scheduling skills
- Ability to work under tight deadlines
- Ability to manage confidential information with discretion
- Ability to interact professionally with all organizational levels
- High communication and team working skills
- Highly motivated and proactive

Key Duties

- Design an appropriate regulatory roadmap matching the overall company strategy.
- Oversee the implementation of the regulatory roadmap.
- Lead and support all the regulatory activities throughout the development of the product (Briefing Document for Scientific Advise, FDA pre-submission).
- Preparation, management and coordination of the regulatory documentation.
- When applicable, prepare, submit and maintain CE mark dossiers (technical file and clinical reporting) and FDA dossiers.
- Be the contact person with the regulatory agencies within the company.
- Design and oversee an appropriate quality management system within the company in compliance with the applicable requirements at each stage.
- Collaborate with the R&D and clinical team of the company.
- Report to and support the Management team of the company.

Parc Científic de Barcelona
Tower R, Floor 1, B04
Baldiri Reixac 4-8
08028 Barcelona (Spain)
+34 93 4020259
www.glycardial.com

GlyCardial Diagnostics	**Human resources**	
Job offer 2019/02	rrhh@glycardial.com	93 4020259

The offer

- Estimated annual gross salary: We offer a competitive salary commensurate with the qualifications and experience of the candidate
- Target start date: March 2019

Application procedure

All applications must be sent by email to the following address rrhh@glycardial.com with the subject "**Job offer 2019/02".**

Applications must include:

- A motivation letter
- A complete CV including contact details
- Contact details of 2-3 referees

Application deadline

Please submit your application by **February 4th 2019.**

Parc Científic de Barcelona
Tower R, Floor 1, B04
Baldiri Reixac 4-8
08028 Barcelona (Spain)
+34 93 4020259
www.glycardial.com