Job description and selection criteria

Job title	Quality Assurance Manager
Division	Medical Sciences
Department	Paediatrics
Location	STRONG, John Radcliffe, Oxford
Grade and salary	Grade 7: £36,024 - £44,263 per annum (with a discretionary range to £48,350 per annum)
Hours	Full-time, with part-time available (0.7FTE/26.25 hours minimum)
Contract type	Fixed-term for one year in the first instance)
Reporting to	Clinical Trials Coordinator & Operations Manager
Vacancy reference	168470
Additional information	*This role meets the criteria for a UK Skilled Worker visa*

The role

This role will assist the Clinical Trials Coordinator & Operations Manager with the quality assurance (QA) activities within the Specialised Translational Research Oxford Neuromuscular Group (STRONG). Based in the STRONG office, you will help ensure best practice, identify risks and mitigation strategies, enhance local Standard Operating Procedures (SOPs), interpret regulatory and audit requirements and provide local advice, training and support for researchers and trial teams.

You will lead on QA, drawing on your experience in clinical research, protocol development, GCP and related audit and inspection requirements to support STRONG in improving health care through clinical trials.

You will be supported by the Research Governance, Ethics and Assurance (RGEA) team. The role of the RGEA team is to ensure that clinical research involving human participant in the University is compliant with the applicable governance and/or regulations through the provision of advice, support and guidance to researchers in a wide variety of clinical research-related activities (please visit the RGEA website: https://researchsupport.admin.ox.ac.uk/contacts/rgea).

Responsibilities

1. *Quality Assurance*

   - Independently review study documents in development and provide expert advice to ensure that they comply with current clinical trial regulations.

   - Drive consistency across projects and processes.

   - Review STRONG processes to ensure compliance with SOPs and regulations.

   - Ensure the quality of all trial documents archived.

2. *Risk Assessment*

   - Review clinical trials to assess risk and lead in the creation of risk assessment and monitoring plans at trial set-up (and throughout the trial, when necessary).

   - Working closely with trial staff, ensure that risk-based monitoring plans are being followed, are effective, and are reviewed at least annually.

3. *Standard Operating Procedures (SOPs)*

   - Take overall responsibility for initiation, review, update, and implementation of STRONG SOPs to ensure continuing compliance with the University Core SOPs, and Oxford University Hospitals Foundation Trust (OUHFT) and UK regulations.

   - Be responsible for tracking the status of all SOPs.

4. *Compliance and Audits*

- Plan and lead proactive audits of systems and trials, including preparation of audit plans, audit reports, and track trials from planning to close.

- Identify areas of non-compliance, instigate corrective action, and follow up as appropriate.

- Prepare for, conduct, and follow up on internal, vendor, and site audits.

- Take responsibility for preparing staff and trial materials for audits by internal and external bodies, supporting staff during audit and with any follow-up actions that be required.

5. *Regulatory Inspections*

- In collaboration with the RGEA and the Clinical Trials Coordinator & Operations Manager, take responsibility for preparing staff and trial materials for inspections by the MHRA or other regulatory bodies, supporting staff during inspection and with any follow-up actions that may be required.

6. *Communication*

- Work closely with the University of Oxford's Research Governance, Ethics and Assurance (RGEA) team.

- Establish and chair committees/groups as appropriate to ensure best practice, and identify risks and mitigation strategies.

- Be proactive in forming links with QA staff working within other University teams and other national and international institutions as required.

- Develop excellent working relationships with all trial managers and trial teams.

- Work closely with the Departmental IT & Information Governance Lead to ensure compatibility across the Department.

7. *Training & Development*

- Ensure that trial staff, including investigators and coordinators, are familiar with, understand and are implementing the relevant SOPs

- Work with the Clinical Trials Coordinator & Operations Manager to enhance the training programme delivered to staff within the STRONG team.

- Work with the relevant colleagues in the Department to design and deliver specific training for units as demands arises, e.g. information governance and safety reporting.

- Be proactive in closely monitoring changes to regulations and guidance relevant to the conduct of clinical research including clinical trial regulations, Good Clinical

Practice (GCP) guidance, data protection regulations, ethical guidance and safety reporting.

8. Undertake other duties as required by the Clinical Trials Coordinator & Operations Manager. Priorities will be established and targets set and regularly reviewed.

Selection criteria

Essential

1. A university degree (or the equivalent relevant education and experience).
2. A background in quality assurance or quality control.
3. Clinical research experience which includes protocol development and implementation.
4. Good experience of conducting, managing, auditing, or monitoring, in a GCP environment.
5. Good knowledge of the following (and the ability to interpret them in a non-commercial environment):
   a. EU Directive 2001/20/EC
   b. Department of Health Research Governance Framework for Health and Social Care 2017
   c. Medicines for Human Use (Clinical Trials) Regulations 2004 and its amendments
   d. Guidelines for Good Clinical Practice (GCP)
   e. Human Tissue Act 2004
   f. Data Protection Act 2018
   g. General Data Protection Regulation (GDPR) 2018
   h. Mental Capacity Act 2005
6. Ability to work constructively as an individual, as part of a close-knit research group, and as part of a University-wide team.
7. A flexible and adaptive approach to work. An organised approach to dealing with large numbers of complex documents and an ability to find proactive solutions under pressure.
8. Excellent communication and interpersonal skills.
9. A sharp, analytical mind, including attention to detail and an ability to think laterally.
10. Excellent IT literacy: evidence of competence with MS Office, particularly Excel, Word and PowerPoint

Desirable

1. Experience of working in an academic or healthcare environment, or in a healthcare-related industry.
2. Experience of working on CTIMPs and Non-CTIMPs.
3. Experience of working in Secondary Care

Underfilling the Post

Whilst the role is a grade 7 (£36,024- £44,263 p.a.) position, we would be willing to consider candidates with potential but less experience who are seeking a development opportunity, for which an initial appointment would be at grade 6 (£32,332- £38,205 p.a.) with the responsibilities adjusted accordingly. This would be discussed with applicants at the interview or appointment, where appropriate.

Pre-employment screening

Standard checks

If you are offered the post, the offer will be subject to standard pre-employment checks. You will be asked to provide: proof of your right-to-work in the UK; proof of your identity; and (if we haven't done so already) we will contact the referees you have nominated. You will also be asked to complete a health declaration so that you can tell us about any health conditions or disabilities for which you may need us to make appropriate adjustments.

Please read the candidate notes on the University's pre-employment screening procedures at: https://www.jobs.ox.ac.uk/pre-employment-checks

Additional security pre-employment checks

This job includes duties that will require additional security pre-employment checks:

- A satisfactory basic Disclosure and Barring Service check due to working with sensitive data.
- This role requires an honorary contract. The department will support the successful candidate in obtaining this where required and appropriate.
- University security screening (e.g. identity checks)

About the University of Oxford

Welcome to the University of Oxford. We aim to lead the world in research and education for the benefit of society both in the UK and globally. Oxford's researchers engage with academic, commercial and cultural partners across the world to stimulate high-quality research and enable innovation through a broad range of social, policy and economic impacts.

We believe our strengths lie both in empowering individuals and teams to address fundamental questions of global significance, while providing all our staff with a welcoming and inclusive workplace that enables everyone to develop and do their best work. Recognising that diversity is our strength, vital for innovation and creativity, we aspire to build a truly diverse community which values and respects every individual's unique contribution.

While we have long traditions of scholarship, we are also forward-looking, creative and cutting-edge. Oxford is one of Europe's most entrepreneurial universities and we rank first in the UK for university spin-outs, and in recent years we have spun out 15-20 new companies every year. We are also recognised as leaders in support for social enterprise.

Join us and you will find a unique, democratic and international community, a great range of staff benefits and access to a vibrant array of cultural activities in the beautiful city of Oxford.

For more information, please visit www.ox.ac.uk/about/organisation.

Specialised Translational Research Oxford Neuromuscular Group (STRONG)

STRONG is led by Laurent Servais, Professor of Paediatric Neuromuscular Diseases. Staff are based within a suite of offices in the academic centre on the third floor of the John Radcliffe Hospital in Headington, Oxford. This rapidly growing research group focuses on paediatric neuromuscular diseases and driving research into early identification, potential treatments, and early intervention for rare disorders.

Major focuses of the group include gene therapy – it is co-lead of a WP in a European Project to evaluate potential marker of gene therapy toxicity in humans – as well as neonatal genetic screening, with the implementation of the first genetic population-based screening in the UK for spinal muscular atrophy being one of its proudest recent achievements. The group is also leading an ambitious program of research into Angelman syndrome, with clinical trials and a natural history study ongoing.

Department of Paediatrics

The Department of Paediatrics is a world leader in child health research and hosts internationally renowned research programmes in drug development, gastroenterology, haematology, HIV, immunology, neuroimaging, neuromuscular diseases and vaccinology. Our work spans from early proof-of concept fundamental science, all the way up to its application in clinical settings.

We continue to shape the landscape of medical science through positively impacting the lives of millions of children from our global research programmes, academic resources, and commitment to success. Our broad research base positions the department in a pivotal role and subsequently a world leader in child health. With research facilitates in the UK and abroad, we work on a global scale, building a paediatric network in the medical science community.

In 2021, we successfully administered a grant value of £130,895,28 obtained through 168 projects. Our strong relationship with funding bodies have also been a contributor to the successes and milestones in children's health research. With strong support from the Wellcome Trust, NIH, Cancer Research UK, UKRI, MDUK, Bill & Melinda Gates Foundation, Academy of Medical Sciences and the NIHR, we have employed 360 + staff, researchers, and students. These figures continue to grow as we expand our activities to overcome the multitude of challenges within children's research health.

For more information please visit: http://www.paediatrics.ox.ac.uk/

The Department of Paediatrics holds a silver Athena Swan award to recognise advancement of gender equality: representation, progression and success for all.

Medical Sciences Division

We are an internationally recognized centre of excellence for biomedical and clinical research and teaching, and the largest academic division in the University of Oxford.
World-leading programmes, housed in state-of-the-art facilities, cover the full range of scientific endeavour from the molecule to the population. With our NHS partners we also foster the highest possible standards in patient care.

For more information please visit: http://www.medsci.ox.ac.uk/

How to apply

Applications are made through our e-recruitment system and you will find all the information you need about how to apply on our Jobs website https://www.jobs.ox.ac.uk/how-to-apply.

Your application will be judged solely on the basis of how you demonstrate that you meet the selection criteria stated in the job description.

As part of your application you will be asked to provide details of two referees and indicate whether we can contact them now.

Please upload all documents **as PDF files** with your name and the document type in the filename.

All applications must be received by **midday** UK time on the closing date stated in the online advertisement.

Information for priority candidates

A priority candidate is a University employee who is seeking redeployment because they have been advised that they are at risk of redundancy, or on grounds of ill-health/disability. Priority candidates are issued with a redeployment letter by their employing department(s).

If you are a priority candidate, please ensure that you attach your redeployment letter to your application (or email it to the contact address on the advert if the application form used for the vacancy does not allow attachments).

If you need help

Application FAQs, including technical troubleshooting advice is available at: https://staff.web.ox.ac.uk/recruitment-support-faqs

Non-technical questions about this job should be addressed to the recruiting department directly at recruitment@paediatrics.ox.ac.uk or using the contact details in the online advertisement.

To return to the online application at any stage, please go to: www.recruit.ox.ac.uk.

Please note that you will receive an automated email from our e-recruitment system to confirm receipt of your application. **Please check your spam/junk mail** if you do not receive this email.

Important information for candidates

Data Privacy

Please note that any personal data submitted to the University as part of the job application process will be processed in accordance with the GDPR and related UK data protection legislation. For further information, please see the University's Privacy Notice for Job Applicants at: https://compliance.admin.ox.ac.uk/job-applicant-privacy-policy. The University's Policy on Data Protection is available at: https://compliance.admin.ox.ac.uk/data-protection-policy.

The University's policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for very senior research posts at **grade RSIV/D35 and clinical equivalents E62 and E82**, which with effect from 1 October 2023 will be 30 September before the 70th birthday. The justification for this is explained at: https://hr.admin.ox.ac.uk/the-ejra.

For **existing** employees on these grades, any employment beyond the retirement age is subject to approval through the procedures: https://hr.admin.ox.ac.uk/the-ejra.

There is no normal or fixed age at which staff in posts at other grades have to retire. Staff at these grades may elect to retire in accordance with the rules of the applicable pension scheme, as may be amended from time to time.

Equality of opportunity

Entry into employment with the University and progression within employment will be determined only by personal merit and the application of criteria which are related to the duties of each particular post and the relevant salary structure. In all cases, ability to perform the job will be the primary consideration. No applicant or member of staff shall be discriminated against because of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, or sexual orientation.

Benefits of working at the University

Employee benefits

University employees enjoy 38 days' paid holiday, generous pension schemes, travel discounts, and a variety of professional development opportunities. Our range of other employee benefits and discounts also includes free entry to the Botanic Gardens and University colleges, and discounts at University museums. See https://hr.admin.ox.ac.uk/staff-benefits

University Club and sports facilities

Membership of the University Club is free for all University staff. The University Club offers social, sporting, and hospitality facilities. Staff can also use the University Sports Centre on Iffley Road at discounted rates, including a fitness centre, powerlifting room, and swimming pool. See www.club.ox.ac.uk and https://www.sport.ox.ac.uk/.

Information for staff new to Oxford

If you are relocating to Oxfordshire from overseas or elsewhere in the UK, the University's Welcome Service website includes practical information about settling in the area, including advice on relocation, accommodation, and local schools. See https://welcome.ox.ac.uk/

There is also a visa loan scheme to cover the costs of UK visa applications for staff and their dependents. See https://staffimmigration.admin.ox.ac.uk/visa-loan-scheme

Family-friendly benefits

With one of the most generous family leave schemes in the Higher Education sector, and a range of flexible working options, Oxford aims to be a family-friendly employer. We also subscribe to the Work+Family Space, a service that provides practical advice and support for employees who have caring responsibilities. The service offers a free telephone advice line, and the ability to book emergency back-up care for children, adult dependents and elderly relatives. See https://hr.admin.ox.ac.uk/my-family-care Childcare

The University has excellent childcare services, including five University nurseries as well as University-supported places at many other private nurseries.

For full details, including how to apply and the costs, see https://childcare.admin.ox.ac.uk/

Disabled staff

We are committed to supporting members of staff with disabilities or long-term health conditions. For further details, including information about how to make contact, in confidence, with the University's Staff Disability Advisor, see https://edu.admin.ox.ac.uk/disability-support

Staff networks

The University has a number of staff networks including the Oxford Research Staff Society, BME staff network, LGBT+ staff network and a disabled staff network. You can find more information at https://edu.admin.ox.ac.uk/networks

The University of Oxford Newcomers' Club

The University of Oxford Newcomers' Club is an organisation run by volunteers that aims to assist the partners of new staff settle into Oxford, and provides them with an opportunity to meet people and make connections in the local area. See www.newcomers.ox.ac.uk.