

# INTERNAL VACANCY

**Job title :** Quality Manager, temporary contract

**Location:** Paris / UK

**Closing date :**

## **Job Summary**

Responsible for site-specific aspects of the Quality Management System to ensure the company meets and maintains all applicable quality and regulatory compliance requirements.

## **Main duties and responsibilities**

- Manage the requirements for quality and regulatory compliance for the manufacture, sale and global distribution of diagnostic products.
- Support for regulatory and customer audits.
- Managing the company's key supplier base from a quality perspective.
- Support and develop data for input into the site management reviews.
- Provide quality and regulatory support to development and OEM projects, including the generation review and approval of process validation documentation.
- Review and approval of technical, regulatory and QMS documentation.
- Assist in regulatory submissions for existing and new products.
- Support compliance of the company's Risk Files in accordance with ISO 14971.
- Assist where required in process and product compliance to assure GMP is maintained for IVD manufacture.
- Maintain the site complaint investigation and vigilance reporting processes, and co-ordinate site PMS activities.
- Site responsibility for the Q-Pulse system.
- Ensure Executive Team (through the HQARC) are advised on any quality or regulatory changes that will impact the Novacyt Paris business.

## **Qualifications and experience required**

- Must be fluent in both verbal and written English and French.
- Should be fully conversant with key regulations for In-vitro Diagnostic Devices.
- Experienced and conversant with current requirements for ISO 9001, ISO 13485 (including CMDCAS), 21 CFR Part 820.
- Qualified internal auditor to ISO 13485.
- Experience managing suppliers from a quality perspective.
- Previous experience in conducting process validation studies.
- Experience in the testing and validation of software would be a distinct advantage.

Hours of Work	37.5 per week
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To apply for this vacancy please send your application to Wendy Karban, Group HR Manager, [wendy.karban@novacyt.co.uk](mailto:wendy.karban@novacyt.co.uk)