About us

FKG Dentaire Sàrl – a Henry Schein company - is at the forefront in the development, manufacturing and distribution of high precision dental products for dentists, endodontists and laboratories. Our mission is to strive to innovate new ways of working: more respectful, more efficient, more agile, more ergonomic, and safer - serving new generations, promoting new visions of life, for us, for you, and for your patients. For nearly a century, we have been constantly reinventing what we thought we knew. We are committed to developing a culture of performance by promoting equity, loyalty and respect.

We embrace change, the kind that empowers endo to Change the game.
Our mission is to make endodontics safe and easy through innovative, high-quality and less invasive solutions

To complete our Regulatory Team, we are looking for a

RA Engineer

Role mission

Participate in the development and deployment of our regulatory affairs processes and report on their effectiveness and any need for improvement

Your responsibilities

- Manage the international registration of medical devices to obtain the approvals needed to market our products
- Ensure the creation and maintenance of technical documentation applicable to our products (CE marking files) and participate in new product development projects as a representative of the QA-RA function to ensure that applicable regulatory requirements are taken into account and met
- Actively participate in maintaining the compliance of our quality management system with applicable regulatory and standards requirements, as well as the corresponding certifications (ISO 13485, CE marking, MDSAP)
- Ensure effective communication with your external contacts, customers or suppliers, as well as other departments within the company, and support them in all matters relating to regulatory affairs
- Lead projects linked to implementation of new regulatory or normative requirements and continuous improvement and contribute to regulatory and normative watch
- Contribute to post-marketing follow-up activities (PMS)
- Participate in various activities of the Quality and Regulatory Affairs Department, in particular: maintaining regulatory databases, handling vigilance cases, conducting internal and supplier audits, managing modifications, analyzing data, handling CAPAs
- Ensures employee awareness of and training in applicable regulatory requirements

Your profile

- Advanced scientific or engineering training
- 3 years' professional experience in medical device regulatory affairs
- Knowledge of the main standards and regulations applicable to our field (ISO 13485:2016, Regulation (EU) 2017/745, 21 CFR Part 820 and other regulations applicable in MDSAP jurisdictions)
- Good knowledge of MS-Office tools (Word, Excel, PowerPoint)
- Good level of written and spoken English (B2), Spanish or Arabic would be a plus
- Team spirit
- Excellent analytical skills
- Pragmatism, proactivity, rigor
- Excellent communication and interpersonal skills

We offer

- A stimulating and dynamic work environment at the cutting edge of industrial automation
- Opportunities for professional development and career advancement
- A collaborative and inclusive corporate culture that values innovation and teamwork
- Attractive benefits (free parking place, home office, flexible work hours, minimum 5 weeks' vacation, health insurance participation)

Entry into function : immediately or to be agreed

If you recognize yourself in this job description, are dynamic and interested in taking on challenges in a growing company, then we look forward to receiving your full application at: rh@fkg.ch.

We look forward to discovering your talent and discussing how you can contribute to our success !