Position: Director of Clinical Affairs
Reporting to: VP of Clinical Affairs

Company Overview:

Prytime Medical Devices, Inc. (The REBOA Company™) is an innovative medical device company that designs, develops, and commercializes minimally invasive solutions for hemorrhage control. Prytime has strong military ties and significant momentum. We are seeking to expand our senior leadership team and move to the next level. Our flagship product is the ER-REBOA™ Catheter, the market leader for endovascular aortic occlusion in trauma. The ER-REBOA™ had $6.15M in commercial sales in 2019.

In addition to success with the ER-REBOA™ catheter, Prytime was just granted FDA clearance (June 2020) on two next generation products and is poised to create additional strategic opportunities and to lead the introduction of these devices in trauma and adjacent specialties.

Our initial focus is the Trauma market and hemorrhage control. Hemorrhage control presents unique challenges for Clinical Support because most procedures using our devices are unscheduled emergencies, making real time clinical support extremely difficult to achieve. In addition, our device is only used in time critical, cognitively challenging life or death situations.

Position Overview

Position Prytime Medical, Inc. is seeking a Director of Clinical Affairs to support all clinical strategy projects and processes throughout product commercialization, innovation, development, and post-market support while managing the clinical department for assigned project(s). Additionally, this position will contribute to the development of Clinical Training, Study, and Product Implementation Protocols and Design while acting as clinical representative throughout clinical research collaborations both internally and externally. This includes contributing to the strategic and operational leadership relative to the direction, planning, execution, and interpretation of all programs and the data collection activities.

Responsibilities

1. The lead clinical account managers and 1099 representative on dedicated customer activities.
2. Working with RA/QA to support submissions, customer complaints, etc.
3. Work as needed with Product Management to support lifecycle management and Clinical Operations/QA to support Clinical Training, Implementation, Study compliance procedures.
4. Collaborate and provide insight on clinical training, very limited market release customer sites and planning, study design and clinical protocols.
5. Work in collaboration with VP of Clinical Affairs and Chief Scientific Officer to act as representative on Clinical Advisory Boards, improving clinical study design and implementing strategies as required.
6. Act as the key interface between KOL, clinical end users and other medical expertise to validate and understand product use and ongoing program requirements.
7. Work in close collaboration with Prytime leadership to provide clinical insight at product roadmap meetings, having significant impact on future product development pipeline.

8. As a management team member, works to establish and approve methods for design and implementation of clinical, projects, including protocols, data collection systems and final reports, clinical activities.
9. Contribute to meeting clinical budget.
10. Operational responsibility for training, labelling, package design, etc. related to US and OUS clinical trials - monitors adherence to protocols requirements.
11. Interacts with and contributes to various inside/outside groups to facilitate all programs.
12. Select, develop, and evaluate personnel to ensure the efficient operation of clinical function.
13. Contributes to and supports the company's research and development, efforts to create high value medical devices to address unmet clinical needs.
14. Develops global clinical affairs strategies, in collaboration with management, regulatory affairs, marketing, research & development, reimbursement and outcomes planning, and obtain approvals by the most effective method possible.
15. Develop and execute Clinical Affairs Strategy to generate data for both regulatory and marketing purposes.
16. Travels to clinical sites for training and clinical trials oversite and act as players coach.
17. Manage KOL / physician-clinician engagement and lead the management of all Clinical Affairs investments and required support.
18. Execute studies in the US, and OUS in full compliance with all applicable GCP requirements, and local and international regulations and standards.
19. Responsible for preparing data for publication, white papers, presentations, etc.
20. Manages team to prepare protocols for projects; reviews final study conduct documents such as study manuals, study plans, study tools, etc.
21. Develops staffing plans according to needs.
22. Participate in Risk management and R&D representing clinical affairs.
23. Provides oversight of individual clinical trials or product implementation to ensure full compliance with protocols and that safety concerns and/or adverse events are identified and appropriate responses to such concerns are executed.
24. Provides advice to the customer complaint report ability team of adverse events and other clinical use issues to regulatory agencies.
25. Determines membership criteria and identifies potential members for clinical events committees and data monitoring committees.
26. Reviews and approves trigger plans for CEC and DMC.
27. Reviews and approves Clinical Risk Benefit Analyses.
28. Reviews and approves study corrective action plans. Prepares for and participates in internal/external study-related audits.
29. Develops and maintains Clinical Investigation, conduct infrastructure – drafting and/or reviewing of SOPs, Protocols, and Work Instructions.
30. Demonstrates thorough knowledge of and coaches' others in the appropriate application of clinical research conduct, laws, regulations, standards, and compliance with applicable SOPs and policies.

Qualifications

- Bachelor's degree in related field and 15+ years' clinical experience, preferably in medical device industry.

- Master's degree (MBA, MSN, MS) or Doctorate highly desirable.
- Extensive knowledge of FDA requirements, hospital, and health care environments.
- 5+ years' experience in direct management of clinical teams required.
- Excellent written and verbal communication skills required.
- Experience interacting with physicians, clinicians, and patients.
- Possesses excellent leadership skills and ability to be very flexible, adaptable, and to work under pressure.
- Self-motivated and self-directed; conscientious approach to work assignments; enjoys the challenges of multitasking and working at a fast pace while staying flexible to shift tasks frequently.
- Excellent interpersonal and negotiating skills; ability to adapt to changing work priorities; and ability to maintain good working relationships while dealing appropriately with sensitive and confidential matters and with a wide variety of personal and telephone contacts.
- Demonstrated record of success and leadership.
- This position could be remote based in either Central or Eastern US.