QualiMed®
A Q3 Medical Company

QualiMed was founded in 1997 as an OEM manufacturer for implantable medical devices with a focus on the development and regulatory approval of coronary stents and their respective delivery devices. Later the business was expanded to peripheral vascular and non vascular implants. In the last years QualiMed started with the development of various biodegradable technologies, drug device combination products, and micro-intervention implants as part of its diversification and competitiveness strategy.

Clinical Affairs Manager

We have an immediate opening for a Clinical Affairs Manager to work in a dynamic medical device research and development environment. This is a high visibility role with a significant and direct impact on the success of the various innovative projects that Q3 Medical Devices Ltd. and its daughter companies are currently developing.

Organisation

Position / Title
Clinical Affairs Manager

Department / Area
Clinical Affairs (CA) Department

Reports to
Chief Risk Officer (CRO)

Personal Skills

Education
Bachelor's or Master's degree in medical, health, life sciences, or engineering.

Professional Experience
A minimum of 3 to 6 years of experience with clinical studies in medical devices with direct responsibility for submissions development and content, or an equivalent combination of education and experience.

Professional Qualifications
- Previous direct clinical study design based on GCP (ISO 14155 and/or US FDA regulations and/or CFDA regulations (China)).
- Experiences in medical writing of CIPs and CIRs based on ISO 14155 and/or QSR (FDA) and/or CFDA requirements.
- Writing and establishing of clinical SOPs.
- Minimum of two years of experience in supervising and directing CRA's.
- Experience in coordination of CROs.
- Previous demonstrated experience in, and responsibility for study budget, enrollment, inventory and progress reporting.
- Demonstrated knowledge of GCP regulatory requirements pertaining to the conduct of clinical studies, show proof of work experience and demonstrated success in conducting and completing investigational studies
- Additional knowledge and experience with International Clinical Studies, knowledge of ISO / FDA / CFDA Quality System Regulations, and other related medical device industry experience is preferred.
- Demonstrated experience with regulations in the medical device and/or pharmaceutical industries
- Knowledge and experiences in ISO 13485, ISO 14971, QSR (FDA) etc.
- Experience in internal and supplier audits as well as statistical methods
- Willing to travel (based on the individual needs)

Training Courses
Prior experience using word processing, spreadsheet, and presentation software. ERP experiences are benefiting.

Languages
Ability to fully communicate using English. Further languages e.g. German, and others are advantageous.

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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Duties, Responsibilities

Principal Duties and Responsibilities

- Manage all study related issues for Q3 Medical and its related daughter companies
- Comfortable to work multitasking and managing many simultaneous requests for field support for studies.
- Demonstrate ability to impact and influence others within a team to take action; interact effectively with various functional groups of the project team; contribute significantly towards the establishment of best practices; serve as a resource and mentor.
- Demonstrate problem-solving strategies developing alternative solutions and contingencies to address issues as they occur.
- Support coaching and feedback and as appropriate, provide performance input to senior management.
- Independently identify potential barriers to project completion and proactively implement effective strategies to avoid such barriers.
- Effectively communicate to all levels of the organization, especially with regard to the RA departments of daughter companies.
- Effectively oversee, supervise, direct, delegate, assist, and advise Clinical Research Associates (CRA) monitoring clinical studies.
- Effectively oversee, supervise, direct, delegate, assist, and advise Clinical Research Organizations (CRO) for clinical studies.
- Demonstrated expertise and strong understanding of the overall project goals, the indication (s) studied and the purpose of the planned studies in meeting the objectives of the project, assist in the development of the clinical plan.
- In conjunction with the senior members of the project team (product management, research, engineering and regulatory affairs) manage administrative aspects of a clinical project/study including, training, study initiation, trial maintenance, data monitoring, data reporting, and payments.
- Supervise and coordinates clinical monitors workload within a project, as required; Plans and initiates the steps involved in the clinical research process; in conjunction with the clinical project leader, manage all aspects of a project in accordance with established timelines, applicable project standards and standard operating procedures.
- Facilitate the IRB review and approval process where required for all new clinical outcomes and comparative investigative sites.
- Monitor the progress of the project and update clinical project leader on an ongoing basis; assist in the resolution of identified issues and assists in the resolution of more complex issues presented by the clinical scientist and engages director as needed.
- Prepare, oversee, and review the preparation of clinical documents, e.g., Protocols, Investigator Brochure, Annual Report updates, Case Report Forms and Clinical Study Reports; participates in the preparation of integrated documents for all clinical outcomes studies.
- Prepare, oversee, and review the clinical risk management, e.g. RMPs, RMRs, etc.
- Assures GCP compliant documentation system that maintains patient confidentiality.

Expected Areas of Competence

- Demonstrated expertise and strong understanding of the overall project goals, the indication(s) studied and the purpose of the planned studies in meeting the objectives of the project, assist in the development of the clinical plan.
- Supervises and coordinates clinical monitors workload within a project, as required; Plans and initiates the steps involved in the clinical research process; in conjunction with the clinical project leader, manages all aspects of a project in accordance with established timelines, applicable project standards and standard operating procedures.

Training program

- Basis is settled.
- Special company, corporate and product training program will be based on the individual skills

Working Conditions

- Working place is QualiMed, Boschstrasse 16, Winsen, Germany.
- Traveling related to the projects.
- Represent the company if necessary on conferences and exhibits.

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