|  |  |
| --- | --- |
| Last updated: | September 2019 |

**JOB DESCRIPTION**

|  |  |  |  |
| --- | --- | --- | --- |
| Post title: | Administrative Assistant (Quality) | | |
| Academic Unit/Service: | Clinical Trials Unit | | |
| Faculty: | Faculty of Medicine | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 2b |
| \*ERE category: | n/a | | |
| Posts responsible to: | PV and Quality Manager | | |
| Posts responsible for: | N/A | | |
| Post base: | Office-based/Non Office-based (see job hazard analysis) | | |

|  |
| --- |
| Job purpose |
| The Southampton Clinical Trial Unit (SCTU) designs, initiates, conducts and analyses high quality national and international clinical trials to directly influence routine clinical practice. SCTU has been awarded full registration with the UK Clinical Research Collaboration and has established quality and regulatory systems to ensure that trials are conducted to the highest standards.  The appointed person will take responsibility, under the direction of the PV and Quality Manager and PV and Coding Officer, to maintain and develop further, SCTU’s quality and regulatory systems. Tasks will be centered around liaison with internal and external research teams, tracking, reporting and filing of quality, contractual and safety documents and setting up new systems to complement those already in place. |

| Key accountabilities/primary responsibilities | | % Time |
| --- | --- | --- |
|  | **Regulatory**  Pharmacovigilance (PV)   * Provide general support to the Quality and Regulatory Team. * To generate reports from spreadsheets and databases as requested, and to participate in relevant trial specific and SCTU meetings. * Manage training and induction resources by monitoring use and status of equipment, identifying requirements, sourcing and obtaining additional resources as agreed by the manager. * Any other duties appropriate to the band assigned by the PV and Quality Manager. | 60 % |
|  | **Quality Management**   * Provide general support to the Quality and Regulatory Team. * To generate reports from spreadsheets and databases as requested, and to participate in relevant trial specific and SCTU meetings. * Manage training and induction resources by monitoring use and status of equipment, identifying requirements, sourcing and obtaining additional resources as agreed by the manager. * Any other duties appropriate to the band assigned by the PV and Quality Manager. | 25 % |
|  | **General**   * Provide general support to the Quality and Regulatory Team. * To generate reports from spreadsheets and databases as requested, and to participate in relevant trial specific and SCTU meetings. * Manage training and induction resources by monitoring use and status of equipment, identifying requirements, sourcing and obtaining additional resources as agreed by the manager. * Any other duties appropriate to the band assigned by the PV and Quality Manager. | 10 % |
|  | The post holder will be expected to take a reasonable degree of responsibility for planning and managing their own workload.  The post holder will receive appropriate induction training into the business of SCTU and practices prevalent within the Quality and Regulatory team; however, they must have the necessary underpinning skills and attitudes to be able to carry out the work, as detailed in the personal specification. | 5 % |

| Internal and external relationships |
| --- |
| Other staff within SCTU  University of Southampton and University Hospital Southampton NHS Foundation Trust to promote good working relationships.  National NHS Trusts to secure and follow-up legal agreements and safety reports.  Medicines and Healthcare Products Regulatory Agency (MHRA) and Regional Research Ethics Committees – regulatory reporting within legal timeframes.  Trial specific groups with external members (Management groups, Trial Steering Committees, Data Monitoring and Ethics Committees) to provide safety reports.  Staff at participating sites, to secure and follow up agreements and safety reports.  Funding bodies e.g. Drug companies – contract and safety information.  Internal and External Chief Investigators (consultants) – safety reporting |

| Special Requirements |
| --- |
| The Quality and Regulatory Assistant will be based at Southampton General Hospital within the SCTU. |

**PERSON SPECIFICATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Criteria | Essential | Desirable | How to be assessed |
| Qualifications, knowledge and experience | GCSE/NVQ2 or equivalent level of qualification or experience  IT Literate to GCSE level;  Fully conversant with Microsoft  Office (in particular MS Word, MS Excel and MS Outlook), web and databases  Experience in using databases for data entry/finding information. Experience in raising and solving data queries.  Previous experience in a busy office environment, with customer service experience | Degree or equivalent qualification and/or experience in a related role.  A basic knowledge of the health service research community; possibly through working in or with the NHS  Knowledge of medical terminology  Knowledge or experience of medical research methodology, statutory clinical trial regulations, GCP and research governance requirements.  Knowledge or experience of quality systems and audit.  IIA or ISO Auditor qualification | Application or interview |
| Planning and organising | Excellent attention to detail including high standards of accuracy  High degree of organisation  Ability to be flexible, proactive and use initiative.    Capability to manage and prioritise a busy workload, sometimes under pressure.  Ability to adapt and refine own work practices.  Ability to work with established and evolving processes and procedures |  | Application or interview |
| Problem solving and initiative | Ability to prioritise tasks  The knowledge and ability to understand and rationalise problems, determine actions and follow good practice and standard procedures. | Able to identify and solve problems by applying initiative to tackle some situation in new ways and by developing improve  d work methods. | Application and interview |
| Management and teamwork | Excellent interpersonal and communication skills, verbal, listening and written, with internal and external stakeholders.  Able to work with and across teams in a busy office environment, share information and constructively support others.  Ability to liaise with individuals at all levels in different establishments. |  | Application and interview |
| Communicating and influencing | Communicates effectively in both spoken and written English  Excellent telephone manner | Negotiating and interpersonal skills. | Application and interview |
| Other skills and behaviours | Personal drive and initiative  Capacity to manage time effectively and a commitment to working to high standards of accuracy.  Proven ability to multi-task.  Experience of working in a team and independently.  Willing to attend courses to update or increase skills |  | Application and interview |
| Special requirements | Aptitude for, and interest in setting up systems |  | Application and interview |

**JOB HAZARD ANALYSIS**

**Is this an office-based post?**

|  |  |
| --- | --- |
| Yes | If this post is an office-based job with routine office hazards (eg: use of VDU), no further information needs to be supplied. Do not complete the section below. |
| No | If this post is not office-based or has some hazards other than routine office (eg: more than use of VDU) please complete the analysis below.  Hiring managers are asked to complete this section as accurately as possible to ensure the safety of the post-holder. |

## - HR will send a full PEHQ to all applicants for this position. Please note, if full health clearance is required for a role, this will apply to all individuals, including existing members of staff.

|  |  |  |  |
| --- | --- | --- | --- |
| **ENVIRONMENTAL EXPOSURES** | **Occasionally**  (<30% of time) | **Frequently**  (30-60% of time) | **Constantly**  (> 60% of time) |
| Outside work |  |  |  |
| Extremes of temperature (eg: fridge/ furnace) |  |  |  |
| ## Potential for exposure to body fluids |  |  |  |
| ## Noise (greater than 80 dba - 8 hrs twa) |  |  |  |
| ## Exposure to hazardous substances (eg: solvents, liquids, dust, fumes, biohazards). Specify below: |  |  |  |
| Frequent hand washing |  |  |  |
| Ionising radiation |  |  |  |
| **EQUIPMENT/TOOLS/MACHINES USED** | | | |
| ## Food handling |  |  |  |
| ## Driving university vehicles(eg: car/van/LGV/PCV) |  |  |  |
| ## Use of latex gloves (prohibited unless specific clinical necessity) |  |  |  |
| ## Vibrating tools (eg: strimmers, hammer drill, lawnmowers) |  |  |  |
| **PHYSICAL ABILITIES** | | | |
| Load manual handling |  |  |  |
| Repetitive crouching/kneeling/stooping |  |  |  |
| Repetitive pulling/pushing |  |  |  |
| Repetitive lifting |  |  |  |
| Standing for prolonged periods |  |  |  |
| Repetitive climbing (ie: steps, stools, ladders, stairs) |  |  |  |
| Fine motor grips (eg: pipetting) |  |  |  |
| Gross motor grips |  |  |  |
| Repetitive reaching below shoulder height |  |  |  |
| Repetitive reaching at shoulder height |  |  |  |
| Repetitive reaching above shoulder height |  |  |  |
| **PSYCHOSOCIAL ISSUES** | | | |
| Face to face contact with public |  |  |  |
| Lone working |  |  |  |
| ## Shift work/night work/on call duties |  |  |  |