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Job Title:	Quality Assurance Engineer
Reports To:	Manager, Quality Engineering and Risk
Location:	13562 Maycrest Way, Suite 5138 Richmond, BC
Date:	2019 January 03

Purpose/Role

The Quality Assurance Engineer works collectively with the Product Design Team and Operations / Chemistry Lab to assist with the assessment and mitigation of risk associated with the design, development, testing, and manufacturing of medical devices, from initial product realization, to production, to post production activities. These include participating in initial risk assessments, as well as evaluating the impact of proposed design and production changes may have on patient risk, and trouble-shooting: acting as a leader in product-related investigations (NCs, Complaints, INVs, CAPAs, etc.), to assess the potential impact to patients.

Position Description

- Work within the Neovasc Risk Management Program to ensure compliance of the company portfolio of products with applicable external regulatory and quality standards, inclusive but not limited to the International standard ISO 13485, ISO 14971 Risk Management, CMDR SOR 98-292, FDA QSR, 21 CFR Part 820 and MDD93/42/EEC
- Act as the 'Voice of Quality' when working with product development teams to ensure that design controls remain effective at mitigating patient risk related to errors or defects in product design or performance.
- Analyze, investigate, troubleshoot products where performance does not meet specifications
- Analyze, investigate and troubleshoot verification test errors and propose test improvements
- Review test protocols to verify and validate designs and proposed design changes;
- Assess the ability of designs to mitigate patient risk in light of emerging information regarding product performance (Non-Conformances, Complaints, Investigations, etc.)
- Lead or facilitate the leadership of quality actions related to current products, (investigation, proposed changes, Non-Conformances, Complaints, INV, CAPA, DCOs, ECRs, etc.) within existing risk-management frameworks.
- Assist with the manufacturability of product through design for manufacturability, design layout, design of jigs and fixtures, and manufacturing procedures; train and supervise technicians on manufacturing and testing products.
- Work with Quality Control to develop test and inspection protocols that ensure efficacy and integrity of processes and products; identify inspection points, sample sizes, etc. to assure quality and risk requirements are addressed; provide detailed reports and make recommendations based on analysis.
- Work with the equipment and facilities team to ensure that equipment used for verification testing is qualified, and work to ensure that qualifications are renewed / maintained as necessary.

- Arrange for purchase of equipment, materials, or parts, and evaluates products according to specifications and quality standards.
- Support validation of in-house and external software for ISO13485:2016 certification.
- Represents product design, verification, validation and continuation engineering in regulatory inspections and notified body audits, acting as an SME for current product design controls, as required.

Qualifications

Education:

- Minimum 4 years of post-secondary education in the field of Science or Applied Science in a related discipline or equivalent combination of education and experience

Experience:

- 3-5 years in a medical device and manufacturing environment
- Biological tissue processing
- Liquid sterilization processing and associated USP standards
- Laboratory practices and chemical preparation
- GMP, ISO, FDA, Health and Safety regulations and validation requirements
- Professional Certification Related to Quality Engineering is recommended (CQE or CSSBB)

Skills:

- Strong problem-solving and computer skills
- Strong communication and organizational skills
- Hands on experience with machines and tools
- General mechanical aptitude
- Ability to provide mentorship to juniors and to work well in a team environment

PLEASE NOTE THAT ONLY CANDIDATES LOCAL TO THE VANCOUVER, BC AREA WILL BE CONSIDERED.