Job Title: Contract Regulatory Affairs Specialist Req 1096-20

LOCATION: Valencia, CA

POSITION SUMMARY:
Working with minimal supervision, manage complex projects/products, including responsibility for the content, assembly, pre-final review, and filing of major medical device applications (e.g., Technical File, Design Dossiers, IDEs, PMAs, 510(k)s) submitted to the FDA, Notified Body (e.g., BSI) and foreign regulatory agencies. Applies regulatory expertise to the evaluation and solution of product development issues.

SPECIFIC DUTIES AND RESPONSIBILITIES:

- Draft, assemble, and file original documentation, Clinical Evaluation Report and submission materials for Technical File or 510 (k) for new or existing products to regulatory authorities to assure that all submissions are accurate, of high quality and well supported by literature and regulatory foundations, are presented in a manner to facilitate review, and are in conformance with appropriate statutes, regulations, and guidelines.
- Draft and/or compile supporting documentation related to such applications and manage any related activities by third parties.
- Interface with clinical research organizations and/or in-house clinical research associates in drafting/assembling regulatory materials.
- Assure regulatory compliance activities on UDI requirements and regulations for Class II, Class I and 510 (k) exempt products.
- Track submissions, initiating internal communications and activities to adequately respond to agency inquiries and requests.
- May interface directly with outside counsel and governmental regulatory personnel, including scientific reviewers, administrative staff, and management, to facilitate the review and approval of regulatory applications.
- Represent Regulatory Affairs on assigned project teams through all phases of product development; communicate regulatory requirements and the impact of regulations to the development team to ensure compliance for global product development, labeling, and/or promotional issues. Attends product development team meetings that include, but are not limited to marketing requirement reviews, system requirement reviews, design reviews, hazard analysis/risk assessment reviews, timeline development/reviews, and V & V reviews. Actively reviews and edits documents associated with product development meetings. Independently review changes in products, product specifications, and manufacturing processes to assess regulatory implications of the change.
- Create Clinical Evaluation report per current EU clinical evaluation report guidelines.
- Review and approve assigned product labeling, advertising and promotional materials, to ensure full compliance with all applicable FDA, EU and other relevant regulations and industry guidelines.
- Review and interpret scientific literature and summarize effectively in writing for clinical evaluation reports.
- Remain current on developments in field(s) of expertise, regulatory requirements, and industry trends.
- Ensure training and compliance with global quality system regulations.
- Perform other essential tasks assigned, i.e. creating departmental SOPs.
- Regular and consistent attendance is required.

EDUCATIONAL REQUIREMENTS:
BA/BS or MS degree in Life Sciences, Engineering, or health care-related discipline. PhD is plus but not required.

EXPERIENCE:
Five or more years of experience in the medical device industry, preferably in a small manufacturing/R&D environment that includes medical writing, clinical studies, regulatory submissions, and regulatory reviews.

KNOWLEDGE, SKILLS AND ABILITIES:

- Must have experience developing, writing, and organizing all aspects of the IDE/PMA/510(k)'s and CE Submissions.
- Must have experience in medical literature research and write clinical evaluation reports based on published clinical data and or published literature.
- Ability to independently analyze and interpret novel clinical, medical and scientific data.
- Current knowledge of current U.S. FDA and global (Canada, Australia, European Union, Latin America, India, China, etc.) regulatory requirements within the medical device industry. Excellent organizational skills and attention to detail.
- Strong analytical, management, communication and interpersonal skills. Good knowledge of MS Office, Internet, databases, etc.
- Ability to work with minimal supervision in a busy environment.
- Excellent writing skills and the ability to write scientific summaries.
- Must be able to handle multiple assignments and perform in a diverse cross-functional team environment.

Contact: Submit resume to careers@bioness.com.

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