We are a small, young independent company with a clear strategic direction, as well as a strong focus on customer orientation and quality. As one of the market leaders, we develop high-quality dental implants made of zirconium dioxide and sell them worldwide through an international network.

To support our Quality & Regulatory team, we are looking for the following with immediate effect or by appointment:

Quality & Regulatory Affairs Specialist (m/f/d), 80 – 100%

Your tasks

- Monitoring and implementation of regulatory requirements for medical devices
- Post Market Surveillance and Risk Management
- Support in lifecycle management, implementation and updating of technical documents
- Submission, maintenance, and renewal of product approvals in the sales markets (USA, EU, etc.)
- Support in the further development and implementation of the QMS quality management system
- Support in the preparation and implementation of internal and external audits

What you bring along

- Bachelor's degree or equivalent qualification in science, engineering, or related field.
- At least 3 years of experience in the field of quality management and regulatory affairs of medical devices is desirable.
- In-depth knowledge of national and international regulations for medical devices (ISO 13485, MDR 2017/745, FDA, etc.). Knowledge of ISO 14155 would be an advantage.
- Know-how in clinical trials, risk assessments and biocompatibility would be an advantage.
- Very good knowledge of German and English, both written and spoken. Additional communication skills in French are an advantage.
- Team spirit, independence, and a structured way of working
- Self-motivated team player who enjoys working in an extended team

What to expect

- A permanent position in an innovative, fast-growing company
- Diverse tasks and independent action
- Performance-related, competitive remuneration
- Cohesion and mutual support in a small team

Do you feel that this exciting challenge appeals to you? Then we would be pleased if you would send your complete CV with a letter of motivation in digital form to the responsible person Ms. Bürki nutcha.buerki@zsystems.com .