



<b>Job Title:</b>	Quality Engineer (Engineer II)
<b>Reports To:</b>	Production Quality Engineer (Engineer III)
<b>Location:</b>	13700 Mayfield Place, Richmond, BC
<b>Date:</b>	2022 November 4

<b>Purpose/Role</b>
Demonstrate commitment to patient safety and product quality through Quality Engineering function support and oversight across Design and Development, Production and Process Controls and Post-Production surveillance activities, in accordance with the Quality System and applicable regulations

<b>Position Description</b>
<ul style="list-style-type: none"><li>• Identifies and resolves exceptions to work assignments – ability to deal with ambiguity.</li><li>• Follow-the-data best practices to identify appropriate actions.</li><li>• Performs exploratory analyses across design and production (Design FMEA, Process FMEA).</li><li>• Participates in Risk Management activities, knowledge of ISO 14971.</li><li>• Participates in Customer Complaints investigation.</li><li>• Has the responsibility and independent authority to make decisions related to product quality, including the disposition of non-conforming product.</li><li>• Supports day-to-day manufacturing operations, including QC, to ensure continuity of compliant product.</li><li>• Participates in validation activities.</li><li>• Compiles and analyses operational, test and validation data to establish technical specifications and performance standards for newly designed or modified products and processes.</li><li>• Participates in regulatory inspections and notified body audits, acting as an SME for areas of responsibility.</li></ul>

<b>Qualifications</b>
<b>Education</b> <ul style="list-style-type: none"><li>• Degree in Mechanical, Manufacturing or Biomedical Engineering</li><li>• 2-3 years' experience in medical device industry mandatory</li></ul>
<b>Experience</b> <ul style="list-style-type: none"><li>• ASQ Certified Quality Engineer an asset</li><li>• Design Quality Assurance/ Design for Manufacturability (DFMEA/ PFMEA)</li><li>• Production and Process Controls</li><li>• Working knowledge of statistics</li></ul>

- Experience with any of the following is considered an asset: Medical Plastic Extrusion/Molding, Polymer Bonding, Balloon Manufacturing
- Familiarity with sterilization methods

**Skills**

- Analytical thinking with strong problem-solving and computer skills
- Strong communication and organizational skills
- Hands on experience with machines, tools and inspections methods
- General Mechanical Aptitude
- Ability to provide leadership and to take initiative as well as work well in a team environment

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