# Senior QA/RA Consultant

***Medical Device Development – Ørestaden, Copenhagen***

**Would you like to be part of a team ensuring the highest levels of patient safety? You will be contributing to the development and approval of intelligent and innovative treatment methods within the medtech industry?**

Medicologic is a leading Danish medtech consultancy and engineering company. Together with our customers we bring new and innovative products on the market with focus on speed to market.

We are growing and thus need additional resources.

**A challenging job with a broad variety of QA/RA assignments**
With a strong pipeline of challenging projects we are seeking a passionate Senior QA/RA Consultant to join our QA/RA team in Copenhagen. Reporting to the Team Manager you will be part of our QA/RA team and interact with customers to solve hands-on QA/RA assignments.

You will support customers with relevant QA/RA activities from development of Quality Management Systems, Risk Management, Process Validation, audits at customer sites or 3rd Party Audits etc.

Being a trained and skilled Auditor is an advantage.

Bringing our customers' products to the market require that you have solid competences in creation of relevant documents needed for CE-marking. This might be risk management, usability testing, product verification, process validation or other relevant activities. Furthermore, having experience with establishment of Technical Files, International Registration Applications etc. will be highly valuated.

Maintaining and improving our own ISO13485 certification will also be part of the job.

**Desired Skills and Experience**
Our preferred candidate has several of the following professional and personal qualifications:

*Qualifications*
- Relevant education degree (B.Sc. or M.Sc.) or equivalent in relevant scientific discipline
- Minimum 5 years of experience in relevant positions
- Strong understanding of ISO13485, 21 CFR part 820, CMDCAS
- Post-market surveillance experience
- Knowledge of CE marking of medical devices
- Skills in creation/maintenance of Quality Management Systems
- Experienced with process equipment and software validation
- Knowledge of apps in medical industry is an advantage
- Training and teaching experience is an advantage
- Certified auditor training

*Competencies (professional and personal)*

- Solution-oriented with an excellent ability to identify a cost-effective approach to QA/RA assignments
- Have a strong collaborative approach towards stakeholders
- A good listener with strong communicative skills
- Strong cultural awareness and a global mindset
- Fluency in English
- Outgoing personality with skills to facilitate and lead projects

**Join a leading medtech consultancy**

Our customer-centric consulting approach will give you an insight into cutting edge medical device development both in Denmark and internationally. We offer a challenging environment with exciting opportunities. We are very ambitious and you will be an important player in helping us realize our growth plans.

We look forward to welcoming you in our engaged, warm and professional environment with sparring from highly experienced experts as well as social events amongst colleagues. We wish the daily work experience to be a steady path towards professional as well as personal growth. Of course, we offer a competitive compensation package including pension and insurance.

**Contact information**

If you want to know more about the job you are welcome to contact Principal Advisor/Team Lead – RA/QA Management, Randi Hauerberg on +45 2247 0155 or rh@medicologic.com.

**Send your application**

Send your application including CV to rh@medicologic.com.
Since this is a priority position interviews will be conducted on an ongoing basis.

We look forward to hearing from you.