

INTERNAL VACANCY

Job title : Quality Control Lead
Location: Southampton - Primerdesign
Closing date : 26th October 2018

Job Summary

The QC Lead role will focus on leading and managing the QC team to ensure that company product quality standards are maintained and to ensure the smooth planning and execution of tasks day to day.

This role uses knowledge of ISO13485 and ISO9001 to ensure company QC compliance to these standards. The role will be responsible for leading any QC process or equipment validation required for QC of RUO and CE-IVD products.

The QC Lead must have excellent communication and organisation skills to liaise with different teams to ensure product transitions smoothly from production to QC. This role will also be responsible for managing the QC team; this involves prioritising workload, overseeing training and overall team performance. The QC Lead must be able to lead by example, focusing on coaching and motivating the team as well as ensuring QC processes are completed to the highest standard.

Main duties and responsibilities

- Provide management and leadership to the QC team ensuring that QC responsibilities are completed and the smooth running of the team.
- Line management responsibilities; including conducting appraisals, managing performance and providing objectives/personal development plans for employees.
- Monitor QC team performance through performance indicators, identify trends and initiate actions based on performance.
- Responsible for recruitment and training of new staff to QC team. Also, identify ongoing training needs for all team members.
- Carry out goods-in, in-process and final QC tests to support manufacturing and R&D activities.
- Ensure QC results are accurately recorded in manufacturing system.
- Perform checks on incoming raw materials and record checks in manufacturing systems.
- Manage QC inventory; ensuring sufficient controls are available.
- Write clear and concise QC SOPs, procedures and policies.
- Initiate required changes to QC documents in accordance with change control procedures; similarly, in conjunction with R&D, for new procedures to support product development.
- Perform stability study testing at scheduled intervals and collate results into stability reports.
- Perform validation activities/studies as and when required for any QC processes.
- Responsible for writing and maintaining accurate Certificate of analysis templates.
- Responsible for ensuring equipment calibrations are carried out and completed on time.
- Ensure that all personal interactions with customers or external suppliers/contractors are professional.
- Process owner for QC ensuring the process is fit for purpose and identifying and leading the implementation of any improvements.

- Ensure all activities comply with Health and Safety legislation.
- Ensure QC processes and procedures are compliant to ISO13485 and ISO9001.
- Resolve issues and risks independently ensuring that where required escalation is performed to the Quality and Regulatory Manager.
- Support QA team with QC audits and perform self – inspection reports when required.

Qualifications and experience required

Essential

- Minimum BSc in relevant scientific field.
- Previous experience of working with a QC team.
- Previous experience working with quality management systems
- Self-motivated and possess leadership skills
- Able to manage workloads priority tasks.

Desirable

- Knowledge and previous experience of qPCR technology and its applications.
- Previous experience of ISO13485/ISO9001

Hours of Work	37.5 hours per week
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For further information or to apply for this vacancy please e-mail Kay Campbell, HR, kay.campbell@novacyt.com
