Job Description

Position:	Head of Clinical
Date:	2024-03-12

Company:
BariaTek is a clinical stage medical device company that aims to become the world leader in the treatment of obesity via minimally invasive endoscopic approaches.
BariaTek first product, the BariTon™, is a soft, atraumatic, reversible implant that is delivered via an endoscope through the mouth in a few minutes in an outpatient setting. The BariTon™ is expected to be the first implant of its kind to mimic the multiple beneficial effects of bariatric surgery (most effective treatment option to date) with no alteration to the patient's anatomy therefore allowing for full reversibility.

Position:
Head of Clinical.

Status:
Employee contract – Full time (CDI).

Key responsibilities:
Reporting to the Chief Executive Officer, your mission will include, but will not be limited to the following:

- Direct the clinical operations from initiation through completion.
- Work with key opinion leaders, investigators, clinical and regulatory experts, contract research organizations and management to assess operational feasibility and lead execution of clinical trials that generate compelling results and advance company goals.
- Oversee the development of SOPs related to the design, planning and execution of clinical trials.
- Develop and manage study timelines and metrics to ensure quality and timeliness of study deliverables.
- Have overall responsibility for the provision of data to be used in various scientific reports and publications.
- Ensure risks are proactively identified by clinical staff and mitigation solutions are implemented as necessary.
- Participate in the selection and qualification of clinical sites and develop relationships with investigators and site staff.
- Lead the selection, management and oversight of contract research organizations and other study related vendors, review vendor contracts and quality agreements, review vendor reports, budgets, and metrics, review and approve clinical vendor invoices against the approved budget.
- Lead the development of study-related clinical plans and documents (e.g., clinical investigation plan, patient facing documents, clinical monitoring plan, case report forms etc.).
- Oversee and provide study-specific training and leadership to clinical research staff, including internal, contract, vendor, and site personnel.
- Plan and manage study-specific meetings (e.g., investigator meetings).
- Assist with publication strategy, regulatory submission support, audits/inspections, and advisory board meetings.
- Ensure all clinical trials are executed in compliance with the US CFR, ISO, MDR, GCP guidelines and applicable SOPs.

- Participate in the planning of quality assurance activities and coordinate resolution of audit findings and CAPAs.
- Develop an understanding of the competitive landscape of the BariTon™ device and relevant therapeutic areas.
- Support investigator-initiated research as needed.
- Participate in regulatory meetings with and submissions to the US FDA, notified bodies, and other competent authorities.

Qualifications:

- BS/BA degree in science/health-related field, advanced degrees such as MS or PhD preferred.
- 10+ years of clinical research experience in international trials of highly complex Class III implantable medical devices.
- Demonstrated ability to lead medical device pivotal clinical trials.
- Experience in working with and overseeing contract research organizations and other external vendors.
- Excellent written and oral communication and presentation skills in English.
- Demonstrated strong and influential leadership skills with proven ability to lead internal and external team members at all levels.
- Demonstrated ability in growing clinical affairs teams from the ground up.
- Experience developing clinical SOPs and plans.
- Excellent working knowledge of ICH GCP guidelines, ISO, MDD/MDR, and CFR regulations.
- Ability to work independently and make appropriate strategic decisions to operationalize and advance clinical trial activities.
- Experience operating effectively within a medical device start-up setting.
- Exceptional organizational skills, ability to manage multiple priorities with meticulous attention to detail.
- Excellent team player and willingness and ability to fill functional gaps in a small organization.
- Ability to extensively travel domestically and internationally as needed.