



Job Title: Risk Management Engineer, Medical Devices

Location: Koropi (Attiki) -Commuting to work is available with Company Buses from Doukissis Plakentias metro station

As a **Risk Management Engineer**, you will have the opportunity to join our development team and participate in the development of innovative drug delivery devices. You will be responsible for identifying and managing system and sub-system risks for complex electromechanical, software driven devices, throughout the product lifecycle.

Job Responsibilities:

- Ensuring complete risk management documentation with responsibility of further developing and implementation ISO 14971 in the internal risk management process for medical devices during their entire lifecycle
- Conducting of hazard analyses, design risk assessments, use risk assessments, system/sub-system risk assessments, and manufacturing-process risk assessments using analysis tools such as FTA and FMEA
- Actively collaborating with design engineers to drive design mitigations and establish effectiveness of the risk control measures
- Supporting the traceability between risks, risk controls, safety requirements
- Leading periodic and event driven risk reviews of the risk management files for commercialized products based on post-market surveillance data.
- Supporting the complaints handling and CAPA teams with assessment of risks related to identified issues
- Supporting the regulatory team with assessment and responses to regulatory agencies and competent authorities related to medical device reporting requirements

Requirements:

- Degree in Electrical Engineering, Mechatronics, Mechanical Engineering, or relevant field of study
- Risk management experience in a regulated industry such as medical device, automotive, aerospace, or defense
- Practical experience in related areas such as system design, hardware/software design, mechatronics and real-time embedded applications



- Excellent written and oral communication skills both in English and Greek

About us:

Micrel Medical Devices is a rapidly growing medical devices company with strong presence in most European and world markets. MICREL designs, manufactures, and markets industry-leading ambulatory infusion pumps for a wide range of therapies such as parenteral nutrition and pain management. Micrel headquarters are based in Koropi, Greece. For more information visit www.micrelmed.com

If you are interested, please send your CV at careers@micrelmed.com, including the job title in the subject.