Project SME- RAQM (Regulatory Affairs and Quality Management)

A Wright Path® is helping clients achieve regulatory compliance and launch their products in the global marketplace with the Right Path, Right Now® approach. We are a rapidly growing organization, trusted name in global regulatory compliance and strategy committed to making a difference for our clients and our communities.

At A Wright Path®, we look for candidates who exemplify our values, show passion for the industry and a commitment to quality service. As a team, we continually develop our skills to stay on the cutting edge within our industry. We go the extra step and train in the highest customer services principles to enhance our client's experiences. We place great emphasis in putting our staff on the Right Path, Right Now® for immediate success and career longevity, helping team members to develop skills who can reap huge dividends for those who embrace them.

Position Summary

The Project SME RAQM has advanced knowledge of global regulatory requirements in order to assist clients throughout the product lifecycle by working closely as part of a cross functional team. The Project SME RAQM acts as the subject matter expert and guides A Wright Path projects, project schedules, and the product introduction process in the global marketplace; guide the decision-making process on regulatory submission issues using historical knowledge and current regulations; guides the training of the A Wright Path® team on regulatory requirements and acts as liaison with the client. While communicating regulatory changes to ensure the client is aware of opportunities, risks and issues, the Project SME RAQM ensures compliance with the regulations and client's processes and procedures. The Project SME RAQM utilizes project planning skills to initiate, plan, execute, and manage client projects. This team member manages change and is flexible when providing solutions for the client. The Project SME RAQM demonstrates collaboration with their A Wright Path® team, client cross functional teams, and regulatory agency partners by building strong and effective working relationships.

Essential Job Functions

- Act as subject matter expert on client project teams to provide compliance guidance and strategic regulatory planning in support of new product development and existing product support.
- Direct compliance leadership in the preparation of regulatory filings for new products, as well as product and manufacturing changes.
- Advise client and A Wright Path® team members regarding current/pending guidance, regulations, Agency/industry initiatives, etc. to ensure regulatory compliance is in alignment with client objectives.
- Apply advanced skills to resolve complex problems not covered by existing procedures or practices.
- Present critical thinking in bringing successful resolution to high impact, complex and/or cross functional problems.
- Review regulatory issues with client and A Wright Path® management.
- Become technical interface with FDA and international reviewers and respond to questions on behalf of the client and A Wright Path®.
- Provide regulatory guidance and support for development and production activities.
- Execute appropriate regulatory tasks for device, manufacturing, or labeling changes.
- Develop and implement Quality System procedures to ensure compliance with 21 CFR 820, ISO 13485, MDD/MDR, AIMD, CMDR and all other applicable global regulations
- Create specialized guidance and develop training for A Wright Path team and clients.
- Maintains awareness of changes in global requirements for effective regulatory submissions and registrations.
- Work effectively with cross-functional staff across multiple sites as well as global external partners.
- Develop regulatory and quality best practices, processes and procedures.
- Represent A Wright Path® in Industry Organizations.

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Specific Job Tasks

- Lead teams within A Wright Path® to ensure that client support is appropriate.
- Continually pursue more efficient and effective operations.
- Assist with the creation, maintenance, and performance of client change management tools: Corrective Action Reports (CAR's), Preventive Action Reports (PAR's), and Engineering Change Orders (ECO's).
- Participate in Supplier Management activities.
- Provide Quality System guidance to client cross functional teams in all aspects of Design Controls, Risk Management, Usability Engineering, Document Controls and all associated processes, policies, procedures, and records.
- Conduct Internal Quality Audits.
- Participate in the development of Management Review Presentations.
- Participate in 3rd party audit and inspection activities (ISO, FDA, etc.)
- Initiate and maintain pertinent metrics, trending, and statistical analysis.
- Ensure that reasonable risk management controls are in place.
- Collaborate with engineering to determine and execute engineering DHF plans in support of regulatory submissions.
- Maintain superior knowledge of competitive technologies in addition to medical and technical developments related to the client's products.
- Review Device History Record (DHR) deliverables to ensure that production activities comply with Mandatory Device Master Record (DMR) requirements.
- Review all Engineering Change Requests and Engineering Change Orders to ensure sound engineering practice, effective and adequate design, product safety, and Quality System compliance.
- Process Nonconforming Material Reports and Rework Orders.
- Remain aware of new or updated regulations, laws, standards and other official enactments that may apply to the client.
- Provide detailed analysis, official recommendations, and gap analyses for new or revised enactments.
- Develop and submit medical device adverse and field corrective actions reports and recall notifications.
- Author and coordinate regulatory product clearance submissions.
- Prepare registration applications, including IDE, 510(k), PMA, CE Mark, and other related regulatory filings.
- Interface with FDA and other regulatory agencies regarding regulatory submission strategy and approval reviews, as per client marketing plans.

Qualifications and Experience Requirements

- A minimum of 10 years related experience in regulatory affairs and quality assurance.
- A minimum of Bachelor's degree in life sciences, engineering, or equivalent education and technical knowledge.
- RAC Certification required
- ASQ Certified Qualified Auditor required
- Advance knowledge of domestic (US) and international (EU, Canada, China, Japan, Brazil etc.) medical device and combination product regulations.
- Experience with managing teams and delegating responsibilities to ensure project schedule.
- Experience with combination products preferred.
- Experience with international submissions and registrations preferred.
- Experience interacting directly with FDA, EU, Health Canada and other international regulatory agencies like PMDA, CFDA and TGA preferred.
- Proven experience working with US FDA, international regulatory agencies on product submissions and registrations.
- Proven experience working with ISO 14971 Risk Management principles.
- Proven experience working with IEC 62366 Usability Engineering principles.

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- Sound knowledge and understanding of quality management system principles and practices.
- Self-motivated with strong organizational skills with strong attention to details and can handle multiple assignments simultaneously.
- Proven ability to work effectively in a team based environment with proven ability to be flexible and adaptable.
- Proven excellent written & oral communication, including presentation, planning and interpersonal skills.

Travel Requirements

10 - 20% (Domestic and International)

A Wright Path®, Inc. is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or protected veteran status.

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