ABOUT THE COMPANY

Steripack Ireland are an exciting business located in a modern state of the art facility in Mullingar Co. Westmeath. We are passionate about serving the world's medical device and allied healthcare industries in offering a range of the highest quality innovative healthcare packaging solutions.

We are building a fantastic team and culture in the business where people are at the core of everything we do. We have exciting plans for growth and opportunities for people to be part of and grow with the business into the future. Whether you're a team member from production operatives to engineering and quality assurance experts, customer service, marketing, sales or have other relatable skill sets look us up @ www.steripackireland.ie to see what opportunity awaits you at Steripack Ireland.

Steripack Ireland have an exciting opportunity for a Human Resources Manager and would love to hear from people who feel they match the profile of the following job description.

POSITION Quality Assurance Engineer

GENERAL FUNCTION

Reporting to the Senior Quality engineer and/or Quality and Regulatory Director the Quality Engineer will work in collaboration with the site team to champion & roll out the strategic initiatives which comply with the quality system requirement of ISO 13485 and ISO 11607 and in combination with customer request. To support our operation, engineering and R&D teams. The quality engineer will facilitate the development of new manufacturing process at the site and enhance the process and related quality system overtime. Customer onboarding and interaction is a significant element of the position.

MAIN DUTIES

- Lead quality improvement programmes using recognised problem-solving and project. management techniques.
- Interface on an ongoing basis with customers to ensure requirements / concerns/complaints are communicated, and corrective and preventive actions are closed in a timely and effective manner. Customer onboarding process is a key element of the position.
- Management of customer documents into the Quality system i.e., Drawings; Purchase
- Specification; Quality Agreements etc. and the training of relevant personnel.
- Drafting and approving of quality documentation to meet Customer requirements i.e.,
- Quality Specification Sheets (QSS), CAPA's, Defect Library etc.
- Trending and track of quality data to support quality improvements across the business

- Lead investigations into material / product issues to ensure a thorough root cause, containment / corrective and preventive action is implemented.
- Adherence to incoming control requirements and supporting the SCAR process when required.
- Participate in the review of validation protocols and reports to ensure quality compliance.
- Executing internal process and system audits.
- Manage quality projects in support of continuous improvement e.g., Lean Projects.
- Co-ordinate activities associated with change management and customer interaction.
- Ensuring the timely and effective closure of day-to-day quality issues.
- Interface with other departments daily.
- Batch paperwork review and final decision to release product for shipment.
- Analysing and reporting of key measures e.g., Ppk's, Cpk's, Cost of Quality, Customer
- Complaints, and Internal/external quality results.
- Coach and drive a culture of compliance and continuous improvement.
- Compliance to all site Environmental, Health and Safety requirements, training and regulations.
- Compliance with all site company policies, procedures, and corporate policies.
- From time to time, support business related activity and perform reasonable additional duties at the request of the Manager.

Qualifications and Experience

- Third level qualification in Engineering / Quality / Science.
- Two + years' work experience in a Medical Device manufacturing environment.
- A working knowledge of quality systems such as ISO 13485 is essential. Experience and knowledge of 21 CFR Part 820 and EU GMP is an advantage.
- Ideally understand sterile sealing manufacturing process.
- An in-depth knowledge of validations and change control management in a Medical Device environment

- A working knowledge of statistics, SPC, and ideally the use of Minitab.
- Auditing experience to the requirements of ISO 13485 / EU GMP / 21 CFR Part 820 is preferred.
- Ideally have a working knowledge of Lean / 6 Sigma tools.

CORE ROLE COMPETENCIES

- Excellent communication skills with internal and external customers, both oral and written.
- Team player with strong work ethic
- Strong written and verbal communication skills
- Ability to manage, mentor and develop people within fast paced and flexible working environment.
- Experience and/or ability to manage cross-functional team meetings, train, or coach other employees; and give presentations.
- The ability to establish rapport with internal and external customers, peers, and employees in all departments.
- Excellent organizational skills.