Job Description

Position:	Head of Quality
Date:	2024-03-18

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 Quality.

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:

- Establish and execute the company's quality strategy to ensure product quality and customer satisfaction.
- Represent the company as the Authorized Quality Management Representative with authorities and external entities.
- Design, implement, manage, and maintain the company's Quality Management System (QMS) in according with the US CRF, ISO 13485 and other applicable norms and standards.
- Organize, prepare, and lead certification audits.
- Design, implement, and manage quality system related metrics, trends, and reports.
- Ensure operations are executed in compliance with the US CFR, ISO, MDR, GMP guidelines and applicable SOPs.
- Manage quality assurance activities and coordinate resolution of audit findings and CAPAs.
- Provide support for the preparation of meetings with and submissions to the US FDA, notified bodies, and other competent authorities.
- Participate in the selection and qualification of suppliers, contract manufacturers, and vendors.
- Ensure risks are proactively identified by internal and external staff and mitigation solutions are implemented as necessary.
- Oversee and provide specific training to staff, including internal, contract, and vendor personnel.

Qualifications:

- BS/BA degree in science/health-related field, advanced degrees such as MS or PhD preferred.
- 10+ years of experience in quality, including few years in a managerial role, of Class III medical devices.
- Pertinent experience in building and managing a QMS.

- Experience in working with and overseeing quality within manufacturing 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 a quality team from the ground up including quality supervisors, engineers, and technicians.
- Project management experience with a strong background in developing timelines and schedules.
- Mastery of GMP guidelines, ISO, MDD/MDR, and CFR regulations.
- Ability to work independently and make appropriate strategic decisions to operationalize and advance quality operations.
- 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.