

Head Of Safety Pharmacology/Study Director

Our client is an independent and privately owned pre-clinical CRO specialising in safety and health research since for over 40 years. The services span toxicology, carcinogenicity, pharmacokinetics and safety pharmacology studies and they have conducted studies that have contributed to product registrations globally.

Their facilities, based near Normandy, are state of the art and studies are performed to meet national and international GLP guidelines, the facilities are accredited by the main regulatory authorities in Europe, the US and Japan.

Part of the business strategy is to deliver a superior service offering by employing the best people and investing in the right technologies allowing clients to get maximum results and return on there invest in the study. As the result of the continuing expansion they have created a position for a Head of Safety/Pharmacology Study Director.

The position reports directly to the Director of Toxicology and Operations

Essential duties and responsibilities

Essential duties as a Manager

- Manage a team of staff
- Supervise the quality of study plans
- Develop and manage the structures necessary for the performance of studies
- Develop and maintain a high level of communication with clients, in liaison with the General and Scientific Management
- Develop and maintain the scientific monitoring
- Assist the Study Directors and the Supervisors of the Safety Pharmacology Department.

Essential duties and responsibilities as Study Director in the Safety Pharmacology Department:

- Establish and write study plans, according to the Sponsor's requirements and in compliance with the different national and international regulations in force
- Supervise the writing and issuing of amendments to the study plans to ensure that the modifications made are justified
- Ensure the distribution of these documents (study plans and amendments) to the relevant persons
- Ensure that the members of staff are aware of and have in their possession the Standard Operating Procedures for the performance of each step of the study
- Ensure that the computerised systems used in the study have been validated
- Supervise the technical aspects of a study and ensure their implementation:
 - Ensure the study is performed to scientific and regulatory standards
 - Evaluate and interpret the effect on the quality and integrity of the study of each deviation from the study plan and Standard Operating Procedures
 - Undertake the necessary corrective procedures as appropriate
- Monitor the Quality Assurance Unit (QAU) receive in time the study plan and all amendments
- Communicate regularly and effectively with the Quality Assurance Unit for the advancement of the study during the course of the study
- Monitor all the data obtained are recorded, interpreted and confirmed by all the documents necessary
- Interpretation, evaluation of the results, the writing up of the study report (in collaboration with the supporting services) and the validity of the data presented
- Certify in the final report the compliance to Good Laboratory Practices

- Monitor the study plan, final report and raw data and all documentary evidence to ensure all are transferred to the Archives after the study has been completed
- Communicate regularly and closely with the Sponsor throughout the study.

Development of commercial activity:

- Develop the commercial activity of the Safety Pharmacology Department in collaboration with the Commercial and Sales Department

Qualifications

- Veterinary, Pharmacy PhD degree or master in science
Strong experience in Pharmacology (at least 5 years) and management are required. Training and continuing education, via internal and external qualification programs together with the possibility to attend national and international scientific symposiums are provided

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