

| Job Title: Clinical Trials Pharmacist | <b>Position Type:</b> Part-time / Full-time – Bank /<br>Fixed-term / Permanent |
|---------------------------------------|--|
| Job Code: ACR-CTPh-0001               | <b>Professional Accountability:</b> Chief Operating Officer                    |

| Company<br>Background | Ascend Clinical Research (ACR) is a clinical trials Site Management Organisation (SMO) offering innovative, agile and high impact solutions in clinical trial delivery, patient recruitment, and professional development of the clinical research workforce. Our organisation specialises in the delivery of multi therapy trials on investigator site level from set up to close out for Phase 2- 4 trials with quality and excellence at its core, as well as local and international partnerships for clinical research workforce training programmes. We place the patient at the core of our service; and actively promote diversity and inclusivity in our patient - centred processes. We are guided by our values of integrity, efficiency, commitment, and safety in practice with our organisational undertakings and stakeholder relations.   |
|-----------------------|---|
| Role Overview         | The post holder will be expected to work closely with the other members of the team to ensure efficient set-up and maintenance of clinical trials and Investigational Medicinal Product (IMP) management, in accordance with the International Conference on Harmonisation Good Clinical Practice (ICH-GCP). The post holder will be a flexible, motivated team player and will develop a good understanding of clinical trials and the legislation applicable to running clinical trials. The work requires initiative, accuracy, high attention to detail at all times, and excellent time management. The post holder will be required to communicate with a broad professional group including clinical staff, as well as members of the public and research sponsors (and CRO). The post holder will be expected to represent ACR. All work will be carried out in accordance with the EU Directive, ICH-GCP, Research Governance and local Standard Operating Procedures and Policies. The post holder will be based at ACR site. |



| Main duties and  |   |
|------------------|---|
| responsibilities | Provide pharmaceutical advice to ACR staff which require pharmaceutical   |
|                  | <ul> <li>Provide pharmaceuticat advice to ACK stant which require pharmaceuticat<br/>resources and dispensing activity</li> </ul>         |
|                  | • To write and update the ACR dispensing standard operating procedures for  |
|                  | clinical trials in accordance with the clinical trial protocols, good clinical  |
|                  | practice, European Clinical Trials Directive and any other relevant legislation and guidance  |
|                  | <ul> <li>To design pre-printed clinical trial prescriptions or set-up treatment on<br/>prescribing system when appropriate</li> </ul>     |
|                  |   |
|                  | • To supervise or perform the clinical check of clinical trial prescriptions  |
|                  | • To liaise with clinical trial representatives of the pharmaceutical industry,   |
|                  | ACR clinical team to ensure that all trials are conducted appropriately and   |
|                  | comply with ICH Good Clinical Practice, European Clinical Trials Directive, legal and local requirements                                  |
|                  | <ul> <li>To calculate overall pharmacy trial fees for the non-aseptic aspects of</li> </ul>   |
|                  | pharmacy dispensing & administration for new and on-going clinical trials   |
|                  | and ensure that the appropriate revenue is raised.  |
|                  | <ul> <li>To attend ACR meetings to give pharmaceutical input into proposed trials, to</li> </ul>  |
|                  |   |
|                  | determine the potential impact on pharmacy workload and give appropriate  |
|                  | timescales for trial initiation after pharmacy requirements have been<br>completed  |
|                  | Provide information and advice to senior leadership team on the potential   |
|                  | clinical and cost implications of clinical trials and the impact after the trials   |
|                  | have been completed; to enable timely and appropriate information is given  |
|                  | to the leadership team, Medicines Advisory Group, regulatory and the Local  |
|                  | Research and Ethics Committee as appropriate  |
|                  |   |
|                  | To attend clinical trials meetings and implement and contribute to the future     planning and dovelopment of the clinical trials carvies |
|                  | planning and development of the clinical trials service   |
|                  | <ul> <li>To attend ACR and external meetings and study days concerned with clinical<br/>trials</li> </ul>                                 |
|                  | <ul> <li>To complete Pharmacy assurance reviews according to HRA guidance and in</li> </ul>   |
|                  | line with timelines indicated by either the HRA (for HRA-managed reviews) or  |
|                  | the Sponsor (for self-managed reviews).   |
|                  | <ul> <li>To support the application and management of Home Office Licenses for</li> </ul>   |
|                  | <ul> <li>To support the application and management of Home Office Licenses for<br/>clinical trials required to have approval</li> </ul>   |
|                  |   |
|                  | General Clinical Practice   |
|                  | • To be accountable for own professional actions, guided by local, national   |
|                  | and professional protocols and legal framework  |



|                    | To maintain current awareness and undertake continuing professional   |
|--------------------|---|
|                    | development to ensure the maintenance of clinical and professional  |
|                    | competency  |
|                    | <ul> <li>Advises and educates Clinical team on IMP management.</li> </ul>   |
|                    | • Advises other health care professionals on the safe, appropriate and cost-  |
|                    | effective use of medicines  |
|                    | • To provide clinical trial related education and training for clinical team,   |
|                    | technicians, and assistants (as appropriate)  |
|                    |   |
|                    | General Pharmacy Role   |
|                    | Provide support to and develop the clinical trials team by providing  |
|                    | pharmaceutical support and advice for all trials that require the dispensing  |
|                    | of medicinal products.  |
|                    | <ul> <li>Participation in weekend, bank holiday, late working and emergency duty in</li> </ul>  |
|                    | agreement with the leadership team  |
|                    |   |
|                    | • To dispense and discharge medication, and final check dispensed products  |
|                    | as needed by the service and to maintain professional competence.   |
|                    | • To be able to utilise all ACR Information Technology systems as are   |
|                    | necessary to complete tasks.  |
|                    | • Follow safe lifting and handling techniques. Be aware of health and safety  |
|                    | issues pertaining to the pharmacy area and ensure the appropriate use of  |
|                    | ACR equipment.  |
|                    | • To ensure adequate medicine stock control procedures are enacted within   |
|                    | the pharmacy dispensary with particular regard to clinical trial supplies   |
|                    | • The post holder is required to comply with all ACR policies and SOPs  |
|                    |   |
| Requirements:      | Knowledge and Experience  |
| Personal Profile – | Evidence of post-registration clinical or technical pharmacy experience (E)   |
|                    | <ul> <li>Previous experience of dispensing clinical trials and clinical trial protocols (D)</li> <li>Technical uniting (c. p. unidaling an atom dead an anting and a starting and</li></ul> |
| (E) = Essential    | <ul> <li>Technical writing (e.g. guidelines or standard operating procedures) (D)</li> <li>Previous research experience (D)</li> </ul>  |
| (D) = Desirable    | <ul> <li>Teaching, one-to-one or group (D)</li> </ul>   |
|                    | Home Office License application (D)   |
|                    |   |
|                    | Aptitudes   |
|                    | Articulate and confident (E)  |
|                    | Able to work alone and as a member of a multidisciplinary team (E)  |
|                    | • Self-motivated (E)  |
|                    | <ul> <li>Flexible and adaptive approach (E)</li> <li>Evaluate attention to detail (E)</li> </ul>  |
|                    | <ul> <li>Excellent attention to detail (E)</li> <li>Detioned and anthusiasm for working with people (E)</li> </ul>  |
|                    | <ul> <li>Patience and enthusiasm for working with people (E)</li> <li>Innovative (D)</li> </ul>   |
|                    | <ul> <li>Innovative (D)</li> <li>Organised approach (E)</li> </ul>  |
|                    | <ul> <li>Organised approach (E)</li> <li>Positive approach to change (D)</li> </ul>   |
|                    | Positive approach to change (D)   |



|               | Committed to providing a high-quality pharmacy service (E)   |  |
|---------------|--|--|
|               | Skills and Abilities   |  |
|               | Excellent oral and written communication skills (E)  |  |
|               | <ul> <li>Knowledge of Good Manufacturing Practice, current standards in aseptic</li> </ul>   |  |
|               | preparation services and professional standards (D)  |  |
|               | <ul> <li>Good interpersonal skills (E)</li> </ul>  |  |
|               | <ul> <li>Problem identification and solving (E)</li> </ul>   |  |
|               | Evidence of ability to complete work on time (E)   |  |
|               | Personal time management (E)   |  |
|               | <ul> <li>Research skills (D)</li> <li>Evidence of continuing professional development (Ε)</li> </ul>   |  |
|               | <ul> <li>Evidence of continuing professional development (E)</li> <li>Ability to use judgement to challenge inappropriate prescribing and</li> </ul> |  |
|               | influence prescribing decisions to enable optimal therapy (E)  |  |
|               | <ul> <li>Knowledge of the legal framework for the conduction of clinical trials and</li> </ul>   |  |
|               | the dispensing, prescribing and administration of medicines (E)  |  |
|               | Understanding of medical and nursing practice, record keeping and  |  |
|               | terminology (E)  |  |
|               | <ul> <li>Computer literate e.g. word processing, use of spread sheets and</li> </ul>   |  |
|               | presentations (E)  |  |
|               | Qualifications and Training  |  |
|               | Professional registration with General Pharmaceutical Council (E)  |  |
|               | Membership of the Royal Pharmaceutical Society of Great Britain (D)  |  |
|               | Postgraduate certificate in Clinical or Technical pharmacy (or equivalent) (D)   |  |
|               | <ul> <li>Postgraduate diploma in Clinical or Technical Pharmacy Practice (D)</li> <li>Up to date GCP training (D)</li> </ul>                         |  |
|               |  |  |
| Location &    | <ul> <li>Will be assigned in 4B Vulcan House, Calleva Park, Aldermaston, Reading, UK<br/>RG7 8PA</li> </ul>  |  |
| Working hours |  |  |
|               | • Working hours Monday to Friday (with potential "out of hours" as per business  |  |
|               | needs)   |  |
| Compensation  | <ul> <li>Competitive salary package plus performance incentives</li> </ul>   |  |
| •             |  |  |
|               |  |  |