

Quality Assurance Engineer



*Quality Assurance
Engineer*

*Leading Med Device
Company*

*Excellent Packages +
Benefits*

Apply in Confidence Today

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Quality Assurance Engineer | West of Ireland

- **Leading Medical Device Company in the West of Ireland**
- **Excellent career progression opportunities along with a generous package**

Oradeo Recruitment is presently seeking interest for an experienced **Quality Assurance Engineer** who will be responsible for driving continuous improvement within the Value Stream, working with the Engineering and Production teams.

Become a **Quality Assurance Engineer** with a Leading Medical Device Company in the West of Ireland. This position would come with an excellent remuneration package and a clear path for career growth and development towards a Senior Engineer and beyond.

Roles and Responsibilities:

- Adhere strictly to company policies and procedures.
- Extensive understanding of products and processes within area of responsibility. Thorough knowledge of all production processes and quality management systems.
- Conform to the requirements of the Quality and Environmental Management System.
- Review, update and maintain existing quality management processes and procedures.
- Maintain detailed and accurate quality records, data analysis and documentation.

- Raise Quality profile and operating standards within the business.
- Deliver on all KPIs that help the business achieve its goal.
- Support projects and initiatives across the plant where required, ensuring key deliverables are achieved in a timely manner and liaising effectively with internal and external customers.
- Initiate and drive continuous improvement opportunities / programs.
- Lead and drive QA initiatives within area of functional responsibility.
- Represent quality interests and concerns on project teams.
- Quality support within the assigned Customer and/or project teams to ensure Customer and QMS requirements are implemented and fulfilled to required GMP standards.
- Lead Quality Engineering activities for the introduction of new product lines through development of product inspection plans, production documentation, process FMEAs and risk management plans. Ensure change requests are effectively managed.
- Lead Quality Engineering activities for existing product lines through maintenance and continuous improvement of product inspection plans, production documentation, process FMEAs and risk management plans. Ensure change requests are effectively managed.
- Ensure that products meet customers' quality and product integrity requirements and continually seek to identify and drive improvements in product and process quality.
- Lead and coordinate/execute process and product validations.
- Provide quality input to cross functional team to support existing product lines with an ability to multi-task and to work in a high paced environment with an awareness of continued impact on production and the plant performance.
- Ensure quality standards are adhered to, and all production processes are carried out according to procedures.
- Investigate root cause of quality issues and following through with timely and effective corrective actions to prevent re-occurrence for customer and internal issues.
- Oversee non-conforming material, customer complaints, CAPA investigations, analysis, and improvement.
- Utilize data analysis and trending, statistical process control, root cause analysis and implement corrective actions.
- Utilize DOE's and other statistical analysis to support product and process optimization or determine causes of process variation.
- Ensure quality inspection instruments are accurate and regularly calibrated, tested and audited.
- Assist with ensuring that the Company retains ISO accreditation.
- Conduct internal audits and external audits as required.
- Host audits of the Company's operations by external bodies (e.g., audits from customers, FDA, audits relating to certification to official standard e.g., ISO 13458)
- Train Graduate and Junior Quality Engineers on policies and procedures and perform an active role in their development and growth.
- Familiarize yourself with a variety of processes to allow you to work across a number of product lines
- An excellent record of attendance and time keeping.
- Other tasks as directed in line with company goals and objectives.

Necessary skills and requirements:

- Level 8 or equivalent Degree in Quality Assurance or similar discipline.
- Minimum of 3 years' experience in a Quality Engineering role with active involvement within a manufacturing floor, preferable in the medical device sector, is desirable.
- Guided by the disciplines of due diligence and compliance in all aspects of work.
- To be a good team member, fully motivated to achieve and demonstrate best practices in line with the department and site objectives.
- Effective communicator and influencer across multi-functional teams, with the ability to manage internal and external customers' requirements.
- Proficient with Microsoft Office.
- Proficient with Syspro, Minitab & Lotus Notes, is desirable.
- Knowledge of ISO 13485, ISO 14971 and QSR 21 CFR Part 820 standards.
- Excellent interpersonal skills.
- Ability to work in a cross functional team.
- Strong proficiency in statistical analysis techniques to investigate and solve problems and improve quality.
- Ability to plan, organise, and prioritise own daily work routine to meet established schedule.
- Ability to drive projects to completion.
- Project Management training is advantageous.

How to Apply:

For more information or to apply, please submit your CV to **recruitment@oradeo.com**

About Oradeo – Oradeo Recruitment are specialists in the life sciences & pharmaceutical, construction & engineering sector. We are a leading service provider in Ireland, UK and Europe for professional recruitment services and the provision of managed labour in Construction & Civil Engineering, Data centres, Mechanical & Electrical, Life Sciences & Pharmaceutical, and Renewable Energies sectors