



Sr. / Engineer – Process Engineering

Attributes	Description
Position / Title	Sr. Engineer - Supplier Quality & Complaints
Department / Area	Quality
Reports to	Head of Quality
Language	English, German
Education	Bachelor of Science or Engineering. Master degree preferred.
Experience	<ul style="list-style-type: none"> • Minimum 3 years in a supplier quality role in Medical Device or Pharma industry. • Exposure of ISO 13485, ISO 14971, MDD and FDA QSR.
Primary Tasks and Responsibilities	<ul style="list-style-type: none"> • Defines the requirements for supplier qualifications and participates in supplier qualification activities • Performs supplier audits • Maintains list of suppliers • Defines and ensure the routine controls including incoming inspection needed to ensure that purchased products are meeting QualiMed specifications. c supplier evaluations • Handles supplier claims including 8D issues • Defines and implement complaint management policies • Handles the complaints • Maintains the complaint log/register, analyse complaints and report to Safety Officer and management team on trending complaints and recommends process / product improvements. • Assists Safety Officer during adverse event reporting and field safety corrective actions • Investigate internal quality issues. Interface with other functional groups in resolving those issues. Provide day-to-day troubleshooting and resolve immediate problems in manufacturing • Analyses quality data to observe trends and develop corrective/preventive actions • Performs other duties as assigned • Participates in continual improvements
Skills / Competencies	<ul style="list-style-type: none"> • Excellent verbal and written communication skills, teamwork skills, and result orientation required. • Ability to work both independently and in conjunction with a team. • Experience in the use of statistical tools (MiniTab/Six Sigma, etc.)
Working conditions	<ul style="list-style-type: none"> • Permanent, full time (40 hrs / week). • Location of work - Winsen, Germany • Travelling up to 10%
Any specific skill requirements	Candidate having USFDA exposure will be preferred.

For more enquiries, please contact:

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