

CHINA-BASED

STUDY DIRECTOR

Title: Study Director

Department: Toxicology Operations

Location: Chengdu, China

Reports to: VP of Toxicology, Pathology, and Laboratory Animal Medicine

Qualifications:

- Masters or Doctoral degree in toxicology or related field or DVM with relevant experience
- Expertise in toxicology, reproductive toxicology, immunology, pharmacology, and/or related fields
- D.A.B.T. or working toward certification
- Excellent computer, communication and writing skills (previous publication preferred)
- Ability to work independently

Study Protocol Responsibilities:

- Communicate with the Sponsor to prepare study protocols
- Arrange for the required amount of test article to be provided
- Approve study formulation procedures
- Approve study milestone schedule, dose preparation schedule, report schedule and calendar
- Prepare study protocols and amendments, obtain appropriate signatures, arrange for distribution and QA audit, if required

Study Conduct Responsibilities:

- Responsible for overall study management including technical conduct of the study, interpretation, documentation and reporting of results
- Primary point of contact with Sponsor on all study related issues. If a project manager has been assigned, the Study Director will instead interact directly with the project manager, unless otherwise directed
- Arrange for the pre-initiation meeting with all of the involved staff
- Be present daily to observe animals and/or discuss findings with staff. Observe initial dose preparation, first day of study and other key study events (e.g. necropsy, clinical pathology sampling)
- Observe study animals on at least a weekly basis
- Review all scheduled study data on a frequent basis
- Perform QC on data from selected studies on a weekly basis
- Respond to QA audits
- Review study conduct to ensure compliance with the protocol, research proposals, and standard operating procedures
- Ensure that all study events, e.g. animal ordering, randomization, shipping of samples, necropsy, are completed as scheduled
- Coordinate study events with the subcontractors as appropriate
- Respond to all quality assurance audits in the required time frame
- Attend regularly scheduled meetings to include staff, pre-initiation, and pre-necropsy meetings
- Reviews training files of all technical staff
- Provide input on staff performance reviews
- Ensure compliance with all facility health & safety requirements

- Monitor budget for the study
- Submit IACUC review form

Study Report Responsibilities:

- Communicate study findings to the Sponsor on a frequent basis
- Respond to all quality assurance audits in the required time frame
- Oversee report writing process including writing summary, results, and conclusions, reviewing drafts, receiving and addressing client comments, interacting with contributing scientists as necessary, and approving the final report
- Ensure that all raw data and specimens are archived upon finalization of the report

Professional / Corporate Responsibilities:

- Assist Business Development (BD) staff in proposal development
- Participate in some BD meetings and presentations
- Perform job functions in accordance with departmental and corporate mission
- Develop and review new procedures, technologies, and SOPs as required
- Approve/Develop new procedures and technologies as required, including development of new standard operating procedures and/or forms
- Assist in developing Health & Safety, AAALAC, and facility programs
- Publish the results of the studies in peer-reviewed journals
- Maintain an active involvement in professional toxicology organizations
- Be knowledgeable in domestic and international regulatory requirements

Email or fax your resume today to:
HR@frontierbsi.com or (301) 515-5562