University of Nottingham
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Role profile

Job title	Quality Assurance Manager	Job family and level	Administrative, Professional and Managerial (APM) Level 4
School/ Department	School of Medicine - Nottingham Clinical Trials Unit (NCTU)	Location	Nottingham Clinical Trials Unit (NCTU), University Park

Purpose of role

The Nottingham Clinical Trials Unit (NCTU) operates a robust Quality Management System (QMS) focused around a suite of standard operating procedures (SOPs) to ensure compliance with regulatory standards within clinical trials. You will support the management and further development of this system, assist in the Quality Assurance and audits of all systems and trials, and conducting staff training in relation to the QMS and SOPs. You will be a member of the Quality Assurance Team and will report directly to the Senior Quality Assurance Manager.

The NCTU is a UK Clinical Research Collaboration registered Clinical Trials Unit (http://www.ukcrc-ctu.org.uk) based in the School of Medicine at the University of Nottingham. The unit's mission is to conduct high quality, high impact multicentre trials to improve health and well-being.

The NCTU has a broad portfolio of trials including studies evaluating medical devices, medicines and complex interventions. The unit currently has around 80 staff, and with the recent investment of strategic development funding from the University this is anticipated to expand to 100 staff over the next 3-5 years.

For further information see: http://www.nottingham.ac.uk/nctu/index.aspx

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	**% time per year**
1	**Quality Management System** ▪ Work closely with the Senior Quality Assurance Manager in further developing, reviewing and maintaining the NCTU Quality Management System (QMS) ▪ Contribute to writing of SOPs and associated Working Practice Documents ▪ Keep up to date with changes in clinical trial regulations and internationally accepted standards for quality management of clinical trials and ensure any changes are incorporated into the NCTU QMS. ▪ Identify and report any major or critical findings or suspicion of fraud as per NCTU procedures	60 %

	▪ Work with trial teams to perform risk assessments, and to ensure strategies to mitigate any identified risks are developed and incorporated into the trial protocol and monitoring plan ▪ Work with trial teams in developing a robust monitoring plan which mitigates the risks identified in the risk assessment ▪ Work closely with the Senior Quality Assurance Manager to ensure monitoring activities maintain adequate and effective oversight of trials ▪ Work with trial teams to ensure monitoring is conducted as per the monitoring plan ▪ Provide expertise in governance and regulatory areas of different trials relevant to the NCTU portfolio of work	
2	**Audit and Inspection** ▪ Lead on the conduct and reporting of internal audits at NCTU, in accordance with the NCTU audit programme and relevant SOPs ▪ Provide summary audit reports and discuss recommendations for improvements in practice with the Senior Quality Assurance Manager ▪ Undertake quality control checks of trial documentation to ensure internal coherence and compliance with Good Clinical Practice (GCP) ▪ To support the Senior Quality Assurance Manager in preparing for and hosting any external audits and inspections (e.g. from Sponsors or regulatory bodies)	20 %
3	**Training** ▪ Ensure NCTU remains up to date with regulatory, ethical and governance developments in clinical trials, by attending relevant conferences and training ▪ Contribute to the development and maintenance of a comprehensive SOP training programme for NCTU staff members ▪ Provide training within NCTU on regulatory, ethical and governance developments in clinical trials and as part of the SOP training programme ▪ Support the Senior Quality Assurance Manager and Line Managers, in maintaining oversight of mandatory training in the unit through the development of Qpulse reports	15 %
4	**Other Responsibilities** ▪ Answer day-to-day queries from NCTU staff members regarding the NCTU QMS and relevant regulations. Provide advice and guidance where necessary ▪ Maintain confidentiality at all times ▪ Any other duties appropriate to the grade and role of the post holder ▪ Any other professional developments and training relevant to the role where funding supports this	5 %

Person specification

	Essential	Desirable
Skills	▪ Ability to communicate and work effectively with colleagues ▪ Ability to work both independently and as part of a multidisciplinary team ▪ Evidence of being self-motivated, organised, and able to take appropriate responsibility ▪ Excellent ability to prioritise, and to work flexibly and effectively under pressure. Able to enjoy and work effectively in a demanding and challenging environment ▪ Excellent MS Office skills (Excel, PowerPoint and Word) ▪ Excellent written and oral communication skills ▪ Excellent attention to detail	▪ Experience in writing audit reports, with findings and actions
Knowledge and experience	▪ Up to date knowledge and understanding of Clinical Trial Regulations, and research governance guidelines ▪ Comprehensive understanding of trial design, trial conduct and trial delivery ▪ Experience of developing and/or maintaining Quality Management Systems, including writing SOPs and related documents ▪ Experience in conducting audits and/or monitoring	▪ Extensive knowledge of all regulations and guidelines relating to clinical trials (e.g. medical devices, advanced therapeutics) ▪ Experience of MHRA and sponsor audits ▪ Experience of reviewing risk assessments and monitoring plans ▪ Experience of delivering training
Qualifications, certification and training (relevant to role)	▪ Relevant degree OR ▪ Proven track record of extensive relevant work experience demonstrating practical and theoretical knowledge of quality assurance in a clinical research environment	▪ Postgraduate/professional qualification in quality management, quality assurance or audit in clinical research or practice
Other	▪ Travel within the UK may be required on occasion for attendance at meetings. ▪ Willingness to adopt the vision and values of the School of Medicine	

Expectations and behaviours

The University has developed a clear set of core expectations and behaviours that our people should be demonstrating in their work, and as ambassadors of the University's strategy, vision and values. The following are essential to the role:

Valuing people	Is always equitable and fair and works with integrity. Proactively looks for ways to develop the team and is comfortable providing clarity by explaining the rationale behind decisions.
Taking ownership	Is highly self-aware, looking for ways to improve, both taking on board and offering constructive feedback. Inspires others to take accountability for their own areas.
Forward thinking	Driven to question the status quo and explore new ideas, supporting the team to "lead the way" in terms of know-how and learning.
Professional pride	Sets the bar high with quality systems and control measures in place. Demands high standards of others identifying and addressing any gaps to enhance the overall performance.
Always inclusive	Ensures accessibility to the wider community, actively encouraging inclusion and seeking to involve others. Ensures others always consider the wider context when sharing information making full use of networks and connections.

Key relationships with others