Job Profile – Clinical Trials Administrator (CTA)

PART I - PROFILE

You are an experienced CTA with a good background in Clinical Research who is passionate about drug development and are seeking a challenging and rewarding career in a quality focussed role, looking to move into the challenge of complex and/or orphan indications in addition to working with Sponsors from Biotech and smaller Pharma Companies or start-up ventures.

We are differentiated in our market as an international, truly full service CRO, focussed on a series of core therapeutic disciplines. Simbec-Orion Group is an ambitious organisation with challenging growth targets both organically and through acquisition. You will support the clinical project team in the following areas: update and maintain clinical systems within project timelines; prepare, handle, distribute, file, and archive clinical documentation and reports; review of study files periodically for accuracy and completeness; prepare, handle and distribute Clinical Trial Supplies and maintain tracking information. Perform administrative tasks to support team members with clinical trial conduct, as needed.

You will hold a minimum of a Diploma/A Levels from Secondary/High School education. Graduate, 4 year college degree or equivalent ideally in science/laboratory background would be preferable. You will have excellent communication and time management skills to manage multiple projects at any one time.

You are a strong team member and understand the need for effective communication at all levels. You will have a demonstrable record for effective relationship building with sponsors, sites and colleagues, as well as strong organisational skills.
PART 2 – EXPERIENCE, QUALIFICATIONS AND ATTRIBUTES

The candidate will have:

• A minimum of a Diploma/A Levels from Secondary/High School education required or equivalent.
• Graduate, 4 year college degree or equivalent ideally in science/laboratory background preferable.
• To demonstrate some previous clinical research experience in a CRO or pharmaceutical environment or similar transferable knowledge.
• May have significant transferable clinical research experience.
• May have significant transferable administrative experience.
• Good computer skills, including word processing and spreadsheets.

PART 3 – JOB DESCRIPTION - JOB FUNCTION

1. Job Summary
• Provides administrative support to the project teams in clinical operations in accordance with ICH GCP, Orion SOPs and local regulations.
• Ensures clinical trial administration is performed such that the subjects’ rights, safety and well being are protected and that the clinical trial data are reliable.

2. Main Job Duties and Responsibilities
• Serves as a member of the project team with the goal to contribute towards efficient management of clinical trials.
• Manages inventories for clinical trials supplies (consisting of laboratory kits, investigational product where applicable, and other supplies), including the tracking and shipment of materials.
• Assists the project team with preparation and shipment of Clinical Trial documentation including: Operating Manual, Investigator Site File, Pharmacy File, Investigator Brochure and Protocol.
• Develops and maintains the study specific investigator database.
• Updates and maintains study tracking systems in accordance with the demands of the study e.g. investigational product tracking, payment tracking, CRF tracking, patient tracking, etc.
• Facilitates the study documents printing process
• Facilitates communication with the sponsor by shipping required documents and packages to sponsors as per project requirements.
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• Assists project managers in the production of study reports and updates.

• Serves as an office based point of contact for all sites during the course of the study in addition to providing phone coverage for travelling team members.

• Prepares investigator budget payments and distributes to investigative sites.

• Develops and maintains good working relationship with investigators and study staff, serving as an ambassador to promote Orion’s high quality and ethical image.

• Facilitates project meetings with respect to the preparation and distribution of materials and final meeting minutes, as well as the coordination of participants.

• Assists with corporate administration activities according to need and availability.

• Sets up and maintains the Trial Master File (TMF) in compliance with ICH GCP and Orion SOPs and as per the Project Manager/Sponsor instructions.

• Allocates space within the TMF room/area for all new Trials ensuring that the TMF index is kept up to date.

• Creates TMF folders as per the Project Manager’s instructions

• Liaises with all Orion departments/affiliates ensuring that all study documentation is filed appropriately.

• Completes the Essential Document Tracker in a timely manner ensuring documents are filed within the TMF upon receipt.

• Prepares the TMF for return to sponsor.

• Prepares the TMF for Orion archive as required.

• Maintains the TMF room/area.

• Performs other duties as assigned by management.
PART 4 – BACKGROUND TO SIMBEC-ORION

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, 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.

Our growth targets aim to see the Group grow from its current size of approximately revenues of £25m ($37m) per annum to £100m ($150m). This will be achieved in part by organic growth but also through further M&A activity.