QUALITY MANAGER (3-5 YEARS OF EXPERIENCE)

Artificial Learning Systems India Pvt. Ltd. is looking for an experienced **QA Manager** with 3-5 years of relevant experience.

Candidate Profile:

An ideal candidate will be one who has a strong background in, and understanding of CE Marking and ISO 13485 certification related work. He/She will have good understanding of the requirements set by the EU Medical Device Directive and other regulatory bodies, the documentation work involved, and the ability to work closely with the product engineering team to understand their work and Supports the development of internal Regulatory systems and procedures.

Main activities:

Maintains existing technical files / design dossiers by reviewing and updating the related documentation, to support CE mark of EU products (medical devices). Ensures that EU regulatory requirements are fulfilled, this includes the Essential Requirement check list, list of applicable International Standards or guidance documents, risk analysis, communication with the suppliers, test report, and Clinical Evaluation Review Archives the approved documents on the server.

Secondary activities:

- Monitor the local regulatory activity and provide periodical feedback to manager
- Maintain regulatory knowledge of European regulations within Artelus
- Ensure adherence to requirements of ISO Certification in every day work

Qualifications:

- Technical Bachelor's Degree in a science discipline
- Regulatory knowledge (European Medical device directive), EN ISO 14971:2012 (Risk management), EN 62366:2008 (Usability), Global IEC Software Standard 62304, FDA 510K, Familiarity with standards related to Quality Management Systems (ISO 13485), etc.
- Very good written and oral communication in English.
- Ease for reading/creating/modifying documents
- Able to work with minimal supervision. Self-motivated team player.

Job Type: Full time, permanent

Job Location: Bangalore

Who are we?

Artificial Learning systems (Artelus) is a 2 year young company, working in the Deep Learning space to solve healthcare problems. The company seeks to make products, which would complement the knowledge and assist clinicians in making faster and more accurate diagnoses.

Our team comprises a group of dedicated scientists trying to make the world a healthier place using the latest advances in computer science and machine learning and applying it to the field of medicine and healthcare.

Why work with Artelus?

We are working on exciting new scientific developments in the area of healthcare, and working with us will get you solid education whatever your level of experience. This is a very exciting opportunity for a young scientist and we look forward to working with you to help you to develop your skills in our R&D center.

What does working with Artelus mean to you?

- Working in a high energy and challenging environment
- Work with International clients
- Work in cutting edge technologies
- Be a part of an exciting path breaking project
- Great environment to work in