



Thread & Lift is a Medical device company specialized in the Aesthetic field and most specifically thread lifting. Our product, named Infinite-Thread®, is a permanent suspension thread. It allows a medical facelift without surgery, with sustainable and natural outcome for the patient encountering subcutaneous tissue lowering. This IIB medical device meets the expectations of the modern patient since it is used without general anaesthesia, with discretion and ensures minimal social withdrawal. We serve patients too young to accept the surgical alternative but also aware of the objective limit of the simple filler injections.

Thread & Lift's customers are health professionals, mainly plastic surgeons, dermatologists and aesthetic practitioners. We sell our suspension thread directly to our customers. To be authorized to buy our product, all of them have been mandatorily trained by one of our experts.

Our ambition is to be a strong and useful partner in their development. That is why we have also developed a large range of services associated to our medical device.

The company is currently ISO 13485-2016 certified and its product, the Infinite-Thread® is CE marked. Today, Thread & Lift is present in 9 countries of Europe.

To support its growth, Thread & Lift is actively looking for one:

QA/RA Manager

Main activities

The QA/RA Manager will take care of the following activities:

- QMS management, maintenance and improvement
- Customer complaints, non-conformities, audits, CAPA management
- Interaction with competent authorities
- Interaction with notified body
- Coordination of registration procedures
- Compliance to applicable standards and directives (ISO 13485, 93/42 CE, MDR),
- Coordination of market authorization
- Ensure products are developed, manufactured, released according to QMS
- Qualification, audits and follow up of contractors
- Support the CEO with materiovigilance

Profile

The successful candidate should meet the following criteria:

- Minimum 3 years of relevant experience in medical devices QA/RA
- Deep knowledge of directive 93/42/CE and ISO 13485 standard
- Full mastering of CE regulation, risk management, quality processes, sterilization validation
- Familiar with FDA processes
- Broad experience in R&D, industrialization, production and V&V
- Experienced in QMS management
- Fluent in French and English
- Start-up mindset

The successful candidate shall be able to:

- Constitute and defend the technical file against the notified body
- Evaluate and suggest best regulatory strategies
- Coordinate the activities around QA and RA internally and with contractors
- Interpret and exploit regulatory and scientific information
- Communicate, read and write regulatory or technical documents (protocols, reports, ...)
- Advise on quality assurance and regulatory aspects
- Release the productions lots

The offer

Full time permanent contract in a challenging environment.

Based in a dynamic and friendly environment in Brussels.

Salary package aligned with experience.