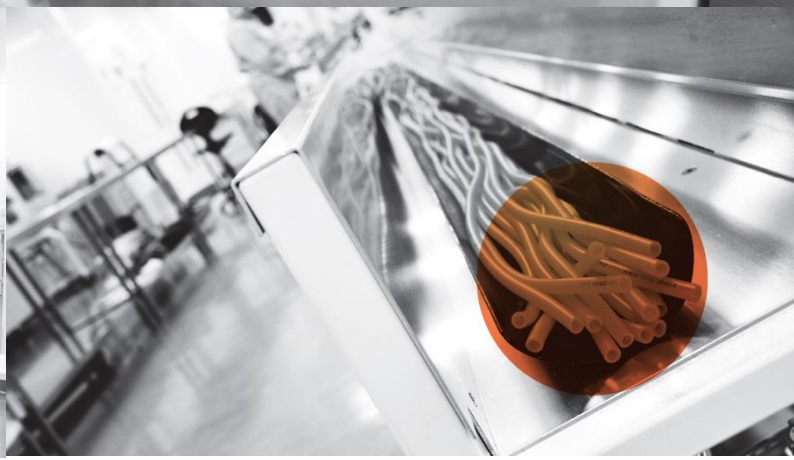
MDR & Technical Administrator



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

£18,000 - £22,000 depending on 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

To apply for this role please submit a copy of your CV and a covering letter to jobs@mi-3.co.uk.

Application Closing Date

Friday 21st May 2021

Job Description

As a leading manufacturer of Medical Devices, Mi3 requires an MDR and Technical Administrator to support in achieving MDR compliance across the organisation.

Key Responsibilities

- Coordinate the readiness activities including maintaining the project tracker, calling meetings, chasing actions, report status for updates to customer etc.
- Updating specifications and technical drawings, work instructions, quality plans, batch records and testing documents; and subsequent SOP updates or creation as applicable.
- Review and update all master artwork files.
- Creation of legacy DHFs.
- Subsequent document administration for the implementation of documents and drawings (all above), including QMS BOMs and DMRs.
- Change control owner for the above works.
- Administrate the applicable FMEA processes.
- Create inspection plans and perform GRR.
- Assist in trials, basic testing and support in the preparation of trials documentation.
- Responsible for the timely escalation of issues to the Line Manager.
- For all tasks, make suggestions for continuous improvement of processes and implement where applicable / requested to do so.
- Adhere to QMS, HSE policies and procedures and all other Mi3 policies and procedures at all times.

Person Specification

- Graduate in a scientific discipline is preferred; other suitable candidates with appropriate experience will be considered.
- Understanding of Quality Management Systems, especially ISO 13485;
- An appreciation of document control and the requirements of BS-8888
- Solidworks user with at least a basic proficiency; moderate proficiency preferred.
- Ability to talk to customers and suppliers and gather the pertinent information.
- Resilient person with tenacity.
- Excellent written English with experience in technical documents / protocols (advantageous but not essential).
- Ability to coordinate, organise and multitask.