QualiMed®
Innovative Medizinprodukte GmbH

Sr. / Engineer - Process Engineering

Attributes	Description
Position / Title	Sr. / Engineer – PE (Process Engineering)
Department / Area	Process Engineering
Reports to	Head of Process Engineering
Language	German, English
Education	Bachelor of Science or Engineering. Master degree preferred.
Experience	Minimum 3 years with 1 years as a process or quality engineering role in a manufacturing environment for Medical Device or Pharma industry. Exposure of ISO 13485, ISO 14971, MDD/ MDR and FDA QSR.
Primary Tasks and Responsibilities	• Serve as Process Engineer who supports manufacturing activities/projects/initiatives to ensure that process are in state of control, optimized and delivering the outputs which meet the pre-defined quality standards. • Participates in process validations, equipment qualifications, engineering changes, control over manufacturing deviations, process optimization/mapping/trending, and risk management activities including risk identification, risk analysis, FMEA, and risk mitigation,. • Maintains the Master Validation Plan (MVP). • Supports service engineers during installation and commissioning of equipment. • Supports Quality Assurance to establish quality requirements at all levels in organization. • Interpretates the feedback from market and transform the inputs for process improvements. • Supports CAPA manager during investigation, RCA (Root Cause Analysis), determination and implementation of actions related to process CAPAs. • Assist/support product complaint investigation activities and participate in returned product examinations/investigations as necessary. • Apply proactive, systematic problem-solving methodologies in identifying, prioritizing, communicating and resolving process quality issues. • Apply the use of Quality Engineering methodologies, tools, statistical techniques, etc. to assist in the resolution of day-to-day quality issues. • Work in accordance with and ensure compliance with the quality system procedures related to areas of responsibility.
Skills / Competencies	• Prior process or quality engineering experience in the medical device • Knowledge of Quality System Standards/Regulations (ISO 13485, 21CFR Part 820, MDD93/42/EEC, ISO 14971 etc). • Experience in the use of statistical tools (SPC, Six Sigma, MiniTab etc.)
Working conditions	Permanent, full time (40 hrs / week).
Any specific skill requirements	Candidate having USFDA exposure will be preferred.

For more enquiries, please contact:
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