Candidate brief for the position of

Vice President, Clinical Science & Technology

Medical Device Innovation Consortium (MDIC)

Contents

About MDIC

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.

Strategic Agenda

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 organizations substantially involved in medical or medical device research, development, treatment, or education; that are involved in the promotion of public health; or that have expertise in regulatory science.

Medical device regulatory science is the scientific discipline for assessing the safety, effectiveness, quality, and performance of medical devices. Advances in regulatory science can reduce the time and cost of medical device development, assessment, and regulatory review by providing more robust, timely, or inexpensive evaluations of technologies.

The US historically invested little in regulatory sciences compared to the basic and clinical sciences, with most advances produced by individual companies or agencies. This led to inefficiencies, duplicative efforts, and the inability to leverage expertise, data, and resources at scale. Moreover, the FDA's Center for Devices and Radiological Health (CDRH) did not have resources to validate and qualify all competing methods and tools created by medical device companies, while other relevant stakeholders lack mechanisms to share pre-competitive proprietary data in order to advance the field.

The work of MDIC is unique and complementary to trade associations such as AdvaMed and MDMA. MDIC works on science, not policy. Members of MDIC share a vision of providing U.S. patients with timely access to high-quality, safe and effective medical devices. MDIC has been designed to pursue several strategies to support this mission:

> Create a forum for collaboration and dialogue, working within a flexible governance structure to encourage broad participation from medical device industry stakeholders, including nonprofits, industry, and government.
>
> Make strategic investments in regulatory science, utilizing working groups to identify and prioritize key issues and to request, evaluate, and implement project proposals that support MDIC's mission.
>
> Provide tools to drive cost-effective innovation, emphasizing education and the development of new methods and approaches with well-documented data and details to enable implementation.

The organization is governed by a Board of Directors that includes the director of CDRH, the director of Coverage and Analysis at CMS, and many C-level executives representing patient organizations, non-profits and industry.

Opportunity

The Role

With proven results from this collaboration among industry, patient groups, and the regulatory agency, the MDIC is seeking a Vice President, Clinical Science & Technology to lead discussions among 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.

Key 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 cybersecurity),
    - and innovating to address emerging areas of focus e.g., safety signal management and education.
- She or he will be responsible for providing oversight for work with partners across industry, specialized consultants and MDIC program directors/managers to promote collaboration within the medical device community, working with the FDA to increase efficiencies throughout the regulatory process.
- He or she 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.
- This critical leader will advise the program directors/managers to move initiatives forward, gain funding, engage members and initiate new projects as appropriate.
- This leader will develop the MDIC programs staff, develop and drive active use of robust project management tools, dashboards, and training to maximize program impact and success.
- 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 for MDIC project work that may provide opportunities to improve the quality, efficiency, and predictability of processes within the FDA regulatory framework.
- This role will interface strategically and operationally with the senior leaders across other areas of MDIC (e.g., NEST Coordinating Center, Health Economics & Patient Access, Operations/HR, Finance, Membership & Communications) providing subject matter leadership and ensuring program alignment for the development of the complete organization.
- This leader will actively participate in strategic planning and growth of Clinical Science & Medical Officer Advisory Committee to advise the organization.
- The Vice President serves 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 patient-focused nonprofit groups.

Reporting Relationship

The Vice President, Clinical Science & Technology will report to the Medical Device Innovation Consortium (MDIC) President & CEO and be a part of the senior leadership team.

Location

The role will be based in the organization's Arlington, Virginia offices. Consideration will be given to commuting or partially remote candidates on a case by case basis.

Candidate Profile

A forward-thinking leader with extensive clinical trials experience in medical devices, fluency with the US regulatory processes for medical technologies, and the strategic vision to proactively identify and address pain points and opportunities for the medical device community.

MEDICAL DEVICE & CLINICAL EXPERIENCE

- 10-15+ years in clinical affairs, research, and /or operations for the medical devices industry at a leadership level, 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, successful management experience to maximize 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
- The intellectual agility to navigate both granular, technical discussions regarding medical device development and regulation, as well as higher level strategic initiatives.

COMMUNICATION & 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.

QUALIFICATIONS

- An MD or PhD in a relevant area of study is preferred, especially with experience in the areas of cardiology, neurology, and/or orthopedics.
- Ability and desire to work from the Arlington, VA office at least 25%, with regular domestic travel.

Search Process

Approach candidates

We will have an initial discussion with you over the phone to determine your interest and suitability for this role, and learn about your background and aspirations.

Interview candidates

Once your interest and suitability has been determined, we will arrange for you to meet live or via video with the Partner leading this search.

Short listing

Having met with candidates who will differ on experience, ambition and background, we will put forward a number of candidates whom we feel most meet the criteria.

Meeting our clients

MDIC will meet the candidates on the shortlist. This will give you the opportunity to really understand the role, the company culture and their expectations of you. You will more than likely have multiple meetings with key stakeholders to get a feel for the business.

Due diligence

As you will appreciate, you will have conducted due diligence on MDIC and they will expect us to do the same for the candidates whom they anticipate would really bring that 'something special' to the business.

Offer and acceptance

MDIC puts together the offer which we convey to you. We will fully support you through your resignation period and beyond.

Ongoing communications

We prefer to maintain contact with all candidates from a search. If you are selected and accept the role, we will meet with you after your first month to ensure that your expectations have been met. If our mutual exploration does not lead to your placement in the role, we will ensure that you gain full feedback and will maintain a relationship with you for the future.

Inclusion & Diversity

MDIC provides equal employment opportunities 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. A core objective of our search process is to identify a diverse set of high potential candidates that supports our and their commitment to diversity and inclusivity.

Confidentiality

We guarantee that any approach we make to you and any discussions we have will be in the strictest confidence. If required, conversations regarding proprietary information may be conducted under the terms of a formal nondisclosure agreement.

Candidate Charter

Talented people are our lifeblood. Whether we approach you about a specific opportunity, or you contact us to share your biography and career ambitions, we want you to have a constructive experience of engaging with Odgers Berndtson.

We recognize that we have a commitment to you as well as to our client, and we undertake that our dealings with you will be professional, courteous, rigorous and honest.

We will:

- Approach you after considered analysis and in relation to roles where we think there is a strong match. Your time is valuable; we don't want to waste it.
- Work to make your candidacy as strong as it can be.
- Represent you effectively and discreetly to our client, based on accurate information that you give us in confidence.
- Be inclusive, open and fair-minded.
- Keep you informed, communicating outcomes promptly, and giving fair and honest feedback where we can.
- Celebrate your success in the event of a successful outcome, and share any lessons in the event of disappointment.
- Take a long-term view, recognizing that you have a multi-year view of your own career. Where possible, we will help you fulfil your ambitions.
- Embrace continuous improvement, for example by carrying out regular independent audits of those we shortlist for roles.

If ever you feel we have not lived up to this charter, please tell us. We want to know. Email info@odgersberndtson.com.

Further Information

Our firm is the largest in both the United Kingdom and Canada and is the second-largest globally, outside of the U.S. It is also the fastest-growing major search firm in the Americas. Odgers Berndtson was established in 1966 and has more than 62 offices in 29 countries. We typically conduct retained executive searches for positions ranging from Senior Directors to C-Suite and Board Members across a broad range of industry verticals.

For this position we will work with the following team:

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