Company: Edwards Lifesciences

Contact: Craig Seipel (Craig_Seipel@Edwards.com)

Job title: Manager, Regulatory Counsel

Job Description:
Make a meaningful difference to patients around the world! Our Legal team works to protect our patients, team members, and innovations with the utmost diligence and care. You'll have the opportunity to work with a dedicated team and build lasting partnerships with stakeholders across our global organization. Your legal knowledge and contributions will help us ensure that we are supporting the needs and interests of the patients we serve.

Work Schedule: Given the collaborative and complex nature of this work, this role is in person full time in Irvine, California with flexibility to work from home as needed.

How you'll make an impact:

The Manager, Regulatory Counsel reports to the Senior Director, Regulatory Counsel and will be responsible for timely review and analysis of clinical contracts, review and approval of advertising and promotion materials, assistance with state licensing, support for sales contracting, and other legal regulatory duties as needed. The Manager provides legal guidance to Marketing and Clinical teams in each of the business units (Transcatheter Heart Valves, Transcatheter Mitral and Tricuspid Technologies, Surgical Structural Heart), and other Business Unit or Corporate functions such as Regulatory Affairs, Compliance, and others.

- Reviewing and advising on a variety of advertising and promotional pieces, including print and digital ads, social media campaigns, speaker presentations, and other materials to determine compliance with applicable regulations and policies and assess corporate risk.
- Reviewing and advising on clinical contracts and a variety of legal issues related to clinical trials
- Developing and harmonizing standard processes and templates; creating, improving, and institutionalizing knowledge base for the Healthcare Regulatory team.
- Developing and delivering legal education to business colleagues in specific areas (e.g., regulatory approval processes, pathways to market (510(k), PMA, etc.), requirements for FDA-regulated clinical investigations, etc.).
- Monitoring legal developments applicable to the Healthcare Regulatory and medical device spaces.
- Other duties and responsibilities as assigned.

What you'll need (Required):

- Juris Doctor from ABA-accredited law school with 2 years of legal experience at a law firm or in-house legal department.

What else we look for (Preferred):

- 3 years of legal experience at a law firm or in-house legal department
- Background in life sciences, MedTech, pharmaceuticals, or related healthcare industry experience
- Experience reviewing and negotiating clinical trial agreements and associated contracts in the medical device or pharmaceutical industry or at a healthcare system.
- Strong written and verbal communication and interpersonal skills, including the ability to convey nuanced legal concepts/issues clearly and succinctly to legal and business decision makers.
- Excellent independent problem-solving, critical thinking, and investigative skills
- Strategic thinking, proactive mindset, and excellent problem-solving abilities.
- Ability to be a team player and a trusted business partner.
- Ability to work under pressure and prioritize projects and tasks appropriately.

Aligning our overall business objectives with performance, we offer competitive salaries, performance-based incentives, and a wide variety of benefits programs to address the diverse individual needs of our employees and their families.

For California (CA), the base pay range for this position is $123,000 to $174,000 (highly experienced).

The pay for the successful candidate will depend on various factors (e.g., qualifications, education, prior experience). Applications will be accepted while this position is posted on our Careers website.

Link to Apply: **https://edwards.wd5.myworkdayjobs.com/EdwardsCareers/job/USA---California--Irvine/Manager--Regulatory-Counsel_Req-42572**