

Position:	Head of Manufacturing
Date:	2024-03-13

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 Manufacturing.

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 the company's short- and long-term manufacturing strategy to ensure world-class manufacturing focused on delivering zero defect quality products, 100% on-time delivery, and year on year productivity improvements towards efficient management of expenses and capital investments.
- Direct the manufacturing and scaling operations from initiation through completion including the potential switch from production via contract manufacturers to the establishment of a dedicated production site.
- Work with contract manufacturers, experts, consultants, and various stakeholders to assess operational feasibility and lead execution of manufacturing and scaling operations.
- Oversee the development of SOPs related to manufacturing and scaling.
- Ensure risks are proactively identified by internal and external contract manufacturer staff and mitigation solutions are implemented as necessary.
- Participate in the selection and qualification of suppliers, contract manufacturers, and vendors, and develop relationships with all these parties.
- Lead the selection, management and oversight of suppliers, contract manufacturers and other vendors, review contracts and quality agreements, review vendor reports, budgets, and metrics, review and approve vendor invoices against the approved budget.
- Oversee and provide specific training and leadership to manufacturing and operations staff, including internal, contract, and vendor personnel.
- Ensure all manufacturing operations are executed in compliance with the US CFR, ISO, MDR, GMP guidelines and applicable SOPs.
- Participate in the planning of quality assurance activities and coordinate resolution of audit findings and CAPAs.
- Participate in regulatory meetings with and submissions to the US FDA, notified bodies, and other competent authorities.

Qualifications:

- Engineering degree.
- PMP and Lean Six Sigma certifications highly desired.
- 10+ years of experience in manufacturing and scaling of Class III medical devices.
- Pertinent experience in conducting and managing manufacturing operations and scaling both internally within the organization and through a contract manufacturer.
- Experience in working with and overseeing contract 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 manufacturing teams from the ground up including production supervisors, engineers, and technicians.
- Project management experience with a strong background in developing production timelines and schedules.
- Excellent working knowledge of GMP guidelines, ISO, MDD/MDR, and CFR regulations.
- Ability to work independently and make appropriate strategic decisions to operationalize and advance manufacturing and scaling 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.
- Ability to extensively travel domestically and internationally as needed.