QualiMed®
A Q3 Medical Company

Team Lead – Q.A.

Position / Title
Team Lead – Q.A.

Department / Area
Quality

Reports to
Head of Quality

Language
English (Essential), German (Advantage)

Education
Bachelor's degree in Science or equivalent

Experience
- Minimum 3 years in a quality engineering role in a manufacturing environment for Medical Device or Pharma industry.
- Exposure of ISO 13485, ISO 14971, MDD and FDA QSR.

Primary Tasks and Responsibilities

General
- QA budget management which includes keeping track on planned vs actual expense.
- Monthly and Quarterly Reporting to Head of Quality.
- Team management which includes but not limited to training of Q.A. Engineers, providing technical support to team members, their performance evaluation etc.
- Maintenance and development of the organization's Quality Management Systems in accordance with current applicable regulatory, business & customer requirements.
- Document and record control.
- Change management.
- Implementation and maintenance of Electronic Document Management System.
- Support on new product development and design changes.
- Approve Design Transfer activities.
- CAPA management.
- Supplier Management.
- Complaint Management.
- Adverse Event Reporting.
- Preparation of Product Safety reports.
- Handling of Internal and External audits.
- Handling of NCR.
- Support on risk management activities.
- Quality & Production data analysis.
- Support in Validations activities.
- Review and release of device history records.
- Issuance of CoC (Certificate of Compliance).
- Develop quality assurance specifications, test methods, sampling plans and related written procedures.
- Apply proactive, systematic & problem-solving methodologies in identifying, prioritizing, communicating and resolving product/process quality issues.

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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Senior Quality Engineer

Skills / Competencies

- Prior quality engineering experience in the medical device.
- Excellent verbal and written communication skills, teamwork skills, attention to detail and results orientation required.
- Effective troubleshooting and problem solving skills.
- Ability to work both independently and in conjunction with a team.
- Knowledge of Quality System Standards/Regulations (ISO 13485, 21CFR Part 820, MDD93/42/EEC, ISO 14971, WHO GMP etc.).
- Experience in the use of statistical tools (SPC, Six Sigma, MiniTab etc.).

Working conditions

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

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