Diagnoptics

Vacancy QA/RA Officer

24-32 hours per week
also suitable for career changers and for junior employees

Diagnoptics Technologies B.V. is an innovative MedTech company based in Groningen, The Netherlands with its origins in the University Medical Center Groningen (UMCG). Diagnoptics is an open, product-oriented organization of professionals committed to improving the prevention and care of cardiovascular diseases and cardiovascular complications.
Diagnoptics develops and markets a non-invasive optical technology for measuring the concentration of AGEs (Advanced Glycation End products) in skin tissue. This innovative technology is used by the AGE Reader and enables health professionals to determine the risk of developing cardiovascular disease. The determination of cardiovascular disease risk is used during pre-operative screening and for personalized treatment of for example kidney patients and diabetes patients. The technology is also used in the AGE Scanner that can be used to screen for diabetes risk or to obtain an objective measure of biological aging.
Diagnoptics sells its products worldwide in collaboration with international partners.

The headquarters in Groningen is primarily concerned with product development, sales, monitoring of outsourced production, quality management and servicing. There is currently a vacancy in the team for a QA/RA Officer. This position is especially suitable for career changers and for junior employees.

You like to:

- Enter and/or grow in the field of quality assurance and regulatory affairs of medical devices
- Become responsible for regulatory compliance of our products and quality management system with the applicable regulations (including MDR, JPAL and KGMP)
- Manage and execute subcontractor and supplier audits
- ‘Stay on the ball’ concerning the applicable medical device regulations and standards

You will be working on:

- Managing the technical documentation of the Diagnoptics products including certification and file review
- Maintaining the Diagnoptics ISO 13485 Quality Management System
- The transition to the EU MDR 2017/745
- Managing the processing of changes, non-conformities, complaints and CAPA
- Contributing to product development and introducing process improvements
- Raising awareness among the team w.r.t. quality requirements

You recognize yourself in the following:

- You have a bachelor’s degree in medicine, pharmacy, engineering or related discipline, and up to two years of professional experience in regulatory affairs or in quality management systems relating to medical devices.
- You are intrinsically motivated to continuously improve yourself
- You have project management experience or would like to gain this experience
- You have experience with statistics and/or Lean Six Sigma or would like to gain this experience
- You are proficient in the Dutch and English languages, both orally and in writing

We offer you:

- A negotiable part-time position for one year with a view to a permanent position
- A traineeship set up in cooperation with a medical device consultancy company
- A cozy office with a fully equipped workplace and opportunities for personal development
- To become member of a multidisciplinary team
- A salary based on your level of knowledge and experience
- If you do not come through an external recruiter, we offer you a signing bonus of 2,000 euro

Interested?

- Please contact Michiel Kregel (operations) at info@diagnoptics.com, 050 5890612
- For applications, please send him your CV and a brief motivation

DIAGNOPTICS TECHNOLOGIES B.V.