QualiMed®
A Q3 Medical Company

Sr. Engineer – Q.A. (Validations)

Position / title
Sr. Engineer – Q.A. (Validations)

Department / area
Quality

Reports to
Team Lead – Q.A.

Language
English (Essential), German (Advantage)

Education
Master of Science or equivalent

Experience
Minimum 3 years in a quality engineering role in Medical Device or Pharma industry. Exposure of ISO 13485, ISO 14971, MDD and USFDA QSR Part 820, GAMP5, GHTF/SG3/N99-10:2004 - Quality Management Systems - Process Validation Guidance, ZLG 3.9 B18, Final Guidance for Industry and FDA Staff, General Principles of Software Validation, FDA guideline on general principles of process validation.

Primary Tasks and Responsibilities
- Responsible for supporting R&D team during initial Process Validation and Qualification activities.
- Responsible for Process revalidation including, drafting of protocol, identification of sample size, test method and reports including validation of risk controls as outcome of Risk Management Process in compliance with ISO 14971.
- Software Validation.
- Supporting Production and Maintenance departments during Operational Qualification.
- Responsible for process validation planning & execution.
- Responsible for maintaining the validation master plan.
- Responsible for using statistical techniques for statistical process control, process validation and process data analysis using MiniTab.
- Responsible for customer account handling for understanding customer needs and coordinating with different departments to implement the needs.
- Responsible for ensuring compliance with applicable international standards and regulatory requirements for validation as well as compliance with internal QMS requirements for validation.
- Collaboration with cross functional departments for performing process FMEA.

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, Germany.

Any specific skill requirements
USFDA exposure

For more enquiries, please contact:
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