LivaNova

Health innovation that matters

Help advance our goals to obtain and maintain medical device approvals globally.

Assist as necessary to obtain medical device market clearances in Europe and international markets as well as support submissions in the US and Canada. Ensure timely preparation of complete and accurate submission documentation. Maintain existing world-wide regulatory clearances, licenses and registrations.

Core activities include:

- Researching, generate and compile the documentation required to support worldwide medical device registration/licensing activities
- Creating and maintain EU technical file
- Responding to information requests to government agencies, distributors, customers and company personnel
- Supporting new product and product modification projects to assure regulatory compliance
- Organizing and maintain internal regulatory files
- Assuring compliance with company policies and procedures
- Assisting in the preparation of 510k and Health Canada submission packets for new products and product modifications

You must:

- Enjoy researching information, generating documentation and maintaining files.
- Have a good understanding of medical devices documentation requirements.
- Have solid writing and organizational skills.
- Be detail oriented and have strong reasoning skills.
- Be able to achieve goals with minimal direction and also follow specific instructions as necessary.
- Be flexible and willing to provide support as needed.
- Be able to maintain the confidentiality of sensitive information.

For this role, your experience should include at least 2 years working in Regulatory Affairs or 5 years working for a medical device manufacturer in an applicable role. A BA/BS University degree is required.

Our Cardiopulmonary Division designs manufacture and distributes devices for worldwide markets. As our Regulatory Specialist, your contributions will ultimately help further our commitment to improving the lives of our patients and their families worldwide!

Are you ready to make a difference? If so, please send your resume to:

scott.light@livanova.com

The facility location is:
14401 West 65th Way
Arvada CO 80004