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A Q3 Medical Company

Team Leader Quality Assurance

Position / title
Team Leader Quality Assurance (Q.A.)

Department / area
Quality

Reports to
Head of Quality

Language
English, German

Education
Master of Science or equivalent

Experience
Minimum 5 years with 3 years in a quality engineering role in a manufacturing environment for Medical Device or Pharma industry. Exposure of ISO 13485, ISO 14971, MDD and FDA QSR

Primary Tasks and Responsibilities

- Responsible for keep tracking on Planned budget vs actual expense and provide data time to time.
- Monthly and Quarterly Reporting (for Q.A. functions) which include but not limited to data of CAPA, Change Control, NCR, Process Capability, Scrap, Training, USFDA readiness, ISO 13485:2016 implementation, plant hygiene control etc.
- Responsible for team management which includes but not limited to training of team member, support team member, their performance evaluation, problem solving etc.
- Maintenance and development of the organization's Quality Management Systems in accordance with current applicable regulatory requirements as stated in Quality Manual.
- Document and Change control: Responsible for meeting requirement of ISO and regulation related to document and change control. Participate in the creation, review and approval and disposition of engineering change requests involving product or process changes.
- Support on new product development and design change project to ensure compliance to internal procedure and regulatory needs.
- Responsible for verifying Design transfer activities to ensure compliance to internal procedure and regulatory needs.
- Responsible for effectively implementation and maintaining of CAPA process. Work as a CAPA coordinator.
- Support internal and external audit activities from various regulators, customers, and consultant as necessary.
- Responsible for management of NCR process.
- Provide quality guidance and participation in conducting risk management activities including, risk identification, risk analysis, FMEA, and risk mitigation.
- Review and analyze production / manufacturing data to determine the primary factors affecting product quality, yield, complaints etc and drive continuous improvement initiative with both internal and external operations as necessary. Include both product and process.

For more enquiries, please contact:
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- Support in Validations activities including equipment qualifications, master validation plans etc.
- Training Management include training monitoring, control and training record management.
- Review and release of device history records including CoC issuance.
- Responsible for plant hygiene control activities.
- Responsible for analyzing customer feedback data and identify action wherever needed with customer service team.
- Develop quality assurance specifications, test methods, sampling plans and related written procedures.
- Apply proactive, systematic problem-solving methodologies in identifying, prioritizing, communicating and resolving quality issues.
- Apply the use of Quality Engineering methodologies, tools, statistical techniques, etc. to assist in the resolution of day-to-day quality issues.
- Build and maintain effective cross-functional relationships with internal departments such as Operations/ Manufacturing, R&D/Engineering, Quality Control, and Regulatory Affairs.
- Work in accordance with and ensure compliance with the quality system procedures related to areas of responsibility.

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).

Any specific skill requirements

USFDA exposure

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