

ZWIVHUYA NDOU

Address: 21981 Basil Street, Protea Glen Ext 28, Soweto 1834

Phone: 081 078 5883 / 061 444 4703

Email: ndouzwivhuya@gmail.com

CAREER OBJECTIVES

To work in a dynamic professional environment with a growing organization and utilize my creativity and innovative thinking for benefit of the organization and myself.

WORK EXPERIENCE

01/02//2023 – up to date

RA QA Clerk, **The Scientific Group**

Responsibilities:

- Attend SAHPRA, SAMED, SALDA Forums to correctly assists colleagues and local and international partners with regulations & updates.
- Source product technical information and keep The Scientific Group documentation up to date for suppliers and distributors (includes agreements, certificates, etc.)
- Communicate with SAHPRA (South African Health Products Regulatory Authority) regarding regulatory queries, standards, rules, and regulations.
- Assist to amend, renew old SAHPRA site licences (e.g., manufacture, distributor and wholesale licences) and apply for new SAHPRA site licences, when required. This includes adding of new products, payment-, retention fees-, certified copies-, supplier/manufactur-, new licence pick-up arrangements.
- Ensure Adverse Events and recalls are reported in a timeous manner to the local regulator.
- Assist suppliers, distributors, and TSG Staff Members with all Regulatory- and QMS queries.
- Assist suppliers, distributors, and TSG Staff Members with individual IVD registrations in all African countries, including South Africa.
- Basic development, -updates and -programming of the SHREQ SharePoint site.
- Assist export team with registrations and regulations in selected African countries.
- Assist to renew supplier quality agreements, keep record of agreements.
- Assist TSG Staff Members with new label- and package regulations as required by SAHPRA.
- Assist to facilitate and Implement QMS practices and workflows.
- Assist to create Policies and Procedures and SOP's
- Assist to train staff on new policies, procedures, and SOP's.
- Administrate and support the close out of audit findings, follow up on evidence for action completion.

- Report any risk, non-conformance detected within TSG to the Compliance Manager.
- Assist with internal and external QMS audits as required.
- Assist with Health, Safety and Environment requirements as required.

01/09/2021 – 31/01/2023

Compliance Assistant, **Surgical Innovations**,

Responsibilities:

- Assist with compiling product registration applications, variations, licence amendments and evaluation responses for submission to the relevant health authorities according to the current content and format requirements in all territories.
- Assist with tracking administrative requirements that include payment requisitions for regulatory applications, amendments, retention fees and licences.
- Maintain records and systems for monitoring and recording product registrations nationally and in other territories.
- Assist with compilation of regulatory and quality documentation such as Quality Manual, Site Master files, reports etc.
- Assist with post marketing surveillance reports (including product complaints, adverse events, field safety corrective actions and recalls) required for manufacturer and regulatory authority submission as per approved procedures and requirements.
- Assist with creating and maintain updated product technical files, medical device files and documentation required for regulatory submissions, ISO 13485 Quality Management System, and licencing requirements.
- Assist with performing due diligence on new products and additions to the lines or registrations as per the regulatory Authority requirements, within the allocated timeframe.
- Provide regulatory and quality support for new product realisation, registration and launch preparation.
- Collaborate and liaise with internal stakeholders as required for regulatory and quality related activities including document and records management, risk assessments, non-conformances, and internal audits.
- Assist with timely electronic and physical filing and correctly superseding of documents in the regulatory and quality information management systems.
- Organise regulatory and quality information management system.
- Keep updated with quality and regulatory requirements in local and export territories.

01/2017 – 01/2018

Administration Clerk (Trainee), Nduma Security Consultants

Responsibilities:

- Perform administrative duties effectively.
- Assist and support administrative staff.
- Assist administrative manager in handling administrative operations.
- Greet clients and visitors and resolve their inquiries.

- Assist and support sales and marketing teams.
- Assist accounts department in accounting functions.
- Prepare and verify accounts receivables and accounts payable records.
- Handle and organize office filing systems effectively.
- Maintain stationery, office equipment and inventories.
- Handle office expenditure within the budgetary limits.

Customer Service Assistant, BidAir Services

Responsibilities:

- Maintaining a positive, empathetic, and professional attitude toward customers always.
- Responding promptly to customer inquiries.
- Communicating with customers through various channels.
- Acknowledging and resolving customer complaints.
- Knowing our products inside and out so that you can answer questions.
- Keeping records of customer interactions, transactions, comments, and complaints.
- Communicating and coordinating with colleagues as necessary.
- Providing feedback on the efficiency of the customer service process.

02/2015 – 11/2015

Stock Counter, EDCON

Responsibilities:

- Receive, store, and issue materials, equipment, and other items from stockroom, warehouse, or storage yard. Keep records and compile stock reports.

EDUCATION

2017 - 2018

Diploma in Business Administration – Richfield Graduate Institute of Technology

2013 - 2014

Marketing Management N4 - N5, Central Johannesburg College (Johannesburg)

2011

National Senior Certificate, Vuwani Secondary School

SKILLS / STRENGTHS

- Knowledge of planning ahead

- Ability to seek stability and predictability.
- Knowledge of public relation and involvement
- Ability to inspire, empower and motivate.
- Negotiation and communication skills
- I am very creative and innovative thinker.
- Ability to work under pressure without any problem.
- Able to learn new skills and adapt to different situations.
- Able to work independently and as part of a team,

PERSONAL PROFILE

Date of Birth	: 02/10/1994
Marital Status	: Single
Nationality	: South African
Home language	: Tshivenda
Other languages	: English, fluent Xitsonga, fluent Sepedi, speak.
ID Number	: 941002 0447 084
Dependent	: Two (2)
Driver's license	: Code 10 (C1)

REFERENCES

Miss Nandipha Gwantshu
Company: **The Scientific Group**
Position: Manager
073 197 0852 / 011 568 9047

Miss Nora Masoga
Company: **Surgical Innovations**
Position: Manager
066 139 2563 / 011 568 9047

Mr. Nemakhavhani NC
Company: **Nduma Security Consultants**
Position: Supervisor
071 767 3696
011 680 0957