Job Role: Regulatory Affairs Manager
Location: Preferably Belgrade or Skopje. Open to other locations
Reporting to: Chief Operating Officer

Established in 1984, MAK-SYSTEM's vision is to design, develop, and deliver globally best-of-breed software to manage Blood, Plasma, Tissue, and Cells from end to end using the best technologies and functionalities for the patient's benefit. Our software solutions continuously support the digital transformation of organizations such as

- Blood Centers
- Plasma Centers
- Transfusion Services
- Tissue Banks
- Stem Cell Labs
- Cell and Gene Therapy (SME to Big Pharma, CMOs, Hospitals)

You will be responsible for MAK International's Regulatory Affairs, ensuring compliance with regulations and liaising with regulatory agencies.

Key Responsibilities

- Ensuring Company and product compliance per the applicable regulations or guidelines and participate in the identification, implementation and verification of the required changes. (FDA CFR 21 Part 820, GAMP 5, ISO 13485, ISO 9001 and other as needed);
- Communication with regulatory authorities and notified bodies including for audits, clearances, certifications, regulatory pathways;
- Providing strategic advice through the product development process;
- Defining employee regulatory training needs, developing training content and delivering to employees;
- Internal and external audit for the relevant sections;
- Coordination of projects regarding product and company registrations, clearance and certifications. (EU MDR, FDA 510(k), ISO 13485, ISO 9001);
- Participate into the documentation conformity assessments across all Departments as needed;
- Stay current on the changes in regulations, standards and guidelines.

This job might be for you if you are:

- Strong relationship builder with the gravitas to influence across all levels of the organisation;
- Motived, autonomous and able to juggle multiple priorities;
- Someone who operates with pace, makes things happen and can respond quickly to issues;
- Passionate about technology.

You will have:

- Bachelor's degree;
- Experience building and leading Regulatory Affairs or Compliance functions in a regulated industry;
- Excellent written and verbal communication and presentation skills in English.

You may have:

- Experience working within medical devices or pharma;
- Experience in working with regulatory agencies;
- Experience working in a global company and across multiple countries;
- Knowledge of software as Medical Device (SaMD);
- Familiarity with European, American and other medical devices' legislation, relevant guidelines, procedures, and requirements;
- Good understanding of quality and regulations such as ISO 13485 and FDA CFR 21 part 820.

Please email l.frisch@mak-system.net if you are interested in applying or discussing location for the role