<table>
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<tr>
<th><strong>Title</strong></th>
<th>Quality Assurance and Auditing Manager</th>
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**Context**

The Penta Foundation is a non-profit organization involved in clinical research and training activities in the area of paediatric infectious disease. The Foundation collaborates with a global network of clinicians and researchers to conduct not only clinical trials but also extensive observational and cohort studies, pregnancy studies, basic science, training and educational programmes. Penta is a unique and ever-growing network of investigators who are leading champions for child health in their home countries.

Research activities are coordinated by a multidisciplinary group from 11 different countries based in 3 cities (Padua, London and Athens) dedicated to the activities of the Penta Foundation.

As Penta continues to grow, we want to ensure we maximize our credibility and prestige at international level as a world-leading organization in child health research and continue to be a point of reference regarding critical paediatric concerns for institutions, the scientific community and the greater public.

Penta is seeking a Quality Assurance Manager to direct and oversee the quality system processes and procedures of the Foundation and its National and International Affiliates.

**Role**

The position will support the Penta Foundation Clinical Quality Assurance program to:

- Negotiate and agree in-house quality standards with the Senior Management.
- Develop QA plans identify critical control points and preventive measures.
- Establish critical limits, monitor procedures, corrective actions, verification procedures and supplier’s qualification and monitoring.
- Provide guidance to operational area managers for the design, implementation, the process policies and procedures, ensuring compliance with all applicable rules and regulations, guidance, and standards.
- Monitor achievement of agreed targets.
- Independent reporting on quality compliance to the board.

The post holder will be expected to be fluent in English and to have excellent verbal and written communication skills enabling close work with the collaborating institutions and clear communication between the project/study collaborators.

Level of salary defined according to experience.

This post provides an exciting opportunity for someone with a track record in Quality Assurance and an interest in paediatric research.
**Location**
This position will be based at the Penta Foundation in Padua, IT.

**Reporting line**
The post holder will report to the COO.

**Key responsibilities**
- Support the operating staff in the implementation of GCP-related quality system SOPs in compliance with applicable regulatory requirements and best practice. Manage evaluation and approval of quality system documentation including but not limited to deviations, change control reports, and document changes for compliance requirements (SOPs, procedures, policies, etc.).
- Provide leadership and oversight for continuous process improvement as new issues are detected, new knowledge becomes available, or change in regulation that add greater reliability, compliance, efficiency, and drive change.
- Provide QA advice based on analysis and interpretation of updates to GCP regulations to assure best Clinical/QA practices.
- Provide leadership and represent Quality Assurance on cross-functional project teams evaluating new quality processes or systems for Projects and Phase I/II/III trials operations.
- Direct and oversee inspection readiness activities and investigations to resolve quality issues. Review and approve corrective/preventive actions to reported audit observations and ensures proper follow-up activities are completed and documented.

**Requirements**
- University Degree or B.S./M.S. in a relevant science field.
- Pharmaceutical QA and operations experiences.
- Current and strong working knowledge interpretation/implementation of EU Regulations, ICH Guidelines and other local government regulatory requirements governing clinical research.
- Ability to deal with ambiguity leading to creative and pragmatic solutions to GCP compliance risk areas.
- Experience supporting regulatory authority inspections is desired.
- Thorough grasp of operational issues and performance standards for QA including key performance metrics.
- Proven ability to work under tight deadlines and pressure in a composed manner.
- Ability to organize tasks, work independently and adapt to changing priorities.
- Ability to function independently within a minimally supervised environment with exceptional attention to detail required.
- Excellent verbal and written communication skills, with the ability to work well in teams and able to prioritize work, manage multiple projects while maintaining quality. Ability to communicate effectively, both verbally and in writing. Ability to influence and advocate course of action of research project.
Advanced software skills (Microsoft Office suite proficiency including Office Word, Excel, PowerPoint).
- Able to read, write, speak, fluently and comprehend the English language. Able to travel approximately 10%-20% both domestically and internationally including overnight stays.

**Working language**

- English and Italian

**How to apply**

- Send a **signed CV** including the following statement: *I hereby agree for the processing of my Personal Data included in my application for the needs of the recruitment process in accordance with the General Data Protection Regulation EU 2016/679.*

- Include a **cover letter** outlining why you wish to apply and how you meet the specified requirements in this job description.

- Include **one reference** in either your cover letter or CV. Please indicate whether we can approach your references prior to an interview.

- Send all materials to **recruiting@pentafoundation.org** and label it ‘Quality Assurance and Auditing Manager’ in the email subject line.

- If you have any queries, please email at **recruiting@pentafoundation.org**