GRAVITAS MEDICAL, INC.

Job Description

Position Title: Director of Quality

Reports To: CEO

Department: Quality

Location: In person at 2332 4th St, Berkeley, CA

FLSA Status: Exempt

PURPOSE OF JOB:

Own the Quality Management System for the Entarik Smart Feeding System, an FDA-cleared, Breakthrough Device-designated sensorized feeding tube and bedside monitor for neonates through adults. Set quality strategy and represent quality to FDA, auditors, partners, and the board, while rolling up their sleeves as well: writing procedures, running CAPAs and complaint investigations, reviewing device history records, qualifying suppliers, and conducting audits. This is a hands-on, results-driven role for someone who executes as well as leads, not a purely managerial or oversight role.

RESPONSIBILITIES:

- Own and maintain the QMS in compliance with FDA QMSR (21 CFR 820), ISO 13485:2016, and ISO 14971.
- Personally author, revise, and manage SOPs, work instructions, forms, and quality records.
- Run CAPA, nonconformance, complaint handling, and MDR reporting, driving investigations to root cause and closure.
- Partner with engineering on design controls, including design reviews, design history files, verification and validation, traceability, and risk management files.
- Lead supplier quality, including qualification, audits, SCARs, and incoming inspection for contract manufacturers and sterilization vendors.
- Review and release device history records and own production and process controls, including process validations (IQ/OQ/PQ), test method validations, and EO sterilization validation.
- Coordinate compliance evidence for biocompatibility (ISO 10993), electrical safety (IEC 60601), and software lifecycle (IEC 62304).
- Plan and conduct internal audits and management reviews, and host FDA inspections and ISO 13485 registrar audits.
- Provide quality and technical documentation in support of 510(k) submissions and other regulatory filings.
- Use AI tools to accelerate documentation, investigations, and record review while remaining accountable for accuracy.
- Build a practical, risk-based quality culture that scales with the company without slowing it down.

REQUIREMENTS:

- 8+ years of medical device quality experience, including ownership of a QMS at a small or mid-size company.
- B.S. in Engineering, a life science, or related discipline.
- Direct, hands-on experience with CAPA, complaints, design controls, risk management, supplier quality, and process validation. You have done the work yourself, not only supervised it.
- Experience hosting FDA inspections and ISO 13485 audits.
- Working knowledge of EO sterilization (ISO 11135), ISO 10993, IEC 60601, and IEC 62304.
- Experience with Class II devices, preferably electromechanical or software-containing systems.
- Clear, concise technical writing and sound judgment about the level of rigor a situation requires.

- Comfort working in a resource-constrained environment as both the strategist and the person executing.

DESIRABLE SKILLS:

- Experience with enteral, catheter, or other patient-contact disposables.
- Experience implementing or migrating an eQMS.
- ASQ CQA, CQE, or CMQ/OE certification.
- Exposure to MDSAP or EU MDR.
- Experience in a start-up environment wearing multiple hats.

Contact hr@gravitasmedinc.com for more info