



Regulatory Affairs Specialist July 2018

Description

HemoSonics, LLC is seeking a Regulatory Affairs Specialist who will support regulatory labeling and other regulatory affairs activities.

The successful candidate will thrive in a small, fast-paced company environment and have experience in a regulated industry, preferably with *in vitro* diagnostics.

Key Attributes of the Successful Candidate:

- Strong organizational skills and attention to detail
- Excellent verbal/written communication and problem-solving skills
- Able to prioritize and manage multiple tasks with minimal direction

Key Responsibilities:

- Project planning, development, execution, reporting and interaction with project team (including obtaining translations for all labeling)
- Review and approve labeling updates to ensure compliance with global requirements and regulatory support where needed
- Create new labeling associated with new product development

Key Knowledge and Skills Required:

- Must have knowledge of US, European and international medical device regulations and standards
- Knowledge of and experience applying 21 CFR 801 and 820 regulations
- Knowledge of international medical device labeling and standards (ISO 15223-1) preferred
- Excellent verbal and written communication
- Self-motivated
- Strong analytical skills
- Technical writing/editing skills and familiarity with document/content management systems preferred



Education and Experience Required:

- A minimum of a Bachelor's degree in Science, Regulatory Affairs or Engineering and 2 years' experience in a regulated medical device environment, or equivalent combination of skills and experience

The position is based in Durham, NC.

To apply, please email your cover letter, resume and salary requirements to:
careers@hemosonics.com

HemoSonics, LLC is an equal opportunity employer. All applicants will be considered for employment regardless of race, color, religion, sex, sexual orientation, gender identity, national origin, veteran or disability status.