Perform – Transform – Together

Compliance Engineer R&D

Medentika® has become synonymous with the successful development of high-quality products in dental implantology. With a determined, dynamic team, we have been meeting the challenges of this rapidly growing market for over 15 years. Our products are continuously, innovatively developed, manufactured in Calw, Germany and sold to more than 50 markets worldwide. The world is growing together, we are all connected and you are in the center of it. "Knowledge and experience are not enough. If you want to make a difference, you need passion."
We are looking for you as our new Compliance Engineer RD (m/f/x). In this role you will be part of an inspired and dynamic team, shaping together the future of our advanced and innovative Medentika prosthetic and implant portfolio. The position is based in Hügelsheim, Germany and reports to the Head Compliance Engineering RD.

Your tasks

- Manage design control compliance for product's change and development activities
- Ensure compliance, plausibility and completeness of related DHF documentation due to processes and regulatory requirements
- Conduct and moderate requirements workshops to ensure completeness and plausibility of product requirements specification and it's translation into design inputs
- Translate regulatory requirements into a product compliance strategy
- Support definition and release of various specifications (such as drawings, labels etc.)
- Support concept and specification engineering projects from a compliance perspective
- Coordinate verification and validation-activities (design output, verification & validation)
- Support and conduct risk management workshops
- Manage usability engineering activities
- Coordination of design transfer activities
- Support product surveillance (products, components, processes)
- Support remediation and implementation of design control related processes
- Perform and support operational CAPA activities (root cause investigations/Measure definition and handling)
- Ensure project documentation according to quality standards
- Enforce compliance to regulations and internal processes

Your profile

- Degree in mechanical engineering, bioengineering, or related field of study
- Experience in a related area such as development, quality management or regulatory affairs of medical device products is required
- Experience in dental industry is a benefit
- Sound knowledge in applicable standards and regulations (MDD/MDR, FDA, ISO) and design control process
- Knowledge in the area of product development, manufacturing and testing, with specific development tools (e.g. FMEA, tolerance analysis, analysis of mechanical properties, statistical analysis)
- Experience in risk management is a benefit
- Experience in usability engineering is a benefit
- Audit experience with notified bodies and authorities is a benefit
- Strong analytical skills and result orientation
- Distinctive interpersonal skills, customer focus and entrepreneurial thinking
- Effective and convincing communication, both verbally and in writing, fluent in
- English and German

Who we're looking for?

Agile Mindset. This is about learning and adapting, continuously improving what we do to deliver a valuable product to our customers. You collaborate and communicate leading to team success

Team player. We love learning from each other, great ideas are shaped and inspired by other ideas in order to achieve the simplest, smartest and safest solution

Innovative. We create space for ideas and love to use the newest technologies. To be cutting edge, we need to stay on top and deliver an amazing digital experience

All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, or disability.

We look forward to your application!

Please send us your cover letter, résumé and certificate to **job@medentika.de**