



**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:



## Clinical Operations Quality Engineer M/F

The **Clinical Operations Quality 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 clinical study projects follow Good Clinical Practices and Kayentis Quality Management System processes.**

- ✓ Participate in the maintenance, continuous improvement, and training of processes related to the provision of services, from study conception and validation through closure
- ✓ Owns the deviation and issue management processes and its continuous improvement. Coach study teams on deviations and issue handling
- ✓ Assess issues for possible escalation into Problems and CAPAs; can lead or participate in CAPA teams
- ✓ Qualify, monitor and audit subcontractors and suppliers involved in the provision of services
- ✓ Support client audits and client inspections
- ✓ Escalate issues with Client Governance and Management as necessary
- ✓ Track, trend and report KPIs on deviations and process quality

### YOUR PROFILE:



- ✓ Master 1 or Master 2 level or equivalent in quality or clinical management
- ✓ Professional experience > 2 years in quality in a life science regulated environment
- ✓ Experience managing deviations or quality management system processes
- ✓ Excellent verbal communication and writing skills
- ✓ Customer-oriented
- ✓ Fluent in English

Preferred:

- ✓ Experience in the pharmaceutical, medical device, or clinical field
- ✓ Deviation and CAPA Management

**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](mailto:career@kayentis.com) <<