QualiMed®
A Q3 Medical Company

Engineer – Q.A.

Position / Title
Engineer Q.A.

Department / Area
Quality

Reports to
Head of Quality

Language
English (Essential), German (Advantage)

Education
- Bachelor of Science or Engineering.
- Master degree preferred.

Experience
Minimum 3 years in a quality engineering/auditing role in a medical device or pharmaceutical manufacturing environment.

Primary Tasks and Responsibilities
- Participates in implementation of quality management system requirements throughout the organization.
- Handles the changes including engineering, process and design changes.
- Maintains the document distribution and change logs.
- Develops the annual audit plan.
- Trains internal auditors.
- Performs internal audits. Acts as “Lead Internal Auditor” and provide ongoing communication/reporting of results to Management Representative (MR) and to top management.
- Supports to MR for management representative functions including Management Review Meetings and External Audits
- Monitors and keep track on progress of non-conformities detected during the audits i.e. Regulatory/Customer/ Supplier/Internal audits.
- Works closely with Regulatoy Affairs department to provide QA support during the regulatory audit and product registrations.
- Participates in Root Cause Analysis (RCA).
- Participates in improvement projects.
- Trains employees on process improvements including the lean concept (Lean Six Sigma).
- Trains employees on Good Manufacturing Practices (GMP).

Skills / Competencies
Certified Lead Auditor (ISO 13485:2016)

Working conditions
Permanent, full time (40 hrs/week)

Any specific skill requirements
USFDA experience/exposure preferred

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