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QC JUNIOR INTERNAL MONITOR X 2 TWO (2) YEAR FIXED TERM CONTRACT LOCATION: CAPE TOWN (CROSSROADS AND PHILIPPI VILLAGE)

The Desmond Tutu Health Foundation (DTHF) is a registered non-profit organisation focused on the pursuit of excellence in research, treatment, training and prevention of HIV and related infections in Southern Africa.

We have fantastic job opportunities across our businesses for talented people wanting to realize their full potential. Could that be you? If so, we invite you to explore the possibility of joining us to play your part in Desmond Tutu Health Foundations' exciting future.

These positions will require the candidate to carry out aspects of quality control and quality assurance, including monitoring study data, site processes and team compliance with required study protocol, procedures, South African Good Clinical Practice as well as applicable regulations per Sponsor Requirement.

Minimum Requirements:

- Grade 12 with a tertiary qualification in a Health related field
- At least 2 years' working experience in a Clinical/Research environment
- At least 2 years' experience conducting internal monitoring/quality assurance/quality control
- Experience in using Databases e.g. Imedidata
- Intermediate knowledge of computer applications like Microsoft Word, Excel and Power Point
- Working Knowledge of procedural document such as Standard Operating Procedure (SOP), Study Specific Procedures (SSP) and Manual of Operational Procedures (MOP)
- In depth knowledge of Investigator Sité File and Essential documents, requirements and
- Strong written and verbal proficiency in English and other local languages
- Excellent ability to build interpersonal relationships and partnerships within a diverse community
- Strong problem-solving and decision-making abilities
- Ability to work under pressure and independently
- Attention to detail
- Excellent Planning and organization abilities

Advantageous:

- Current SA Good Clinical Practice (GCP) certificate
- · Valid Driver's License, with own car
- Previous experience in SAHPRA and Ethics submissions
- In depth understanding and knowledge of Regulatory (SAHPRA) and Ethics Guidelines

Responsibilities:

- Review of the source data against the entries in the study database eCRF to confirm accuracy (QC)
- Review the source data (SDV) against guidelines to confirm compliance to protocol, procedures, patient safety, data integrity, and SA GCP and Quality Management plan amongst others

PASSION | INNOVATION | PROGRESS

- Log and review protocol deviations and suggest corrective and preventative actions
- Implementation of corrective and preventative actions within a reasonable time
- Follow the monitoring plan for the study, site and or DTHF
- Assist the site by providing input regarding development and implementation of a clinical quality management plan, in line with requirements by funders and regulators
- Assist the site with all regulatory submissions and approvals and manage the process with support from the QA manager (HQ DTHF)
- Review all the HREC and SHAPRA approvals and communication to ensure that all applicable approvals and notifications are in place
- Review the Investigator Site File for completeness and accuracy assisting the site to keep it up to date
- Write Monitoring Report after each visit and communicate findings to the PI and site staff for corrections
- Regularly feedback sessions with HQ QA Manager
- Review and report outstanding issues at the site, for example Serious Adverse Events (SAEs), adherence to protocol and data quality issues
- Verify study conduct in accordance with national and International Guidelines, site SOP's, Study SSP's and protocol
- Assist the sites with Audit preparations
- Prepare reports to DTHF/C QA Manager for review

Value and Tenure:

The value of the post is R31569,84 per month (gross before deductions). Start date is 1 March 2024 but flexibility on a start date can be discussed.

Values fit: Passion Innovation Progress Integrity Respect Excellence

Submit CV, motivation letter with certified copy of highest qualification and details of three (3) current contactable referees in a single PDF file by 25th January 2024. Incomplete applications will not be considered.

Visit the DTHF Career page to view the advert DTHF-108 and apply: DTHF Career Page

NB: Only short-listed candidates will be contacted. We are committed to equity in our employment practices. It is our intention to appoint individuals with the aim of meeting our equity objectives. We reserve the right not to appoint if no suitable candidates are identified.

I understand and accept that by applying for this position, I authorized DTHF to process my personal information in accordance with its internal operational requirements.

I further understand that the personal information I disclose to DTHF will be processed in accordance with the requirements set out in the Protection of Personal Information Act and may include the transferring thereof to third parties for the purposes of verification.

This job may be removed before it expires.

If you have not heard from us within four weeks after the closing date please consider your application as unsuccessful.

Desmond Tutu Health Foundation is a child-friendly organisation committed to the protection of children.

For more information about the organization, please visit our website.