Ndlovu Care Group is a South African NGO based in a rural environment, Elandsdoorn, Limpopo Province which provides comprehensive integrated Health, Child Care & Community Development and Medical Research services as part of a large-scale development program

Visit our website www.ndlovucaregroup.com

Ndlovu Care Group is currently looking for the following motivated candidate for the Quality Assurance (QA) Associate position at the Ndlovu Research Centre in Elandsdoorn (Groblersdal):-

Quality Assurance Associate

Job Purpose:

To implement and monitor compliance with SA GCP guidelines and/or international GCP guidelines, regulations and Ndlovu Research Centre (NRC) SOPs within clinical trials.

Minimum Qualification:

Health Scientific Degree or any other relevant qualifications.

Minimum Experience:

- At least 3 years working experience in clinical trial setting or relevant field
- Previous experience in either Quality Control or Quality Assurance will be an advantage

Main Duties and Responsibilities:

- Support development and implementation of the Clinical Quality Management Plan (cQMP) across functional teams within Ndlovu Research Centre (NRC).
- Assist with Clinical Quality Management Plan (CQMP) programs including but not limited to:
    - Verification of study participant files according to the relevant study requirements and established checklists

    - Verification of effective resolving of CQMP queries
    - Compile monthly reports including but not limited to key performance indicators, including protocol deviations, CAPA tracking of preventive actions, including non-compliance to protocol schedule of assessment.
- Develop and maintain Quality Assurance Standard Operating Procedures (SOPs) including site SOPs including review and update as necessary.
    - Manage list of all site SOPs, templates, forms, and advice on review dates
    - Ensure SOP's contain sufficient information to ensure consistent and repeatable execution of the processes to be performed.
- Implement Document Control System including but not limited to:
    - Ensure that all the document master lists are up to date
    - Issuing controlled copies of logs and forms as required
    - Issuing controlled copies of newly implemented SOPs, Study Protocols and Study Specific SOP's to relevant functional teams and departments as required and withdrawing of all superseded issued controlled copies.
- Assist with review of data recording forms to ensure that:
    - The established documentation formats and review procedures are followed.
    - Implement data QC check and recording forms to trace specific actions, persons, times/dates and resources used.
- Support and track training and meetings at NRC to ensure Quality Assurance and Quality Control procedures and processes take place according to protocols, study-specific SOPs and NRC set SOPs.
    - Perform QC checks on Investigator Site Files and performs source data verification.
    - Review protocol deviations per study and determine in collaboration with the Chief Medical Officer the risk.
    - Support sections and study teams to conduct root cause analyses and implement corrective and preventative actions for quality issues/deviations
- Responsible for equipment maintenance, including but not limited to:
    - Updating of the equipment calibration and verification schedule
    - All equipment calibrations and verifications are up to date as per instruction booklet and calibration schedule
    - The use of equipment is within its intended purpose and within its required performance specifications
- Assist with the performance of internal audits to ensure that:
    - All study procedures are conducted in accordance with the protocol, SOPs and appropriate legislation
    - Audit trail is available to trace any changes to data, the dates of changes and the person responsible
- Assist with the performance of external audits/inspections to ensure that:
    - SOP is followed throughout, from notification until submitting responses to audit/inspection findings

- Bring any identified risk and/or queries about the validity of the data and participant safety and well-being to the attention of the Chief Medical Officer.

Candidates should submit their motivation letter and detailed CV to HR Administrator Malesela Moabelo at fax number 013 262 3498 or by e-mail to recruitment@ndlovu.com

Please note that if you have not had a response from us within 7 days after the closing date of this advert, you can deem your application as unsuccessful.

Closing date: ***18 April 2023***