matricel
ALL IT TAKES TO REGENERATE

matricel Konrad-Zuse-Str. 6, 52134 Herzogenrath, Germany

Regulatory Affairs Specialist (m/f/d)

Matricel GmbH is a fast growing, successful biomedical company with worldwide activities. We develop, produce and distribute innovative medical devices for clinical applications in the regenerative medicine. The resorbable implants made of collagen are used for bone and tissue regeneration in the dental field, orthopedics, trauma surgery and plastic surgery.

To strengthen our Regulatory Affairs team in Herzogenrath, we are looking for a

Regulatory Affairs Specialist (m/f/d)

as soon as possible (40 h / week)

Primary duties & responsibilities:

- Coordination of projects to implement new regulatory requirements (i.e. MDR (EU) 2017/745) and supporting other departments to comply with these regulatory requirements
- Supporting development projects for RA aspects, creating development-related and technical documentation for medical devices, editing existing technical documentation
- Communicate and work with national and international Regulatory Affairs agencies
- Support the development of national and international regulatory strategies
- Initiate and implement projects for new or updated regulatory requirements to ensure continuous market access
- Generate, support and review of clinical evaluations, post-market clinical follow-up (PMCF) activities, clinical studies, risk management, etc

Preferred qualification:

- Master or comparable academic degree in Biomedical Science, Chemistry, Pharmacy, Natural Science or equivalent
- Relevant experience as Regulatory Affairs Specialist in the field of medical technology, preferably in an international context
- In-depth knowledge of standards and regulations such as: ISO 13485, ISO 14971, 21 CFR part 820, MDSAP, MDR, other international regulatory requirements
- Experience in registration of medical devices in China, Japan, Brazil desirable
- Creation and updating of plans & reports according to MDR (e.g. SSCP reports, PMCF reports, PSUR)
- In-depth knowledge of clinical evaluations, post-market clinical follow-up (PMCF) activities, clinical studies, risk management, etc.
- Languages: Fluent in German, English, both in conversation as well as in writing

We offer good development opportunities in a dynamically growing company with a highly motivated team. If you are interested in the advertised position, please send your complete application documents including your earliest entry date and desired salary by email to Stephanie Brehm (stephanie.brehm@matricel.com).