PART I - JOB PROFILE – Technical Writer II, Regulatory Affairs & Technical Writing

Simbec-Orion Group is looking for a Technical Writer II to join the rapidly expanding Regulatory Affair & Technical Writing Team. For this role, you require experience in medical writing and clinical trials either in a clinical research organisation (CRO) or pharmaceutical or biotechnology company. You will be seeking a challenging and rewarding career in a friendly, fast paced and exciting environment.

Simbec-Orion Group is an ambitious organisation with challenging growth targets both organically and through acquisition. We are differentiated in our market as an international, truly full service CRO, focused on a series of core therapeutic disciplines.

As Technical Writer II, you will be expected to author and review Technical Writing and Regulatory documents for Simbec-Orion projects, with the main focus on clinical study reports (CSRs) and clinical study protocols of studies that cover a wide range of therapeutic indications. You will need to ensure that these documents comply with the latest ICH and industry guidelines. You will be responsible for ensuring that finalisation of these documents occur in a timely manner and ensuring that the client and management are kept fully informed of all aspects of the deliverables.

You require a degree in life sciences or equivalent, in a scientific or healthcare discipline and should have a proven track record of experience within regulatory medical writing or other transferable clinical research experience. You will need excellent communication and time management skills to manage multiple project deliverables at any one time.

As Technical Writer II you will collaborate with internal and sponsor team members to interpret, distil and summarize complex data concepts. You should be confident in authoring CSRs or similar clinical trial documentation and familiar with clinical trial methodology, statistical principles / concepts used in clinical research, experience in interpretation of statistical analysis. The successful candidate will be focused on delivering quality work, with excellent grammatical, editorial and proofreading skills.

PART 2 – EXPERIENCE, QUALIFICATIONS AND ATTRIBUTES

Profile of Preferred Candidate	Essential Requirements	Desired	CV / Testing / Interview
Education	• A scientific degree (BSc level)	• Upper second class and higher	CV
Experience	• A minimum of 1 year to 3 years medical/regulatory/publication writing field in the pharmaceutical/biotech industry or CRO environment • Experience with authoring CSRs • Experience in creating, managing, authoring and editing clinical protocols and/or other types of clinical documents	• A minimum 3 years' experience either in CRO or pharmaceutical company	CV / Interview
Key Skills	• Familiar with clinical trial methodology, statistical principles / concepts used in clinical research, experience in interpretation of statistical analysis • Excellent grammatical, editorial and proof-reading skills. Consistently demonstrates ability to produce quality work. • Analytical skills, including analyses and problem solving. Ensures work produced is technically accurate, clear and appropriate. • Effective time management of deliverables, flexibility, the ability to multitask and creating solutions. • Strong computer skills and general computer literacy	• Demonstrates a thorough understanding of ICH-GCP	Interview
Key Attributes	• Professionalism • Energetic • Motivated • Self-starter • Ability to work independently and as part of a team • Strong attention to detail	• Quick learner	Interview
Language	• English	• Any other European Language	Interview

PART 3 – JOB DESCRIPTION - JOB FUNCTION

JOB TITLE	Technical Writer II
ROLE HOLDER	[state role holder's name (including known as if appt)]
DEPARTMENT	Regulatory Affairs & Technical Writing
DIVISION	Orion Clinical
LOCATION	Based in Slough
CONTRACT TYPE	Permanent Full Time
REPORTING TO	Technical Writing Manager or Director of Regulatory Affairs & Technical Writing
DIRECT REPORTS	Not Applicable
INDIRECT REPORTS	Not Applicable

ROLE HOLDER		Date:
LINE MANAGER		Date:
NEXT REVIEW DATE		

JOB PURPOSE
You will prepare Technical Writing and Regulatory documents for Simbec-Orion projects, with the main focus on clinical study reports (CSRs) and clinical study protocols of studies that covers a wide range of therapeutic indications, whilst ensuring compliance to ICH-GCP and other industry regulations and abiding to Standard Operating Procedures (SOPs). Your responsibilities include providing support and assistance with other Technical Writing and Regulatory documents.

PRINICPAL DUTIES
1. To produce Technical Writing and Regulatory documents, mainly clinical study reports (CSRs) and clinical study protocols
2. To assist in writing and production of other Technical Writing and Regulatory documents (e.g., patient narratives, case record forms (CRFs), Investigator Brochures (IBs) and other supportive clinical development documentation)
3. Editing and formatting of Technical Writing and Regulatory documents, including CSRs, CSR appendices, protocols and other supportive clinical development documentation
4. Quality control (QC) and review of Technical Writing and Regulatory documents (e.g., CSRs)
5. Liaise with the project team to source appropriate data, information and documentation to fulfil requirements of the allocated TW task
6. Adhere to set timelines of the allocated TW task
7. Adhere to budget requirements of the allocated TW task
8. Compliance to ICH-GCP and Industry guidelines, as well as Simbec-Orion SOPs
9. Use appropriate IT and software tools to ensure the correct format and presentation of documents

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.