Compliance Specialist

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 Compliance Specialist communicates the global regulatory requirements to our clients throughout the product lifecycle by working closely as part of a cross functional team. This team member interprets and communicates regulatory changes to ensure the client is aware of opportunities, risks and issues while being responsible for ensuring compliance with the regulations and client's processes and procedures. The Compliance Specialist follows project schedules to initiate, plan, execute, and manage client projects and manages change while being flexible when providing solutions. The Compliance Specialist 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

- Become a member on client project teams to provide compliance guidance and strategic regulatory planning in support of new product development and existing product support.
- Support compliance leadership within A Wright Path® in the preparation of regulatory filings for new products, as well as existing product design changes.
- Advise client regarding current/pending guidance, regulations, Agency/industry initiatives, etc. to ensure regulatory compliance is in alignment with client objectives.
- Communicate status and completion of assigned tasks to A Wright Path® compliance management.
- Follow Quality System procedures to ensure compliance with 21 CFR 820, ISO 13485, MDD/MDR, AIMD, CMDR and all other applicable global regulations.
- Develop proficiency and maintain awareness of changes in global requirements for effective regulatory submissions and registrations.
- Assist in the development of regulatory and quality best practices, processes and procedures.
- 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.

Specific Job Tasks

- 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.
- Conduct Internal Quality Audits.
- Assist with 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.

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- Collaborate with engineering to determine and execute engineering DHF plans in support of regulatory submissions.
- Review Device History Record (DHR) deliverables to ensure that production activities comply with Mandatory Device Master Record (DMR) requirements.
- Review 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.
- 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.
- Assist in the submittal of 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.

Qualifications and Experience Requirements

- A minimum of 2 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 desired
- ASQ Certified Qualified Auditor desired
- Knowledge of domestic (US) and international (EU, Canada, China, Japan, Brazil, etc.) medical device regulations.
- Experience with combination products desired.
- Experience with international submissions and registrations preferred.
- Experience working with US FDA and International Regulatory Bodies on product submissions.
- Experience working with ISO 14971 Risk Management principles.
- Experience working with IEC 62366 Usability Engineering principles desired.
- 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.
- Demonstrates ability to work effectively in a team based environment with proven ability to be flexible and adaptable.
- Demonstrates excellent written & oral communication, including presentation, planning and interpersonal skills.

Travel Requirements

10 - 20% (Domestic and International)

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