PART 1 – Medical Monitor

Simbec-Orion Group, the new group created by the merger of two established CROs, is looking for a Medical Monitor to join their medical department.

You will be joining a team of select industry professionals ensuring that trials and projects 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 initially work under the supervision of senior medical colleagues, and you will acquire increasing independence, responsibility and accountability as you demonstrate knowledge, ability and skills.

Working as part of a team, the role of the Medical Monitor involves the oversight of clinical trials, ensuring that high quality data is collected and provided to our clients. Depending upon the specific requirements of the assigned projects, the successful candidate’s responsibilities may include the evaluation of subject’s eligibility for inclusion into specific studies. You will be called upon to discuss study issues with either Sponsors or clinical investigators. You will be required to monitor the data of a study (including safety events), participate in review meetings or provide reports regarding the conduct of a study. You will take appropriate action in the event of any abnormal findings. In addition, you may be required to participate in Business Development activities as well as other activities related to other departments within the company (including post-marketing pharmacovigilance projects).

The successful candidates will have a medical degree and be GMC registered with a license to practice. A postgraduate qualification or the pursuit/completion of Diploma of Pharmaceutical Medicine/Postgraduate Medical Specialist Training in Pharmaceutical Medicine is desirable.

The successful candidate should feel comfortable working in a fast paced, hands-on, growth-orientated work environment.

The candidate must be able to relate well with people at all levels and have the flexibility to work well as part of a team or individually. The right person will develop relationships with many people within the organisation and with clinical/non-clinical experts and Sponsors.

The candidate should be looking for a challenging role, which will make a major contribution to a company that is gearing itself for significant growth.
## PART 2 – EXPERIENCE, QUALIFICATIONS AND ATTRIBUTES

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<tr>
<th>Qualification Required</th>
<th>Desired</th>
<th>Measured</th>
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<tr>
<td>• Medical degree</td>
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<td>CV</td>
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<td>• GMC Registered and licensed to practice</td>
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<td>CV</td>
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<th>Experience Required</th>
<th>Desired</th>
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<td>• Minimum of 1 year post-registration (if Foundation training was completed) in a UK medical facility.</td>
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<td>CV / Interview</td>
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<td>• Minimum of 2 years’ experience post-registration.</td>
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<th>Competence Required</th>
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<td>• Excellent written and verbal communication skills</td>
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<td>Interview</td>
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<td>• English Language</td>
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<td>• Formal presentation skills</td>
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<td>• Organisation and planning</td>
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<td>• Problem analysis and problem-solving</td>
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<td>• Adaptability</td>
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<td>• Judgment</td>
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<td>• Decision-making</td>
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<td>• Effective team work</td>
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<td>Interview</td>
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<tr>
<td>• English Language • Additional European Language</td>
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<td>Interview</td>
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PART 3 – JOB DESCRIPTION – Medical Monitor

JOB TITLE Medical Monitor

ROLE HOLDER

DEPARTMENT Medical

DIVISION Orion Clinical

LOCATION Slough, UK

CONTRACT TYPE Permanent Full time (1.0) FTE

REPORTING TO Medical Director

DIRECT REPORTS None

INDIRECT REPORTS None

ROLE HOLDER

Signature

Date:

LINE MANAGER

Signature

Date:

NEXT REVIEW DATE


JOB PURPOSE

The purpose of this position is to support the oversight of clinical trials, ensuring that high quality data is collected and provided to our clients. This position will involve a variety of tasks ensuring the safe conduct of the study as well as demonstrating Simbec-Orion’s excellence by interacting with Sponsors and Clinical Investigators in an effective and problem-solving way. By exhibiting a high level of medical expertise, this position will also have involvement in some Business Development activities as well as other activities related to other departments within the company (including post-marketing pharmacovigilance projects).

PRINCIPAL DUTIES

1. Exhibits and transmits the highest ethical standards in the management of clinical trial programs and client liaison.

2. Provides medical support to the project teams.

3. Participates in all stages of the clinical trial set-up process including: feasibility assessment; protocol design; CRF design; investigational site selection.

4. Acts as Medical Monitor / Advisor for assigned trials or programmes.

5. Takes responsibility and supports PV in particular steps of case processing (Serious/Adverse Event reports, reviewing or performing quality check of data entry of reports in the safety database; abides the deadlines for expedited submissions; codes according to coding dictionaries; communicates with study team and competent authorities as required)

6. Takes responsibility for and initiates the medical input into and review of: protocols; CRFs; adverse events; clinical study reports; data management and statistical tables and listings; audit reports; clinical study reports.

7. Maintains knowledge of relevant laws, directives, regulations and guidelines and disseminates same to clinical project teams (including global pharmacovigilance framework)

8. Researches and prepares training on therapeutic areas and indications of relevance to Orion and external study team as appropriate. Maintains an awareness of trends and changes of importance in management of those indications.

9. Initiates and maintains interactions with key opinion leaders and investigators in therapeutic areas of interest to Orion.

10. Works on Business Development activities as required
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.