SCREENING PHYSICIAN, MEDICAL DPEARTMENT

MERTHYR TYDFIL/CARDIFF

PART 1 – CANDIDATE PROFILE

You are an experienced Physician with a strong background in General Medicine or Emergency Medicine with an interest in drug development and are seeking a challenging and rewarding role in a busy Phase I Clinical Pharmacology Unit.

You will be joining a team of select industry professionals ensuring that trials are performed to acceptable medical and scientific standards, meeting the requirements of the sponsor and the business and in accordance with prevailing regulatory guidelines.

You will be responsible for ensuring that each subject is fully aware of the trial that they will be participating in and obtain their written consent. You will be expected to screen healthy volunteers and patients according to study specific inclusion and exclusion criteria as per study protocols as well as perform general screening, monitoring and post study clinical examinations for all studies running in the Simbec Clinical Pharmacology Unit. You will also be responsible for the review of ECGs and Vital signs and timely evaluation of laboratory test results as well as for the reporting and discussion of any clinical significant abnormal results and/or changes from base line, taking action where required.

You will have the competence to evaluate each subject's eligibility for inclusion into specific studies in accordance with information contained in the Investigator's Brochure, Protocol and Informed Consent documentation.

You are resilient, highly efficient and should feel comfortable working in a fast paced clinical research environment. You are able to work to strict timelines and ensure your work is conducted to the highest standards. You are a strong team leader and understand the need for effective communication and relationship building at all levels.

Training will be provided and supervision will be in place.

You will be based at the Research Campus in Merthyr Tydfil (where the Group's Phase I unit, Simbec Research, and many of the Group's central and administrative departments are located) or the Simbec Cardiff Screening Centre.

PART 2 – EXPERIENCE, QUALIFICATIONS AND COMPETENCIES

QUALIFICATION Required	Desired	Measured
Medical Degree		Certificate
GMC Registered with a License to Practice		Certificate / GMC Website
ALS Certification		Certificate
EXPERIENCE **Required**	**Desired**	**Measured**
If Qualified before 2005: 2 years post-registration experience - involving direct patient care and experience of prescribing and monitoring the effects of drugs.		CV/Interview
If Qualified after 2005: 2 years clinical experience post-Foundation (or equivalent) in approved training posts or evidence of close involvement on a regular basis with the management of patients through multi-disciplinary team meetings		CV/Interview
	Previous CRO experience	CV/Interview
COMPETENCE **Required**	**Desired**	**Measured**
Excellent organization and time management skills. Ability to effectively manage any changes to priorities/deadlines		Interview
Attention to detail and high quality standards		Covering letter/CV/Interview
Responsive and proactive		Interview
Resilient. Ability to keep functioning effectively and respond constructively in a fast paced environment or in response to challenges arising		Interview
Logical and analytical thinker, with good problem solving skills		Interview
English Language – fluent, written & spoken		Covering letter/CV/Interview
Proven ability to work effectively in a team environment/independently as required		CV/Interview
Flexibility and adaptability to meet the changing needs of the business		CV/Interview
Professional communication with colleagues, volunteers and third parties that adapts to your audience		Covering letter/CV/Interview
Strong computer skills including but not limited to the knowledge of a Clinical Trial Management System (CTMS), Electronic Document Management System (EDMS), and MS-Office products such as Excel and Word.		CV/Interview

PART 3 – JOB DESCRIPTION

JOB TITLE	Screening Physician
ROLE HOLDER	
DEPARTMENT	Medical
DIVISION	Simbec Research
LOCATION	Merthyr Tydfil/Cardiff, UK
CONTRACT TYPE	***Need 37.5hrs, but can be job share***
REPORTING TO	Medical Director
DIRECT REPORTS	NA
INDIRECT REPORTS	NA

ROLE HOLDER		Date:
LINE MANAGER		Date:
NEXT REVIEW DATE		

JOB PURPOSE
• To medically screen and supervise research on healthy volunteers and patients for all trials undertaken by Simbec Research Ltd • To ensure that trials and projects are performed to acceptable medical, scientific and ethical standards and meet the requirements of Regulatory Requirements

PRINICPAL DUTIES	
1.	Fully explain each study and obtain written informed consent from trial subjects.
2.	To perform general and study specific screening, monitoring and post study clinical examinations.
3.	Review and evaluate in appropriate and timely fashion Vital Signs, ECGs and Laboratory test results etc. for all studies.
4.	Report and discuss any clinically significant abnormal result and/or changes from baseline and action taken to the designated Study Principal Investigator and / or Medical Director.
5.	Evaluate subject's eligibility for inclusion in a specific study according to the information contained in the Investigator Brochure, Protocol and Informed Consent Document.
6.	Ensure communication with volunteers' General Practitioners regarding their participation in a study, collaborative care and follow-up.
7.	To monitor, assess and record any adverse events and in conjunction with the designated Principal Investigator and/or Study Physician and decide on the medical management of clinically significant events.
8.	Timely review of protocols and subject information as needed, preparation of study specific training slides,
9.	Act as Sub-Investigator, study physician for designated studies ensuring adequate continuity of care of trial subjects throughout study.

PART 4 – BACKGROUND TO SIMBEC-ORION GROUP

Simbec-Orion Group Limited ("Simbec-Orion" or the "Group") was created in June 2014 by the merger of Simbec Research Limited ("Simbec") and Orion Clinical Services Limited ("Orion").

As a result of the merger, Simbec-Orion is today a full service CRO covering first in human Phase I clinical studies through to pivotal Phase III studies and Phase IV post marketing studies. Simbec-Orion supports its clients with our own in-house full service central laboratories (branded as Seirian Laboratories) pharmacovigilance, data management and statistics, IMP management/pharmacy, medical management. We have expertise in all drug types, dosage forms and delivery mechanisms and in later stage development and have six core therapeutic disciplines:

- oncology,
- rare and orphan diseases,
- respiratory disorders,
- dermatology,
- infectious disease & vaccines, and
- translational medicine.

We operate internationally serving clients anywhere in the world with physical operations in the United Kingdom, France, Germany, Italy, Spain, Czech Republic, Poland, Australia, South Africa and the United States of America. We have a combined staff approaching 250 people with the greatest concentrations in the UK and France.

It is our objective to become widely recognised as being a significant international full service CRO known for its excellence both across its range of services and in its therapeutic disciplines. We compete effectively against many of our larger competitors by offering a broader range of services and with greater depth of knowledge in our chosen therapeutic areas.

Given the background of a number of our senior leadership team, we think with the same focus as our clients - as drug developers and not simply as outsource service providers. Our goal is to meet their actual needs and not simply execute a study.