Quality Engineer Careers in the Medical Device Industry

Exploring Opportunities and Responsibilities

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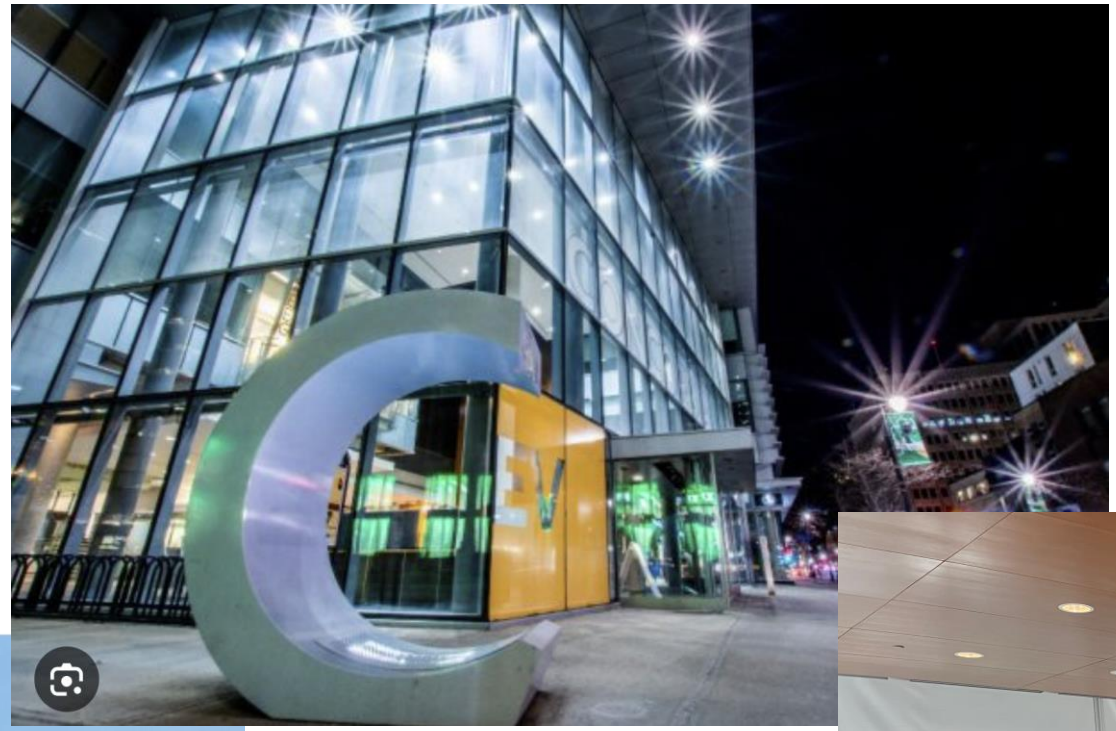

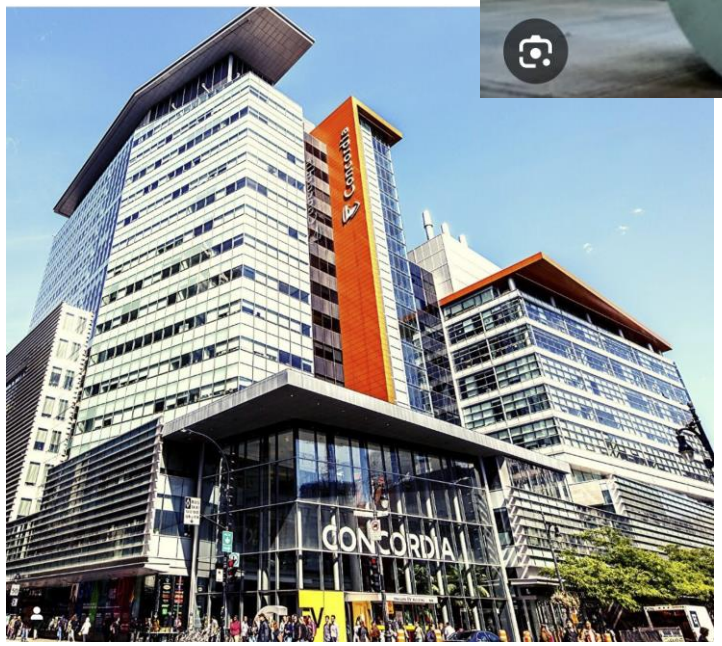
CONCORDIA

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Myself

- First student to enroll in the CIISE in 2004
- Supervisors: Dr. Zeng & Dr. Yang
- Master of Quality Systems Engineering (MASc) in 2007
- ASQ Certifications: CQE, CRE, CSSBB, CQA
- RdQCC LLC (located at San Diego, CA)
- Client served: JnJ, Medtronic, Philips, BD, Zimmer, Abbott, Google life science, Syncardia…
- Involved projects: Robotic surgical, artificial heart, heart pump, pacemaker, ICD, stent graft, ventilator, orthopedic……

Introduction to Quality Engineer Careers

- Quality engineers play a crucial role in ensuring the safety, effectiveness, and compliance of medical devices.
- They actively contribute in all stages, including design, development, manufacturing, and post-market surveillance of medical devices.
- Key quality engineering areas include: design control, risk management, audit, nonconformance material, sample size, process control, gage R&R….

Three Pillars of Quality

Key Responsibilities of a Quality Assurance

- Quality Assurance (QA)
  - ✓Design Control: Ensuring that medical devices are designed and developed in accordance with regulations and standards (ISO 13485, FDA 820.30).
  - ✓Risk Management: identifying and mitigating risk associated with medical devices throughout their lifecycle. (ISO 14971, IEC 62304, 62366, 10993)
  - ✓Job Titles: Design quality engineer, design assurance engineer, quality assurance engineer, risk management engineer, R&D quality engineer
  - ✓Technical expertise: requirements management, logic thinking, design principles, testing methodologies
  - ✓Projects Involvement: NPI, FDA remediation, EU MDR remediation
  - ✓Certifications: ASQ Certified Quality Engineer (CQE), CRE

Key Responsibilities of a Quality Engineering

- Quality Engineering
  - ✓Non-conforming materials, FAI, PPAP, CAPA
  - ✓Process studies and validation, MSA, GR&R, verification & validation
  - ✓Post market surveillance: complaint handling, failure causes
  - ✓Job Titles: Quality engineer, quality control engineer, operations quality engineer, process quality engineer, manufacturing quality engineer, validation engineer
  - ✓Technical expertise: statistical analysis, manufacturing, supply chain
  - ✓Project Involvement: Sustainable projects, continuous improvement, LEAN, Kaizen, Kanban, MRB
  - ✓Certifications: ASQ CQE, CSSBB, CSQE, CMQ

Key Responsibilities of a Quality System

- Quality System
  - ✓Document control: Change control, QMS, SOPs, quality manual, training programs
  - ✓Audit: internal QMS audit, 3rd party audit, supplier audit
  - ✓Compliance: industry standards, regulations
  - ✓Job Titles: Document control specialist, quality auditor, supplier quality engineer
  - ✓Technical expertise: Document management tools (SAP, MasterControl),GDP, FDA cGMPs, MDSAP, interpersonal skills
  - ✓Project Involvement: process audit, product audit, system audit, supplier audit
  - ✓Certifications: ASQ CQA, CSSBB, CMDA

How AI impacts our Quality Engineering

- Risk analysis: predict potential risks, including failure modes, hazards, hazardous situations, harms based on requirements and complaints.
- Risk control: identify root causes and propose risk mitigations.
- Manufacturing defects: analyze production images and videos to detect and address manufacturing defects.
- V & V tests: generate comprehensive test plans and test protocols, including steps, test cases, and activities to ensure critical functionality is thoroughly verified.
- QMS documentations: create essential QMS documents, including Quality Manual, SOPs, WIs, templates

Additional Cents

- Keep curiosity for the new things.
- Embrace continuous improvement.
- Open to contractor or consultant roles.
- Explore the abundant job opportunities in the field of quality.
- Join ASQ (American Society for Quality): with 80,000 members across 140 countries and 250 volunteer-run local ASQ sections. It is a valuable professional network.

Questions and Answers