Metrion Biosciences
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Granta Park
Great Abington
Cambridge
CB21 6AL

GLP Study Director Job Description

Job title:	GLP Study Director and Project Manager
Position Description:	The Study Director represents the single point of study control with ultimate responsibility for the overall scientific conduct of the study and ensures compliance with Good Laboratory Practice (GLP) regulations. This is the prime role of the Study Director, and all duties and responsibilities, as outlined in the GLP Principles, stem from it. The position will involve management of Metrion Biosciences' newly created GLP hERG laboratory. The candidate will be expected to work closely with Metrion's management and business development teams to ensure studies are completed to expected turnaround times. Liaison with clients will also be a key aspect of the role.
Reporting to:	Test Facility Management.
Key Responsibilities and accountabilities:	The Study Director is responsible for ensuring that GLP studies are conducted in compliance with: • UK GLP Regulations, SI 1999 No 3106; amendments, SI 2004 No. 994. • No 1 OECD Principles on Good Laboratory Practice and Monographs. • No 8 OECD The Role and Responsibilities of the Study Director in GLP Studies. Activities undertaken by the GLP Study Director will include: • Reading and understanding all relevant Standard Operating Procedures (SOPs) issued by the Document Controller and, if required, completing a Reading Record Form. • Maintaining an understanding of the GLP regulations and OECD documents listed above, as well other relevant legal and regulatory documents. • Maintaining an accurate and up-to-date training file. • If required, assisting the business development team with preparing and issuing quotes for performing GLP studies. • Interact with the Sponsor, Test Facility Management and, if relevant, the Test Site to enable the preparation of Study Plans. • Approve Study Plans by signing and dating them and ensuring that they are signed by the Sponsor and Test Facility Management.

	• Manage the process of initiating and conducting the GLP studies by working closely with the other staff members, including QA. Ensure that the staff have access to the necessary files, including the Study Plan. • Ensure that the necessary reagents and Reference Item are available and within their expiry dates. • Ensure that the necessary equipment is calibrated and/or serviced within the correct timelines. • Ensure that the computer systems have been validated. • Prepare and execute any Amendments, Deviations and File Notes as required. • Maintain effective communication with the Principal Scientist at the Test Site to ensure that Phase Studies progress smoothly. • Ensure that QC checking of crucial aspects of GLP experiments, analysed data, graphs, figures and draft Reports are performed. • Ensure that all relevant information from each Study is filed in the respective Study Files. • Work closely with Test Facility Management to host auditors and inspectors and address any comments/issues raised in inspection reports. • Act as the point-of-contact with QA and address any comments raised in QA reports. • Work with the Archivist to ensure that documents, such as the Study Files, are archived in a timely fashion. • Work with the Document Controller to ensure that SOPs, Forms and Templates are kept up to date. • Assist with training of Metrion staff to GLP standards.
Minimum Experience and Qualifications	Ideally the GLP Study Director should have: • A BSc/MSc or PhD in a relevant subject area. • At least three years' experience of working in a GLP lab. • Familiarity with manual patch-clamp electrophysiology.
Preferable qualifications	• At least two years of study director experience. • Experience of performing manual patch clamp electrophysiology. • Experience of working in a role that involves managing relationships with clients.
Attributes	1. The capability of strictly adhering to SOPs and ensuring compliance from other team members. 2. Being highly detail oriented. 3. Possessing excellent communication skills.

Principal Contacts	• Test Facility Management • QA • GLP Electrophysiologists • Tissue Culture Scientists • Archivist(s) • Principal Scientist
Working with Metrion Biosciences	• Metrion Biosciences offer a competitive salary, commensurate with qualifications and experience, and a comprehensive benefits package including health insurance.