Harmac Medical Products. is a leading, award-winning contract manufacturer of single-use medical devices, serving the global marketplace for more than 35 years. With headquarters in Buffalo, NY and facilities in Ireland and Mexico, this opportunity is based in our Irish site in Castlerea, Co. Roscommon.
Harmac, a privately held company, provides innovative technical solutions and manufacturing services for leading Fortune 500 med-tech companies and high potential start-ups.
Harmac's mission is to change the lives of patients, employees and the communities in which we work.

Job Title:	**Quality Assurance Engineer**
Department:	**Quality Assurance**
Reporting To:	**Quality Engineering Manager**

SUMMARY: Reporting to the Quality Engineering Manager, the Quality Assurance Engineer will provide ongoing Quality support in an effort to maximise production quality performance, including identifying root cause, implementing corrective/preventive action on all quality issues in production. Scope of role will also include addressing any customer and internal related issues identified in the manufacturing process and validation of new processes/products ensuring effective implementation of the required QMS documentation.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Adhere strictly to company policies and procedures.
- Extensive understanding of Harmac products and processes within area of responsibility. Thorough knowledge of all Harmac 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 Harmac's and 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.

QUALIFICATIONS AND EXPERIENCE REQUIRED:

- 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.