



Senior Quality Engineer

Position / Title

Sr. Q.E.

Department / Area

Quality Assurance

Reports to

Team Lead – Q.A.

Language

Ability to fully communicate using English and German

Education

Bachelor of Science or equivalent

Experience

Minimum 3 years in a quality engineering or design quality role.

Minimum 5 years of professional work experience within the medical device manufacturing or development industry.

Primary Tasks and Responsibilities

General

- Support in preparation, reviewing, and approving IQ, OQ, PQ, and other relevant documents, reports, and protocols associated with the validation lifecycle.
- Leading the development and implementation of the control strategy for the processes.
- Review on procedures and systems that are in place and ensure compliance with GMP and other regulations.
- Participation in the review and disposition of all quality attribute and variable data against specification and drawing.
- Involved in several continuous improvement projects associated with quality enhancements and operational lead initiative.
- Support the closeout of change control, deviations, continuous quality improvements identified during the development and deployment projects.
- Training and development of personnel on new processes and systems.

Design Control

- Support new product development and design change project to ensure compliance to the internal and regulatory needs.
- Ensure that customer requirement are incorporated into product's functional specifications.
- Participate in all design reviews to provide input on process compliance and design quality indicators.
- Provide quality guidance and participation in Validation, Qualification activities including, review of the protocol and identification of sample size, test method, and reports.
- Responsible for verifying Design transfer activities to ensure compliance to the internal procedure and regulatory needs.
- Provide training to the R&D team on regulations applied to new product development and any design change.

Risk Management

- Create and update Risk Analysis files in consultation with the development team.
- Provide guidance on Risk Management planning to R&D.
- Facilitate FMEAs (Design and Process).

Other

- Monthly and quarterly reporting to reporting manager.
- Support internal and external audit activities from various regulators, customers, and consultants as necessary.

For more enquiries, please contact:

QualiMed Innovative Medizinprodukte GmbH Boschstraße 16, 21423 Winsen, Germany +49 4171 6578 0
www.qualimed.de



Senior Quality Engineer

Skills / Competencies

- Knowledge of Quality System Standards/Regulations, Design Control requirements (ISO 13485, 21CFR Part 820, EU MDR, MDD93/42/EEC, ISO 14971, etc.).
- Project Management.
- Excellent verbal and written communication skills, teamwork skills, result orientation required.
- Ability to work both independently and in conjunction with a team.
- Good knowledge of LEAN and Six Sigma manufacturing principles as well as working knowledge of Statistical Process Controls.
- Excellent written and verbal skills in English & German.

Working conditions

Permanent, full time (40 hrs/week), Work location – Winsen (Luhe).

For more enquiries, please contact:

QualiMed Innovative Medizinprodukte GmbH Boschstraße 16, 21423 Winsen, Germany +49 4171 6578 0
www.qualimed.de