Job title: Company Quality Assurance Pharmacist **Job grade**: TBC **BU**: New business development	**Job Level: Professional** **Section**: Regulatory **Reports to**: Responsible Pharmacist
Core Description	**Key Deliverables / Primary Functions**
The Company Quality Assurance Pharmacist ensures that Company Products comply with the local and international Quality Assurance Standards. This function includes certifying legal compliance of the same and ensuring the quality assurance function throughout the processes involved, including product release.	• Vendor qualification: Spearhead the vendor selection process according to company SOPs; conduct vendor inspection audits in compliance with current Good Manufacturing Principles and Quality Assurance principles, of all 3rd party contractors who manufacture, pack, test, and warehouse or distribute any company product • Quality system support: Assist with confirmation of implementation of Quality Technical Agreements. Visit the contractors regularly and maintain contact to sustain quality partnerships. Define quality improvements plans to support continuous improvements to the contractor quality systems. Independently periodically assess the overall quality risk associated to the contractor. Act on adverse trends to improve contractor quality compliance. • Change control: Assess product related change proposals from a quality and GMP perspective. Support submissions of accepted changes through regulatory compliance. Manage the timing of implementation of change at the contractor. • Deviation control: Independently evaluate the impact of the deviation to the quality of the product. Where necessary initiate a deviation report to the responsible pharmacist and assist in any investigation and proposal of corrective and preventative action. Manage the implementation of any proposed corrective action and provide feedback so that the deviation can be closed. • Audit support: Assist with self-inspection audits and support the responsible pharmacist with Afrivet Business management audits by South African regulatory bodies with regard to GMP/ ISO:13485 • Lot/Batch approval: Where required in accordance with local regulations • Stability: Ensure that the contractor is operating a Stability Surveillance program for Afrivet products in accordance with GMP requirements and that any Out of Specification (OOS) stability results are promptly handled and communicated. • Quality Control: Support the product quality control by confirming and authorising pre-approved labels for printing, performing regular spot checks of incoming FPP to the warehouses for label compliance, fill volume and container compliance with registered specifications • Quality system: Contribute to the development and maintenance of SOPs. Participate in technical/quality meetings to ensure GMP/GCP guidelines are adhered to. Ensure a consistent approach to the interpretation and implementation of GxP standards of the animal health industry

	• Regulatory support: Support the process of documentation retrieval and collation to support product registration renewals. Act as QA focal point for regulatory communications and changes. Assist in the compilation of product Safety Data sheet.
Core Functional Knowledge/ Skills	**Competencies (Behaviour)**
• Contribute to the development and maintenance of the company quality system • Participate in the development of guidelines to ensure consistency of contractor standards • Demonstrates knowledge of the range of animal heath products and regulatory requirements • Has strong broad GMP and technical knowhow • Takes initiative and is proactive and persistently purses to closure • Is diplomatic in communication with internal and external customers • Excellent organizing skills and able to prioritize own work and act to work independently and as part of/team lead • Willing to travel up to 20%	Strong analytical thinking, problem solving skills, attention to details, shows strategic ability, leads change, honest and consistent, team player, high level of integrity in all customer and business related activities.

Minimum Person Requirements		
Qualifications	**Experience**	**Certification/ Professional Registration**
A degree in pharmacy	At least 2 years' experience in QA/QC type roles supporting commercial pharmaceutical operations	Registration with the South African Pharmacy Council

Special Requirements
Required to travel internationally and locally - valid driver's license. Willing to sign an NDA and adhere to restraint of trade requirements

Compiled by: Caryl Wilson

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