

THE UNIVERSITY OF NOTTINGHAM
RECRUITMENT ROLE PROFILE FORM

Job Title:	Quality Assurance Manager
School/Department:	School of Medicine, Nottingham Clinical Trials Unit
Job Family and Level:	Administrative, Professional and Managerial Level 5
Contract Status:	This post will be offered on permanent contract
Hours of Work:	Full time, 36.25 hours per week. Applications from those wishing to work part time will be considered (minimum 29 hours per week). Please indicate on your application the hours you wish to work.
Location:	Nottingham Clinical Trials Unit, Queen's Medical Centre
Reporting to:	NCTU Director

Purpose of the Role:

The post holder will join our multidisciplinary management team, and play a key role in delivering high quality clinical trials at the Nottingham Clinical Trials Unit (NCTU). The post holder will be responsible for ensuring NCTU is compliant with national and international standards for the conduct of clinical research.

NCTU operates an innovative Quality Management System (QMS) to ensure compliance, which has been commended by the Medicines and Healthcare products Regulatory Agency. The post holder will be responsible for management and further development of this system, for Quality Assurance and audits for all trials, and for staff training in relation to the QMS and standard operating procedures. The post holder will use their extensive experience in clinical trials and Good Clinical Practice (GCP) to provide expert advice to NCTU staff and to other QA staff within the University and Nottingham University Hospitals NHS Trust.

Working Environment:

The Nottingham Clinical Trials Unit (NCTU) is a UK Clinical Research Collaboration registered Clinical Trials Unit (<http://www.ukcrc-ctu.org.uk>) within the School of Medicine at the University of Nottingham. The unit designs and conducts high quality national and international multicentre trials across a range of health topics, including skin conditions, obstetrics and gynaecology, gastroenterology, stroke, ophthalmology, cancer, rehabilitation and genitourinary medicine. NCTU primarily conducts late phase pragmatic trials, and has expertise in trials of medical devices, clinical trials of investigational medicinal products (CTIMPs) and complex interventions.

NCTU is a busy multidisciplinary research environment with over 50 staff and is expanding following significant investment from the University. For further information see: www.nottingham.ac.uk/ctu

	Main Duties & Responsibilities:	% time per year
1.	<p>Management and development of the NCTU Quality Management System:</p> <ul style="list-style-type: none"> • To be responsible for management, review and development of the NCTU's Standard Operating Procedures (SOPs) and associated working practice documents, to ensure continuing compliance with the UK regulations and quality standards. • To be responsible for developing and maintaining the NCTU's Quality Management System to a high standard. • To review new trial protocols and other essential documents to ensure compliance with current clinical trials regulations and guidance. • Working with the chief investigator and trial manager, to prepare a risk assessment and appropriate risk-based monitoring plan for all new trials. • To be responsible for monitoring and maintaining compliance with the risk-based monitoring plan and the data management plan. • To liaise with the Sponsor research governance representatives. • To be responsible for maintaining an appropriate document control system for printed and electronic versions of all NCTU SOPs, including drafts, active and superseded versions. 	40
2.	<p>Auditing of the Quality Management System</p> <ul style="list-style-type: none"> • To design and implement an audit strategy to measure compliance. • To lead the NCTU QA team, including chairing meetings, preparing agendas and ensuring accurate minutes. • Working with the QA team, to be responsible to develop a review plan to monitor compliance with SOPs, protocols and ICH GCP developing and implementing strategies (CAPA plans) to deal with non-compliance, and implementing and managing change effectively. 	25
3.	<p>Training and quality control</p> <ul style="list-style-type: none"> • To be responsible for staff training to a high standard with NCTU SOPs, and the relevant regulations and guidance for clinical trials. • To be responsible for developing and implementing an appropriate competency framework for staff training and development relevant to clinical trials. • To be responsible for evaluation and regular review of staff training. • To contribute to training programmes for other University staff and external delegates on the NCTU's short course programme. 	20
4.	<p>Ensuring NCTU is compliant with national and international quality assurance standards:</p> <ul style="list-style-type: none"> • To advise the NCTU management team on national and international standards for the conduct of clinical research, and to ensure the unit is 	5

	<p>compliant.</p> <ul style="list-style-type: none"> To keep up to date with changes to the trial regulations, to ensure staff are kept appropriately up to date, and to ensure changes are incorporated appropriately into NCTU systems and practice. 	
5.	<p>Inspections</p> <ul style="list-style-type: none"> To take a leading role in inspections by both sponsors and Regulatory Authorities To be responsible for preparing staff and trial materials for inspections by the MHRA, other regulatory bodies or Sponsors; supporting staff during inspection and with any follow-up actions that may be required 	5
6.	<p>Any Other duties as appropriate to the role and level</p> <ul style="list-style-type: none"> Line management responsibilities for the QA team, including recruitment, supervision and support for trial monitoring staff To monitor and review project management and operational procedures and processes to ensure correct quality standards and to inform future scheduling. 	5

Knowledge, Skills, Qualifications & Experience

	Essential	Desirable
Qualifications/ Education	<ul style="list-style-type: none"> Relevant Degree or Professional qualification in QA, or equivalent 	<ul style="list-style-type: none"> MSc, or equivalent in Quality Management in Scientific Research and Development
Skills/Training	<ul style="list-style-type: none"> Up to date, extensive knowledge and in-depth understanding of all regulations and guidelines applicable to clinical trials Excellent report writing skills including experience in writing of Standard Operating Procedures (SOPs) Highly computer literate and experienced in using several computer software packages to include the Microsoft Office Suite 	
Experience	<ul style="list-style-type: none"> Previous experience of working in a similar quality assurance role supporting clinical trials Experience of working within and contributing to the running of a Quality Management System 	<ul style="list-style-type: none"> Experience of being involved in inspections and audits by regulatory authorities such as the MHRA Familiarity with early phase CTIMP studies

	<ul style="list-style-type: none"> • Familiarity with phase III and IV CTIMP studies • Experience in auditing processes and procedures, ideally within clinical trials • Extensive experience of overseeing clinical research QA activities 	<ul style="list-style-type: none"> • Knowledge of Medical Devices Regulations
Personal Attributes	<ul style="list-style-type: none"> • Exceptional verbal and written communication skills • Able to work independently and as an effective member of a multi-disciplinary team • Willingness to travel within the UK on occasion • Willingness to adopt the Ethos and Principles of the School of Medicine. 	



The University of Nottingham strongly endorses Athena SWAN principles, with commitment from all levels of the organisation in furthering women's careers. It is our mission to ensure equal opportunity, best working practices and fair policies for all.

The School of Medicine holds a Silver Athena SWAN in recognition of our achievements in promoting and advancing the representation of women in science, technology, engineering, medicine and mathematics (STEMM). Please see <http://www.nottingham.ac.uk/medicine/about/athena-swan.aspx>

Appendix 1

The University of Nottingham

Described by the Times Good University Guide 2017 as "the nearest Britain has to a truly global university" The University of Nottingham has award-winning campuses in the UK, China and Malaysia and hosts a global academic community in all three countries. The University has an institution-wide commitment to embedding an international dimension across all of our activities enabling us to produce graduates who are empowered to excel in a challenging global environment and deliver genuinely world-changing research.

Our reputation for world-class research has yielded major scientific breakthroughs such as Nobel-winning MRI techniques, drug discovery, food technologies and engineering solutions for future economic, social and cultural progress.

Already ranked among the UK's elite universities and global polls for research excellence, our reputation for world-class research has been further enhanced with the 2014 results of the Research Excellence Framework (REF).

In addition to scoring highly in quality rankings covering major disciplines in science, engineering, the social sciences, medicine, business and the arts, it is Nottingham's research power rankings which demonstrate the impressive volume of excellent research which is carried out. We are now ranked 8th in the UK on a measure of 'research power' which takes into account both the quality of research and the number of research-active staff who made REF returns, confirming Nottingham's place in the top tier of the world's elite higher education institutions.

The main University campus is set beside a lake, in an extensive belt of woodland, parks and playing fields. The 330 acre University Park Campus is the focus of life for more than 32,000 students and houses the majority of the University's academic schools and many of the central Services. The Jubilee campus is situated 2 miles away from the University Park, and provides extra capacity. The University Medical School is situated next to the University Park. Together with the University Hospital, it forms the Queen's Medical Centre (QMC).

University of Nottingham Medical School

Nottingham has a strong reputation for both clinical medicine and teaching. As one of the most popular medical schools in the country, it is able to select excellent students and produce and attract good junior doctors.

The School of Medicine comprises the Divisions of Cancer and Stem Cell Sciences, Child Health, Obstetrics and Gynaecology; Clinical Neuroscience; Epidemiology and Public Health; Primary Care; Psychiatry and Applied Psychology; Rehabilitation and Ageing; Medical Sciences and Graduate Entry Medicine; Respiratory Medicine; Rheumatology, Orthopaedics and Dermatology and the Nottingham Digestive Diseases Centre. The School also hosts the Education Centre, the Centre for Interprofessional Education and Learning, the Clinical Research Facility, the Clinical Skills Centre, NIHR Design Service East Midlands, Nottingham Clinical Trials Unit, PRIMIS and Medical Imaging Unit.

The School of Medicine brings together in one School staff undertaking research for the benefit of the health of patients. It includes all primary care and hospital-based medical and surgical disciplines, principally in the Queen's Medical Centre and City Hospital Nottingham Campuses, Royal Derby Hospitals NHS Foundation Trust and also at the University's main campus and at the King's Meadow and Jubilee Campuses. Most of our School's Senior Researchers and Teachers are also clinicians who dedicate 50% of their time to patient care within the Nottingham University Hospitals NHS Trust & Royal Derby Hospitals NHS Trust. This close juxtaposition brings cutting-edge clinical care to our patients and clinical relevance to our research and teaching. We are closely integrated with our full time NHS clinical colleagues, many of whom are themselves leaders in research and teaching and who work closely with the University and this increases the mutual benefit from integration between the University and NHS.

Mission:

Our mission is to improve human health and quality of life locally, nationally and internationally through outstanding education, research and patient care.

Priorities:

1. **Teaching and learning**, particularly training tomorrow's doctors and teaching specialised postgraduates
2. **Research and research training:** We will perform and support the highest quality "big" research which impacts on human health and disease
3. **Partnership with the NHS** and other healthcare providers
4. **Visibility and profile of the School of Medicine:** We will do what we do better, and we will tell others about it

Ethos and principles:

1. **Having people and patients at the heart of all we do:** our teaching and learning, our research and our patient care
2. **Contribution within the School of Medicine and to society** beyond our immediate roles; helpfulness and service
3. **Openness and fairness**, with particular emphasis on communication (both internal and external) and on equality and diversity among students and staff
4. **Personal and group responsibility** for all aspects of our work, within a culture of opportunity and reward

Our research spans 11 major themes, ranging from cancer to vascular medicine. We work closely with industry and the NHS. Our world-leading research ranges from basic and translational science through to clinical trials, epidemiology, and health services research. Our clear theme is improving human health, underpinning a vibrant postgraduate research training programme leading to PhD or DM. Many of our academics are clinicians, using their expertise to provide cutting edge specialised treatment to NHS patients; reflecting our ethos that patients are at the heart of all we do.

The partnership between University of Nottingham and Nottingham University Hospitals NHS Trust was recently awarded by NIHR, a transformational £23.6 million to to expand their pioneering work into new treatments and diagnostics for a wide range of health problems, establishing a new Biomedical Research Centre (BRC), which will incorporate two existing smaller Biomedical Research Units in the city. The Nottingham BRC will be the leading UK hub in five key areas of health research:

- Deafness and hearing loss
- Gastrointestinal and liver disease
- Respiratory medicine

- Musculoskeletal disease
- Mental health technology

At the core of the Biomedical Research Centre will be Nottingham's world-leading expertise in magnetic resonance imaging (MRI). It means the latest medical imaging research and technology pioneered here can be translated into real benefits for patients in all five of the BRC's research areas.

In the 2014 Research Excellence Framework the four Units of Assessment included in the School of Medicine were among the six most improved in the whole University since RAE 2008: Over 80% of our research in 2014 was graded as world-leading or internationally excellent. Our research spans 11 major themes and ranges from basic and translational science through to clinical trials, epidemiology, and health services research. We work closely with industry and the NHS. Our research is underpinned by a strong postgraduate research training programme leading to PhD or DM. Our major research themes are in Cancer and Stem Cells; Child Health, Obstetrics & Gynaecology; Clinical Neurosciences; Dermatology; Digestive Diseases; Epidemiology and Public Health; Mental Health; Musculoskeletal physiology and disease; Primary Care; Rehabilitation and Ageing; Respiratory Medicine; and Renal Medicine.

The School of Medicine trains tomorrow's doctors on a vibrant undergraduate medical course with a unique intercalated BMedSci, as well in a specialised graduate-entry programme built around clinical problem solving. We teach medicine and related disciplines at both undergraduate and postgraduate level. We have a dedicated clinical academic training programme and are committed to training PhD and doctoral research students and to supporting postdoctoral clinicians and scientists in their research.

Professor Tony Avery is Dean of the School of Medicine.

For further information, please see our website <http://www.nottingham.ac.uk/medicine>

Nottingham

Central within the East Midlands, Nottingham is a vibrant and prosperous city with something to offer everyone. It is one of the UK's leading retail centres and has a huge variety of restaurants, bars and nightclubs which attract people from all over the UK. Culturally, it has good theatres, an arena which attracts both national and international performers and a range of historical interests relating to subjects such as the lace industry, Lord Byron and DH Lawrence. Nottingham is also known for sport, being the home of Trent Bridge Cricket Ground, Nottingham Forest and Notts County Football Clubs, the National Water Sports Centre and the Nottingham Tennis Centre. There is a good network of roads with easy access to the M1 and the A1, a fast frequent rail service to London and other major cities. Nottingham East Midlands Airport is only eighteen miles away.

The city is set within a county of outstanding natural beauty which includes Sherwood Forest, Wollaton Park, lively market towns and wonderful historic buildings. Housing is relatively inexpensive and, in addition to the two Universities, there are excellent schools and colleges available.

To find out more about Nottingham, use the following links:

Nottingham County Council – Tourism <http://www.experiencenottinghamshire.com/>

University of Nottingham <http://www.nottingham.ac.uk>

Zoopla (Guide to local properties) <http://www.zoopla.co.uk/>

My Nottingham (information on schools, term dates, school transport etc.)

<http://www.nottinghamcity.gov.uk/index.aspx?articleid=8524>