

## Job description and selection criteria

<b>Job title</b>	Quality Assurance and Compliance Director
<b>Division</b>	Medical Sciences
<b>Department</b>	Paediatrics
<b>Location</b>	Department of Paediatrics, Oxford Vaccine Group, Churchill Hospital, Oxford
<b>Grade and salary</b>	Grade 9: £52,815 - £61,198 per annum (with a discretionary range to £66,857 per annum)
<b>Hours</b>	Full time
<b>Contract type</b>	Fixed-term (two years)
<b>Reporting to</b>	Director of Global Operations Oxford Vaccine Group
<b>Vacancy reference</b>	172361
<b>Additional information</b>	<i>Applications are to be made online, please see the advert for the closing date.</i>

## The role

Reporting to the Director of Global Operations, Oxford Vaccine Group, the Quality Assurance and Regulatory Compliance Director is an autonomous senior position responsible for promoting quality and improving performance, by ensuring that the group meets its legal and regulatory obligations when conducting research. The post holder will be a recognised authority in quality assurance and will be a major contributor to the ongoing development of innovative quality assessment and compliance methodology, including the growth of an in-house clinical trial monitoring team.

The postholder must be highly visible and a respected source of advice on both large strategic actions and small practical issues. They will work closely with other team leads to: develop

processes and provide training of the wider multidisciplinary team; provide oversight and knowledge to the research group; developing new policies and strategies with the group.

They will manage the Quality Assurance team, setting clear task objectives, developing productive working relations and line-managing the other members of the team.

## Responsibilities

- To be an active member of the senior management team, contributing ideas to improve the efficiency and effectiveness of the group providing operational leadership with due consideration for regulatory and procedural compliance.
- Critical review and enhancement of research procedures ensuring they meet local/global regulatory requirements and quality standards, whilst remaining streamlined.
- To provide professional leadership and act as an accessible resource to OVG staff to ensure that OVG research is in compliance with University policies and procedures as well as legal and regulatory requirements such as Local and National Clinical Trials Regulations, GCP, GMP, GDPR, HTA, HSE.
- Develop strategic corrective action plans to resolve issues that arise during study conduct. Investigation of incidents at sites, and (working with other senior trial staff) establishing root cause analysis, implementing CAPAs and considering wider impact (both within and across trials).
- Development of auditable documentation and procedures including SOPs, Study Manuals.
- Working with other members of the senior management team and academics, to map out the implementation plan for introduction of new processes and procedures across the group mitigating against risk to research delivery and to manage the resolution of any issues that threaten such delivery.
- Working collaboratively with global multidisciplinary study teams, at times across multiple time zones.
- Training and mentorship of clinical trial research team to ensure delivery of quality research in a highly regulated environment.
- To contribute to and evaluate the study design, feasibility and logistics of proposed new studies and provide advice on regulatory requirements.
- Promote the research group locally and nationally, disseminate research outcomes to advance knowledge in the area of operational delivery; represent the research group at external meetings/seminars and liaise with sponsors, stakeholders, national agencies, and professional bodies.

- To identify and drive initiatives and developments with regards quality assurance systems and methods that improve trial quality and leverage the strengths of on-site and central research oversight.
- Act as point of contact for Regulators, Quality Auditors and Clinical Trial Sponsors on all matters related to quality and compliance.

## Selection criteria

### Essential

- Quality assurance and/or clinical trials experience at senior level in a devolved, complex and varied working environment.
- Extensive experience of working in clinical trials (in particular CTIMPs), with in-depth knowledge of clinical trials regulations (within UK and world-wide) and proportionate application of such guidelines.
- Proven ability to contribute to strategic planning and organisational development.
- Knowledge and experience of a variety of trial monitoring methods and a desire to further develop clinical trial monitoring methodology, with a particular emphasis on risk-based approach.
- Proven people-management skills. The ability to manage and engage a varied team with a range of functional responsibilities and inspire confidence from the team.
- Experience of managing change with confidence; a resilient approach to problem-solving.
- Experience of providing specialist advice to external industry, university, or research councils.
- Self-motivated and works efficiently under pressure with careful attention to detail.
- Excellent written, verbal, interpersonal and communication skills.
- Demonstratable ability to lead, develop and motivate a team.
- Experience of regulatory inspections and sponsor audits.

### Desirable

- Proven experience of developing and managing a Quality Management System including document control and non-compliance management.
- Experience of providing supervision and delivering training on clinical trials regulations and governance.
- Willingness to travel nationally and internationally.

## 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>

### Hazard-specific / Safety-critical duties

This job includes hazards or safety-critical activities. If you are offered the post, you will be asked to complete a health questionnaire which will be assessed by our Occupational Health Service, and the offer of employment will be subject a successful outcome of this assessment.

The hazards or safety-critical duties involved are as follows:

- Travel outside of Europe or North America on University Business

### 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 the nature of this position which involves working with highly sensitive data.
- 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.

The University of Oxford has recently published their New Ways of Working framework to ensure professional service staff can continue to support the University's academic mission whilst working on site or remotely. For more information, please visit <https://hr.admin.ox.ac.uk/new-ways-of-working>

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](http://www.ox.ac.uk/about/organisation).

## Oxford Vaccine Group

The Oxford Vaccine Group (OVG) is led by Andrew J Pollard, Professor of Paediatric Infection and Immunity. Staff are based within a purpose-built centre on the Churchill Hospital site and form part of the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM). The aim of OVG is to co-ordinate expertise in the study of microbial diseases and the immune response to microbes, in order to facilitate research on the development and implementation of vaccines. This may include new, improved or combined vaccines for the adult and paediatric population. There is currently a large focus on delivering the COVID-19 vaccine trials.

Core group members include two Consultants in Vaccinology, a Director of Clinical Trials, a Senior Clinical Trials Manager, adult and paediatric clinical research fellows, adult and paediatric research nurses, project managers, QA manager, IT manager, and an administration team. The Infection and Immunity Laboratory includes post doctorate scientists, research assistants and DPhil students. Wider group members include professionals from a range of specialities including immunologists, microbiologists, statisticians, a community paediatrician, the local Health Protection team and a bioethicist.

More information about OVG may be found at the website: <http://www.ovg.ox.ac.uk>

## 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 facilities in the UK and abroad, we work on a global scale, building a paediatric network in the medical science community. We are committed to inform and inspire external audiences worldwide through our public engagement and outreach activities.

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, MRC, 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.

You will be asked to upload a CV and a supporting statement. The supporting statement must explain how you meet each of the selection criteria for the post using examples of your skills and experience. This may include experience gained in employment, education, or during career breaks (such as time out to care for dependants)

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](mailto: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](http://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 70<sup>th</sup> 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](http://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](http://www.newcomers.ox.ac.uk).