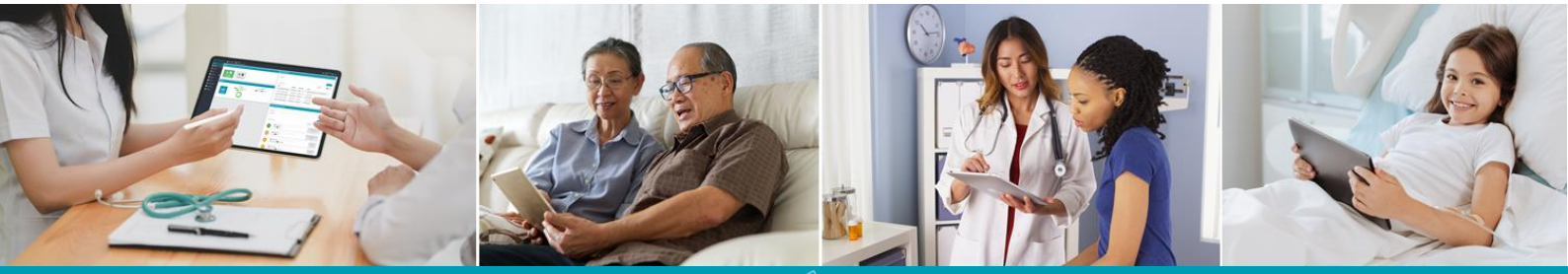


KAYENTIS is a software solutions provider specialized in clinical trials.

Our core competence is in patient data capture and processing solutions (eClinical Outcome Assessments = eCOA) and we are now expanding towards Decentralized Trials functionalities.

With 16 years of global experience in eCOA, Kayentis has supported more than **260 clinical trials** in **79 countries** with more than **90,000 patients**. Its head office is located in Meylan, near **Grenoble** (France), Kayentis is also present in **Boston** (USA) and **Tokyo** (Japan).

Joining Kayentis' teams means choosing a fast-growing company committed to improving clinical trials and the **well-being of its employees**.

KAYENTIS is growing! Develop your career with us!
Join an international, cohesive and dynamic team and develop new skills!

For more information about **Kayentis**, visit our career page, or have a look at our employee satisfaction survey results. Make sure to follow us on the social media platforms below for our latest news and updates:

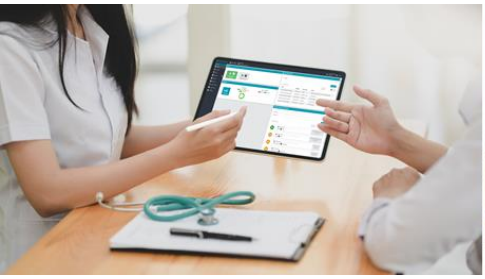
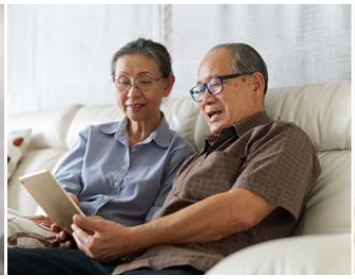
Software Quality & Risk Engineer M/F

The **Software Quality & Risk Engineer** **permanent position** is based in Meylan, (Grenoble).

YOUR ROLE:

As part of Kayentis Quality & Regulatory team, you contribute to the quality and reliability of Kayentis Solutions by ensuring development activities are carried out in accordance with regulatory requirements applicable to computerized systems used in clinical investigations.

- ✓ Participate in the maintenance, continuous improvement, and training of processes related to the design and development of Kayentis Solutions and Services, including the appropriate consideration of :
  - Risk management
  - Validation principles and guidelines such as ISPE GAMP© 5
  - Electronic records and electronic signatures requirements (21 CFR Part 11)
  - IT Interfaces
- ✓ Maintain the Validation Master Plans of Kayentis Solution and Interfaces, and Kayentis business tools
- ✓ Perform a quality review of development deliverables prior to release
- ✓ Participate in the maintenance and continuous improvement of IT processes
- ✓ Maintain Kayentis risk management and validation processes. Train and Coach teams on Kayentis Quality Management System processes and applicable requirements.
- ✓ Support the following quality processes as applicable to the development and IT processes:
  - Internal and client audits
  - Qualification, monitoring and audits of applicable suppliers and subcontractors
  - Validation of computerized systems

YOUR PROFILE:

- ✓ Master degree level or equivalent in quality, risk management, or software engineering
- ✓ Professional experience > 5 years in life science or medical technology development
- ✓ Excellent collaborative skills
- ✓ Good verbal communication and writing skills in French and English
- ✓ Customer-oriented

Preferred:

- ✓ Experience in the pharmaceutical, medical device, or clinical field
- ✓ Experience with risk management standards such as ISO14971
- ✓ Experience with GAMP© 5 guidelines or 21CFR Part 11 implementation

YOUR BENEFITS :

- ✓ Flexible working hours
- ✓ Bonuses
- ✓ Meal vouchers
- ✓ Bike allowance

Are you interested in this opportunity?
>> Contact us and send us your CV at career@kayentis.com <<