**Job title**
GMP Production Manager

**Division**
Medical Sciences

**Department**
Nuffield Department of Medicine (NDM), Jenner Institute

**Location**
Clinical BioManufacturing Facility, Old Road, Headington, Oxford, OX3 7JX

**Grade and salary**
Grade 8: £41,526 - £49,553 per annum. Depending on experience this post may be offered at grade 7 with reduced duties.

**Hours**
Full time

**Contract type**
Fixed-term for 3 years in the first instance, with the possibility of renewal dependent on future funding

**Reporting to**
Head of Production

**Vacancy reference**
143367

**Additional information**
Funded by the Department
Support with relocation is available if required

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**The role**

The Clinical BioManufacturing Facility (CBF) is central to translating The University of Oxford's world-leading medical research into real world impact. Numerous products successfully manufactured at the CBF have entered Phase I/Phase II clinical trials, including those targeting Malaria, HIV, Tuberculosis, Zika, Cancer and Crohn's Disease.

Reporting to the Head of Production the post holder will play a key role in the manufacture of a wide range of Investigational Medicinal Products, including vaccines, and Advanced Therapy Medicinal Products for clinical trials according to the principles of Good Manufacturing Practice (GMP). The post holder will be pivotal to the success of upcoming manufacturing campaigns through their leadership of the Production Team, partnership with other managers within the CBF, and collaboration with academic teams developing innovative medicinal products.

This post would be particularly suited if you want to leverage your skills and knowledge of GMP to meaningfully impact the lives of millions of people. It is the ideal opportunity to develop your career in biopharmaceuticals at the interface between academia and industry.
Responsibilities

- Lead the programme of manufacturing and storage of clinical-grade products and intermediates, ensuring compliance to the principles of GMP
- Proactive planning of cleanroom activities for each manufacturing campaign ensuring setting of and adhering to defined budgets and timelines
- Line management of the Production Team to include guidance in continual personal and professional development
- Agree clear task objectives, organise and delegate work to other members of the Production Team, and supervise and train members of the Production Team in GMP processes
- Design and implement strategies to ensure efficient and compliant transfer of new processes and projects into a cleanroom environment.
- Provide technical subject matter expertise throughout manufacturing projects, from initial grant applications to final regulatory submissions.
- Ensuring specialist GMP activities such as equipment maintenance, validation programmes, cleanroom cleaning, environmental monitoring and sterilisation/fumigation processes are performed correctly and on time
- Conduct GMP manufacturing processes and cleanroom activities as required
- Close communication with the Pre-GMP Manager to ensure timely technical transfer and transition of Pre-GMP starting materials from Process Development to Production
- Writing, development, approval and maintenance of Standard Operating Procedures, Production Batch Records, Manufacturing Instructions, Study Plans and Reports and ensuring their strict implementation
- To complete Quality Management System documentation (CAPAs, Change Controls, Deviations) to a high standard in full compliance with the requirements of regulatory bodies
- Liaising and communicating efficiently with other teams in the CBF and with collaborators and colleagues in other units and departments of the University
- Performing other duties commensurate with the grade and level of responsibility

Pre-employment screening

All offers of employment are made subject to standard pre-employment screening, as applicable to the post.
If you are offered the post, you will be asked to provide proof of your right-to-work, your identity, and 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 so that we
can discuss appropriate adjustments with you), and a declaration of any unspent criminal convictions.

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

**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 (OHS), and the offer of employment will be subject a successful outcome of this assessment.

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

- **Work with any substance** which has any of the following pictograms on their MSDS:

![Pictograms](image)

**Selection criteria**

**Essential selection criteria**

- A degree in the biological sciences with post-graduate experience in the area of biopharmaceuticals manufacture
- In-depth working knowledge of GMP
- Hands-on experience in the manufacture of biologicals, ideally viral vectored vaccines, within a regulated environment
- Extensive experience in cell culture with proven aseptic technique
- Ability to independently plan and manage a GMP manufacturing campaign
- An ability to understand technical and scientific processes with a proactive and creative approach to problem solving
- Highly developed organisation skills, with an ability to work under pressure and meet competing deadlines
- Excellent written and verbal communication skills, including the ability to prepare documentation to meet regulatory requirements
- Strong interpersonal skills and ability to work effectively with others

**Desirable selection criteria**

- Practical experience of process development including adenovirus or poxvirus vector production and purification
• Knowledge of virus like particle (VLP), recombinant protein and monoclonal antibody production processes

• The ability to work closely and communicate clearly with staff at all levels

• Experience in managing staff

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 2016/17 exceeded £564m and we rank first in the UK for university spinouts, 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)...fostering your career in science

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.

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

The Nuffield Department of Clinical Medicine has been presented with a Departmental Athena SWAN Silver award in recognition of the commitment made to promote gender equality through
our organisational and cultural practices and our efforts to improve the working environment for both men and women. For more information please see our Departmental Athena SWAN pages: www.ndm.ox.ac.uk/working-for-ndm/aboutndm/athenaswan/.

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 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).

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/. 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: 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/universitypolicyondatatprotection/.

The University’s policy on retirement

The University operates an Employer Justified Retirement Age (EJRA) for all academic posts and some academic-related posts. 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+/

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.
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 www.admin.ox.ac.uk/personnel/staffinfo/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 www.sport.ox.ac.uk/oxford-university-sports-facilities.

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 www.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 www.admin.ox.ac.uk/personnel/permits/reimburse&loanscheme/.

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 My Family Care, 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 www.admin.ox.ac.uk/personnel/staffinfo/benefits/family/mfc/.

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 www.admin.ox.ac.uk/childcare/.

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 www.admin.ox.ac.uk/eop/disab/staff.

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/.

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.