

Senior Analytical/QC Research Fellow

Department	Cancer Research UK Formulation Unit, SIPBS		
Faculty	Faculty of Science (www.strath.ac.uk/science/)		
Staff Category	Research	Reference No	318464
Reports To	Professor Gavin Halbert	Grade:	8
Salary Range:	£41,526 - £51,034	Contract Type:	Fixed Term (Until 30/09/21)
FTE:	1.0	Closing Date	Tuesday, 22 September 2020

Job Advert

The Cancer Research UK Formulation Unit is a unique, internationally renowned and MHRA cGMP licensed facility for the pharmaceutical development of novel anti-cancer agents for initial clinical trial in man. A senior vacancy has arisen for an experienced analyst to lead and manage the pharmaceutical quality control and development laboratory within the Unit covering analytical method development and active, excipient and finished product analysis to cGMP. In addition, the post holder will be required to participate in a management role including internal and external planning and liaison functions and contribute to the quality and research agenda within the Formulation Unit and Institute. A PhD qualification in an appropriate discipline along with experience of pharmaceutical analysis and method development within a cGMP setting and staff management is essential. Eligibility for registration as a Qualified Person, with the MHRA is desirable.

Job Description

Brief Outline of Job:

To provide and manage at a senior level all aspects of pharmaceutical quality control within the Formulation Unit, reporting to the Unit Director and Assistant Director. The post holder will be required to manage, supervise and provide training in all aspects of pharmaceutical analysis associated with the development and manufacture for clinical trial of investigational medicinal products. Duties will include, method development and validation, approval of analytical specifications, quality control analysis of raw materials and finished products and approval or rejection of materials. The post holder will also be required to approve and monitor contract analysis, ensure that adequate records are maintained, liaise externally with Cancer Research UK national and international colleagues and contribute to the quality assurance activities associated with the Unit's GMP status. Publication of research activity where possible is required, along with participation in some aspects of the wider Departmental and University functions.

Main Activities/Responsibilities:

1.	Manage the Formulation Unit's analytical and quality control activities related to the development and manufacture for clinical trial of investigational medicinal products to cGMP standards.
2.	Manage and participate in analytical method development and validation for investigational medicinal products of novel anti-cancer agents and associated raw materials.
3.	Manage and approve the preparation of analytical specifications for active pharmaceutical ingredients, raw materials and investigational medicinal products.
4.	Manage and participate in the formulation development of investigational medicinal products, especially the conduct of development and real time stability studies.
5.	Manage the Formulation Unit's analytical equipment portfolio and laboratory environment to ensure compliance with cGMP.

6.	Provide reports and liaise with external Cancer Research UK personnel and associated colleagues to provide project associated information, including where required attendance at external meetings.
7.	Contribute to Formulation Unit quality assurance functions associated with the Unit's licensed Good Manufacturing Practice status, especially quality control systems.
8.	Collaborate with colleagues and Unit staff to publish research results.
9.	Engage with stakeholders in order to ensure project delivery within the allocated budgets and contracted time-scales.
10.	Any other duties that may be assigned including practical laboratory studies when required.

Person Specification

Educational and/or Professional Qualifications

(E=Essential, i.e. a candidate must meet all essential criteria to be considered for selection, D=Desirable)

E1 Good honours degree in appropriate analytical discipline to Formulation Unit activities

E2 PhD degree in appropriate analytical discipline

E3 Membership of relevant professional body appropriate to Formulation Unit

D1 Eligible for submission as Qualified Person to MHRA

Experience

E4 Significant breadth and depth of knowledge of pharmaceutical quality control within a cGMP setting associated with the development and manufacture of investigational medicinal products.

E5 Experience of the analytical development, validation and specification setting

E6 Experience of research and publication

E7 Management, supervision and direction of laboratory staff

Job Related Skills and Achievements

E8 Ability to plan, organise and deliver research programmes in a timeous manner

E9 Problem solving and work scheduling ability including task delegation

E10 Evidence of organisational and planning skills commensurate with position

E11 Computer literate with standard software packages

E12 Computer literate and familiar with specialist analytical equipment software

Personal Attributes

E13 Ability to plan, organise and prioritise personal workload to achieve deadlines.

E14 Ability to work within and contribute to a team environment.

E15 Strong interpersonal communication (written and verbal) and influencing skills, including the ability to influence at senior level within and outside the employing organisation. Ability to present complex information in an accessible way.

E16 Consistent ability to complete and solve complex tasks and issues accurately that have high degrees of ambiguity.

Other Relevant Factors

E17 Enthusiastic organised individual and adaptable team player.

E18 Ability to undertake travel to Cancer Research UK meetings throughout the UK.

E19 Capable of forming sound, evidence-based judgements, making choices, assessing risks to delivery and taking accountability for results.

Application Procedure

Applicants are required to complete an application form including the name of three referees who will be contacted before interview without further permission, unless you indicate that you would prefer otherwise. Applicants should also submit a Curriculum Vitae and a covering letter detailing the knowledge, skills and experience you think make you the right candidate for the job. Applicants should also complete the Equal Opportunities Monitoring Form.

Other Information

Further information on the application process and working at Strathclyde can be found on our website (<http://www.strath.ac.uk/hr/workforus>).

Informal enquiries about the post can be directed to Professor Gavin Halbert, g.w.halbert@strath.ac.uk.

Conditions of Employment

Conditions of employment relating to the Research staff category can be found at: [Conditions of Employment](#).

Rewards and Benefits

Our staff have access to a wide range of outstanding benefits that include financial rewards, family friendly and wellbeing benefits and career development opportunities, details of which can be found [here](#).

Pre-employment health screening

An offer of appointment will be subject to a medical assessment by Occupational Health. An individual who accepts an offer of employment must complete a confidential medical questionnaire and forward it to the Occupational Health Nurse within 5 days of receipt. If further information is required the individual may be contacted by the OHN or a Medical Advisor and a personal appointment with the individual may be arranged. An unconditional contract of employment will not be issued until Human Resources receives confirmation that applicant is fit to undertake the duties of the post.

Probation

Where applicable, the successful applicant will be required to serve a 12 month probationary period.

Pension

The successful applicant will be eligible to join the Universities' Superannuation Scheme. Further information regarding this scheme is available from [Payroll and Pensions](#).

Relocation

Where applicable, the University offers a relocation package to support new employees who meet the eligibility criteria. The relocation package is offered as a contribution towards costs incurred, and is designed to be flexible, allowing staff to use the financial support available in the way that will be most helpful to them. Further details are outlined in the Relocation Policy.

Interviews

Formal interviews for this post will be held in mid September 2020.

Equality and Diversity

We value diversity and welcome applications from all sections of the community.

The University currently holds a Bronze Athena SWAN award, recognising our commitment to advancing women's careers in science, technology, engineering, maths and medicine (STEMM) employment in academia.

University Values

The University's Values capture what we're all about: who we are, what we believe in and what we stand for. [Our Values](#) have been derived from how we act and how we expect to be treated as part of Strathclyde.



Conditions of Employment

Research Staff

1. GENERAL CONDITIONS

Members of staff are subject to the Charter and Statutes and the Ordinances and Regulations of the University, published in the Calendar, and to any amendments or additions thereto approved by the University Court and, in the case of the Charter and Statutes, the Privy Council. Staff are also expected to familiarise themselves with, and adhere to, general University policies and procedures, as published on University web pages.

The University Court recognises Strathclyde Universities and College Union (SUCU) as the sole body with which it will negotiate and consult on all collective issues concerned with the terms and conditions of employment of Research Staff. Such terms and conditions may be varied by the University Court after negotiation and consultation with SUCU.

Each member of staff is responsible for the proper performance of allocated duties to the person or persons specified in the member of staff's letter of appointment and any accompanying papers.

The University is committed to ensuring that its business is conducted in an open and transparent manner and will take all appropriate steps to address risks of bribery or corruption. Members of staff are required at all times to act honestly and with integrity and to safeguard the resources for which they are responsible. The University has in place a robust Public Interest Disclosure (Whistleblowing) Policy to enable concerns to be brought to its attention. This is available at www.strath.ac.uk/publicinterestdisclosure. Other relevant policies, e.g. Fraud Prevention and Conflicts of Interests, can also be found on the University's website.

Any member of staff may at any time be exposed to commercially sensitive information, information related to potentially valuable intellectual property or information which may otherwise be of a confidential nature. This information, which could be found anywhere in the University, may be written or disclosed orally, can include information of a commercial or technical nature, and may be owned by the University or by third parties. The University requires all employees to keep any such information confidential in the first instance and not disclose, publish or otherwise disseminate it without prior consent of the University. Such confidentiality obligations are commonplace and in the commercial interests of the University. When in doubt advice should always be sought from Research and Knowledge Exchange Services prior to disclosure.

The University operates probationary periods for new staff, the duration of which will be specified in individual letters of appointment. The normal probation period for posts in this staff category is 9 months for those at grades 6 and 7, and 12 months for grades 8 and above. Further guidance on probationary procedures is published at <http://www.strath.ac.uk/staff/policies/hr/>.

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Further information on the terms and conditions specified in this document and other staffing policies and procedures can also be found at www.strath.ac.uk/hr.

2. SALARY

Appointments are made at an appropriate salary point on the University's grading structure, with initial placing determined according to qualifications and experience. Increments are paid to staff on the 12 month anniversary of their appointment. Where this is not the first of the month, the increment will be paid on the first of the month directly

after the 12 month anniversary. This allows 1 progression to the next point on the salary scale until the top guaranteed point of the scale is reached.

Salaries are paid directly to staff members nominated bank account, normally on the second last working day of the month.

3. HOURS OF WORK

Working time is that required to fulfil the duties of the post. The University Court recognises that research staff carry out these duties in a variety of ways appropriate to the nature of the research activity, but expects regular contact to take place between the research staff employee and the supervisor/granholder (where these positions are occupied by different individuals) during normal working hours on week days. There are exceptions to this pattern which may involve contact at other locations or in the evenings, or at weekends, but these arrangement will be made with the agreement of the member of staff concerned.

Duties may, by arrangement with Head of Department/School/Director, include some teaching associated with the post (up to a maximum of 40 hours per semester) for which no additional payment will be made.

Additional work which does not fall within the scope of that described above may by arrangement attract payment which must be authorised and processed through the payroll.

4. HOLIDAYS

Annual leave entitlement is 31 days per year to be taken by agreement with the line manager. For staff members working on a part-time basis, holidays will be calculated on a pro-rata basis.

In addition to annual leave there is an entitlement to eleven public holidays per year which should be taken on days that the University is closed for this purpose. The University presently closes for four additional days over the Christmas and New Year period. **These additional days count against the annual leave entitlement.**

For staff members working on a part-time basis, public holiday entitlement will be calculated on a pro-rata basis.

Annual leave and public holiday entitlements should be taken in the leave year to which they relate. Up to five days leave can be carried forward into the new leave year subject to line management agreement. In exceptional circumstances, Heads of Department/School/Director may approve carry forward of accrued annual leave in excess of five days.

The University's expectation is that staff take all accrued holidays prior to their termination date. If staff have exceeded their entitlement the University will deduct an equivalent number of days pay from final salary payments.

5. SICKNESS ABSENCE

During any period of absence through illness or injury provided the appropriate notification and certification procedures have been followed the University will pay a member of staff (having taken account of the aggregate of all periods of absence due to illness during the twelve months immediately preceding the first day of the current absence) as follows:

Period of Continuous Employment at start of absence from work	Full Pay	Half Pay
Less than 1 year	1 month	1 month
1 year but less than 2 years	2 months	2 months
2 years but less than 3 years	4 months	4 months
3 years but less than 5 years	5 months	5 months
5 years or more	6 months	6 months

In order to manage the University's sick pay scheme the University requires to maintain sickness absence records on individual members of staff. When making payments after the expiry of statutory sick pay the University will deduct an amount equivalent to any benefit normally payable by the Department of Work and Pensions. For full details on the general University policy in this area please refer to the Sickness Absence Management Policy at www.strath.ac.uk/staff/policies/hr.

6. PENSIONS

If you are under age 75 at the date your appointment commences you will automatically become a member of the pension scheme operated by the University – the Universities Superannuation Scheme (USS). You will be admitted to the career revalued benefits scheme called the USS Retirement Income Builder, the contribution rate that currently applies is 9.6% of pensionable salary. A threshold applies to the maximum salary that counts towards the USS Retirement Income Builder. From 1 April 2019, the threshold is £58,589.70 per year. Contributions based on salary above the monthly equivalent rate of the threshold are paid to the defined contribution section of the scheme called the USS Investment Builder. Information regarding USS can be found in the scheme booklet located on the website: <https://www.uss.co.uk/members/members-home/resources/factsheets-and-member-guides>. The scheme booklet is called 'Your Guide to the Universities Superannuation Scheme'.

The exception to automatic membership of the pension scheme applies if your post is located out with the UK in an EU member state. If this is the case membership of USS is not available to you.

The University operates a salary exchange arrangement, Pensions Plus, for members of the USS. Pensions Plus enables pension contributions to be made in a manner so that both employees and the University can benefit from available National Insurance Contribution savings. You will be automatically included in Pensions Plus, provided it does not adversely affect your take-home pay or your ability to claim certain state benefits. If your earnings fall below the Pension Plus pay protection limit you will be opted out of Pension Plus. This will not affect your membership of the USS.

New members of staff may opt out of USS within three months of taking up appointment and will then be treated as if they had never been a member of the scheme. After three months members of staff who wish to withdraw from USS during their employment will be required to give a minimum of 28 days' notice in writing to the University. Any member of staff who wishes to opt out should contact the Pensions Section, Finance, in the first instance (pensions@strath.ac.uk). Please note that if you are a member of Pensions Plus and withdraw from USS with less than two years of membership, or cease employment with the University and have less than two years of USS membership, the option of a refund of pension contributions will not be available to you. Instead, USS must provide you with a pension benefit that is payable from your retirement date.

The University reserves the right to alter or withdraw Pensions Plus as it sees fit or as required to comply with legislative changes. Withdrawal or amendment of Pensions Plus will not affect your membership of USS. If you do not wish to participate in Pensions Plus but wish to remain in

the pension scheme please contact the Pensions Team who will provide you with a non-participation form.

Information regarding pension scheme membership can be found on the Pensions pages of the University's website. Full information regarding USS can be found on the USS website – www.uss.co.uk

7. PLACE OF WORK AND RESIDENCE

Members of staff will be based on the John Anderson Campus, unless otherwise stated in the letter of appointment. The Department/School in which the post is initially placed will be specified in the letter of appointment although there will be an expectation to work at such other places as required in the course of employment.

If the need arises for members of staff to work outside the UK for a period (or periods) of more than one month then such arrangements will be subject to mutual agreement. Members of staff would then be provided with a statement in advance setting out the terms covering such periods of employment.

The University does not normally place specific restrictions upon the place of residence of members of staff. All staff are, however, expected to reside in a location which is compatible with the satisfactory fulfilment of all the duties associated with their appointment.

8. CONSULTANCY/FURTHER ACTIVITIES

To support the strategic objectives of the University and to facilitate individual professional development, the University encourages staff to engage in professional activities with outside bodies related to their field of work. In many cases, such activity will be approved on the basis that it represents University knowledge exchange activity and should therefore be treated as part of the individual's overall workload and managed through the University's systems. It is also recognised that there will be some cases where an activity is entirely separate from the University and should thus be notified/approved as a personal business activity. For further information please refer to the "University Procedure in relation to Work for Outside Bodies including Consultancies", which forms part of the employment contract and can be accessed at www.strath.ac.uk/hr

9. DISCIPLINARY AND GRIEVANCE PROCEDURES

Further information on the University's disciplinary and grievance procedure can also be found at www.strath.ac.uk/policies/hr or on request from Human Resources.

10. NOTICE AND TERMINATION

Members of staff are employed on the conditions indicated in individual letters of appointment and any accompanying papers. The University is not obliged to give notice of termination or continue any employment beyond the end of that period. Where the period of the contract of employment is for one year or less it may be terminated short of the fixed term period by one months notice on either side. Where the period of the contract of employment is for more than one year, or where there have been a further contract or series of contracts immediately consecutive, the employment may be terminated short of the fixed term period by three months' notice on either side, except during the probationary period when the notice period is one month.

If the appointment is for a fixed term it will expire at the end of the period without the necessity for notice.

Revised April 2019