

Quality Assurance Manager, Acarix A/S

Acarix is looking for a Quality Assurance Manager to support our rapid growth and global expansion of our innovative CADScor® System.

We are looking for an experienced Quality Assurance Manager who is seeking to join a medical technology startup company, with the potential to have significant impact on patients and health care systems worldwide. You have experience with maintenance and continuous improvement of the Quality Management System according to ISO 13485 and can ensure that Acarix meet the ever-increasing demands from the authorities to secure high quality standards every step of the way as well as compliance with requirements in the Medical Device industry. You thrive on working in a fast-paced environment, juggling many balls and handling high complexity. You are a highly pro-active/solution-oriented person with versatility to shift from strategic level to "hands on" execution. You enjoy international environments and cross-functional teamwork. You are fluent in English. You would like to be part of an engaged and passionate team in a straightforward, open, transparent, and collaborative atmosphere.

Key responsibilities:

- Maintenance and continuous improvement of the Quality Management System according to ISO 13485/ 21 CFR part 820, incl. SOPs, process monitoring, audits etc.
- Ensure compliance in EU, US and other markets
- Continuously keep our quality system updated in D4
- Drive investigation of root causes to deviations and customer complaints.
- Develop and drive CAPA activities the organization
- Lead and train the organization to ensure compliance
- Plan and execution supplier evaluation and monitoring activities.
- Take lead on and conduct mock FDA Audit, internal audits and follow up

Qualifications

- We expect an ambitious candidate who has a consistent track record of excellent achievements
- Minimum of 3 years of relevant work experience within Quality management, preferably within med-tech
- A degree (Bachelor or Master) in pharmacy, engineering, biology or similar.
- Able to set the right quality standards and ensure compliance, based on the regulatory requirements
- Able to communicate clearly and effectively with stakeholders, and keep a respectful tone, even when the message is not easy
- Strong English skills both in writing and speaking.
- Detail oriented with ability to organize, plan and track
- Actively demonstrating highest level of professionalism, ethical behavior, compliance, and integrity

As a person you are well organized and can focus on details, but at the same time can drive initiatives and collaborate with a wide range of stakeholders. As the last gatekeeper in our production process, you can resist the pressure from a busy operation and stand guard for our product quality and eventually patient safety.

What we offer:

We're an informal, flat organization and for the right candidate we offer a position with autonomy and mandate. The distance from idea to execution is short. We offer a very hands-on position focused on developing and maintaining our global quality system. Focus markets are US and Europe.

The Quality Assurance manager will report indirectly to the RA Manager and directly to the COO and be part of the Operations management team.

The position is based in Hellerup, Denmark.

International travelling of approximately 10-20 days/year is expected.



Want to know more?

We expect you are fast paced and thus will be able to send your application within 2 weeks by 23/4-2022. Please send your application and CV to Thomas.lundstroem@acarix.com

If you want to know more about the position you are welcome to contact COO, Thomas Stig Lundstrøm, Thomas.lundstroem@acarix.com or phone (+45) 2082 0120

About Acarix:

Acarix offers the CADScor®System, an innovative, non-invasive, ultra-sensitive analytical medical device. After receiving the CE-mark, Acarix was listed on Nasdaq First North Premier in 2016 and in 2020, Acarix was approved by FDA further supporting the great growth potential of the CADScor®System designed to support a safe, reliable and cost-effective rule-out of significant coronary artery disease (CAD).

Our vision is to create a paradigm shift in the early diagnosis and assessment of cardiac and vascular diseases. Overall, we are working on making sure that everyone, be it a health care professional or a patient, who wants or needs a CADScor®System assessment, should be able to get one in a timely manner.

Our mission is to be the world leader in AI-based rapid diagnostics of coronary heart disease. We will continue to develop the CADScor®System to listen to millions of hearts to reduce human and health-economic burden in the diagnosis of CAD. It is further our mission to develop additional acoustic medical technologies, primarily in the field of cardiology.

Our strategy is to develop and provide a non-invasive, quick, reliable diagnostic aid for healthcare professionals investigating patients with symptoms related to coronary artery disease. Our CADScor®System is intended to be used early in the diagnostic pathway to easily rule out those patients at low risk, giving patients peace of mind, and recommending those patients at elevated risk to undergo further evaluation. By providing CADScor®System to internal medicine and cardiologists, we intend to establish a new market segment where CAD can be ruled out early, in first line contact. The CADScor®System is sold to clinics, hospitals, and integrated health network systems, in combination with individual, single-use RFID patches, to which the actual ultra-sensitive microphone is attached, and a patient risk assessment can be performed.

These diseases are characterized by vague and non-specific symptoms, whose connection to the cause cannot be detected without comprehensive diagnostic testing.

By providing a tool for general practitioners and cardiologists, Acarix works to establish better options to help rule out CAD early.

The CADScor®System is sold to clinics at minor capital investment, in combination with the disposable single-use patches, to which the actual ultra-sensitive microphone is attached.

Our global office is in Malmö, Sweden, our working language is English, written and verbal.

See www.acarix.com for more.