QUALTY AND REGULATORY AFFAIRS (QARA) SPECIALIST ID: 13102020

Employees are the key to success in our organization. We value our employees and their skills in furthering the cause of helping lives. This opportunity is in the IZiel Healthcare division. IZiel Group is in the business of providing engineering and regulatory services, engineering design and analysis and resource placement services. We work with global medical device manufacturers, automotive, engineering and oil and gas clients. Thorough leadership, robust work planning methodology and exceptional customer service are the key enablers of our success.

POSITION DESCRIPTION:

The Quality and Regulatory Affairs (QARA) Specialist will provide leadership in the quality and regulatory affairs function to understand regulatory requirements of medical devices, create relevant documentation and providing consultancy as an expert in regulatory affairs for IZiel clients. The RA specialist will work with clients in India and globally across USA and Europe to provide solutions for getting approvals for their products for launch in the Europe and USA. The candidate will require to go through extensive training in various country specific regulations as needed to keep themselves up-to-date with the latest and greatest updates as well as represent IZiel at various forums from time to time. The position will require support to make our clients high-end products compliant to the new CE Medical Device Regulation (MDR).

POSITION RESPONSIBILITIES:

- Having extensive knowledge of regulatory pathways for medical devices approvals in various countries with primary focus on US & European regulatory pathways.
- Ability to research data and develop a regulatory strategy for approval of products for medical device manufacturers. Experience in creating and documenting a regulatory strategy successfully will be a plus.
- Should have knowledge of USFDA establishment registration & device listing.
- Ability to write 510(k) and PMA applications with relevant information and input from the engineer in teams.
- Experience with preparing design & development documentation to align with the regulatory strategy.
- Experience for compilation of technical file/design dossier as per USFDA and CE guidelines.
- Need to do documentation as per FDA & CE-MDR regulations and ISO standards. Perform audit compliances, analysing gaps, shortcomings as per FDA/ISO regulations.
- File Annual reports and manage regulatory changes per the respective FDA and CE mark guidelines.
- Understanding of cGMP regulations per 21 CFR and ISO 13485. Understanding of Risk Management per ISO14971.

DESIRED/PREFERRED QUALIFICATIONS:

- Bachelor’s with 8+ years of experience OR Master’s with 6+ years of experience.
- Willingness to travel, if required
- Strong Communication Skills (Written & Oral)
- Team Player
- Technical Writing
- Experience in client co-ordination
- Experience with basic statistics and/or reliability methodologies.
- Detail oriented, ability to read various standards and guidelines & define implementation details.