WEISS-AUG GROUP
MANUFACTURE SMARTER

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Quality Engineer

Hiring organization
Weiss-Aug Group

Employment Type
Full-time

Job Location
220 Merry Lane, 07936, East Hanover, NJ

Date posted
June 15, 2022

Description

Sr. Quality Engineer must have at least 5 yrs. experience in medical device quality or equivalent experience. Represent the customer to ensure that the customer's quality expectations are clearly understood and being met. Directly manages technical personnel including inspectors, programmers, and quality engineers. Supports manufacturing and engineering departments in quality engineering and inspection related activities.

Responsible for overseeing the coordination and on-time/in-budget completion of all quality project tasks which may involve some or all of the following technologies: measurement of progressive stamping parts and tooling, insert molding parts and tooling, factory assembled automation, and other related tooling/processes.

Performs the following functions and or manages those who: design, install and evaluates quality assurance process sampling systems, procedures, and statistical techniques; designs or specifies inspection and testing mechanisms and equipment; analyzes production and service limitations and standards; recommends revision of specifications when indicated.

Requires a 4-yr engineering, technical or management degree or substitute experience; graduate degree in engineering, technical or management discipline is preferred.

Ability to manage direct reports with varying technical and engineering backgrounds required.

Responsibilities

• Manage/Coordinate team of engineers and technical staff.
• Manage Programs: Including Technology, Metrology and Cross Functional Teams from Manufacturing, Engineering, and other internal/external resources.
• Represent the customer to ensure that the customer's quality expectations are clearly understood and being met.
• Provide leadership to technical teams responsible for successful launch of multiple complex programs.
• Responsible for overseeing the coordination and on-time/in-budget completion of all quality projects which may involve some or all of the following technologies: measurement of progressive stamping parts and tooling, insert molding parts and tooling, factory assembled automation, and other related tooling/processes.
• Advanced Product Quality Planning (APQP) including completion of related documentation, including but not limited to: DOE's, FMEA's, Process Flowcharts, Control Plans, Capability Studies and Gage R&R's (MSA Studies)
• Ability to participate in product design (R&D) meetings with Medical Customers associated with Print Discussions, GD&T Methodology, Tolerance Stack-Up Discussions, and general "Best Practices" from a Quality Perspective.
• Oversee the creation and distribution of quality project schedules. Ensure that quality project milestones and deadlines are met including assignment of responsibilities, monitor progress and report status to management/customer.
• Identify trends or shifts in Production Measurement Data through Oversight of the

Inspection Team
• Execute Engineering Studies on Existing and New Programs to facilitate and part optimization and debug.
• Involvement in Tooling Kickoff, Specification Review, Design Review and Lessons Learned (Postmortem) Meetings pertaining to quality issues during a program.
• Involvement in the change control process (ECO) relating to Engineering documentation.
• Involvement in the management of key suppliers as required by projects. Interface with outside suppliers to ensure they provide product or services on-time and to quality specifications.
• Assist in determining needs for additional personnel and/or training in order to meet program quality needs.
• Identify and facilitate new and/or special equipment needs along with Manufacturing Engineering for smart measurement and verification.
• Interface with customer on technical and schedule-related issues. Ensure program progress is communicated to customer at regular intervals.
• Mediate conflicts between departments. Forge compromise and consensus between team members.
• Assist in identifying areas for continued improvement and opportunities to gain organizational knowledge.
• Participate in customer, internal and registrar quality system audits in support of in-process inspection and new program qualification.

Qualifications
• Minimum of 5 yrs. experience in quality.
• Experience in medical device/life science industry required.
• Experience with management of direct reports and technical staff.
• Experience with product design, program/project management, and understanding of tight tolerance manufactured products is required.
• Requires a 4-yr engineering, technical or management degree or substitute experience.
• Ability to read blueprints and other technical documents. Understanding of ANSI/ISO drawing standards and GD&T dimensioning required.
• Ability to use SolidWorks for product/tooling design preferable.
• Knowledge of quality inspection tools and methods required. Familiarity with Statistical Process Control (SPC) tools and methods also preferable.
• Knowledge of GMP/ISO Quality Systems required.
• Knowledge of TQM, Six Sigma or Lean Manufacturing principles preferable.
• Knowledge of progressive metal stamping and/or insert molding processes desirable.
• Participate actively in a team-oriented environment. Provide leadership to cross-functional teams whenever necessary with ability to lead in all areas of a manufacturing organization.
• Proficient in Microsoft Word, Excel, and Powerpoint.
• Knowledge of Plex software preferable.
• Use of Minitab, required.
• Experience and knowledge in Statistical Analysis, SPC, required.
• Experience in Validation/PPAP, required.
• Exceptional analytical and computational skills. Knowledge of problem-solving tools and techniques preferable.
• Excellent verbal and written communication skills.
• Demonstrated high level of negotiation and conflict-resolution skills.
• Demonstrated high level of creativity and innovation.
• Demonstrated decision-making capability.
• Demonstrated customer interfacing skills, including “soft skills” needed to facilitate engineering discussions/technical reviews.

Job Type- Full Time

We provide excellent company benefits and a competitive salary. We are an equal opportunity employer.