

Quality Assurance manager to SGS DNA in Köping/Västerås (temporary)

Our Quality Assurance manager will go on maternity leave and we are now looking for her substitute during her leave. During 2019 SGS DNA will go through an interesting journey since we are increase the number of employees and by the end of 2019 we will move to new larger location in Västerås! All this to meet the increasing demand for our products.

SGS DNA is a reputable company that is part of the QIAGEN Group. The company is located in Köping and has 60 employees. We work with customized medical devices for primarily diagnostics (IVD) but also other applications. The company also provides certain related services such as analysis and stability studies. We apply Medical Technical Directives, ISO13485 (EU) and 21CFR820 (USA). We are focused on international markets for molecular diagnostic and other areas of medical applications like personalized healthcare.

Position Description

- ➔ As the QA Manager you are responsible for the Quality Management System and all related processes of SGS
- ➔ Budget and leadership responsibility for a motivated team of 5 coworkers
- ➔ Member of SGS management team

Position Requirements

- Ensure GMP work is done in compliance with applicable guidelines (e.g. cGMP, 21 CFR Part 11, ISO9001, ISO13485)
- Runs Quality Assurance Processes (e.g. complaints, deviations, CAPA, changes, etc.)
- Management of projects to improve procedures and establish standards
- Responsible to conduct regulatory inspections and customer audits
- Review relevant regulatory submissions
- Give guidance and day-to-day support for the QA team

Personal Requirements

- 3 + years Quality Assurance experience for a Medical Device manufacturer or similar
- Degree in a biological, chemistry or comparable disciplines
- Good knowledge about - cGMP, FDA 21 CFR 820
- Proofed Leadership skills
- Effectively communication and negotiation skills
- Effective decision making
- Good knowledge of MS office, ideally experiences with QMS software, LIMS
- Good Swedish and English knowledge ,fluent in spoken and written
- Preferably knowledge about LEAN and Continuous Improvement Processes



Welcome with your application as soon as possible. Selection takes place on a regular basis and the position may be assigned before the closing date.

Working time/Duration

The position is a fixed term from end of March 2019 until March 2020

Full time, 100 %, 40 hours/week.

Contact persons

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Kenneth Abrahamsson, Unionen, 0221-29650 (telephone exchange)

Application

Please send in your application by email: work@sgsdna.com

Attach a personal letter and CV

Please apply for the position as soon as possible, last application date is 2018-12-31.