QualiMed®
A Q3 Medical Company

Quality Engineer

Position / Title
Q.E.

Department / Area
Quality Assurance

Reports to
Head of Quality

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).

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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Other

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

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