



Quality Assurance Officer: Compliance

Ref: QAC14/2025

Closing Date: 20 March 2025

The Quality Assurance Officer: Compliance is responsible for implementing and maintaining the quality management systems at OBP

Main Responsibilities include: * Manage, monitor and maintain the allocated Quality Management system(s) (ensure numbers are issued according to procedure and a register is in place, maintained and up to date) * Ensure all allocated Quality Management system documentation is correctly completed, closed out, scanned and archived * Ensure compliance to all applicable regulations and internal procedures by proactively interpreting regulatory and quality requirements * Ensure that a Vendor management schedule is in place, monitor vendor audits, and follow up on outstanding CAPA plans for close out * Participate in investigations of quality related complaints and write reports where needed. * Monitor and report on developing trends * Participate in the investigation of incidents, OOS, deviations, discrepancies, root cause investigations or test failures as required * Support allocated operational area(s) of responsibility in closure of non-conformances/deviations, change controls, CAPAs and investigations * Review and approve Corrective Actions and Preventative Actions (CAPA) in order to meet compliance requirements * Review and approve change controls for quality and regulatory compliance impact and determine requirements for implementation * Perform QA checks of areas of responsibility on a monthly basis and ensure that observations are documented and followed up * Conduct internal audits on site as per assigned audit schedule * Ensure that area(s) of responsibility are audit ready * Ensure audit readiness within own role through closing out audit findings timeously * Support QA department with Regulatory audits and 3rd party audits * * * Support other department functions pertaining to projects, other initiatives or cross departmental work * Contribute towards the mitigation of the department's risk profile by implementing sound governance and compliance processes and tools to identify and manage risks.

Minimum Requirements: * Degree in Microbiology / Biotechnology Pharmacy, Biological Sciences or a similar field NQF 7 * ISO 9001 and/or cGMP auditing certification * Minimum 3 years' experience in Quality Assurance within the pharmaceutical/ biotech manufacturing industry * Experience in quality management systems within a cGMP facility is advantageous * Quality and Regulatory compliance knowledge, i.e. SA GMP, PIC/S and WHO as well as application.

Remuneration: A Paterson Grade C remuneration package will be offered that is commensurate with experience and qualification of the successful candidate.

NOTES:

OBP reserves the right to fill any of its positions.

Suitably qualified candidates should submit their applications online at [PNET https://www.pnet.co.za](https://www.pnet.co.za) by the closing date. No late applications will be accepted or considered after the closing date.

Only shortlisted candidates will be contacted.