Product Development Engineer at Lapara Surgical

For Biomedical or Mechanical Engineers who are looking for a new challenge, Lapara Surgical is offering a position as a product development engineer. Lapara Surgical is a startup with an innovative approach to making laparoscopy more affordable and widely accessible, by offering the 'Minimal Invasive Assistant' (MIA). The MIA is a fully mechanical, robotic system that facilitates benefits for patients, surgeons, and hospitals. Currently a Proof of Concept version is tested and validated and needs further development into clinical prototypes. To bring our product into the next phase, new designs and smart solutions need to be developed. Are you the creative mind who likes to invent new principles, spend hours in a workshop to test new ideas, and likes to work in a small team, then send us your resume and an introduction letter why you are our next "mechanical genius".

Job responsibilities

- Design and develop new laparoscopic and surgical instrumentation and develop improvements and modifications to current products
- Interact with manufacturing, regulatory affairs, product management, and other functional departments to define and develop product requirements and concepts
- Generate product models, concept layouts, and prints using a CAD software
- Perform the required activities and generate the appropriate documents to ensure compliance with CE and FDA Design Control regulations, and to support CE, 510(k) submissions
- Develop mechanical test protocols and coordinate activities required to fabricate test parts and complete mechanical testing
- Be responsible for the integration of all subparts of the final product
- Be responsible for initial patent review of designs for freedom to operate
- Perform other special projects and functions as assigned by manager
- Brainstorming and executing mechanical design concepts in all phases of the development cycle
- Generating innovative designs
- Generating dimensional and tolerance analyses or be responsible for the analyses by others
- Driving failure analyses and Design of Experiments (DOEs) to reach design solutions and corrective actions
- Manage development process

Qualifications

- A minimum of a Master's degree in Engineering or related discipline is required; Mechanical Engineering degree is preferred
- A minimum of 2 years product development or design control experience in mechanical products is required
- Experience working in medical device regulations, including GMP (Good Manufacturing Practices), QSR (Quality Systems Regulations) and ISO (International Organization for Standardization) quality requirements is preferred
- Strong product quality development experience with a proven track record in product development verification/validation, process verification/validation, and design/process failure modes and effects analyses is preferred
- Prior experience working with surgical medical devices is preferred
- Experience in value engineering and design-for-manufacturing is preferred
- Knowledge of CE and FDA 510(k) submissions process and regulation controls is preferred
- Demonstrate strong initiative and follow through in executing project responsibilities, overcoming obstacles and balancing multiple priorities effectively through strong technical and/or project leadership experience
- Strong problem solving, decision-making, and root cause analysis skills is required
- Knowledge of CAD software is required (Solid Works preferred)
- Willing to work with cadavers and within an Operating Room setting is required

Interested?

Please send an email to info@laparasurgical.com with an application letter and resume or call Product Manager Renée Molman on +31644127671 with any questions you might have about the job position or about Lapara Surgical BV.