



## Engineer – Quality Assurance (Q.A.)

### Position / Title

Engineer - Quality Assurance (Q.A.)

### Department / Area

Quality

### Reports to

Head of Quality

### Language

English, German

### Education

- Bachelor of Science or Engineering or equivalent.
- Master's degree preferred.

### Experience

- Minimum 3 years a manufacturing environment for Medical Device or Pharma industry.
- Exposure of ISO 13485 & ISO 14971.

### Primary Tasks and Responsibilities

#### General

- Participates in supplier qualification activities
- Participates in supplier qualification/development activities
- Conducts supplier audits and follow open items to closure
- Defines and ensure the routine controls including incoming inspection to ensure that purchased products meet QualiMed specifications
- Guides incoming inspection team to handle supplier claims including 8D issues
- Review supplier manufacturing processes, collaborate with suppliers on process improvement and value enhancement opportunities
- Summarizes the inputs from supplier issues and communicate internally communicate with development, process engineering & supply chain on opportunities for quality improvement
- Performs periodic supplier evaluations
- Maintains supplier files and list of suppliers
- Monitors the process performance using the SPCs (Statistical Process Controls) and work closely with process engineering to stabilize/improve the processes
- Participates in CAPA, NCR and Risk Management activities.

#### Process Quality Support

- Participate in investigation of process quality issues
- Supports process Engineering during the new equipment / process setup
- Data Analysis on Process Performance / Quality

**For more enquiries, please contact:**

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



## Engineer – Quality Assurance (Q.A.)

### 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.
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- Experience in the use of statistical tools (MiniTab/Six Sigma, etc.)

### Working conditions

Permanent, full time (40 hrs/week)

### Any specific skill requirements

USFDA experience/exposure preferred

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