QA/RA Manager – Medical Devices

The Opportunity

Metabolomic Technologies Inc. is a small but growing company developing metabolomics-based in vitro diagnostics. Our lead product PolypDx™ is the first and only urine-based screening test for the detection of adenomatous polyps and colorectal cancer. We are seeking a QA/RA Manager to lead regulatory and quality initiatives as we prepare for regulatory approvals in the US, Canada and Europe.

Position Description

The QA/RA Manager will provide regulatory leadership and guidance to a small cross-functional team to ensure the company's compliance with medical device (in vitro diagnostic) regulations in the US, Canada, and Europe. A key responsibility will be to implement and maintain the company's quality management system (QMS) to ensure compliance with the FDA Quality System Regulation (21 CFR Part 820), Canadian Medical Devices Regulations (CAN/CSA-ISO 13485:2016 MDSAP) and EU In Vitro Diagnostic Regulation (ISO 13486:2016).

Responsibilities

- Implement and maintain the company's QMS system including developing applicable policies and procedures (SOPs) in collaboration with management and other team members.
- Ensure that the company's QMS system is compliant with the requirements of the FDA Quality System Regulation (21 CFR Pat 820), the Canadian CAN/CSA-ISO 13485:2016 MDSAP standard, and EU ISO 13485:2016.
- Integrate risk management practices (ISO 14971) into the company's QMS.
- Coordinate internal and regulatory quality system audits.
- Conduct site audits of vendors and contractors as required.
- Ensure overall compliance with applicable medical device regulations in the US (21 CFR 800-1299), Canada (SOR/98-282), and EU (Regulation (EU) 2017/746).
- Provide support and training to team members on medical device regulatory requirements and QMS.
- Assist senior management with developing and implementing regulatory strategies in consultation with the company's regulatory consultants and partners.
- Facilitate the company's interaction with regulatory authorities on regulatory issues and submissions (Pre-Sub meetings, IDE/ITA applications, PMA applications, etc.).
- Provide input to product development plans, project schedule and budget as it relates to regulatory requirements.
- Proactively maintain and communicate knowledge of new developments in regulatory and quality standards applicable to the company's business plans and future strategies.

Preferred Qualifications

- B.Sc. in Science, Engineering or other relevant field; advanced degree or QA/RA certification (CQA, RAC, etc.) an asset.
- 7+ years direct experience in medical device QMS and regulatory affairs.
- Strong working knowledge of medical device ISO standards and FDA/Health Canada/EU regulations.
- Direct experience with FDA and/or Health Canada submissions.
- QA/RA experience with in vitro diagnostics and Software as a Medical Device (SaMD) is an asset.
- Strong interpersonal skills with the ability to work effectively with all team members, consultants and contractors in a flat organizational structure.

Compensation

MTI offers a health benefits plan and employee stock options. Salary will be commensurate with experience and qualifications.

Application

Please submit a cover letter and CV by email to: jobs@metabolomictechnologies.ca with "QA/RA Manager" in the subject line.

We thank all applicants in advance for their interest; however, only applicants selected for an interview will be contacted.