Since its foundation in 1994, SPIGGLE & THEIS Medizintechnik GmbH has successfully established itself with the development and distribution of product specialities in the field of ENT surgery. We are an independent and fast-growing company in the medical sector and sell our products in over 70 countries worldwide. In order to meet the increasing workload and our own requirements, the following new positions are available to strengthen our existing team:

1. Specialist (m/f/d) Clinical Affairs and Market Surveillance / Full time

Your tasks:

- Preparation and implementation of post-market clinical follow-up studies, as well as planning, preparation, conduct and evaluation of clinical trials according to EN ISO 14155.
- Planning, creation and maintenance of CERs (Clinical Evaluation Reports)
- Preparation of clinical PMS plans and reports, post-market surveillance reports and periodic safety update reports.
- Risk assessment of market surveillance - and vigilance-data and evaluation of complaints data for market surveillance and clinical evaluation.
- Maintenance of the product registration in Eudamed.

Your ideal profile:

- PhD/master/diploma in life science, master of engineering (medical technology) or comparable academic background.
- Alternatively: several years of practical work experience in medical technology and/or regulatory affairs or development.
- Experience in scientific research and creation of scientific papers would be an advantage.
- Very good knowledge of Excel and statistical analysis.
- Business fluent in German and English language.
- Willingness to take responsibility, diligence and flexibility.
- Customer orientated and independent way of working.
- Ability to communicate and work in a team.
- Confident handling of MS Office.

2. Specialist (m/f/d) Regulatory Affairs Instruments / Full time

Your tasks:

- Preparation and maintenance of high quality product documentation according to international regulatory requirements.
- Supporting the product development in all regulatory issues with a focus on reusable surgical instruments, endoscopes and high-frequency instruments.
- Plan and conduct pre-clinical testing for reusable surgical instruments.
- Coordination of regulatory projects with the respective stakeholders and support the Person Responsible for Regulatory Compliance (PRRC) in the conformity assessment of products.
- Coordinate and implement change control processes.

Your ideal profile:

- PhD/master/diploma in life science, master of engineering (medical technology) or comparable academic background.
- Alternatively: several years of practical work experience in medical technology and/or regulatory affairs or development.
- Practical medical technology know-how is an advantage.
- Business fluent in German and English language.
- Willingness to take responsibility, diligence and flexibility.
- Customer orientated and independent way of working.
- Ability to communicate and work in a team.
- Confident handling of MS Office.

3. Specialist (m/f/d) Regulatory Affairs Disposables / Full time

Your tasks:

- Preparation and maintenance of high quality product documentation according to international regulatory requirements.
- Supporting the product development in all regulatory issues with a focus on lipo harvesting products, ENT-catheter and PVA-products.
- Planning, coordinating, implementing, and testing of documents focusing regulatory affairs.
- Planning, organisation and implementation of risk management activities according to EN ISO 14971.
- Coordination of regulatory projects with the respective stakeholders and support the Person Responsible for Regulatory Compliance (PRRC) in the conformity assessment of products.
- Coordinate and implement change control processes.

Your ideal profile:

- PhD/master/diploma in life science, master of engineering (medical technology) or comparable academic background.
- Alternatively: Professional experience in the certification of medical devices as well as in the creation or compilation of regulatory documentation.
- Initial knowledge of the requirements of the Medical Device Regulation (EU Regulation 2017/745) is an advantage.
- Business fluent in German and English language.
- Some initial experience in project management.
- Customer orientated and independent way of working.
- Ability to communicate and work in a team.
- Confident handling of MS Office.

For all positions we offer:

- Open corporate culture with flat hierarchies.
- Extensive on-the-job training for a successful start.
- Informal working atmosphere.
- Holiday and Christmas bonus.
- Company pension scheme.
- Opportunity to work part time in home office.

If this sounds appealing to you, please send your application, stating the earliest possible starting date, your salary expectations as well as your CV and references by e-mail to: bewerbung@spiggle-theis.com