



Job Title: Plant Manufacturing Manager - Biomedical devices

Location: Natick, MA

Qualifications:

- Bachelor's Science/Engineering (Required)
- 3+ years of experience in operations within a medical device facility
- Thorough knowledge and understanding of medical device manufacturing under Current Good Manufacturing Practice (cGMP) and ISO 13485
- Experience working under a medical device Quality Management System (QMS)
- Military experience is considered favorably

Company Background:

Helios Cardio Inc. is a Massachusetts based company that produces next generation medical devices for cardiac surgery with the first products based on processing of animal tissues. This is a dynamic and high growth opportunity position at an early stage organization about to take-off. Chosen candidates will be joining an experienced management team with proven success in this space.

Job Description:

Helios Cardio is seeking a Manufacturing Manager with experience in designing, implementing, and managing medical device manufacturing processes meeting US (FDA) and international (EU / MDR) quality standards. A qualified candidate will be well-suited to oversee all manufacturing operations and personnel with a goal of establishing a routine, timely, cost-effective, and reproducible production process meeting high quality standards. The candidate will be expected to independently generate and implement new plans, strategies, and production procedures across all aspects of manufacturing. The Manufacturing Manager will also participate in the hiring, training, and management of a production team.

Responsibilities:

- Designing, writing, and executing medical device manufacturing processes from inception to launch including workflow, equipment design, manufacturing layouts, and required personnel
- Designing, writing, and executing manufacturing process validations; overseeing team execution of equipment and process validations (IQ/OQ/PQs)



- Managing, directing, and coordinating all daily operations and leading manufacturing team members to meet processing schedules, production orders, and making decisions concerning staffing, work procedures, and assignments while ensuring worker safety.
- Ensuring a stable and quality working environment with training for effective performance. Proactively addressing issues with employees. Conducting timely performance reviews. Coordinating effective delegation of work assignments and training.
- Reviewing operations and conferring with technical or administrative staff to resolve production or processing problems.
- Hiring and training manufacturing personnel in the operation of new and existing equipment, processes, and procedures to maintain a culture of excellence in manufacturing and quality
- Leading and/or supporting DCRs; CAPAs, and NCs related to the manufacturing process.
- Working with Quality to ensure that all processes are in compliance with standards and requirements.
- Managing component, raw materials, and WIP inventories
- Developing and implementing a defined roadmap for product development with milestones, critical path evaluations, and early warnings for potentially late milestones