Job Description

Regulatory Affairs Specialist (m/f)

Your contribution to our success:

You are responsible for regulatory affairs activities to assist in regulatory submission, annual reports, registrations and listings. Assure compliance with applicable medical device regulations per jurisdiction, guidance and standards. Assist in creation and maintenance of regulatory files.

Qualification:

- Minimum of 2 to 3 years regulatory or equivalent experience within a Medical device or pharmaceutical company, CRO, or similar organization
- Write, analyze, and edit technical documents to support country- specific regulatory submissions and compile submissions in a format consistent with applicable guidance documents, including investigational device submissions in USA, Canada and Europe. Work with other departments

and communicate the submission requirements when documents are needed for regulatory submission
- Experience from supporting external regulatory agency audits, providing regulatory input to minimize potential for findings of non-compliance
- Knowledge on maintenance and update regulatory authorizations, such as IDEs, 510(k)s, Canadian medical device licenses, and CE dossiers for EU, NRTL certifications etc. Assure that appropriate maintenance of registrations occurs including renewals, device listings, site registrations, supplements for changes and annual reports. Support approval in other regions as required.
- Scientific knowledge, must be able to digest complex data while keeping the big picture through good analytical skills

Competencies:

- Excellent written and Verbal communication skills with the ability to listen, articulate and advocate
- Proactive, high performance, result oriented and manage projects with ethical integrity
- Technical system skills (e.g. MS office applications, databases, efficient online research)
- Manage multiple projects and deadlines
- Ability to identify compliance risks and escalate when necessary
- Demonstrate both creative and critical thinking skills
- 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

C-RAD Positioning AB

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