Role Profile- Senior Pharmacovigilance Executive

PART I

You are an experienced Pharmacovigilance Executive with a strong background in Pharmacovigilance who is passionate about the safety in drug development / post-marketing use and seeking a challenging and rewarding career.

We are an ambitious organisation, expanding our international, full service, boutique CRO; growing by bringing together the best possible people, healthcare professionals and drug developers from all areas of clinical development. Orion Clinical is the full-service clinical development division of Simbec-Orion Group.

Simbec-Orion Group, the new brand created by the merger of two established CROs, is looking for a Senior Pharmacovigilance (PV) Executive, Orion Clinical/Pharmacovigilance in the United Kingdom to join the rapidly expanding Pharmacovigilance Team in Slough. Reporting into the Pharmacovigilance (PV) Manager, this is an important role in the growth of Simbec-Orion Group.

You will hold a degree in life sciences, ideally a graduate, postgraduate, 4-year college degree, or equivalent, ideally in a scientific or healthcare discipline and you will have a proven track record in Pharmacovigilance. You will also have 4 years or more experience in the CRO or pharmaceutical industry including 3 years or more pharmacovigilance experience. 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 and colleagues.

You are confident in presenting to colleagues and sponsors with high standards for the quality of material presented.

PART 2 – EXPERIENCE, QUALIFICATIONS AND ATTRIBUTES

Profile of Preferred Candidate	Essential Requirements	Desired	CV / Testing / Interview
Education	• Graduate, postgraduate, 4-year college degree, or equivalent, in a scientific or healthcare discipline.	• Project Management Certification • Certification/Specialization in Clinical Research	CV
Experience	• 4 years or more experience in the CRO or pharmaceutical industry including 3 years or more pharmacovigilance experience. • Proven record of involvement in training, mentoring and team work. • Awareness of global regulatory environment. • Awareness of pharmacovigilance environment. • Experience in Aggregate Reports (DSUR/PSUR)	• Experience in broad range of therapeutic areas • Experience in team and process set-up	CV / Interview
Key Skills	• Clinical and Post-marketing pharmacovigilance management • Established experience in Aggregate Reports (DSUR/PSUR) • Regulatory intelligence • Audit/regulatory inspections • Train, coach and mentor other members of staff. • Client relationship management • Devising and establishing processes and procedures. • Experience with ARGUS or ARISg	• Knowledge of QPPV tasks like RMP, SDEA, SPC updates, PSMF etc. • Quality and compliance management • Experience clinical database	CV/Interview
Key Attributes	• Energetic • Strong attention to detail • Strong interpersonal skills • Proactive • Excellent planning and problem solving skills • Confidence and influencing • Logical thinking, accurate and analytical • Ability to work independently and as part of a team • Passion • Self-starter • Ability to coach/mentor others	• Commercially astute • Customer focused and service orientated • Ability to work through change	Interview
Language	• English	• English	Interview

PART 3 – JOB DESCRIPTION - JOB FUNCTION

JOB TITLE	Senior Pharmacovigilance Executive/Senior PV Executive
ROLE HOLDER	
DEPARTMENT	Pharmacovigilance
DIVISION	Orion Clinical
LOCATION	Slough, UK
CONTRACT TYPE	Permanent Full time
REPORTING TO	Pharmacovigilance Manager
DIRECT REPORTS	Not Applicable
INDIRECT REPORTS	Not Applicable

ROLE HOLDER		Date:
LINE MANAGER		Date:
NEXT REVIEW DATE		

JOB PURPOSE
To perform the role of PV Project Lead on a range of studies/projects and ensure deliverables are maintained to a higher standard and in line with the contractual agreement; and carry out PV tasks on other studies/projects. Be involved in training PV Executives and mentor them. Work with the PV Manager to address any project concerns and assist the management team during audits and SOP generation.

PRINICPAL DUTIES
1. Serves as Pharmacovigilance (PV) Project Lead: a. Acts as primary point-of-contact for client for day-to-day operations. b. Writes Safety Management Plan, configure and validate safety database for specified projects, act as Responsible person for PV if required, add users and products within EudraVigilance, including review and updates to client products as required, prepare Serious Adverse Event Reporting forms, review study Protocols and Case Report Forms and maintains the safety section of the Trial Master File. c. Ensures all PV tasks as per the Orion-Client contract are carried out within the agreed/regulatory timelines. d. Primary person responsible for set-up, maintenance and close-out of project from PV. e. Liaises with client and other internal departments to address any concerns/issues and work diligently until resolution. f. Escalates concerns/issue to Orion PV Management team. g. Tracks and communicates regular invoice units to Finance team for on-time invoicing to the client. h. Identifies out-of-scope activities for assigned PV projects and liaise with PV Manager in order to initiate and process change orders.
2. Performs PV tasks: a. Receive, triage, data entry, event and drug coding, safety narrative, safety queries, quality check and reporting of ICSR/ESRs. b. Write Development Safety Update Report (DSUR)/Periodic Safety Update Report (PSUR) in collaboration with client and internal project stakeholders; and reports DSUR/PSUR to clients, regulatory authorities, ethics committees, investigators and project team personnel, as required, within agreed/regulatory timelines. c. Perform clinical and safety database reconciliation; and generate and shares monthly SAE line listings. d. Assist with or perform safety literature search and review.

e. Assist with or perform global regulatory and IRB intelligence. f. Assist with or perform post-marketing activities like Risk Management Plan (RMP), Pharmacovigilance Safety Master File (PSMF), Summary of Product Characteristics (SPC) updates, Signal detection, and writing/reviewing Safety Data Exchange Agreement (SDEA).
3. Meetings: a. Attends and represents PV department at Investigator meetings, including presentation of any PV listings. b. Attends client meetings, as appropriate. c. Attends project specific meetings with other internal departments.
4. Training: a. Train and mentor new employees, as required.
5. Assists with preparation and/or participates in client or regulatory authority audits.
5. Audits a. Represents PV department during for-cause/maintenance client audits or regulatory authority inspections. b. Represents PV department during pre-qualification client audits.
6. Assists with generation and review of departmental SOPs and Working Procedures.
7. Other responsibilities as assigned by the Management team.

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.

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. – remove if lower level role