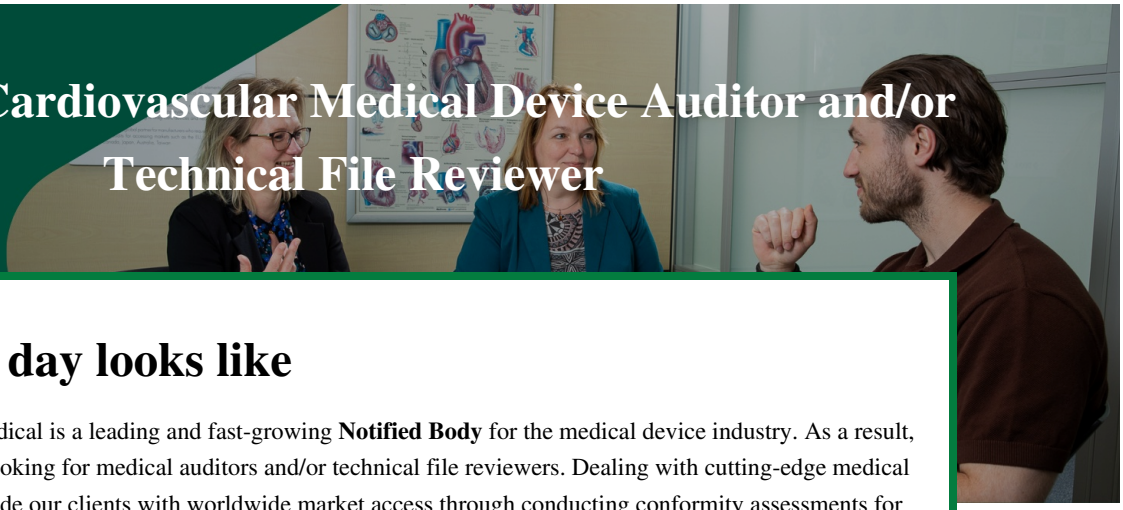
DEKRA – Cardiovascular Medical Device Auditor and/or Technical File Reviewer



How your day looks like

The business line Medical is a leading and fast-growing **Notified Body** for the medical device industry. As a result, we are consistently looking for medical auditors and/or technical file reviewers. Dealing with cutting-edge medical innovations, we provide our clients with worldwide market access through conducting conformity assessments for high-risk devices. We work together with a global team of approximately 150 experts, with the ultimate goal to ensure patient safety.

DEKRA already certifies many manufacturers of **cardiovascular** medical devices. This ranges from active implantables (e.g. pacemakers), to non-active implantables (stents, scaffolds, heart valves) and related non-active devices (PTA and PTCA catheters, guidewires etc.). Our main interest is in high risk, innovative products in the area of interventional cardiology. Our customers range from small innovative start-ups to large multinational, and are located within the Netherlands, within Europe and outside Europe.

Responsibilities

After an extensive internal training program at our office in Arnhem, you will:

- **Independently** execute audits and related processes;
- Be responsible for the assessment of technical files and the auditing of quality systems for you customers, ranging from highly innovative start-ups to large multinationals, both nationally and internationally;
- Act as a key point of contact and maintain frequent contact with customers, colleagues, external experts such as physicians, contractors and authorities;
- Have the opportunity to represent DEKRA at conferences;
- As auditor you travel approximately 20-30% of the time, both within and outside Europe;
- As technical file reviewer it is possible to work 28 – 40 hours a week.

What we expect from you

- A bachelor or university level degree in physical, life and/or engineering sciences is a must;
- A minimum of 4 years of full-time work experience in the medical device industry, including at least 2 years in research & development or quality assurance/regulatory affairs;
- Experience in the following device category and area of expertise: **cardiovascular devices**;
- Experienced with quality management systems (ISO 13485) and relevant laws and regulations, at least CE (MDD/MDR);
- Project management and auditing experience is considered an advantage;
- English language skills are a must;
- You are preferably already live in the Netherlands or are willing to relocate to the Netherlands.

Here is what we offer

- Competitive salary and comprehensive benefits;
- A variable performance **bonus scheme**;
- **25 vacation days** and **13 ADV (Additional Days Off)** for ample relaxation;
- Travel and remote work allowances;
- Discount on various insurance plans;
- Abundant opportunities for **career growth**, supported by multiple training programs;
- Engage in a challenging role within a cohesive team of proficient experts in a dynamic and international setting.

More about DEKRA

DEKRA is the world's largest non-listed expert organization in testing, inspecting, and certifying according to international safety and sustainability standards. Founded in Germany in 1925, the company's mission was to inspect vehicles to ensure traffic safety. Today, we offer a wide range of services, from product safety testing, audits, and inspections to damage assessment and HSE consulting. We operate in over 60 countries to ensure safety on the road, at home, and in the workplace worldwide. Explore all our services here.

We have a clear mission: as a leader in testing, certification and inspection, we ensure that products, assets, and technologies are safe, reliable, and sustainable – building trust between people and technology. And you are welcome to join! Discover more about DEKRA here.

Questions?

Do you have any questions about this vacancy? Please contact Jaimie Houtters. You can reach her at +31 6 29 65 86 96 or by email to recruitment.nl@dekra.com.

DEKRA likes to look for new colleagues itself, acquisition in response to this vacancy is therefore not desirable.

https://www.dekra.nl/nl/home/