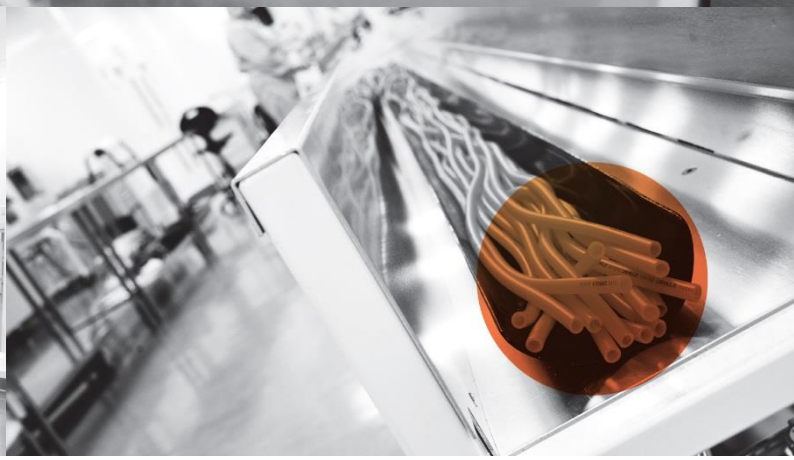
Quality Engineer



About Mi3

Founded in 2006, Mi3 is a specialist partner in the design, development and manufacture of complex plastic medical, pharmaceutical and scientific devices. Supporting clients from an early stage concept interpretation to development and design for manufacture. Mi3 can be contracted for one or more parts of the product life cycle or the entire process, assisting with:

- Market and technology research
- Concept creation and design
- Development and prototyping
- Pilot to full-scale production
- Sterilisation
- Regulatory and technical documentation.

What You'll Gain

The successful candidate joining the quality team at Mi3 will be part of a dynamic operation working towards zero product non-conformance and a culture of continuous improvement, as well as being an integral part of our growth journey. In supporting Production you will personally develop your skills and experience in these areas:

- Medical device product quality requirements and inspection
- Auditing
- Data collection and analysis to make meaningful decisions
- KPI reporting
- Providing effective training
- Problem solving and error proofing
- Process development
- Process improvements
- Procedural improvements
- Collaboration and team working.

Location

The role is based at the Mi3 facility in Blackburn, Lancashire.

Salary

Competitive salary commensurate with qualifications and experience.

Benefits

25 days holiday plus bank holidays.

Pension contributions.

High Street Discounts.

Type of Contract

Permanent - 37.5 hours per week.

Start Date

As soon as possible.

Application Process

Please apply for this role via LinkedIn

Application Closing Date

Friday 30th April 2021

Job Description

The Production Quality Technician is responsible for day-to-day operational quality activities within Production. The duties are varied from Production quality, spot auditing, initial failure investigation, inspection and testing, coordinating rework exercises, operator training and supporting the implementation of agreed improvements.

Key Responsibilities

- Owner of Non-Conformance processes responsible for compliance, maintenance and the output of processes including driving timely closure and evaluating adequacy of investigations and associated corrective and preventative actions.
- Owner of Quality Operational NCRs, Failure Investigations and CAPAs and QRAs.
- Responsible for trending product and process quality data and escalating issues in a timely manner.
- Responsible for the site product and environmental testing plan, ensuring its continued suitability and implementation including creation of governing procedures and work instructions etc. and managing the microbiology sub-contractor.
- Responsible for the sterility testing programme as directed by the Mi3 Sterilisation Expert or sub-contractor.
- Responsible for generating Specifications and Quality Plans to meet customer requirements.
- Responsible for establishing the appropriate inspection criteria, validation of inspection using techniques such as GR&R and training of inspection.
- Using statistical or other appropriate techniques to monitor and improve product related processes including validation sampling plans.
- Responsible for conducting batch review and release.
- Developing and implementing error proofing and control strategies in product related processes.
- Responsible for regular reporting of Quality status through Audits and other measures.
- Provide QE expertise to suppliers such as problem solving, error proofing and FMEA.
- Internal/external auditor as required by the schedule.
- Conduct or support validation activities.

Additional Responsibilities

- For all tasks, make suggestions for continuous improvement of processes and implement where applicable / requested to do so.
- At busy times reasonable requests may be made to perform duties of a similar nature
- Provide cover for Quality Technician roles during periods of absence.
- Adhere to QMS, HSE policies and procedures and all other Mi3 policies and procedures at all times.

Qualifications and Experience

Essential

- BSc in a scientific or engineering discipline with the required skills, knowledge and abilities that are typically acquired through a minimum of 3 years' experience in the medical device industry.
- Proficient in the knowledge of applicable standards, regulations and requirements e.g., GMP, GDP, MDR, MDSAP, ISO 13485 and ISO 14971.
- Advanced knowledge of medical device Quality Engineering, Manufacturing, Failure Investigation/Problem Solving, RCA and CAPA.
- Advanced level skills with Microsoft Office (Outlook, Word, Excel etc.).
- Ability to work effectively and independently with minimal guidance in a fast-paced environment.
- Time management skills including multi-tasking competing priorities as needed.
- Having a positive attitude, a desire to learn and be challenged.
- Demonstrated self-motivation and ethical behaviour.
- Must be an effective team player with the ability to mentor, lead and problem solve to provide solutions to the business.
- Confident and open personality who can communicate effectively, both written and orally with people at all levels.
- Six Sigma Green Belt or working knowledge of similar problem solving tools.
- Demonstrable experience of leading projects.
- Good to advanced understanding of the product and process validation lifecycle and requirements.
- Good understanding of specifications is essential.

Desirable

- Internal and/or external auditing experience or qualification, to ISO 13485 preferred.
- Knowledge of device sterilisation would be beneficial.