Boulder iQ
Innovation to Quality

Job Title: Regulatory Affairs Professional (Full-Time)

Location: Boulder, CO

Who we are:

Boulder iQ: Bringing Products to Market from Product Concept through Manufacturing.

Boulder iQ is an expert contract consulting firm providing all the services a life science company needs to get its product to market. With years of experience in regulatory, quality, product development, manufacturing and contract EO sterilization, our single-source solution speeds the product development and regulatory submissions process. Our experts help companies navigate through the process of getting medical device, diagnostic and combination products to the market quickly.

Boulder IQ is expanding its regulatory practice and is seeking all levels of Regulatory Affairs Professionals, including Director, Manager and Specialists. The Regulatory Affairs Professionals are responsible for various regulatory affairs projects and assignments, which may include analyses, evaluations, strategy recommendations and the preparation, and submission of documentation for regulatory submissions, registrations and product licenses. As an integral member of the Regulatory Affairs team, this position handles necessary regulatory activities required to support market entry and compliance of products, and helps ensure procedures comply with corporate and regulatory agency specifications. These positions may support both domestic and international activities. Knowledge of regulations and standards including (but not limited to): EU MDD/MDR, FDA, CA-FDB, and ISO regulations/standards, is preferred, along with an ability to perform at high-levels in a fast-paced, high-growth dynamic environment.

What You'll Do:

Be a leader and team member of a growing regulatory and quality team focused on bringing innovative solutions to the market

- Deploying the Regulatory Program to ensure aggressive product approval and adoption within the framework of international regulations and standards including, but not limited to ISO13485; 21 CFR 803, 806, and 820; the current Canadian Medical Device Regulations (SOR/98-282); Medical Device Directive 93/42/EEC (and all applicable amendments); EU Medical Device Regulations (EU MDR) 2017/145; and MHLW Ordinance No 169, among others.
- Prior experience in authoring 510(k)'s, De Novo, CER's, and Technical Files
- Prior experience dealing with the FDA to determine product classifications (513G)
- Prior experience working through topics with the FDA through q-sub meetings and responding to questions related to 510(k), De Novo and similar submissions
- Create detailed project schedules, plans and timelines.
- Proactively drive RA project deliverables with cross-functional and cross-business unit team members to support successful product submissions, registrations and reports.
- Track project milestones and deliverables and provide regular status updates on completion and closure.
- Perform regulatory assessments and strategy recommendations in support of new products or proposed product/process changes.
- Perform complaint reportability analyses.

- Generate, coordinate and handle regulatory submission documents for new products or changes to existing health authorities' filings.
- Plan, write, submit, coordinate and support new product notifications, international registrations and other submissions as required.
- Represent Regulatory Affairs and partner with various cross-functional teams throughout the organization (i.e. Marketing, Professional Education, Operations, R&D, Quality, including international cross-functional teams) on projects and other related tasks.
- • Partner with Clinical and Medical Affairs to support clinical deliverables and reports.• Partner with Quality and R&D to support regular product risk review activities as well as reporting activities required by EU MDR (i.e. post-market surveillance, reporting, etc.)
- Conduct research of regulatory issues and information and dissemination of regulatory information to all levels of the organization.
- Identify procedure and process enhancements for the continuous improvement of the Regulatory Affairs team.
- Proactively drive activities to meet and/or exceed company objectives, milestone and timelines as they relate to regulatory activities.
- Perform other related duties and responsibilities as assigned.
- Contribute to our culture of being collaborative, respectful, transparent, ethical, efficient, high-achieving, and fun!

What You'll Need:

Education / Experience Requirements

- BS or BA degree in the physical sciences; advanced degrees a plus
- minimum 5 years of experience in regulatory affairs or equivalent; medical device experience is strongly preferred.
- EU MDR experience
- **Hands on experience in authoring at least 10 complete 510(k)'s**

Specialized Skills / Other Requirements

- Ability to perform at a high level in a thriving environment.
- Basic knowledge of regulations and standards, including FDA, CA-FDB, EU MDD/MDR, CMDR, MHLW, MFDS and ISO regulations/standards, for example ISO 10993 (requirements for biocompatibility).
- RAC certification is a plus.
- Experience with Quality Management Systems, CAPA, audits and inspections by the FDA and EU notified bodies and remediation of 483 observations and warning letters is a plus for these positions.
- Ability to focus and achieve scheduled milestones, including contingency planning.
- Strong verbal and written communications with the ability to effectively communicate at multiple levels in the organization.
- Strong team-working and organizational skills with a drive to complete tasks in the face of obstacles and time constraints, and a willingness to collaborate wherever needed.
- Proficiency in MS Office software programs especially Word, Excel, Outlook and PowerPoint.
- Ability and willingness to travel up to 10% of the time.

Working Conditions:

- Remote or On-Site

- Ability and willingness to travel up to 10% of the time.

Benefits:
Boulder iQ is located in the city of Boulder, CO, an area known for smart and ambitious people who also value work-life balance. We are located close to many outdoor activities including hiking, biking, skiing, climbing and camping. Our team is focused on providing the best services we can to our clients in the best location. Additional benefits Boulder iQ provides:

- Health, Dental and Vision insurance
- Paid Time Off
- Company Holidays
- 401(k)

Boulder iQ is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, religion, color, national origin, sex, sexual orientation, gender identity, age, status as a protected veteran, among other things, or status as a qualified individual with disability