Job Vacancy

Job detail	
Job title	Quality Assurance Assistant
Business unit	Equipharm Specialised Distribution
Geographic location	Pretoria
Line manager	Medical Devices and GDP Manager
Number of immediate subordinates / reportees	Nil

Key Performance Areas (Core responsibilities & outputs of the position)

Will support the delivery of operational excellence, working in partnership with the business areas to implement improvement opportunities and effective use of the Quality Management Systems. The following responsibilities are key to how this support can be provided:

- Able to plan effectively to meet set timelines.
- Identify root-causes of a problem, prioritise and identify solutions.
- Contribute to continuous improvement by formulating reports, trending and data analysis.
- Support other members from the Quality team.
- Maintain excellent working knowledge of continuous improvement tools and methodologies.
- Effectively manage the operational tasks within the Quality Management System (QMS) including but not limited to:
    - Change Controls
    - Non-conformances / Deviations
    - Complaints
    - CAPAs
    - Risk Management
    - Effectiveness
- Create, review and approve relevant standard operating procedures, work instructions and forms.
- Ensure that appropriate standards of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and ISO 13485:2016 are maintained.
- Maintain Clinigen paper and electronic records for quality documentation.
- To communicate relevant aspects of the quality system to employees, as necessary, in order to support product and service quality.
- Support as required in internal, external and Regulatory audit programs. This includes report writing and managing of audit observations/ responses.
- Escalate to management when product quality or patient safety is at risk.
- The list of duties is not intended to be exhaustive, but gives a general indication of the tasks involved. It is the nature of the company that tasks and responsibilities are, in many circumstances, unpredictable and varied. All employees are, therefore, expected to work in a flexible way when the occasion arises and acknowledge that tasks not specifically covered in their job description are not excluded.

Minimum Requirements

EDUCATION

- Matric (Grade 12)
- QA qualification

EXPERIENCE

- +3 years' experience within quality assurance role or related
- Knowledge of Guidelines on GMP, GDP and ISO 13485: 2016 of medicinal products and medical devices for human use
- Understanding on the conditions of the SAHPRA licences

SKILLS / COMPETENCIES

- Sound knowledge of MS Office (Excel, Word, PowerPoint and Outlook)
- Excellent planning, administrative and organisational skills
- Excellent attention to detail

BEHAVIOURAL QUALITIES

- Working independently and as part of a team
- Strong communicator at all levels
- Self-motivated and disciplined
- Solutions orientated
- Ability to be responsible and accountable
- Ability to change priorities and act urgently as and when required

DESIRABLE SKILLS & EXPERIENCE

- Strong Quality Assurance experience
- Team player with strong interpersonal communications skills.

General working conditions

- Valid driver's license with own car
- Must be able to work outside office hours when required or requested to do so

Application:

If this role is of interest to you please email your CV to liezel@clinigen.co.za.

Closing date for applications will be 23rd of April 2021.