

Job description and selection criteria

Job title	Qualified Person
Division	Medical Sciences Division
Department	Nuffield Department of Medicine (NDM)
Location	Clinical BioManufacturing Facility, Churchill Hospital, Headington, Oxford
Grade and salary	Grade 9: £47,263 - £54,765 per annum
Hours	Full time
Contract type	Fixed-term to 31 st July 2021 in the first instance
Reporting to	Facility Head
Vacancy reference	139770
Additional information	

The role

You will undertake Qualified Person (QP) responsibilities as defined in the Code of Practice for Qualified Persons of the Institute of Biology, the Royal Pharmaceutical Society or the Royal Society of Chemistry. As part of this, you will also be named as a QP on the MHRA license MIA (IMP) 21584 held by the Clinical BioManufacturing Facility in accordance with the requirements of European Community Statutory Directive 2001/20/EC and when in force Regulation 536/2014.

The role includes the responsibility for certifying Investigative Medicinal Products (IMP)s for use, ensuring compliance of operations with regulatory requirements, and QP declaration for imported products and supporting the management of the portfolio of QP activities. This includes the following: Importation of IMPs to the EU, certification of GMP compliance, clinical trial labelling activities and batch certification to trial. The Qualified Person will support all CBF activities, providing expert advice on research and manufacturing programmes for Principal Investigators across the University and externally. The QPs are central and pivotal to the operation and the quality standards of the CBF. This is an unusual and highly varied role due to



the nature and scope of the translational products being manufactured at the CBF, often for diseases where the correlate of protection is unknown.

Responsibilities

The QP will be responsible for carrying out legal duties as a QP in accordance with Directive 2001/20/EC (and when in force regulation 536/2014), ensuring compliance with the requirements of Annex 13 of the EU Guidance on GMP for clinical IMPs and where relevant Annex 16 Certification by a Qualified Person and Batch Release.

Reporting to the Senior QP, your duties will be varied, however, the key duties and responsibilities are as following:

- Performing QP activities conducted under the CBF's MHRA MIA (IMP) 21584.
- Implementation of the requirements of EU Commission Directive 2001/20/EC and when it comes into force Regulation 536/2014.
- Supporting the CBF Senior Management Team with the maintenance of the manufacturing authorisation MIA (IMP) 21584 including submissions of variations to the Medicines and Healthcare products Regulatory Agency (MHRA).
- Providing advice to Principal Investigators at the University of Oxford on the interpretation and application of current relevant legislation and guidance that has an impact on IMP manufacturing as related to clinical trials activity. Provide support and guidance to enable novel manufacturing processes and products that meet the requirements of EU GMP.
- Providing input into the CBF's Quality Management System, working with the Head of Quality to ensure that it is robust, effectively implemented and utilised in order to support competent decision making for IMP certification and release, including: review, approval and authorisation as applicable (policies, procedures, specifications, standard operating procedures, validation and other documents).
- Responsible for GMP certification of IMPs manufactured at the CBF and third party suppliers, ensuring compliance of operations with regulatory requirements.
- To review Clinical Trials Authorisations in conjunction with the manufacturing documentation to allow QP batch certification of a given IMP for clinical trial.
- To assist with the preparation of documentation to support Regulatory Submissions.
- May be responsible for investigation and reporting of suspect / defective medicinal products relating to the provision of IMPs by the CBF.
- To manage clinical trial specific labelling of IMPs on behalf of CBF customers.
- Review and approve Technical Quality Agreements.
- Provide expert QP guidance and advice to sponsors and other members of University Staff.
- In the absence of the Head of Quality, act as lead for customer and regulatory audits/inspections.
- To present the work of the CBF at internal and external scientific and business meetings.

- Meet the requirements of continuing professional development required to maintain QP status, attending appropriate MHRA seminars, scientific and QP training opportunities.
- Support and train CBF staff and sponsors with all aspects of GMP.
- To undertake such other duties as may be required from time to time that are commensurate with the grade and responsibilities of this post.
- To conduct themselves with due regard to the University Equal Opportunities and Data Protection policies.
- You will occasionally be required to work outside normal working hours.

Essential Selection criteria

- Eligible to be a Qualified Person
- Experience with the manufacture of biological, sterile medicinal products
- Competent and experienced in managing all aspects of Quality Assurance and compliance management procedures within a GMP regulated environment
- Sound knowledge of EU GMP guidelines (EudraLex Volume 4), and its amendments and the ability to interpret these in a non-commercial environment
- Past experience of leading validations of assays / equipment / processes and facilities
- Experience in self inspections and supplier auditing
- Excellent organisational skills and a keen eye for detail
- Proven ability to work within a small team and to communicate effectively with people at all levels
- Significant scientific and / or technical expertise working in a GxP environment, along with several years' experience in a manufacturing or Quality role

Desirable selection criteria

- Extensive biopharmaceutical / advanced therapies/ vaccines experience
- A broad understanding of technical and scientific processes, including bioprocessing methodology
- Project Management skills
- Higher Degree in Life Sciences

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. Income from external research contracts in 2015/16 exceeded £537.4m and we rank first in the UK for university spin-outs, with more than 130 companies created to date. 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

Medical Sciences

The Medical Sciences Division is an internationally recognized centre of excellence for biomedical and clinical research and teaching.

We are 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: www.medsci.ox.ac.uk

Nuffield Department of Clinical Medicine (NDM)

The Nuffield Department of Clinical Medicine (NDM) is one of the largest departments of the University of Oxford and is part of the Medical Sciences Division, with responsibility for a significant part of the teaching of clinical students within the Medical School. The Department also has a substantial research programme which requires high quality administrative management.

NDM has significant financial turnover and complexity, resulting from its diverse research portfolio, its geographical spread and its close links with NHS funding and strategic teams involved in the development and delivery of increasingly integrated clinical research platforms.

...fostering your career in science

For more information please visit: www.ndm.ox.ac.uk/home

The University of Oxford is a member of the [Athena SWAN Charter](#) and holds an institutional Bronze Athena SWAN award. The Nuffield Department of Medicine holds a Silver Athena SWAN award to recognise advancement of gender equality: representation, progression and success for all.

For more information please visit:

<https://www.ndm.ox.ac.uk/working-for-ndm/aboutndmatheneswan/>

The Jenner Institute

The Jenner Institute was founded in November 2005 to develop innovative vaccines against major global diseases. Uniquely it focuses both on diseases of humans and livestock and tests new vaccine approaches in parallel in different species. A major theme is translational research involving the rapid early-stage development and assessment of new vaccines in clinical trials.

For more information please visit: department website <http://www.jenner.ac.uk/>

Clinical BioManufacturing Facility

The Clinical BioManufacturing Facility, part of the Jenner Institute, is the University of Oxford's Medicines and Healthcare Products Regulatory Agency (MHRA)-approved GMP (Good Manufacturing Practice) manufacturing facility, where the basic research into vaccines and potential advanced therapies can be translated into the manufacture of novel vaccines classed as Investigational Medicinal Products (IMPs) for use in first in human clinical trials.

The CBF has over 20 years' experience producing biological IMPs according to GMP for early phase clinical trials. It has a Manufacturer's Authorisation for Investigational Medicinal Products (MIA IMPs) from the MHRA. The CBF has manufactured almost 20 novel vaccines for first-in-man studies, as vaccines for infectious disease and cancer therapy and has supported over 60 clinical trials.

For more information please visit: <http://www.cbf.ox.ac.uk/home>

How to apply

Before submitting an application, you may find it helpful to read the 'Tips on applying for a job at the University of Oxford' document, at

http://www.ox.ac.uk/about_the_university/jobs/research/

http://www.ox.ac.uk/about_the_university/jobs/professionalandmanagement/

http://www.ox.ac.uk/about_the_university/jobs/supportandtechnical/

If you would like to apply, click on the **Apply Now** button on the 'Job Details' page and follow the on-screen instructions to register as a new user or log-in if you have applied previously. Please provide details of two referees and indicate whether we can contact them now.

You will also 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).

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

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

All applications must be received by **midday** 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 departments.

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)

Should you experience any difficulties using the online application system, please email recruitment.support@admin.ox.ac.uk. Further help and support is available from [www.ox.ac.uk/about the university/jobs/support/](http://www.ox.ac.uk/about_the_university/jobs/support/). To return to the online application at any stage, please go to: www.recruit.ox.ac.uk.

Please note that you will be notified of the progress of your application by automatic emails from our e-recruitment system. **Please check your spam/junk mail** regularly to ensure that you receive all emails.

Important information for candidates

Pre-employment screening

Please note that the appointment of the successful candidate will be subject to standard pre-employment screening, as applicable to the post. This will include right-to-work, proof of identity and references. We advise all applicants to read the candidate notes on the University's pre-employment screening procedures, found at:

www.ox.ac.uk/about/jobs/preemploymentscreening/.

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: www.admin.ox.ac.uk/councilsec/compliance/gdpr/privacynotices/job/. The University's Policy on Data Protection is available at:

www.admin.ox.ac.uk/councilsec/compliance/gdpr/universitypolicyondataprotection/.

The University's policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for all academic posts and some academic-related posts. From 1 October 2017, the University has adopted an EJRA of 30 September before the 69th birthday for all academic and academic-related staff in posts at **grade 8 and above**. The justification for this is explained at:

www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+/.

For **existing** employees, any employment beyond the retirement age is subject to approval through the procedures: www.admin.ox.ac.uk/personnel/end/retirement/acrelretire8+/.

From 1 October 2017, there is no normal or fixed age at which staff in posts at **grades 1–7** 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.

Information Security

Information is critical to The University of Oxford operations and failure to protect information increases the risk of financial and reputational losses. NDM is committed to protecting information, in all its forms, from loss of **confidentiality, integrity** and **availability**. Users are required to complete information security awareness training and are responsible for making informed decisions to protect the information that they process. Wilful failure to comply with the policy and baseline will be treated extremely seriously by the University and may result in enforcement action on The Nuffield Department of Clinical Medicine and/or an individual.

For full details please see [University Information Security Policy and Implementation Guidance](#)

Benefits of working at the University

University Club and sports facilities

The University Club provides social, sporting and hospitality facilities. It incorporates a bar, café and sporting facilities, including a gym. 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 www.sport.ox.ac.uk/oxford-university-sports-facilities.

Information for international staff (or those relocating from another part of the UK)

If you are relocating to Oxfordshire from overseas, or elsewhere in the UK, the University's International Staff website includes practical information related to moving to and settling in Oxford such as advice on immigration, relocation, accommodation, or registering with a doctor. See: www.internationalstaffwelcome.admin.ox.ac.uk/

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 to settle into Oxford and to provide them with an opportunity to meet people in the area. See www.newcomers.ox.ac.uk/

Childcare

The University has excellent childcare services with 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 www.admin.ox.ac.uk/childcare.

Family-friendly benefits

The University subscribes to My Family Care (www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/mfc/) and staff are eligible to register for emergency back-up childcare and adultcare services, a 'speak to an expert' phone line and a wide range of guides and webinars through a website called the Work + Family space.

Disabled staff

We are committed to supporting members of staff with disabilities or long-term health conditions. Please visit www.admin.ox.ac.uk/eop/disab/staff for further details including information about how to make contact, in confidence, with the University's Staff Disability Advisor.

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 www.admin.ox.ac.uk/eop/inpractice/networks/

Other benefits

Staff can enjoy a range of other benefits such as free visitor access to the University's colleges and the Botanic Gardens as well as a range of discounts. See www.admin.ox.ac.uk/personnel/staffinfo/benefits