

Director of Medical Device Safety



COMPANY BACKGROUND

[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.

Location: Arlington, VA or Remote

ROLE: DIRECTOR OF MEDICAL DEVICE SAFETY

The Director of Medical Device Safety will focus on developing and executing the Active Surveillance program for medical devices to provide real-time device safety information that means better outcomes for patients who depend on devices to improve their health. In this hands-on role, the Director will foster collaboration across multiple stakeholders to envision the future of Active Surveillance and lead implementation of the shared vision.

This person will work closely with national leaders and key stakeholders in the health technology ecosystem including regulators, payers, industry, academia, health systems, clinicians, and patients/patient advocacy. They will apply their experience with the infrastructure and methodologies needed for active surveillance in design and execution of the system. Additionally, this person will have a long-term mindset, incorporating features within the initial set-up which will enable a capable, long-term, ongoing active surveillance across the medical device landscape.

This member of the NEST Coordinating Center (NESTcc) Leadership Team will manage cross-functional projects and lead broadly across the ecosystem to drive towards tangible outcomes. This role is for someone who is a self-starter, loves envisioning and implementing complex programs, and has in-depth knowledge in the principles of active surveillance for medical products.

KEY RESPONSIBILITIES

- As subject matter expert and NESTcc Lead, works closely with FDA, the chosen vendor, and other key stakeholders to develop strategies and address scientific and technical issues related to design, planning, and implementation of surveillance (with an early focus on signal detection)
- Maintain awareness of current methodologies, tools, and applications to ensure fit-for-purpose and innovative approaches to meet the surveillance needs for medical devices; identify new ideas for surveillance that are specific and measurable while promoting an innovative mindset throughout the organization
- Oversee day-to-day management of the design, build, testing, and use of the active surveillance system architecture, in collaboration with FDA and other stakeholders
- Develop and maintain collaborative relationship with key stakeholders; serve as primary contact for FDA and other collaborating institutions for Active Surveillance
- Drive safety data collection and delivery strategy in compliance with industry data and safety standards
- Partner with internal and external cross-functional teams in resolving issues and developing continuous process improvement initiatives
- Champion a culture of accountability and professionalism that is driven by milestones and timelines

KEY REQUIREMENTS

- At least 3 years of professional experience (minimum 7 years with Master's degree) in a technical position conducting signal detection, active surveillance and/or real-world data analyses of medical products
- Proven experience in observational study design, analysis, and interpretation, preferably focused on active surveillance
- Travel up to 25% may be required
- Comfortable discussing complex surveillance and methodological matters with those who have little familiarity as well as those with deep expertise
- Natural ability to build relationships, lead and educate with excellent interpersonal and influence management skills
- Outstanding organizational and project management skills, ability to do complex multi-tasking, takes initiative
- Ability to work proactively in fast-paced environment, both independently and as part of a team
- Ability to represent Medical Device Innovation Consortium (MDIC) and NEST to senior industry leaders in a professional manner

- Building relationships with C-suite executives or senior leadership

EDUCATION

- Master's degree in epidemiology, health outcomes, biostatistics, population science, operations research, informatics, or other medical product-focused clinical data evaluation is required; Doctorate in this area strongly preferred.

COMPENSATION

An attractive compensation package commensurate with this senior leadership role will be provided.

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