**NHS GRAMPIAN**

**JOB DESCRIPTION**

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| 1. **JOB IDENTIFICATION**   **Job Title: Clinical Trials Support Worker**  **Department(s): Pharmacy Department, Aberdeen Royal Infirmary**  **Hours: 37.5 hours per week**  **Grade: Band 3** |

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| 1. **JOB PURPOSE**  * To provide comprehensive and high quality administrative support as required to the Clinical Trials Unit, Pharmacy and to assist in the efficient operation of the unit. * To provide support to Pharmacists and Technicians in the provision of dispensing, receipt, storage and accountability of Investigational medicinal products within Pharmacy Clinical Trials. * To input data relating to the issue and monitoring of Clinical Trial products and filing of associated documents. |
| **3. ORGANISATIONAL POSITION** |
| **4. SCOPE AND RANGE**   * The Clinical Trials support worker Higher Level is an active part of the team providing a Clinical Trials service to NHS Grampian. * The clinical trials unit within pharmacy is involved in approx 150 studies at any one time at varying stages from set-up to close down. * The clinical trials unit dispenses approx 2,000 prescriptions/3,000 items per annum |
| **5. MAIN DUTIES/RESPONSIBILITIES**  The following are done under the guidance of, and are supervised or checked by the Clinical Trials  Co-ordinator (senior Pharmacy Technician) or Pharmacist   * Check that all the relevant Clinical Trials documentation is present in the Pharmacy files and is the correct version. * Photocopying, scanning and filingof Clinical Trial documentation * Recording specific detail as required on trial specific documentation (eg dates, numbers, batch numbers, expiry dates). * Filing of electronic data into Trial Specific folders and paperwork into Pharmacy folders * Keep any Clinical Trials electronic data up to date and organised * Receipt and storage of Clinical Trial medicines including maintenance of accountability logs. * Dispensing, labelling and documentation of Clinical Trial Medicines. * Monitoring of Refrigerators and Freezer and reporting any faults or temperature deviations * Ensures that all work processes are carried out in accordance with Standard Operational Procedures (SOPs) and Standing Financial Instructions * Communicate any problems with or deficiencies in documentation to the line manager. * Setting up appointments and preparatory work for visits by Clinical Research Associates (CRA’s) and Trial Monitors, and assisting them at their visits. * Assist in the ordering of Clinical Trial medicines * Routine monitoring of expiry dates of Clinical Trial medicines | |
| 1. **SYSTEMS AND EQUIPMENT**  * Pharmacy stores computer system (currently CMM V.8 system) * E-mail system (personal and generic email) * Photocopier / Scanner * Telephone * Refrigerator/Freezer * Internet * NHS Grampian Intranet * Pharmacy computer systems (e.g. Q-Pulse), Microsoft word, Power point and Excel programmes * Interactive Voice Response System / Interactive Web Response System * SReDA (Scottish research database) * Chemocare electronic prescribing system * Working to SOP’s (Standard Operating Procedures)   Systems of work are controlled under Guides to Good Clinical Practice, Good Manufacturing Practice, Internal training folders and Quality Assurance procedural systems such as Standard Operating Procedures, Standard Dispensing Records, Master Record Sheets and various sectional task lists. | |
| **7. DECISIONS AND JUDGEMENTS**   * Responsible for administration of own workload to ensure that departmental workflow is maintained. * Responding appropriately and effectively to the daily requirements of the Clinical Trials unit. * Works within established procedures defined within standard operational procedures. * Ensures accuracy of documentation received and reporting of any discrepancy. | |
| **8. COMMUNICATIONS AND RELATIONSHIPS**   * Clinical Trials Pharmacists, Clinical Trial Co-ordinator, Clinical Trials support worker * Other Pharmacists, Technicians and Assistants within the Pharmacy Department * NHS ward and departmental staff (e.g research nurses, doctors, administration staff, research and development (R&D) personnel) * Pharmaceutical company CRA’s and trial monitors, Trial managers | |
| **9. PHYSICAL DEMANDS OF THE JOB**   * Prolonged use of computer terminals under artificial lighting * Lengthy periods of time spent sitting in one position / area at computer terminal * Working in an environment lacking natural daylight and fresh air * Prolonged periods of concentration when checking documentation * Ensuring accurate and efficient processing of fine print documents * Frequent light physical effort over sustained periods is required and also occasional heavy lifting   (up to 12kg) | |
| **10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB**   * Responding appropriately to un-planned, urgent / emergency activities and requests from a range of pharmacy and healthcare professionals. * Understanding the need for constant vigilance, for accuracy and compliance with worksheets and tasks and checking own work thoroughly before involving others in final or in-process checks * Prioritising assigned tasks to ensure efficient, effective and safe work practices * Dealing with queries from pharmacy and other healthcare staff, and trial Sponsor/monitor * Awareness of the requirements for patient and data confidentiality | |
| **11. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB**   * Training to GPhC support staff approved levels with entry into SVQ level 2, Pharmacy Services   accredited training - essential   * SVQ in Administration or equivalent * Experience of working to written operating procedures * Recognised basic literacy and numeracy skills * Ability to use initiative within pre-set boundaries * Good communication and interpersonal skills * Ability to work on own, and as part of a small team * Accurate and methodical in approach to work tasks * In-house training on work processes, documentation and working within controlled environments * Specific information on Clinical Trials - desirable * Intermediate level I.T experience * Familiarity with standard Microsoft Office packages, Word & Excel * Advanced keyboard and basic computer skills * Operational knowledge of the pharmacy stores computer system (CMM v.8) – desirable, but training can be provided * Certificate of training in Good Clinical Practice (GCP) This can be undertaken once in post * Individual study specific training as designated by the study CRA/Trial manager | |

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|  | **NHS GRAMPIAN**  **PERSON SPECIFICATION** | |
| The Person Specification should meet the demands of the job and comply with current legislation. Setting unnecessary standards may, for example, unfairly discriminate against one sex, the disabled or minority racial groups. Applicants should be assessed in relation to their ability to meet the real requirements of the job as laid down in the job description. Shortlisted candidates **MUST** possess all the essential components as detailed below. | |

# POST/GRADE: Clinical Trials Support Worker (Band 3)

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| **ATTRIBUTES** | **ESSENTIAL** | **DESIRABLE** |
| **Qualifications** | **SVQ level 2 in Administration/I.T or equivalent, or willing to train to this qualification. Willing to train to SVQ level 2 in Pharmacy** | **SVQ Level 2 in Pharmacy**  **Good Clinical Practice certificate** |
| **Experience** | **General appreciation of how hospitals work**  **Previous experience working in an office**  **Good organisational and administration skills.** | **Experience of working as part of a team.**  **Previous pharmacy experience.** |
| **Special aptitudes and Abilities** | **Good written/oral communication skills**  **Good time management skills**  **Ability to plan, prioritise and organise** | **Accurate data input skills** |
| **Disposition** | **Well presented**  **Confident personality**  **Good team worker** | **General interest in Pharmacy** |
| **Physical requirements** | **General good health**  **Meets Trust standards for absence**  **Ability to work under pressure** |  |
| **Particular requirements of the post** | **Self motivated. Able to work as part of a team.**  **The ability to handle sensitive, confidential information and diplomacy** |  |

**LOCATION/HOSPITALS: Based at Aberdeen Royal Infirmary**

**WARD/DEPARTMENT: Pharmacy Department**

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| **MAJOR RISKS IN DOING THIS JOB** |
| *Please indicate the major risks the job holder could face in doing this job e.g. lifting patients/objects, working with hazardous substances, dealing with violence and aggression..*  Handling of Investigational medicines, including hazardous substances eg Cytotoxic agents. Occasional lifting of heavy objects. Long periods of use of computer screen/laptop. |