Quality Engineer

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- **Leading Medical Device Company in the Sligo**
- **Excellent career progression opportunities along with a generous package.**

Oradeo Recruitment is presently seeking interest for a **Quality Engineer** in our clients Division located in Sligo. This position comes with an excellent remuneration package and a clear path for career growth.

Duties and Responsibilities:

- Provide technical quality support to Project Manager, Design Engineers, Production manager and clients.
- Work closely with Engineering team and the client to establish and maintain compliant product specifications.
- Quality review of process validation plan, protocols, and reports.
- Co-ordinate and contribute to the generation and maintenance of compliant product risk management files.
- Issue, review, and release of lot records to manufacturing.
- Co-ordinate and review of testing and release of sterilise product.
- Quality review of SOP’s, Work instruction’s, template’s, Material specifications etc. to ensure compliance to applicable regulatory standards and cGMP procedures.
- Review and approve product change controls.
- Liaise with suppliers and clients on quality related issues.
- Perform an active role in further development and continuous improvement

of the QMS.
- Support QMS as quality coordinator in investigation, root cause analysis, disposition, and corrective action of non-conformances & customer complaints.
- Perform CAPA reports.
- Support clients in product submission to applicable regulatory authorities.
- Support Quality Department in implementing and maintaining QMS.
- Conduct internal audits and compilation of associated documentation.
- Support and assist in the preparation for customer and surveillance audits.
- Updates job knowledge by participating in educational opportunities.
- Other such duties as may be assigned from time to time by their manager.

Minimum requirements related to the position:

- Minimum Degree in a Science or Engineering discipline.
- 3-5 Years' experience working in a medical device environment.
- Strong knowledge of ISO 13485, FDA regulations 21CFR 820.
- Strong knowledge of MDR & FDA product submission requirement.
- Internal/external auditing experience would be an advantage.
- Validation experience including Sterilization, process and packaging validations would be beneficial.
- Knowledge of Medical Device manufacturing environment including cGMP would be an advantage.
- Strong understanding of the general principles of ISO 14971.
- Strong decision-making ability, coupled with the ability to work on own initiative with minimum supervision and ability to multitask and prioritise is required.
- Demonstrate detailed working knowledge of the medical device industry.
- Excellent written and verbal communication skills, with the ability to communicate appropriately with different Engineering teams, Project Management, suppliers and customers.
- Self-motivated, flexible with a desire to learn new tasks.
- Excellent attention to detail with strong numerical and problem-solving ability, while maintaining awareness of longer-term objectives.
- Capacity to maintain the highest level of confidentiality internally and externally.
- Excellent MS Office experience (Word, Excel, PowerPoint etc.).
- High level of teamwork and engagement.

For more information about this position or other opportunities, contact Tracey Hayden at Oradeo Recruitment confidentially on +353 087 1005229 or apply in confidence.

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 and Renewable Energies

sectors