

COMPANY

DiagnOptics Technologies BV (www.diagnoptics.com) is a medical technology company with its head office in Groningen. Diagnoptics develops and markets a non-invasive technology for measuring the concentration of AGEs (Advanced Glycation End products). This innovative technology called AGE Reader enables e.g. health professionals to determine the risk of developing (pre-) diabetes and cardiovascular disease.

Diagnoptics is a spin-out of the University Medical Center Groningen (UMCG) where work is carried out in a professional manner in an open and informal atmosphere. In 2013, Diagnoptics introduced the AGE Reader mu, a medically certified tabletop product for general practitioners and diabetologists. In addition, Diagnoptics recently introduced a compact handheld scanner for wellness applications whose measurement results are made visible via Bluetooth in an app on a mobile device. Diagnoptics sells these products worldwide through a network of international partners.

The team in Groningen currently consists of 10 people and primarily focuses on development, outsourcing to subcontractors, regulatory compliance, and back-office servicing.

TASKS AND RESPONSIBILITIES

As Regulatory Officer you are a member of our R&D team and you have the following tasks and responsibilities:

- Responsible for the product documentation of Diagnoptics
- Provide regulatory input for product development
- Process control compliance with the MDD and with other medical devices relevant to Diagnoptics (JPAL, KGMP)
- Managing the transition to the MDR 2017/745
- Managing the QMS and its implementation
- Introduce process improvements
- Organizing audits
- Coordinate product training
- Contribute to research and processing of non-conformities, complaints and CAPAs

REQUIRED EXPERIENCE AND SKILLS

- Minimum education: Bachelor degree in engineering (e.g. electronics, mechanics, biomedical, industrial engineering & management)
- Minimum 3 years experience as QA / RA
- Demonstrable experience with the MDD and other relevant legislation
- Experience with ISO 13485
- Experience with project management preferred
- Methodically and analytically strong
- Excellent command of the Dutch and English language in word and writing

MORE INFORMATION

Are you interested in this position, or do you have questions or want to discuss other possibilities? Please contact Michiel Kregel (manager operations) via m.kregel@diagnoptics.com or 050 5890612.

Acquisition as a result of this vacancy is not welcome.

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