QualiMed®
A Q3 Medical Company

Regulatory Affairs Associate

1. Organisation

Position / Title
Regulatory Affairs Associate

Department / Area
Regulatory Affairs

Reports to
Head of Regulatory Affairs

2. Skills

Education
Master Degree in Pharmacy or Medical Technology or Biomedical Engineering or equivalent masters degree preferred with a focus on and special skills, respectively, in Regulatory Affairs and Quality Management.

Experience
Experiences in Regulatory Affairs and/or Quality Management in the field of medical devices for 1 to 2 years are mandatory.

Specialized Knowledge
- Good knowledge about international performance of formalities and requirements in licenses and registration of medical devices.
- At least 1 to 2 years' experience in the medical device industry.
- Experience of Medical Device CE Marking.
- Experience of Medical Devices in international markets.
- Regulatory experience in pre- and clinical studies.
- ISO 13485 experience.
- ISO 14971 and ISO 10993-ff experience. Skills in product and process qualification, verification and validation.

Personal Skills
- Ability to work in a team as well as independently.
- Ability to work under pressure.
- Reliability.
- Good organizational and communication skills.
- Analytical and systematic working (structured work).
- Fluent English in speaking and writing.

Training Courses
MS Office, MS Project, general IT skills.

Languages
English required, German is advantageous, additional languages are welcome.

3. Requirements

Duties
- Development, coordination and realization of certification and registration strategies and plans for new and existing products in ROW market.
- Co-ordination together with Sales dept. and for new/existing products registration/renewal in ROW market. Co-ordination with Customer Service for fulfilling regulatory related request for customers.
- Execution of Clinical Evaluation Reports as per MEDDEV Guidance Rev.4 and MDR requirements.
- Support on PMCF Studies and PMS activities. Co-ordination with relevant department and preparation of PMCF (Post Market Clinical Follow-Up) plan and compile PMCF Report.

For more enquiries, please contact:
QualiMed Innovative Medizinprodukte GmbH Boschstraße 16, 21423 Winsen, Germany +49 4171 6578 0
www.qualimed.de

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- Active participation on Risk Management activities and execution of Risk Management Report as per ISO 14971.
- Remediation of CE Technical Files as per MDR requirements for transition to CE Certification for legacy products under EU MDR and perform periodic updates. Prepare and update of product technical files for CE certification for new products or for modified products.
- Manage communications with customers as per project requirements.
- Active support to Quality department and PRRC for compilation of reports and notifications (for example DIMDI, EUDAMED, recalls, vigilance, PSUR, etc.).
- Revision of labels and instructions for use (IFU).
- Handle change request related to regulatory related documents.
- Provide regulatory assessments for post-approval product and manufacturing changes. Evaluate changes to controlled documents for impact on submissions and filing requirements including a technical review for proposed changes and supporting documentation.
- Collaborate with development team, Support and cooperation regarding the compilation of verification and validation plans and reports.
- Participate as Regulatory Representative on project teams.
- Support on Quality management System compliance in general (e.g. ISO 13485, FDA QSR 21 CFR Part 820, MDSAP, South Korea KGMP) and in the area of overlapping tasks (e.g. Labelling, Packaging, IFUSs) adjustment of RA QMS on FDA and GMP requirements.
- Support on internal audits.
- Support regarding complaints and CAPA-process.

Working Conditions

- QualiMed, Winsen, Germany.
- The main part of working time is expected in the office at QualiMed.
- Traveling related to the projects.
- Represent the company, if necessary, on conferences and exhibits.
- Well organized, detail oriented, multi-tasking capability and independent working in an open space work environment. Focused work also in case of continuous work-related interruptions.

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