Ndlovu Research Centre (NRC) is part of Ndlovu Care Group (NCG), which has a footprint in the community of Elandsdoorn, Sekhukhune district, Limpopo province, South Africa for over 25 years with high interest field of Health Care, Child Care & Youth Development, Local Infrastructure and Academic and Clinical Research.

Visit our website www.ndlovucaregroup.com

Ndlovu Research Centre is currently looking for the following motivated candidates to work at Ndlovu Research Centre in Elandsdoorn, Moutse East, Limpopo:

Regulatory Affairs and Quality Assurance Manager

Job Purpose:

To ensure legibility, completeness, and consistency of data by being responsible for internal monitoring, validation and auditing of participant's source and CRF files. To perform quality assurance activities in accordance with the unit's Quality Assurance Plan and Sponsor regulatory requirements and ICH GCP requirements.

Minimum Education and Training:

- 3-year Diploma or Degree in a medical, health, or scientific field is mandatory
- Preferably Human subjects' protection training, preferably CRA (Clinical Research Associate) training
- Complete and accredited ICH/GCP course and SA GCP 2020 training course.
- Good administrative and organisational skills with meticulous attention to detail.
- Sound knowledge of good clinical practice.
- An ability to work independently in a team and be pro-active.
- Computer skills in Microsoft Office (Excel on intermediate level)

Minimum work-related Experience:

- Minimum 2 years' experience of on-site monitoring as RA/QA Officer or CRA.
- An exposure to audits will be an advantage
- Be familiar with the internal monitor activities

Main Duties and Responsibilities:

Quality Assurance Duties

- Review and verify CRF's and source documentation to ensure accuracy and completeness and compliance with applicable regulations.

- Identify trends of inconsistencies and deviations to the requirements and regulations listed above.
- Document findings relating to the monitoring of CRF's and source documents by completing SDV forms and disseminate these findings to the appropriate clinical staff.
- Ensure that SDV forms are returned timeously and include adequate documentation that findings have been resolved appropriately.
- Assist in conducting root cause analyses of problems encountered during monitoring, including drafting of CAPA (Corrective action, preventative action) plans, to ensure the overall improvement of patient safety and data quality on site.
- Develop and present training materials pertaining to Quality management activities/issues on site to all staff as required.
- Assist in reviewing specified records prior to site sponsor audits or inspections by other regulatory bodies.
- Review Site Monitoring Reports generated by monitors to assist in identifying trends and errors in completing CRF's and source documents and apply this knowledge to improve subsequent monitoring reports.
- Generate monthly monitoring reports that included a quantitative and qualitative review of source documentation and CRF's monitored.
- Ensure site readiness for new protocols Develop tools and source documents to ensure protocols are adhered to and smooth collection of required data.
- Apply knowledge of the organizational systems, structures, policies and procedures to achieve results.
- Follow through to ensure that productivity standards are consistently and accurately maintained.
- Provide appropriate resolution for tasks or deadlines not met.
- Provide CQMP reports as per the SOP.
- Be able to develop and review SOP's for study related studies.
- Take ownership for driving own career development.
- Ensure that submissions for all protocols are done timeously and accurately.
- All relevant staff are submitted and approved and/or notified.
- All relevant trackers for ethics submissions, study protocols, compliance certificates relevant to the study, relevant compliance trainings etc. are done up to date.
- Prepare RA/QA reports for the studies to be submitted to the PI and to the Ndlovu Care Group Board.
- Ensure All ethical reports are prepared and submitted timeously to the PI for approval prior to submission to relevant authorities.

Regulatory duties:

- Prepare and assist in the inception of new studies using Study Readiness Tracker
- Ensure that all study documents / correspondence are submitted to the local ethics body (IRB/REPC) and clearance certificates are obtained before commencement of the study and during the study, as required in consultation with the PI as per sponsor/IRB/Ethics Committee and SAHPRA requirements.

- Ensure that the approved study documents are also submitted to Limpopo Provincial DOH for notification and/or approval via the NHRD website.
- Ensure that new staffs are submitted to the sponsor and Regulatory bodies according to the sponsor's needs.
- Ensure that all Investigators and relevant staff are approved or notified first before executing any study related activities.
- Ensure safe keeping of study documents (re: signed and approved Protocol, Clearance Certificate, Agreement Letters, Investigator's Brochure, Regulatory approval, Monitoring Reports, Financial Disclosures, etc.).
- Ensure that all amended documents are implemented as directed by the sponsor and retrieval of all old documents from staff and shredded accordingly.

Other:

- Support and drive the organization's core values. Maintain a positive attitude. Respond openly to feedback.
- Supervise and manage the duties of subordinates to ensure optimal staff utilization and maintenance of sound labour relations.
- Perform and facilitate performance development and assessments.
- Identify substandard performance by team members and take necessary corrective action.
- Coach and train subordinates and team members to ensure the acquisition of knowledge and skills required by the organization.
- Promote harmony, teamwork and sharing of information.
- Actively and consistently maintain high standards of professionalism in all aspects of personal presentation and delivery

Candidates should submit their application and detailed CV to Pertunia, HR Administrator, 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: 03 June 2022