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Title: Vice President, Clinical Science & Technology	Job Code: Full Time, Exempt
Reports to: President and CEO	Location: Arlington
Revision Date: January 2019	

Organization Overview:

MDIC is the first-ever public-private partnership (PPP) created with the sole objective of advancing medical device regulatory science to expedite development, assessment, and review of innovative medical technologies. The MDIC is a nonprofit organization that operates in partnership with all stakeholders within the ecosystem including FDA to improve the medical technology environment.

The overall mission of the MDIC is to support the FDA’s vision to achieve first in the world patient access in the US and to assure the safety and effectiveness of medical devices through the Total Product Life Cycle. The organization is dedicated to making the medical device regulatory process more expeditious, transparent and effective to ensure innovative technology is readily available to US patients.

MDIC is a nonprofit 501(c)3 organization that operates in partnership with the FDA to improve the medical technology environment. Participation in MDIC is open to representatives of organizations that are substantially involved in medical and/or medical device research, development, treatment, or education; that are involved in the promotion of public health; or that have expertise in regulatory science.

Position Overview:

With proven results from this collaboration between industry, patient groups, and the regulatory agency, the MDIC is seeking a Vice President, Clinical Science & Technology to lead discussions between all parties to identify ways to reduce costs, speed time to market, document efficacy and safety of medical devices, and provide oversight for regulatory science initiatives. Demands for medical device evidence development addressing patient safety, therapeutic efficacy, quality design and performance, risk management, and benefit-cost determinations are increasing. In accordance with the MDIC mission to advance medical device regulatory science, MDIC has launched methods, tools, and resources aimed at improving patient access to cutting-edge medical device innovation.

Objectives and Responsibilities:

- The Vice President, Clinical Science & Technology, is responsible for the proactive leadership and development of the regulatory science initiatives of the MDIC across the areas of clinical science (e.g., early feasibility studies, clinical trial innovation, coordinated registry networks, clinical diagnostics, science of patient input), data science and technology (e.g., external evidence methods, computational modeling and simulation, Case for Quality), and innovate to address

emerging areas of focus e.g. cybersecurity, safety signal management and education.

- He/she will be responsible for the operations of areas of responsibility and for providing oversight for work with partners across industry, specialized consultants and MDIC program directors/managers to execute the MDIC's objectives of promoting collaboration within the medical device community to work with the FDA to increase efficiencies through the regulatory process.
- The Vice President, Clinical Science & Technology will actively engage in the various program Steering Committees comprised of members of the major medical device companies, regulatory agencies and other stakeholders to identify opportunities and oversee program work streams and deliverables. The Vice President will advise the program directors/managers to move initiatives forward, gain funding, engage members and initiate new projects as appropriate.
- This individual will execute on top talent management to develop the MDIC programs staff, develop and drive active use of robust project management tools, dashboards, and training to maximize program impact and success.
- He or she will provide effective advisement to team members and steering committees on work plans to drive performance and tools utilization.
- This individual will be responsible for bringing thought leaders from the FDA, industry and nonprofits together for collaboration and to identify Clinical Science & Technology common needs and areas of MDIC project work that may provide opportunity to improve the quality, efficiency, and predictability of processes within the FDA regulatory framework.
- This role will interface strategically and operationally with the senior management leaders across other areas of MDIC (e.g., NEST Coordinating Center, Health Economics & Patient Access, Operations/HR, Finance, Membership & Communications) to decrease barriers and increase success for the program objectives and integrate or align where feasible for overall development of the organization. Actively participate in strategic planning and growth of Clinical Science & Medical Officer Advisory Committee to advise the organization.

Requirements:

Education

- An MD or PhD is preferred with extensive clinical trials experience in the medical devices, and a preference for experience in the areas of cardiology, neurology, and/or orthopedics.

Medical Device and Clinical Experience

- 10-15 years minimum of experience in clinical affairs/research/operations for the medical devices industry at a leadership level (e.g., director, VP), including direct or indirect management of adjacent areas such as biostatistics, clinical IT, data management, and outsource partners
- Advanced medical device development expertise
- Proven track record of successful development and management of global clinical trials and clinical organizations

- Ability to set objectives for team members, drive accountability, and manage performance, while being recognized as a role model, mentor, and strong leader
- Direct and successful talent management experience to maximize effectiveness of individual and team performance
- Proven experience developing robust evidence strategies across the lifecycle of medical devices (i.e., from bench to clinical development, and post-market)
- Experience with regulatory submissions and the approval and oversight process for medical device development
- Ability and vision to innovate tools, methods, and approaches for the medical device regulatory process to be more expeditious, transparent, predictable, and effective

Communication and Leadership Skills

- Promote innovation within the medical device community and work to enhance trust among stakeholders with advanced communication skills to influence and collaborate with key thought leaders and regulatory agencies
- Strong interpersonal skills (i.e. team player) and ability to establish sound working relationships with people in various functions and organizations across the medical device ecosystem
- Strength in development of strategic plans to identify, grow and evolve regulatory science programs in key areas of need
- Advanced analytical and communication skills
- Strong and consistent focus on metrics and deliverables, proactively identifies barriers and works to mitigate and manage risks
- Sound clinical, technical, and operational judgment
- Ability to manage interactions with C-level individuals and a comfort with presenting to high-level executives from different stakeholder groups.

Reporting Relationships:

- The Vice President, Clinical Science & Technology will report to the Medical Device Innovation Consortium (MDIC) President & CEO and be a part of the senior management team.
- The Vice President will provide strategic and subject matter expertise and leadership and oversight to program directors/managers and serve as the MDIC's senior Clinical Science and technical liaison with the medical device ecosystem thought leaders, governmental agencies including FDA, CMS and NIH, and nonprofit (patient-focused) organizations.

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.

