

« Project Associate, Software compliance specialist » - Job description**Mission (by order of importance)**

- Deliver remote and on-site consulting services to Clients in collaboration with the Project Manager
- Gradually, act as Project Manager for projects where software lifecycle management is central
- Contribute to the business development of Medidee by identifying and contracting new Clients
- Contribute to the performance of internal support systems of Medidee (reporting, quality system)
- Contribute to the strategic analysis of markets, services and methods of service provision of Medidee.

Activities

- Deliver consulting services to Clients comprising but not limited to:
 - Analysis of the product classification of standalone software as per MDR / IVDR / FDA regulations
 - Analysis of the risk classification of software as per 62304 and/or FDA guidance
 - Development, documentation and implementation of software related quality management systems and related support activities for Clients
 - Support the implementation of a compliant software lifecycle management process including the use of effective tools for bug tracking and management, releases management, configuration management, etc.
 - Development of risk management strategies, procedures and files, support risk and vulnerability analysis.
 - Development and documentation of design verification and validation strategies for software products, including for technologies such as Artificial Intelligence, Machine Learning, Blockchain and cybersecurity aspects
 - Delivery of open and Client trainings related to Software compliance
 - Development, documentation and review of regulatory files for medical devices and ancillary products
 - Performance of QMS and Technical Documentation compliance audits for Clients
 - Scientific and clinical research (i.e. formalization of clinical and scientific evaluation)
 - Support for clinical investigation design, submission, conduct and reporting.

Profile

- 3+ years software engineer ideally but not mandatory with experience in the medical field, either on embedded systems, or on standalone software
- Experience of software development tools and environments such as Jira, Git, or equivalent
- Good understanding of software testing strategies including software continuous integration
- Strong interest in best practices and compliance aspects
- Acquired or natural leadership behaviors for managing projects and coaching clients
- Ability to deliver training to professionals.