

## Junior QA Manager

### **MedEnvision the company**

MedEnvision is a successful young and dynamic company selling products worldwide (Europe, US, Australia, etc). The company originates from an innovative idea coming from a surgeon who wanted to improve his efficiency in the OR. A coherent group of people, with an academic and industrial background, put their heads together in 2011 to investigate the idea and its feasibility. Shortly afterwards, MedEnvision was founded and the ISO13485 certificate was obtained. After patent examination and subsequent patent application in 2012, the first prototype was clinically tested. Currently, MedEnvision launches three product lines, which are all CE marked and FDA listed.

For our offices in Aarschot we're looking for a motivated colleague to further support our growth.

### **Function**

- Manage and execute the QA activities supported by our legal officer
- Manage and execute all activities related to the company's Quality Management Systems
- Manage and execute all technical files regarding current and new products
- Manage Product Documentation and Product labeling review and approval
- Manage sub-contracting Quality Agreement review and approval
- Manage Quality Assurance activities related to Incoming Inspection
- Manage customer complaints and CAPA management
- Manage the supplier's production QC and regulatory compliance improvement programs

### **Competences**

- Bachelor or Master degree in a relevant field
- Knowledge of and experience regarding technical testing process of medical devices
- Knowledge of and experience regarding Production Quality & Process Validation
- Knowledge of and experience regarding clinical validation and testing of medical devices
- Proficient in the English language, both written and verbal
- Knowledge of and experience regarding ISO13485 and MDR are a plus
- MS Office

### **Personality**

- Autonomous character
- SME minded

### **MedEnvision offers**

You'll work in an innovation driven organization with an entrepreneurial and transparent culture. MedEnvision offers you an attractive salary and the opportunity to take the lead in our QA activities.

### **Contact**

administration@medenvision.com