

Senior Regulatory Affairs Specialist

Location – Sarasota, FL (Hybrid)

Job Description

If you are detail oriented and thrive on taking on new challenges, then this role is for you! You will work directly with the Operations and Design teams to support the rapidly growing manufacturing of REACTHEALTH'S leading product. If you enjoy being part of a collaborative team, building relationships and making a difference, then we want to hear from you!

The Senior Regulatory Affairs (RA) Specialist assesses product changes for reportability to appropriate regulatory agencies. Responsible for maintaining a strong collaborative partnership with cross-functional team members that facilitates organizational success by protecting patient/user safety and meeting business needs.

Key Responsibilities include:

- Prepare and maintain regulatory submissions, maintain 510k product registrations.
- Approve design/manufacturing changes. Analyze product changes for impact to current regulatory filings
- Maintain current standards list. Identify and lead projects to comply with latest standards (FDA expectation)
- Regulatory Intelligence: Monitor regulatory environment (FDA), Provide regulatory environment update in Management Reviews
- Primary point of contact for FDA interaction (questions/responses). Participate in FDA inspection as needed.
- Recall administration
- Participate in/lead internal audits
- If plan to market in other geographies, stay current on regulatory requirements. Lead CE mark requirement definition/implementation
- Support maintaining a cGMP compliant Quality Management System to ensure the Quality System is established and maintained in accordance with FDA 21 CFR 820, cGMP, (MDD 93/42/EEC, MDR 2017/745,) and ISO 13485 regulatory requirements.
- Develop relevant regulatory procedures and work instructions as necessary.
- Lead audit readiness initiative. Investigate and document issues relating to the product, process, or Quality System relevant to the regulatory compliance.

Qualifications

Key qualifications and experience include:

- Bachelor's degree in engineering or life science discipline, or equivalent experience
- Minimum 7 years of RA experience in the medical device industry
- Strong understanding of ISO 13485 and FDA 21 CFR Part 820 requirements
- Strong understanding of statistical techniques
- Understanding of regulatory requirements for software submission a plus
- Regulatory Affairs Certification (RAC) highly preferred
- Excellent communication and documentation skills

- Strong organization and attention to detail skills