MONOGRAM ORTHOPAEDICS
JOB DESCRIPTION
CONFIDENTIAL AND PROPRIETARY INFORMATION

Job Title: Operations Manager
Job Location: Austin, TX
Reports To: CTO

Job Summary

The Operations Manager – Design Transfer will lead the planning, coordination, and execution of transferring the design and manufacturing of a Class II robotic TKA system including accessories and implants from a start-up development environment to a qualified contract manufacturer. This role will ensure that all activities meet regulatory requirements under ISO 13485 and 21 CFR Part 820, while achieving operational readiness for finished device assembly, testing, and release. The Operations Manager will collaborate cross-functionally with HW, Systems Engineering R&D, Quality, Regulatory, Supply Chain, and the Contract Manufacturing Organization (CMO) to deliver a compliant, efficient, and sustainable manufacturing process.

Qualifications and Work Experience Required

- Bachelor's degree in Engineering, Operations Management, or related technical discipline.
- 7+ years of operations or manufacturing experience in medical devices, with at least 3 years in design transfer or NPI (new product introduction).
- Strong knowledge of **ISO 13485:2016** and **21 CFR Part 820** compliance requirements.
- Demonstrated experience in working with contract manufacturers and leading cross-functional projects.
- Proven ability to manage process validation, quality documentation, and DFM activities.
- Exceptional project management skills, including scheduling, budgeting, and risk management.
- Six Sigma, Lean Manufacturing, or PMP certification.
- Experience in a start-up or high-growth medical device company.
- Preferred Experience with Class II or Class III robotic surgical systems or orthopedic devices.
- Must be detail oriented with strong written, verbal, interpersonal, and organizational skills
- Experience operating in a cross-functional, multi-site development environment
- Strong leadership and team-building skills.
- Excellent communication and negotiation abilities.
- Analytical thinking and data-driven decision making.
- Ability to work in a fast-paced, dynamic start-up environment.
- Commitment to quality, compliance, and patient safety.

Essential Duties & Responsibilities

- Serve as the primary liaison between the legal manufacturer (Monogram) and CMO, ensuring effective communication and issue resolution.
- Lead the end-to-end design transfer process from prototype to commercial production for the robotic TKA system.
- Work with Engineering to resolve design for manufacturability (DFM) and process optimization opportunities.
- Establish and manage the transfer project plan, timelines, deliverables, and resource allocation.

- Drive the implementation of manufacturing processes, assembly lines, and test systems at the CMO site.
- Ensure alignment of device master records (DMRs), device history records (DHRs), and associated documentation
- Oversee process validation (IQ/OQ/PQ) activities in compliance with regulatory standards.
- Collaborate with the CMO to develop manufacturing instructions, assembly procedures, and quality inspection plans.
- Facilitate first article inspections, pilot builds, and ramp-up production runs.
- Establish supplier quality agreements, manufacturing KPIs, and performance monitoring processes.
- Ensure adherence to ISO 13485 and 21 CFR Part 820 requirements throughout the transfer.
- Partner with Quality Assurance and Cross-functional teams to ensure effective risk management per ISO 14971.
- Lead or support internal and external audits related to manufacturing readiness and compliance.
- Maintain robust document control practices and configuration management.
- Collaborate with Regulatory Affairs to ensure all manufacturing changes are captured in regulatory submissions as required.
- Support post-market manufacturing changes, CAPAs, and continuous improvement initiatives.
- May require occasional travel to contract manufacturing site.