



ESI Technologies Group, part of the Indutrade Group, is the leading supplier of Process Equipment & Engineering Solutions into the Pharmaceutical, Chemical and Biotechnology Industries in Ireland & UK. The continued expansion of our Life Science business portfolio has resulted in the requirement for the following position:

### **Senior Quality Assurance Engineer - Life Science (Ultrapure Division)**

Reporting to the Quality Manager, this position will be based in our Cork headquarters. With a primary focus on our Life Science (Ultrapure) product portfolio, this person will have responsibility for the related Quality function for the company including the development and maintenance of the Quality Management System, and operating in line with cGMP guidelines, including associated SOPs, customer audits and change notifications. Also including all aspects of Quality within the facility including machines, equipment conformance and calibration.

This person will work with the cleanroom assembly, Procurement / Supply Chain for the facility to ensure final product shipped meets all relevant Quality standards and responsible for the Training programme for all staff including cleanroom operators.

Our Ultrapure division offers solutions for the bio-pharmaceutical industries in Ireland, UK and Benelux with our comprehensive Life Science product range. We have built up a strong portfolio of official distribution agreements.

#### **Essential Duties and Responsibilities**

- Facilitate the implementation and development of Standard Operating Procedures.
- Support and influence the clean room assembly, sales, and cross-functional teams in efforts to prevent and correct quality issues during all phases of a product's life cycle.
- Responsible for supply chain compliance and quality records.
- Responsible for Audits (Suppliers & regulatory – ISO) including planning, coordination, compliance & reporting / documentation. Liaise with Sales and Purchasing / Supply chain on same.
- Develop and maintain change notification programme.
- Responsible for RMA & CAPA procedures and operation of same.
- Report on the performance of the management system to leadership.
- Champion and lead continuous improvement of the quality management system.
- Lead process improvement initiatives using a systematic approach.
- Communicate regularly with customers, suppliers, and internal team members.
- Attending educational workshops and reviewing professional publications.
- Benchmarking quality activities & keeping up to speed with relevant standards such as ISO /GMP.
- Participate in customer and supplier visits with the sales team to facilitate auditing & evaluation as appropriate.
- NDA Policies, T & C's, Supply and Quality Agreements.
- Meet deadlines and work towards set team and departmental targets.
- Other duties as deemed necessary by company management to support this role.

#### **Education, Skills and/or Experience**

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required.

- Bachelor's or associate degree in a technical, science or business-related field plus 2 years' experience OR a minimum of 4 years working in or on an ISO 9001:2015 QMS in a similar role.
- Must have knowledge and experience working in an organization certified ISO 9001:2015.
- Must have experience with CAPA management.
- Prior experience with FMEA, Risk management, Change Management a strong plus.

- Professional certifications, including ASQ Quality Engineer, Quality Improvement Associate and/or Lean Six Sigma training is a plus.
- Must possess a strong understanding of Quality tools, concepts, and methodologies as well as relevant regulatory requirements.
- Strong communication (both verbally and written) and interpersonal skills, excellent attention to detail.
- Strong planning, organization, multi-tasking, and problem-solving skills.
- Strong customer service orientation with the ability to work in a collaborative environment.
- Ease with data collection, management, and analysis.

This is a great opportunity to join a division of ESI with a developing portfolio, within an already well-established company, as part of the Indutrade group.

Job type: Permanent.

Remuneration package is commensurate with experience.

Applications in writing to:

The HR/Training & Development Manager, ESI Technologies Ltd., North ESK Business Park, Dunkettle, Cork, or via email to: **hr@esitechgroup.com**

Replies only provided to those who are shortlisted.