



Quality Assurance Manager

Summary:

The Quality Assurance Manager is a member of the site leadership team and the primary advocate for ensuring industry leading quality standards for the products Swiss-Tech provides to our customers. The Quality Assurance Manager is also responsible for ensuring all of Swiss-Tech's processes and procedures adhere to the Quality Management System to maintain ISO-9001, AS9100 and ISO-13485 certification.

Duties/Responsibilities:

- Leader of the Quality Assurance department including the Quality Engineering and Quality Inspection functions.
- Acts as a catalyst to inspire and motivate others both cross functionally and within the QA function to act with a sense of urgency to ensure customer quality and service expectations are met or exceeded.
- Serve as the Management Representative of the AS9100, ISO-9001 and ISO-13485 Quality management system. Manage the internal, external, and third-party audit system and corrective action/preventative action (CAPA) process.
- Acts as the primary interface with customers to resolve issues of non-conformance, print interpretations and applications of standards.
- Primary owner of the Material Review Board (MRB) process, execution, and issue resolution.
- Establish, measure, and communicate key performance indicators (KPIs) such as COPQ, PPM (internal & external), first pass yield, CAPA, non-conformances and others to track functional and organization-wide performance.
- Responsible for the implementation, training, execution, validation, and on-going monitoring of statistical process control (SPC) as a production tool.
- Train the production workforce to ensure the proper inspection skills and use of inspection equipment are used to ensure correlation of in process inspection, final inspection, and customer receiving inspection.
- Responsible for ensuring all inspection measuring and test equipment (IMTE) is maintained and calibrated per defined calibration schedules and processes.
- Partners with NPI Engineering and Manufacturing Engineering to ensure Quality related tasks are completed on time for deliverables such as FAIRs, SPC programming and validation, PPAPs, FMEAs, inspection equipment programming and process documentation.
- Ensure compliance with safety policies, OSHA, EPA and DNR regulations. Enforce the PPE requirements
- Is a champion for continuous improvement to eliminate waste and improve quality including the application of lean/six-sigma tools

Qualifications:

- A thorough understanding of the ISO-9001, AS9100 and ISO-13485 quality standards and their application in a manufacturing environment.
- Experience with the management and audit processes for ISO-9001, AS9100 and/or ISO-13485 including the corrective action process.
- Extensive experience with inspection equipment, processes, standards, training, and gage R&R.
- Experience with machining processes including turning and milling. Swiss machining experience is a big plus.
- Focused on processes. Ability to train, coach and monitor to ensure processes are consistently followed and maintained.
- Experience as a primary communicator with customers. Ability to share information in a structured, logical manner. Demonstrated sense of urgency dealing with customer issues
- Experience managing regulatory compliance such as ITAR, DFARS and EAR.
- Experience with lean/six-sigma tools such as 5S, poke-yoke, kaizen, Kanban, standard work, 5-whys, DMAIC, fishbone diagrams, FMEA, A3 and 8D. Six-sigma greenbelt or blackbelt certification preferred.
- Demonstrated ability to lead and inspire others, to positively change morale and the ability to change behaviors in others in a participative, team environment. Experience with organizational behavior models such as Shingo or Baldrige is a plus.
- Experience with the leadership and management of a quality functional organization including inspection, calibration, compliance, and engineering.
- A team player. Ability to partner with cross-functional leaders to drive operational excellence and organizational leadership.

Education/Experience:

- Bachelor's degree in an engineering discipline (BSME, BSIE preferred). Master's degree in engineering or MBA a plus
- 5+ years' experience leading a Quality Assurance department or function
- US citizen or permanent resident