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

Title: Program Director, Clinical Diagnostics	**Job Code:** Full Time Exempt
Reports to: Vice President, Clinical Science & Technology	**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.

In September 2016, the FDA awarded a grant for the National Evaluation System for health Technology (NEST) Coordinating Center (NESTcc) to MDIC. The mission of NESTcc is the creation of structures for responsible sharing and efficient analysis of real-world evidence to inform and empower patients, accelerate medical device innovation, and improve healthcare outcomes. Stakeholders across the medical device ecosystem stand to benefit from improved use of real-world evidence (RWE) generated in the routine course of care.

Position Overview

The Program Director is responsible for providing leadership for work groups of member volunteers tasked with delivering regulatory-grade tools and methods that support development, assessment and review of innovative new devices and technologies for patient benefit. Providing a predictable path for innovation will help patients benefit through quicker access to more cost-effective advanced diagnostic technologies in less time. The programs in Clinical Diagnostics aim to identify and pursue projects that will improve diagnostic testing and product development using novel regulatory science approaches developed through collaboration between MDIC stakeholders. Key area of focus are; earlier detection of many diseases and conditions, personalized medicine, regulatory processes for IVD tests, reference samples that can be made available to the public to improve the accuracy, reliability and transparency of NGS-based oncology tests, creating an evidence framework that test

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sponsors can use to make decisions on how to develop credible evidence of analytical and clinical validity and clinical utility, a framework for utilizing real-world data as a source of evidence that can be used to support regulatory and reimbursement decision-making for in vitro diagnostics etc. The Program Director supports the board champion, steering committees, and work groups through project planning, timelines, deliverables, and meeting facilitation and action item follow up. As a Program Director, the individual assists with grant and contract submissions to support program funding. 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 MDIC VP, Clinical Science and Technology.

Objectives and Responsibilities

- Advance the field of data science and medical device regulatory science.
- Promote collaboration and innovation within the medical device community with a special focus on the relationship between the FDA, CMS, and the private sector, and work to enhance the trust between all stakeholders.
- Create tools, methods, and approaches that will assist stakeholders in developing new. products; assess the safety and effectiveness, quality and performance of these products.
- Driven to achieve objectives and deliverables in the timeline required by steering committee.
- Provide education about the medical device regulatory process.
- Provide education about the needs of the medical device community.
- Support making the medical device regulatory process more expeditious, transparent, predictable, and effective.
- Use established relationships with key stakeholders from industry, non-profits, and government including FDA and CMS to define and develop strategic areas of focus and opportunity.
- Create a vision for defined opportunities and secure funding through membership support, grants and contracts.
- Complete and manage the detailed program and project plans so “clarity of purpose” can be established among team members and communicated broadly to membership and interested stakeholders.
- Achieve critical mass of qualified membership to staff the steering committee and projects.
- Establish and implement revenue, expense and staffing plans to appropriately grow the capability of the Program.
- Establish the plan and appropriate relationships to deliver educational and administrative services.
- Develop messages on project status in support of marketing and communication to advance utilization of tools, methods, and approaches.

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- Present and publish as needed to expand the reach of the MDIC work products to advance innovation within the medical technology industry (Medtech) and other stakeholder communities.
- The employee will be responsible for communicating project plans and status to the VP, CEO, board champion, steering committee, working group members, and other stakeholders throughout the Medtech ecosystem.

Requirements

- Bachelor of Science degree in a STEM or other technical discipline (e.g., engineering, technology, statistics, health services research); advanced degree a plus.
- 10+ years professional experience and 5+ years management experience in Medtech or Life Science industry in a product development or other technical function (e.g., Research, Biostatistics, HEOR, Quality).
- Program management or equivalent experience with increasing levels of responsibility leading complex projects.
- Understands the medical device and or diagnostics product development lifecycle approach and process for taking a product through development to market.
- Experience leading matrixed volunteer teams to achieve program results (i.e., team members from various disciplines or organizations without direct reporting relationships).
- Influence management at junior and most senior levels of organizations.
- Ability to coordinate and facilitate technical experts from various disciplines (within and outside of his/her own areas of expertise).
- Excellent verbal and written communication skills.
- Excellent interpersonal and influence management skills.
- Experience identifying and managing relationships with communications and marketing vendors/consultants.

Other Skills/Abilities

- Ability to represent MDIC at public forums such as conferences and symposia.
- Comfortable participating as a panelist and present at public forums.
- Demonstrated skills and ability to create a vision, generate broad support and secure resources and funding to support.
- Excellent influence management skills.
- Experience with Microsoft suite of products.

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- Self-directed.
- Experience working with virtual teams.
- Collaborative working style.
- Entrepreneurial.

Reporting Relationships

- The employee with report to the VP, Clinical Science and Technology.

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

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.