Position Title: Technical Writer

We are seeking a talented technical writing professional who is passionate about the medical device/software industry to join our Engineering team. You will be part of a creative group working on challenging problems, while learning from others in an agile and dynamic environment. The Technical Writer is responsible for creating and ensuring documentation for design documents, scientific validation documents, technical documents and instructions for use of products, meet the applicable standards and regulatory requirements.

General Responsibilities:

- Provide technical writing in product design documentation and technical documents as necessary for all aspects of medical device and software development to meet the ISO 13485 / US FDA Quality System Regulations and other relevant standards and regulations.
- Work with Engineering, QA and Regulatory teams to gain an understanding of the products to develop the design control documentation and coordinate the product user guides and development of related documentation.
- Work with Regulatory Affairs team on product submissions and associated reporting including clinical evaluation reports (CERs) and risk management reports as per ISO 14971 standard.
- Work with Clinical Application Specialists and Product Support teams on product deployment related documents, including preparation, execution, and supporting publications.
- Be part of project design team consisting Product Management / QA / Engineering to understand the project specific documentation requirements and timeline.
- Identify and report documentation related issues found during verification and validation testing and follow up on the resolutions.
- Work closely with software developers, application specialists and product managers to understand user scenarios, requirements, and typical usage workflows and ensure these are captured in the relevant design documentation and instructions for use.
- Gather the scientific and clinically significant new features of the product and document relevant algorithms, reference scientific papers and validation reports.

Technical Skills/Experience:

- 2+ years of technical writing experience in medical device or software or any related industry.

- Software proficiency in Microsoft Office and other desktop / online publishing tools.
- Proficiency in desktop and online documentation publishing tools.

Beneficial Experience/Skills:

- Professional educational credentials on Technical Writing.
- Previous experience in Medical Device or Software related technical writing.
- Experience working with regulated medical products or previous medical device experience is preferred.
- Other international language skills will be a plus.

Educational Requirements:

- A minimum of diploma in technical writing or related field.

About the Company:

Circle Cardiovascular Imaging Inc. is a Calgary based company that develops analytics software for the evaluation of cardiovascular MR and CT images. Circle Operates worldwide and has installations of their products cmr[42], cvi[42], and report[42] in over 25 countries. Circle's goal is to contribute to quality in cardiovascular imaging and research, maximizing the achievable benefit for patients by enabling healthcare providers to accurately and effectively analyze cardiovascular images.

Circle Cardiovascular Imaging Inc. holds globally recognized ISO 13485:2003 certifications from the prestigious British Standards Institution (BSI). This certification includes Standards Council of Canada (SCC) endorsement under Canadian Medical Device Conformity Assessment System (CMDCAS) scheme. In addition to ISO 13485:2003, the company quality system is established and maintained to comply with European Medical Device Directive 93/42/EEC and US FDA Quality System Regulations, 21 CFR Part 820.

While we thank all those who apply, please note that we will only be contacting those selected for an interview. No phone calls or unsolicited agency referrals please. Only applicants who are authorized to work in Canada will be considered for this position.

Please send your resume with a cover letter attention of Shirantha Samarappuli to the following;

Email: shirantha@circlecvi.com
Fax: +1 403 338 1895

Mail: Circle Cardiovascular Imaging Inc.
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