Job Title	**:**	**Regulatory & Quality Coordinator**
Department	:	Research Department
Report to	:	Head of Research Department
Location	:	FPD East London
Annual salary range	:	R293,227 – R394,823

(Please note that the salary range mentioned is indicative only. The offer to the successful candidate will be determined within this salary range, based on the candidate's relevant qualifications and experience).

Purpose of the position:

The main purpose of this position is to ensure compliance with local and international regulations, GCP standards, and quality management processes for clinical research studies. This position involves managing documentation related to regulatory submissions, overseeing quality assurance, and collaborating with internal study teams and external regulatory authorities to maintain high standards of quality, compliance, and safety.

Scope of work:

- Monitor and ensure adherence to the Institutional Quality Management System (QMS), site Quality Management Plan (QMP), and study-specific Clinical Quality Management Plans (CQMPs).
- Conduct regular internal quality assurance visits to research sites to ensure compliance with GCP, SOPs, regulatory requirements, and quality standards.
- Support the implementation of quality improvement initiatives and corrective actions.
- Investigate quality issues and provide recommendations for resolution.
- Analyse quality review findings to identify trends and areas for improvement.
- Train study teams on quality standards.
- Assist with the preparation and submission of regulatory documents to relevant authorities (Ethics, SAHPRA, DoH).
- Maintain accurate and up-to-date documentation of regulatory submissions and quality assurance activities.
- Ensure proper document control, organization, and traceability.
- Prepare and present regular reports on the status of regulatory submissions, quality metrics, and any identified risks.

Qualifications:

- A three-year Bachelor's degree in life sciences, health sciences, or a related field.
- Post graduate qualification (advantageous).
- Valid GCP certification (advantageous).

Experience and knowledge required:

- Minimum of 5 years' experience in the clinical research environment.
- 2-3 years of experience with regulatory and quality assurance activities in a research setting.
- Knowledge of quality management systems.
- Knowledge of clinical trial regulations, ICH/SA GCP Guidelines and regulatory requirements.

Additional requirements:

- Proficiency in reading, speaking, and writing English.
- Proficiency in Microsoft Office (Word, Excel, PowerPoint, Outlook, Teams, Planner).
- Valid driver's license.
- Willingness to travel to research sites.

Application process:

Interested candidates should apply by accessing the following link:

https://vacancies.fpdsiu.co.za/

Closing date for applications:

26 August 2025 at 16h00

The Foundation for Professional Development fosters a diverse and inclusive workplace. We invite and encourage qualified candidates with disabilities to apply for positions within our organisation. In line with the company's Employment Equity Plan, preference will be given to suitably qualified male candidates from designated groups.

Please note:

Only shortlisted applicants will be contacted. If you have not been contacted within four weeks after the closing date of this advertisement, please accept that your application was unsuccessful. The company reserves the right not to make an appointment.