

# QA/RA MANAGER

Posted on 21 mars, 2022

**Company Name** Medfield Diagnostics

**Location** Gothenburg

## Job Description

*Are you interested in medical devices that will support Stroke and TBI victims, and save money for society? Welcome to join us as our new QA/RA Manager.*

As a QA/RA Manager, you work in close cooperation with all functions within the company and you'll have a great impact on how the work is set up. You are committed to quality and regulations and secure that company guidelines and overall decisions are followed.

You will ensure effective implementation of a quality management system according to ISO 13485. An important task will be developing the organization's competence of requirements of medical devices product development, including employees, consultants and temporarily engaged persons.

## Your responsibilities include, but are not limited to:

- Management representative with responsibility and authority that includes:
  - ensuring that processes needed for the quality management system are documented
  - reporting to top management on the effectiveness of the quality management system and any need for improvement
- Ensuring that:
- the conformity of the devices is appropriately checked, in accordance with the quality management system before a device is released
- post-market surveillance is done in accordance with the requirements in the MDR
- reporting obligations (regarding incidents) are fulfilled
- Budget responsibility
- Product release and product recall
- Document approval

## Qualifications

- Relevant university degree and professional experience in quality management systems and/or regulatory affairs in medical devices
- Knowledge of relevant standards, e. g ISO 13485, ISO 14971, ISO 14155

- Knowledge of FDA regulatory requirements

To be successful in your role you are ambitious on behalf of the business, customer focused and passionate about delivering value to health care professionals.

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to [ann.rutt@moveup.se](mailto:ann.rutt@moveup.se) If you have questions regarding Medfield or this open position, please contact Ann at 0733-44 09 00. We are screening applications continuously.

*By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.*

## Om företag

### **Medfield Diagnostics AB**

There is a great need for portable and fast methods to improve screening of patients with brain injuries. Prehospital diagnostics can save lives, minimize the risks of disability and thereby reduce society's costs. Medfield Diagnostics AB (publ) aims to improve the diagnosis of brain injuries. Early diagnosis enables faster treatment, minimizes unnecessary suffering and improves the patient's chance of recovery, leading to cost savings for care and society. Medfield is developing artificial intelligence and microwave-based instruments, primarily to examine patients with brain injuries, which can be used by healthcare professionals both inside and outside hospitals.

[www.medfielddiagnostics.com](http://www.medfielddiagnostics.com)

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