Quality Systems Technician

About Aran Biomedical:

Aran Biomedical design, develop and manufacture implantable medical devices, as an outsource partner to many of the leading, global medical device companies. Our innovative technology focus and biomaterials expertise foster a dynamic culture, which delivers next-generation implantable solutions.

About the Role:

As Quality Systems Technician, you will support quality system compliance activities including review of standards and follow up to ensure satisfactory closure of identified gaps. You will also provide support for the document control activities and support audit preparation activities.

Duties and Responsibilities:

- Compliance to applicable regulatory standards and current GMP procedures and practices.
- Maintain QS documentation and records in a compliant state
- Support / maintain the document and record control processes
- Support and actively participate in audits (internal and external)
- Complete/Support administrative review for Complaint / Manufacturing Investigations
- Initiate and process Engineering Change Notices for document updates
- Actively support activities associated with the Supplier management process
- Actively participate in the initiation and implementation of Corrections, Corrective & Preventive actions
- Actively participate in continuous process improvement initiatives
- Escalate potential deficiencies to ensure timely resolution
- Collate/ trend and present Key Performance Indicators and Quality data to support communications and Management review
- Participate in training events to continuously develop and maintain competencies
- Respond to non-standard requests from customer need
- Support quality system compliance activities including review of standards and follow up to ensure satisfactory closure of identified gaps
- Act as a Trainer for completion of responsibilities associated with Quality Systems and document control
- Provide support for the document control activities and personnel
- Support audit preparation activities
- Provide support for audit follow up activities

Qualifications:

- Level 7 or 8 Degree in Manufacturing / Quality Engineering / Life Sciences

Skills and Experience:

- Minimum of 2 years' experience working within the Medical Device / Pharmaceutical Industry.
- Previous work experience within QS/QA/QC environment.
- Knowledge of Medical device Regulatory requirements (e.g. ISO13485, FDA QSR 21CFR Part 820)
- Knowledge of and adherence to Quality systems
- Good computer skills in usage of MS Office Suite - Microsoft word / Excel / PowerPoint
- Ability to work on own initiative as well as part of a team
- Good documentation skills with strict attention to detail
- Logical and methodical approach to work practices and processes
- Strong written and verbal communication skills are essential
- Basic understanding of statistical techniques
- Resilient to deal with challenging situations
- Capable of influencing change
- Highly motivated
- Self-aware / Optimistic / Empathetic