



Quality Assurance Engineer

Location: Bidford

Overview:

Reporting to the Quality Manager to provide a quality assurance function at the BVI Bidford site. This will include:

- Liaise with production and supplier personnel as appropriate on quality issues
- Maintain and develop knowledge of quality improvement techniques
- Undertake quality improvement projects

Key Responsibilities:

- Responsible for producing quality specifications, purchasing specifications and procedures and for their consistent implementation.
- Responsible for Validation of new or existing processes (where appropriate) in conjunction with process engineering.
- Responsible for investigating and resolving quality issues and providing production support.
- Responsible for liaising with production, quality, supplier and technical personnel to identify and implement quality tools (e.g. Six Sigma, Lean)
- Responsible for supporting the internal quality audit function.
- Responsible for preparing summary reports for management review and other formal review meetings.
- Responsible for coordinating activities relating to CAPAs/NCRs & SCARs.
- Responsible for maintaining IFS QM module.
- Responsible for adhering to the requirements defined within the Company's health & safety, environmental and quality policies and systems.
- Responsible for addressing QA issues as directed by the Quality Manager.
- To ensure that you as an associate meet the requirements regarding Quality and GMP standards as detailed in the Company Quality policy.



Requirements:

- Minimum HNC/HND or equivalent in engineering or related Quality discipline and/or relevant experience gained within BVI or similar manufacturing environment.
- Minimum of three years' experience in a Quality Assurance role, preferably gained within the medical devices industry.
- Regulatory affairs experience a benefit but not essential.
- Knowledge of medical device regulations (FDA, ISO 13485, MDD and EU MDR).
- Trained internal auditor to ISO 13485.
- Good problem analysis ability.
- Knowledge of Six Sigma techniques an advantage.
- Must be able to work in cleanroom environment.
- Good interpersonal and communication skills.
- Must be computer literate with knowledge of Microsoft Office software an advantage.
- Must be willing to participate in Developmental training programs.
- Must be able to maintain confidentiality in support of the Company and its Associates.
- Adhere to and maintain the Company's Health and Safety Policy.