

POSITION DESCRIPTION

ADVANCED QUALITY ENGINEER – HEALTHCARE

SUMMARY: Individual will plan and direct all quality engineering activities for new product launches from disciplined requirements reviews through highly standardized IQ/OQ/PQ validation protocols.

RESPONSIBILITIES:

- Work with Strategic Engineering Team, Business Unit Manager, the Technology Center, and Manufacturing, on advanced quality planning to effectively bring new programs from concept to production.
- Work with customers to ensure advanced quality plans including critical dimensions, control plans, process flow diagrams, SPC plans, FMEA's, etc. are initiated during the earliest stages of each program.
- Manage inspection process (metrology) for assigned projects.
- Perform scientific validations including DOE's and statistical analysis.
- Work with plant based Quality Engineering Managers and Quality Engineers to ensure proper utilization of advanced quality planning tools consistent with ISO-TS procedures.
- Actively seek responsibility for all aspects of Quality Engineering for all assigned customers and projects.
- Assume accountability for meeting all ISIR and part submission dates.
- Closely monitor and report project status (GYR format) to Engineering Manager on a weekly basis.
- Participates in all engineering team program design reviews and weekly team meetings.
- Performs other related duties as assigned.

QUALIFICATIONS:

- Experienced in injection molding tight tolerance medical parts and familiarity with sub-assemblies and contract manufacturing.
- Preference given to individuals with engineering or technical degree and/or 10 plus years of hands on experience in precision molding and quality assurance.
- Must have experience writing and carrying out IQ/OQ/PQ validation protocols.
- Experience in a medical device or FDA regulated environment.
- Preference given to individuals with demonstrated regulatory validation experience for Class II and Class III Medical Devices, including 510K submissions.

- Preference given to individuals who are an ASQ Certified Quality Engineer, a Six Sigma Black-belt, or are currently pursuing certification.
- Prefer this individual to have a working knowledge in Design of Experiments (DOE), and ability to implement theories during qualification phases of new programs.
- Proficiency working with Microsoft Excel, Word, and other software products.
- Experience with Minitab or other statistical software strongly desirable.
- Skilled in metrology tools, and Geometric Dimensioning and Tolerancing (GD&T).
- Must have working knowledge of probability and statistics, with college credits preferred.
- Must be able to understand and interpret blueprints of plastic parts, assemblies and systems.
- Able to work effectively in a team environment.
- Able to identify problems and communicate solutions in a constructive and positive manner.
- Attention to detail; excellent organizational and record keeping skills.
- Ability to lift up to 40 lbs.

EDUCATION:

BS Engineering or related field