



**PRECISION EXTRUSION, INC.**

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## **QUALITY ASSURANCE ENGINEER**

The Quality Assurance Engineer will work in a Quality Assurance environment to ensure that the design, development, manufacturing and support of products meet the requirements of ISO 9001 and 13485 and other applicable Quality Standards. This position is a multi-disciplinary position with opportunities to work on future products and current product and process improvement.

The Quality Assurance Engineer will represent Quality Assurance on product/process development teams as well as participate in development, review and approval of test protocols and reports. Qualified candidates may do design verification and validation testing for products, equipment, software, methods, packaging, stability studies and process controls.

Additionally, the Quality Assurance Engineer will interact with suppliers on quality issues and perform complaint analysis to determine root cause.

The candidate should be knowledgeable in the plastic extrusion industry to perform successfully.

### ***Job Description:***

- Plays a key role in implementing and executing Quality System in accordance with ISO
- Oversee all aspects of the Validation Program ensuring compliance, has primary responsibility for product and process validation consistent with customer requirements. Writes and deploys IQ/OQ/PQ protocols and validation reports
- Lead and direct activities of other supporting quality functions as necessary and serve as a business partner with R&D and customer service/support to ensure design-for-quality
- Lead quality assurance tasks in product development, manufacturing and service to ensure processes are capable and quality tools and systems are in place
- Take as a personal mission the improvement in quality and reliability of assigned products in a manner that is clearly visible to our customers
- Drive analysis of product quality performance data to identify high priority product issues relating to safety, complaints and systemic customer dissatisfaction issues
- Lead investigative teams to determine root cause and effect process improvement plans

- Troubleshoot process and equipment validation issues by working closely with manufacturing and development to resolve
- Provide training to ensure proper implementation and use of quality tools and procedures
- Review Production and QC records and perform product release
- Support implementation of corrective actions to solve production/quality issues
- Must be able to work independently on assigned projects/programs
- May have responsibility for directing the work efforts of technicians

***Qualifications:***

- Bachelor's Degree in Science or Engineering
- 3 + years experience in quality assurance preferably in the medical device industry
- Strong analytical and organization skills as well as a methodical approach to data driven problem solving
- Excellent writing skills for report preparation. Good verbal communications as well as good interpersonal skills
- Must have the ability to review and evaluate scientific and technical standards and translate those requirements into efficient, effective internal processes as they pertain to Quality Systems
- Experience with ISO 9001 or 13485 and GMP/QSR regulations and requirements
- Experience in risk assessment, design control, engineering problem solving and root cause analysis
- 6 Sigma training and/or ASQ certification or equivalent a plus
- Familiar with tool maker microscopes, video microscope, and other QA hand tools
- Familiar with calibration equipment is a plus
- Experience with MS Office Suite (e.g. word, excel, PowerPoint, and outlook)

***Job Location:***

Glens Falls, NY, US

***Position Type/Classification:***

Full-Time/Exempt