MAK-SYSTEM

INTERNATIONAL GROUP

Job Role: QMS Specialist (Medical Devices)
Country: North Macedonia or Serbia
Reporting to: Head of Quality Assurance

A typical day might include:

- Working with the head of quality assurance, and managers across the business to identify and implement improvements to QA procedures, improve internal compliance, and implement corrective and preventive activities – including change controls, quality systems, product release procedures and other software life cycle controls
- Reviewing documentation to ensure accuracy, completeness, user friendliness, and compliance, including with GDPR
- Review documentation supporting GMP activities for accuracy, completeness and compliance
- Leading, coordinating, or performing deviation investigations
- Preparing registrations and certifications of new products for the EU and FDA
- Participating in internal and external audits, and implementing their recommendations
- Collecting, maintaining, and storing Quality System and medical device product records, including Device History Records, Design History File and Device Master Records
- Reviewing and evaluating customer complaints; supporting root cause determination and risk assessment
- Providing training to other parts of the business on Quality Management, and procedures
- Raising awareness, visibility, and communication on quality initiatives to support assigned quality goals and priorities

Your key relationships will be:

- Head of Quality Assurance
- Chief Operating Officer and QARAC
- Developers and Head of Product Engineering
- Project Managers

This job might be for you if you:

- Have a strong eye for detail
- Enjoy improving how things are done, as well as making sure they get done
- Are good at rolling up your sleeves and getting things done
- Care passionately about ensuring the safety of our customers' patients
- Have good written, oral, and presentation skills in English
- Are a problem solver and critical thinker
- Are a strong team player, with good critical thinking skills

You will have:

- At least 2 years' experience working within a regulated industry in Quality Assurance (preferably medical device or pharma)
- Good understanding of quality regulations; ISO 9001, ISO 13485 and 21CFR820;
- Proficiency with Microsoft Office, including Microsoft Word, Excel, PowerPoint, etc. to perform critical job functions, trending, reporting metrics etc.;

You may have (nice to have but not essential):

- A Bachelors degree, preferably in a related discipline

If you are interested, please send your application at: jobs.mk@mak-system.net; D.Kiprijanovska@mak-system.net