Quality Assurance/Regulatory Affairs Specialist

Vesco Medical, based in Columbus, Ohio is a vibrant company that is organized around our customers. Vesco Medical is backed by 50 years of experience in the manufacture of disposable medical devices. Our products comply with applicable regulatory requirements as established by ISO 13485, U.S. Food & Drug Administration (21 CFR Part 803, 806, 820), MDD 93/42/EEC, CMDR registered Quality Management Systems. The person in this position will work closely with the Vesco R+D Lead to ensure that the quality system is implemented, monitored and maintained in accordance with all applicable regulatory requirements.

Responsibilities:

- Develop and implement regulatory strategies and prepare FDA (IDE, 510k, PMA, 513G) and international submissions (CE Mark, TGA, CMDR, etc.) for new products and product changes as required to ensure timely approval for market release and in accordance with applicable regulations, standards, and guidance.
- Monitor industry and regulatory trends to develop strategy and provide guidance related to these trends.
- Advise technical, marketing, and sales personnel on regulatory requirements (e.g. Design Controls, CE Marking, IDE, IRB, Labeling, and Promotion).
- Maintain Vesco Medical's Medical Device Listing and Device Establishment registration forms.
- Work with Manufacturing and R&D to ensure that products are developed and produced according to applicable regulations and standards.
- Ensure adequate follow-up through the implementation of corrective and preventative actions (CAPA) as required.
- Monitor and audit recall/field action activities to assure compliance with Standard Operating Procedures related to corrective actions, CFR requirements and customer complaints.
- Strengthen quality awareness throughout the organization, support technical services and process improvements. Eliminate barriers and proactively investigate quality issues using appropriate process improvement and problem solving techniques.
- Manage the risk assessments and follow-up activities and ensure visibility for potential risks.
- Ensure timely product disposition in compliance with all applicable regulatory and legislative requirements.
- Oversee maintenance of database(s) or spreadsheet(s) for the worldwide regulatory status of products.
- Assist in the development of an effective Document Control Management system, including relevant Standard Operating Procedures (SOPs) and Work Instructions (WIs) for the proofing, filing, copying, scanning, archiving, retrieval, and maintenance of all controlled documents and records required by applicable regulations.
- Assist in the management of the Quality Assurance Processes to be followed in the event of a complaint, deviation, CAPA, recall or field action per 21 CFR 803, 806, 820 and ISO 13485. Coordinate and participate in investigations.

Required Qualifications:

- Excellent quantitative and analytical skills
- Ability to prioritize tasks in a fast-paced environment
- Strong written and oral communication skills required
- Proficiency in Microsoft Office (Word, Excel, PowerPoint)
- Bachelor's Degree in Engineering or related field.

Desired Qualifications:

- Knowledge of 21 CFR 803, 806, 820, ISO 13485 and all applicable requirements and regulations to support the manufacture and distribution of medical devices
- Minimum of 5 years Quality Assurance and Regulatory Management