Quality Engineer Position at FlexDex Surgical

FlexDex Surgical (www.flexdex.com) is an exciting medical device OEM built on a research and technology developed at the University of Michigan. The company, located in Brighton, MI, is developing and commercializing a suite of articulating endoscopic instruments for minimally invasive surgery. Leveraging fundamental innovations in mechanism design and robotics, these affordable instruments provide enhanced dexterity, intuitive control, and ergonomics which so far, have been seen only in multi-million-dollar robotic surgical systems. FlexDex’s first generation needle driver was launched in the US in 2017 and has gained significant attention and praise at various surgical conferences since that time.

Quick Overview: [https://youtu.be/q0pEYkMlzYE](https://youtu.be/q0pEYkMlzYE)

Surgeon Reaction: [https://vimeo.com/210646341](https://vimeo.com/210646341)

Wonderful Engineering claims that FlexDex has "Redefined the Essence of Robotic Surgery".

Impact on Healthcare: [https://vimeo.com/238057183](https://vimeo.com/238057183)

Surgeon Interview: [https://vimeo.com/386141238](https://vimeo.com/386141238)

To help realize its vision, FlexDex Surgical is looking to hire an experienced Quality Engineer with a strong, diverse, background in supplier and design quality. The candidate must have a strong understanding of design controls, transfer of designs to manufacturing, conducting audits, managing nonconformity issues, and leading continuous improvement projects. The candidate’s responsibilities include maintaining purchasing controls and supplier quality procedures within the Quality Management System, conducting supplier audits, identifying critical to quality attributes, developing control plans for qualification, and leading production phase tasks (e.g. tooling qualifications, design history file management).

Key requirements for the job include:
- Bachelor’s or Master’s degree in Engineering or related discipline
- 5 years experience in related role
- Auditing experience (with auditor certification preferred)
- Knowledge in the application of medical device regulations and industry standards
- Ability to manage nonconformity issues and contribute to continuous improvement efforts (e.g. CAPA)
- Strong foundation in identifying Critical to Quality (CTQ) attributes and developing control plans for qualification
- Foundation in mechanical engineering fundamentals and design principles (e.g. dynamics, materials)
- Understanding various manufacturing processes (e.g. injection molding, CNC machining) is a plus
- Effective communication skills and ability to develop effective relationships with existing and potential suppliers
- Self-driven, motivated to work with a fast-pace team, and strong desire to make an impact.

By joining FlexDex, you will become a member of a high-performing team of individuals who are driven and passionate about developing product that will positively impact the health and wellbeing of our customers.

Applicants please email jobs@flexdex.com with a subject line of “Quality Engineer.” Please attach your resume and a cover letter summarizing your key skills and experiences at a minimum.

Candidate submission deadline: March 6, 2020