1501 Wilson Blvd. Suite 910
Arlington, VA 22209
202-828-1600
www.mdic.org

Title: SRS Technical Project Manager, Clinical Science and Technology	**Job Code:** Full time exempt
Reports To: Program Director, Clinical Diagnostics	**Location**: Arlington, VA

Organization Overview

The Medical Device Innovation Consortium (MDIC) is the first-ever 501(c)3 public-private partnership created with the sole objective of advancing medical device regulatory science for patient benefit. As a membership based organization, MDIC brings together representatives of the Food and Drug Administration (FDA), National Institutes of Health (NIH), Centers for Medicare & Medicaid Services (CMS), industry, non-profits, and patient organizations to improve the processes for development, assessment, and review of new medical technologies. Our work is unique and complementary to trade associations such as the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association (MDMA). Members of MDIC share a vision of providing U.S. patients with timely access to high-quality, safe and effective medical devices.

Position Overview

The Somatic Reference Samples (SRS) Technical Project Manager will be responsible for the day-to-day coordination of stakeholders, consultants, and staff supporting the programmatic needs of the SRS Project. This project will develop somatic reference samples that can be used to develop and benchmark performance of molecular diagnostic tests for cancer. This position will oversee the engineering of priority variants, coordinate sequencing performed by multiple contractors and laboratories, coordinate validation with NIST Principal Investigator and selected laboratories, facilitate the process to make publicly available the genomic datasets on Precision FDA and NIH repositories. This position will oversee the SRS project plan, including any modifications to the plan, to make validated reference samples available.

In addition, this person works closely with staff and consultants to support SRS project initiatives. The individual must have strong communications skills and project management experience with scientific initiatives; be technically adept with administrative IT tools such as the Microsoft Office product suite including project management software (SmartSheets or equivalent). The person must be highly organized and detail oriented, with the ability to take appropriate initiative. The person must be able to work well in a fast-paced quickly evolving environment. As a member of the MDIC team, he/she also contributes to the general advancement of MDIC goals, including membership advancement and support. This position reports to the Clinical Diagnostics Program Director and will have exposure to national leaders in the patient, medical device industry, academic and regulatory institutions, and organizations.

Objectives and Responsibilities

- Provide general support and coordination of SRS programmatic activities to engineer and validate reference samples that can be used to develop and benchmark performance of molecular diagnostic tests for cancer.
- Complete assigned deliverables in consultation with the Program Director, Clinical Diagnostics
- Provide regular updates on progress to the Program Director
- Support MDIC's mission of advancing the field of medical device regulatory science
- Coordinates, executes, and facilitates meetings with external partners and stakeholders, including acting as a liaison with funding agencies
- Represents MDIC at conferences and other events and meetings
- Contributes to the overall development of MDIC, taking on responsibility or additional duties that may fall outside the general duties listed above

Requirements

- Understanding of the reference sample development process
- Understanding of Next Generation Sequencing methods
- Understanding of molecular diagnostics
- Understanding of CRISPR technology
- Bachelor of Science/Arts degree or equivalent experience
- Ability to coordinate and manage multiple priorities and prioritize tasks and complete tasks in a timely manner
- Ability to work in a fast-paced environment with multiple demands
- Experience supporting and managing the development of processes and materials to support scientific initiatives
- Use and maintain strict confidentially, discretion, and judgment in dealing with confidential, sensitive and controversial issues in all aspects of work
- Excellent computer skills, including Microsoft Office
- Excellent organizational skills with impeccable attention to detail
- Excellent verbal and written communication skills with the ability and comfort to interact professionally with staff, board members, and stakeholders
- Excellent interpersonal skills
- Experience identifying and coordinating relationships with professional services vendors/consultants
- Ability to follow-up and follow through on actions as necessary

Other Skills/Abilities

- Professional experience in reference sample development and molecular diagnostics preferred
- Ability to be flexible and work collaboratively as a team within a dynamic, start-up work environment
- Interest in the medical device industry and enterprise with a willingness to engage in continuous learning and professional and personal growth
- Interest in working and engaging with different stakeholder groups
- Experience with a variety of web-based tools including RingCentral, Box.com, Microsoft Office, SmartSheets, Zoom, WebEx and ability to adapt to new collaborative technologies as they become available
- Self-motivated, self-directed and a quicker learner
- Experience working with virtual teams is a plus

- Some travel will be required

Reporting Relationships

The employee will report to the Clinical Diagnostics Program Director.

NOTE: This scope of services is not intended to be all-inclusive. Individuals may be asked to perform other related duties as required to meet the ongoing needs of the organization.

To apply, please submit a resume and cover letter to: careers@mdic.org

MDIC provides equal employment opportunities (EEO) to all employees and applicants for employment without regard to race, color, religion, sex, national origin, age, disability, or genetics. In addition to federal law requirements, MDIC complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation, and training.

MDIC is an Equal Opportunity Employer.