SUBTLE MEDICAL

Job Description

Job Title	Data Protection and Quality/Regulatory Specialist
Department	Product (IT/Security/Privacy, Quality Engineering and Regulatory Affairs)
Reports To	Head of IT/Security/Privacy, Head of Quality Engineering and Regulatory Affairs
Job Location(s)	Remote, or Hybrid in SF Bay Area
% Travel	15%
Salary Range / Hourly Rate	$60k to $80k

Position Summary

The Associate Data Protection and Quality/Regulatory Specialist is a hybrid entry level role at Subtle Medical to support privacy and regulatory/quality teams. Specifically, establishing improved processes around data protection, and supporting specific regulatory/quality tasks. This role joins a small, high performing team, and has the opportunity to make a positive impact felt across the whole company. Based on performance of the selected candidate and company needs, the role can grow into new areas over time.

Subtle Medical is the world leader in applying deep learning to the acquisition of medical images in order to enable faster, safer, and smarter medical imaging. We are committed to transforming the healthcare ecosystem by building and delivering responsible AI solutions that create a measurable impact on the radiology workflow and patient experience. Our vision is that every human being has the opportunity for a timely diagnosis, high-quality care, and a longer, healthier life.

Currently, Subtle Medical has two FDA-cleared & CE-marked AI software products that are in clinical usage in over 400 hospitals and imaging centers worldwide with a third FDA-pending. Subtle has a robust multi modality product portfolio and continues to invest heavily in research and development.. Our team consists of world leading radiologists, scientists and engineers from top universities like Stanford, Harvard, and MIT many with past experience at leading equipment manufacturers like GE, Philips and Siemens. Subtle Medical has been recognized multiple times by CB Insights as a global Top 100 AI Company and Top 150 Digital Health Company. We continue to grow and expand and welcome those to apply

Position Summary

who desire to empower patients and physicians with better healthcare.

Subtle Medical is an equal employment opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, protected veteran status, or any other characteristic protected by law.

Responsibilities

Job Duty

Data Protection:

- Assist in development and implementation of company-wide data protection program
- Participate in the investigation and resolution of IT, Security, or Privacy incidents.
- Create, revise, and maintain IT and security policies and procedures.
- Participate in the security vulnerability testing and remediation process.
- Provide support for internal and external compliance audits.
- Perform periodic access and security configuration audits.

Quality Engineering:

- Participate in Supplier Quality, including qualification of distribution partners in global territories.
- Support internal/external QMS audits, NC/CAPA, Defect Management, and Risk Management as assigned.

Regulatory Affairs:

- Assist in the review of advertising and promotional items.
- Perform medical device classifications for platform products in global jurisdictions.
- Assist in design change impact analysis.

Support and participate in other duties as assigned, with priority for the interests and skill sets of the candidate.

Qualifications	
Key Competencies	• Cross-functional collaboration, communication, and project management skills. • Technical writing skills, document formatting skills, and knowledge of Good Documentation Practices (GDP). • Transforming regulation / laws into actionable procedures. • Basic knowledge of information security and privacy concepts and best practices. • Proficient Google Drive or Microsoft Office tools. • Proficient with remote working tools (chats, video conference, etc.). • Proficient in internet searching for and gathering of information about regulation, suppliers, and more. • Ability and willingness to learn new skills and specializations.
Education	• Bachelor's degree in a relevant field, Master's degrees are welcomed. • 0-2 years of relevant work experience.
Work Experience	• Executing projects with multiple stakeholders. • Summarizing regulation / laws into reports (or equivalent such as a literature review). • Following up with stakeholders for a project. • Technical writing, document formatting, diagram making.
Nice to Haves	• Working knowledge of Quality Management System (QMS) regulations and applicable familiarity with ISO 13485, ISO 14971, IEC 62304, and IEC 62366, ISO 27001, GDPR, CCPA/CPRA • Nonconformance (NC)/Corrective and Preventive Action (CAPA) with Root Cause Analysis (RCA) experience. • Information design skills to make pretty diagrams, tables, and charts. • Familiar with tools: Atlassian Jira, Atlassian Confluence, and eQMS. • Familiar with medical devices, radiology, artificial intelligence. • Prior internship or full-time work in related areas.

Want to apply?
Please email careers@subtlemedical.com with your resume/CV and any applicable information.