GLOBAL REGULATORY AFFAIRS MANAGER

Posted on 10 augusti, 2021

Company Name OssDsign

Location Uppsala

Job Description

OssDsign is expanding and looking for a **Regulatory Affairs Manager** to join their business in Uppsala. This is an opportunity to work with exciting products and dedicated people in an international environment!

Responsibilities

- Maintains and communicates current knowledge of the developments and changes to applicable laws, regulations and industry standards
- Develop and implement regulatory strategies for new and modified products and regulatory processes
- Representing Regulatory affairs as core team member in product development, product improvement and production improvement projects
- Manage submissions to obtain and maintain global regulatory approvals of products
- Communication with competent authorities and/or notified body regarding pre-submission strategy/regulatory pathway development, testing requirements, clarification and follow up of submissions under review
- Procurement and management of external regulatory consulting and contracting resources to assist, as agreed with senior management.
- Review and approve product and manufacturing changes for compliance with applicable regulations.
- Review and approve device labelling and promotional materials to ensure compliance with applicable regulations.
- Provide internal expertise and guidance in interpreting regulations and agency guidelines
- Represent Regulatory Affairs in internal and external audits

Qualifications

- Minimum Master of Science in Engineering/Chemistry/Biology/Medicine or similar
- Desireable to have at least 8-10 years experience within the Medical Device industry .

- At least 5 years experience within Medical Device Regulatory Affairs. Knoweledge of, and experience in, the Orthopaedics sector an advantage
- Background from product development and/or production based environment.
- Deep knowledge on medical device regulations in EU, US and desireable also Japan
- Experience of regulatory requirements for implantable class III medical devices and implantable custom made devices
- Experience of compilation and submission of technical documentation for implantable class III medical devices
- Experience of both compilation of documentation for both the 510(k) and PMA/IDE FDA pathways
- Ability to interpret the regulations in different countries.
- High degree of integrity and responsibility and ability to work independently of others.
- Ability to work as part of a team and to work with people from across the whole company.
- Able to speak and write fluently in English and Swedish.
- Ability to communicate effectively with global regulatory authorities
- Ability to clearly communicate options, opportunities and risks to internal stakeholders.
- Robust and persuasive, with the ability to effectively resolve functional disagreements with a collegiate, non-confrontational style
- Organized, structured and accurate way of working.
- Strong analytical skills.

Apply today!

To apply, please send your CV and a cover letter asap to Daniel Kremer at; daniel.kremer@moveup.se

If you have questions regarding this open position, please contact Daniel at +46 (0)733 87 27 24.

By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.

Om företag

OssDsign is an innovator, designer and manufacturer of implants and material technology for bone regeneration. We are surgeons, scientists and engineers - committed to improving outcomes in cranioplasty and spinal surgery.

By combining clinical insight with proprietary material technology and patient-adapted design,

OssDsign supplies an expanding range of tailored solutions for cranial repair and spinal fusion. OssDsign's technology is the result of collaboration between clinical researchers at the Karolinska University Hospital, Stockholm, and material science experts at the Ångström Laboratory at Uppsala University.

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