

Position: Vice President, Quality Systems and Regulatory Compliance**Status:** Open, Full Time Position**Start Date: October/November, 2021**

TriVirum, Inc., based in Northern California, is seeking qualified candidates to fill the position of Vice President, Quality Systems and Regulatory Compliance. This position reports directly to the CEO.

Roles and Responsibilities:

- Overall responsibility and accountability for the development and operation of quality and regulatory functions in the U.S., the U.K, and other locations • Design and implement quality and regulatory systems, procedures and reporting required to meet FDA, MHRA, ISO, IEC and other agencies in the countries in which products are sold
- Ensure compliance with the FDA GMP, ISO, and IEC standards for medical device manufacturers
- Documentation management including DHF and DMR, SOPs, manufacturing procedures, training records, audit and other documents
- Direct supplier qualification inspections and insure material compliance • Publish monthly, quarterly and annual quality metrics and compliance reports
- Serve as the Company Representative to all regulatory agencies • Recruit and manage the Quality Systems Team
- Provide clear and accurate Board level performance reports • Work closely with the VP Operations to insure that quality issues and CAPAs are addressed in a thorough and timely manner

Requirements and Experience:

- Proven track record managing medical device quality systems • In-depth knowledge of FDA GMP, ISO and IEC standards for medical devices • Demonstrable track record of continuous quality improvement • History of successful FDA and ISO quality audits
- Leadership, personnel management and organizational development skills