Job Description

Kvalitetsingenjör/ Quality Engineer (m/f)

Your contribution to our success:

The Quality Engineer is responsible for reviewing and analyzing complaint data, performing root-cause-investigations to establish corrective action plans and implement corrective actions, developing and performing test methods for product testing and investigations, writing and updating procedures as required to ensure the quality system is compliant with regulations including the FDA Quality System Requirements (QSR), ISO 13485, Canadian Medical Device Regulations (CMDR), and the Medical Devices Directive (MDD) / Medical Device Regulation (MDR). Perform all job duties while adhering to HIPAA requirements.

Qualification:

- 2 to 3 years' experience as a Quality Engineer in the medical device industry
- BA/BS degree in science or another technical field
- Medical Device Quality System Knowledge Including 21 CFR Part 820 (QSR) & ISO 13485
- Demonstrated skills in statistical analysis

- Strong computer skills
- Individual must have a hands-on approach
- Experience participating in internal and external audits (e.g., FDA, Notified Body, Supplier)
- Strong organizational and time management skills
- Experience with CAPA, complaint investigation, field action processes and risk management
- Team Player

Competencies:

- Recognized as a technical leader within the company and engenders trust when working with customers or suppliers
- Capable of leading a Continuous Improvement Team, CAPA team, or working with a customer or supplier to resolve product quality issues
- Works effectively on cross functional teams to establish appropriate processes pertaining to quality
- Excellent written and oral communication skills
  Ability to formulate responses to common inquiries or complaints from customers and regulatory agencies
- Ability to review, analyze, summarize, and interpret data; draw conclusions and make appropriate
- recommendations and decisions; write reports; and give oral presentations
- Fluent in English and Swedish

What we are offering for you:

- Interesting position in an innovative, fast growing company
- Young team within a global positioned organization
- Short decision-making processes supporting an efficient working environment
- High level of individual responsibility and attractive possibilities for self-development
- Our core values are: Professional, Organized and Honesty

Company:

C-RAD is a global Medtech Company with its headquarter in Uppsala.
We are developing and selling innovative solutions for cancer treatment. The focus is on a cutting-edge technology for patient positioning, monitoring and imaging within radiation therapy.
We are market leader in our field and have established a global presence. C-RAD is a stock listed company at NASDAQ Stockholm.

We are looking for a Quality Engineer to strengthen our team.

Next steps:

Candidate assessment is done on a rolling basis.

If this vacancy is attractive for you, we are very much looking forward to receiving your application:

Leo Glatkowski
Director Quality and Regulatory Affairs

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