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Job Description

Job Title:	**Part-time Senior Drug Safety Officer (Hybrid)**
Location:	**Abingdon, Oxfordshire**
Pay Range:	**Market Rate Pay – depending on experience and skills**

About Oxford Biotherapeutics:
Oxford BioTherapeutics (OBT) is a clinical-stage biotechnology company developing antibody therapeutics for the treatment of cancer. You will play an integral role in the pre-clinical development of novel immuno-oncology therapeutics. Our OGAP® platform is the world's largest, cancer specific, membrane protein library, directly measuring plasma membrane protein expression in patient tumors. OGAP is used to identify novel, highly tumor specific antigens for novel first-in-class ADC, Bispecific T-cell Engager (BITE®) and Chimeric Antigen Receptor (CAR) targets. Our lead asset, OBT076, is an Antibody Drug Conjugate (ADC) in Phase 1b clinical development. Our clinical and pre-clinical pipeline of novel biologics is balanced between internal programs, focused on ADCs and checkpoint regulators, and externally partnered programs with key innovators in oncology such as Boehringer Ingelheim, ImmunoGen and Genmab.

Purpose of the Role
This is a new part-time role, suitable for an experienced consultant or contractor, to lead and support the set-up and maintenance of the company's internal drug safety and pharmacovigilance system and processes.

Roles and Responsibilities:

- Support and authoring of drug safety related SOPs.
- Lead and manage drug safety and pharmacovigilance activities, ensuring compliance with relevant regulations, industry standards, and company policies.
- Oversee the collection, assessment, reporting, and follow-up of adverse event data from clinical trials and post-marketing surveillance, ensuring accurate and timely submissions to regulatory authorities.
- Develop and maintain Standard Operating Procedures (SOPs) and work instructions related to drug safety and pharmacovigilance processes.
- Collaborate with cross-functional teams, including clinical operations, medical affairs, regulatory affairs, and quality assurance, to ensure a proactive and integrated approach to drug safety.

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- Provide guidance and oversight for signal detection and risk management activities, including periodic safety update reports, risk management plans, and post-authorization safety studies.
- Serve as a subject matter expert on drug safety and pharmacovigilance, providing guidance and training to internal and external stakeholders as needed.
- Monitor and analyse drug safety data to identify trends, patterns, or signals that may warrant further investigation or action.
- Maintain current knowledge of relevant guidelines, regulations, and industry best practices related to drug safety and pharmacovigilance.
- Collaborate with the CRO to ensure seamless transition of drug safety services in-house, and manage ongoing relationships with external vendors as needed.
- Prepare and present drug safety and pharmacovigilance updates to senior management and other stakeholders, as needed.

Please note the roles and responsibilities for the position include but are not limited to the above.

Knowledge, Experience, and Skills:

- Bachelor's degree in a related field (e.g., pharmacy, nursing, life sciences) required; advanced degree (e.g., PharmD, MD, PhD) preferred.
- A minimum of 7 years of experience in drug safety/pharmacovigilance within the biotechnology or pharmaceutical industry.
- Demonstrated experience in drug safety/PV in oncology studies
- Demonstrated knowledge of global pharmacovigilance regulations and guidelines, including ICH, FDA, and EMA requirements.
- Experience with the collection, assessment, and reporting of adverse event data in clinical trials and post-marketing settings.
- Strong analytical and problem-solving skills, with the ability to identify trends and signals in complex data sets.
- Excellent written and verbal communication skills, with the ability to effectively convey complex information to diverse audiences.
- Detail-oriented, with strong organizational and project management skills.
- Ability to work independently and as part of a team, and to manage multiple priorities and deadlines.
- Familiarity with safety database systems and electronic data capture tools.

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Behaviours

- Team player
- A positive attitude
- Enthusiasm
- Self-motivated
- A flexibility and agile approach
- Readiness to learn new methods

Equal Opportunities Statement

We are committed to equality of opportunity for all employees and contractors. Applications from individuals are encouraged regardless of age, disability, sex, gender reassignment, sexual orientation, pregnancy and maternity, race, religion or belief and marriage and civil partnerships.

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