Senior Quality Engineer

Reports to: Senior Director of Quality and Regulatory

Overview

The Quality Engineer reports to the Senior Director of Quality and Regulatory and supports quality processes for medical device development and manufacturing at Portal Instruments. This person handles multiple projects and tasks, from product inception through manufacturing and product launch.

The QE represents Quality on internal and external project teams for both design and manufacturing. This role also supports quality systems, product design verification & validation, medical device software validation, manufacturing process validation, customer feedback, corrections and removals and corrective and preventive action investigations and implementation.

Role and Responsibilities

This person may be called upon to participate in the following areas:

- Design Controls – Support Verification & Validation (test plans, protocols, reports), test method validation, Incoming Inspection, lot release of engineering, clinical and commercial devices, nonconforming product disposition, review of design documentation, calibration and equipment validation (IQ/OQ/PQ)
- Quality Systems – Support continuous improvement of quality system procedures in accordance with 21 CFR 820, ISO 13485, EU MDR, MDSAP, and ISO 14971
- Risk Management – Maintain the risk management file for Portal Instruments products throughout their lifecycle
- CAPA – Participate with other team members in all aspects of Corrective and Preventive action process as required, including documentation of CAPA, root cause investigation, and implementation of improvement activities
- Complaint Handling – Participate in complaint processing and trending, and failure investigations as needed
- Management Review – Assist management representative in compiling and trending Management Review metrics
- Supplier Management – Perform vendor audits and interact with vendors surrounding Supplier Corrective Action Requests (SCAR)

- Audits – Conduct and/or participate in internal and external audits as needed
- Software – Work with software team and support software development in compliance with IEC 62304
- May be called upon to guide / manage junior engineers

Required Skills and Experience

- B.S. degree in Engineering, Science, or related discipline required. Master's degree in engineering or MBA a plus.
- Minimum 5 years of experience. Experience in a medical device environment preferable, including experience with both design and manufacturing.
- Strong working knowledge of 21 CFR 820, ISO 13485, and ISO 14971. Experience developing or modifying Quality Management Systems in accordance with these regulations is desired.
- Knowledge and experience with MDSAP, EU MDR, IEC 62304, and ISO 60601 requirements a plus
- Proven track record in new product development and commercialization, post-launch experience a plus
- Experience working with contract manufacturers and establishing relationships with suppliers is a plus.
- Knowledge of sterilization processes for medical devices a plus
- Good communication skills, both written and oral.
- Knowledge of statistical sampling and analysis
- Possess a high sense of urgency, good judgement, creative problem solving, initiative and common sense.
- Present a professional demeanor and demonstrate an ability to work effectively with a diverse group of individuals.
- Must be energetic, work quickly and efficiently with detail and accuracy.
- Must be able to effectively manage multiple priorities in a fast paced and dynamic environment.

About Portal Instruments

Portal is transforming medicine by allowing chronic patients to self-inject their biological drugs with a needle-free device. This innovative drug delivery system replaces auto-injectors and is overwhelmingly patient preferred. Issued from MIT Research and easily connected to the cloud, the Portal device allows biopharmaceutical companies to augment their biological therapies and differentiate them from competitors. The device captures injection data in real time and transmit those via the cloud to all stakeholders for optimal care. Portal's business model is to partner with biopharmaceutical companies and co-develop drug/device combination products. The company has partnerships with Takeda Pharmaceuticals, LEO Pharma, Sanofi SA and 3M. It is currently at the pre-launch stage with pilot lines producing products for clinical evaluation. Come join us on this exciting journey of making chronic patient care and comfort a priority.

Working at Portal Instruments

- Portal Instruments is looking for unique individuals who want to make a difference in the lives of patients and how medicines are delivered today
- Portal Instruments offers employees the opportunity to work in a fast-paced start-up that values innovation, creativity, accountability, teamwork, and openness while providing excellent leadership and development opportunities
- Portal Instruments is committed to challenging implicit bias and creating an equitable work environment. We are proud to be an equal opportunity employer. All qualified candidates will receive consideration without regard to race, ethnicity or national origin, sexual orientation, gender identity or expression, genetics, military service, age, family status, or disability.
- Portal offers a competitive salary, a comprehensive benefits package, including stock options, a 401(k) retirement plan, a health and dental plan and a chance to make a difference in the lives of thousands of patients.

To Apply: Please submit a resume and cover letter to: careers@portalinstruments.com. You will be contacted if your background meets Portal's needs.