Miracor Medical is a class IIb/III medical device company specialized in improving clinical outcome of patients with impaired cardiac function, active in interventional cardiology. The company has developed a high potential proprietary technology that consists of hardware, software and catheter(s).

The technology is in advanced clinical stages, with various potential therapeutic applications (among others acute infarct and heart failure). More than 190 patients have been treated with the recent version of the technology. The company aims at getting CE Mark and approval from FDA to run a pivotal study in the next 2 years.

Miracor Medical's offices are based in Awans, Belgium**.** The company is now looking for talented and enthusiastic talents to expand its international team. For additional information about the company and its technology, please visit www.miracormedical.com.

Miracor Medical offers a culturally diverse English speaking working environment in the heart of Europe, Belgium, a few hours away from Europe's capital cities.

To support the development of the company, we are looking for a (m/f):

Senior R&D Manager

Responsibilities:

- You initiate and manage related projects.
- You guide/manage risk management activities.
- You create/review technical documentation and processes (as part of DHF, DMR, QMS).
- You create verification and validation plans and coordinate their execution; apply statistical techniques in order to define samples sizes.
- You organize and execute subjective evaluations (product reviews) to ensure all (product) requirements are met.
- You review manufacturing documentation such as procedures/processes, BOMS and drawings.
- You transfer and oversight of parts of manufacturing processes.

Profile:

- Master's degree in Engineering, Informational Systems or Computer Science.
- 10+ years' experience working in development of Class III (minimum IIb) medical devices (or other relevant regulated industry).
- Ideally experience with hardware/software and catheters.
- Experience in creating Risk Management plan, (Software) Hazard Analysis, DFMEA, PFMEA, Risk Management reporting.
- Deep understanding of MDD (MDR), FDA 21 CFR 820, ISO13485 and ISO14971 standards

- In-depth knowledge of the concepts of: design control, engineering change control, statistical techniques, verification and validation methods/protocols, design history files (DHF) and device history and master records (DHR/DMR).
- Extensive understanding of statistical analysis, measurement and calibration systems, quality testing, sampling and inspection, process control, SOPs, etc.; Six Sigma certificate.
- Excellent organisational and communication (oral and written) skills.
- Ability to work on teams as well as individually.
- Fluent in English (oral and written).

Offer:

- A challenging and diversified position within a high-potential innovative medical device company.
- To work in a human size, dynamic, respectful and professional environment.
- International exposure, with learning and development opportunities.
- An attractive compensation package in line with the position responsibilities and your experience.

Interested?

Please send your CV together with an adapted cover letter/email via hhttp://www.pahrtners.be/job/senior-rd-manager/ or to recruitment@pahrtners.be or directly to Miracor at office@miracormedical.com . Ref: Sr R&DM. Your application and related information will remain strictly confidential.