STELLENAUSSCHREIBUNG

Zum nächstmöglichen Zeitpunkt soll die Position eines Regulatory Specialist Medical Device besetzt werden. Gesucht wird ein

Regulatory Specialist Medical Device (m/w)

(am Standort in Hannover oder Hamburg)

zu den Aufgaben / Verantwortungsbereichen:

- The Regulatory Specialist is responsible for executing and supporting internal regulatory review processes for the appropriate regulatory compliance documentation of medical devices including raw materials, manufacturing processes and products across the European and International Market including U.S.
- The position supports the interactions with the product life cycle management, the development process the supply chain, internal teams, external customers and a variety of regulatory bodies
- Execute and assist internal regulatory review processes for product life cycle and product development
- Execute and improve internal records systems especially regulatory flies (Technical File, PMA, 510k)
- Assist in SOP development, review and implementation
- Support the evaluation of regulatory impact on current and new products
- Represent regulatory affairs on assigned product and project teams
- Transferpreisdokumentation
- Assist the investigation and evaluation of regulatory history, guidelines, policies and regulation specific to products and markets
- Provide regulatory input to product life cycle process including new product development processes, manufacturing, sales and customers
- Assist in the development of regulatory strategy and update strategy based on regulatory changes
- Written and verbal communication with customers and regulatory bodies

zur Person und Anforderungen:

- Dipl.-Ing./Bachelor´s degree (BS) in Engineering, Physics, Chemistry, Biology or a related discipline
- 2+ years related experience in medical device or pharmaceutical industry
- Knowledge of applicable international regulations and standards (MDD, CMDCAS, 21CFR820, ISO 13485 and OSO 14971)
- Able to travel up to 10%
- Ability to evaluate complex medical and technology circumstance
- Fluent in German sand excellent English language skills, ability to communication with regulatory bodies verbal and in written
- Excellent Written and Verbal Communication Skills
  - Ability to think strategically, exercise judgment and problems solve
  - Ability to identify compliance risks and escalate as necessary
  - Ability to work in a multi-functional team environment

Bitte senden Sie Ihre Bewerbungsunterlagen bestehend aus einem Anschreiben und Lebenslauf per E-Mail an Frau Astrid Völker (a.voelker@nikkiso-europe.eu, 040-414 629 44 19)