

# KAGISHO ATHENASIUN MAMAILE

## SKILLS

Quality Assurance/ Quality Control/Validation	
• Laboratory test method development and validation	• SMEs Management
• Vaccines handling and testing	• GMP guidelines and standards, eg. SAHPRA (MCC), ICH, PIC/S, WHO, SA GMP, ISO, PDA and EU GMP
• Pharmaceutical quality system	• Good Laboratory Practices (GLPs)
• Quality control testing (Micro)	• Good Document Practices (GDocPs)
• Laboratory test method development	• Good Manufacturing Practices (GMPs)
• Stability testing	• Process validation, cleaning validation, and method validation
• Report writing	• ISO 9001(Introduction and Auditing)
• Trending analysis	• ISO 13485 (Manufacturing of Medical Devices)
• Document and Record Management	• Designing and implementing QMS and processes.
• Root cause analysis	• SOP writing, system and process reviews
• Change management	• Validation plan, assessments, specifications, protocols, and reports (participate in the execution and report writing)
• Out of specification (OOS) investigations	• Process Validation, Cleaning Validation, CSV (Excel Spreadsheets) (execute and report writing)
• Corrective and Preventive Action (CAPA)	• IQ, OQ, PQ and Re-Qualification (report writing)
• Deviation management	• Internal audits (participate)
Leadership, Business and Marketing Management	
• Employee performance management	• Customer Relationship Management (CRM)
• Preparation and Initiating disciplinary enquiry	• Strategic Planning
• Handling conflicts and grievances	• Project Management
• Occupational Health and Safety (OHS)	• Financial Accounting and Management
• Internal Audits (perform and participate)	• Strategic Sales and Marketing
• Quality Management	• Customer Relationship Management (CRM)
• Risk Management	• Business Process Management and Business Intelligence
• Digital Marketing (Online advertising, video marketing, social media, email etc.)	• Service and Retail Marketing
Computer Skills	
• MS Office: Advanced Word, Advanced Excel, PowerPoint and Outlook	• MS SharePoint
• DiaDoc Electronic Document Management System	• EtQ Quality Management System
• Caliber ® Quality Management System	• SAP

## WORK EXPERIENCE

**Adcock Ingram (Pty) Ltd, Clayville, South Africa**  
**Process and Cleaning Validation**

**August 2020 to Current**  
**January 2019-June 2020 (Contract)**

- Involved in the writing protocols, execution and writing reports of process and cleaning validation of the Sterile (Eye Drop), High-Volume Liquid (HVL) and General Manufacturing plants.
- Coordinating and executing the various validation projects and protocols as per Validation Master Plan.
- Technical resource needed to help with the design, development, evaluation, or troubleshooting of validation processes and cleaning, testing procedures, or other systems, especially with regards to process validations.
- Write documentation associated with Process Validation program using the SAHPRA guidelines.
- Support the development, implementation and execution of cleaning and process deliverables. Support the development and analyses and reports.

**Johnson & Johnson (Pty) Ltd, Cape Town, South Africa****Sept 2018-December 2018*****Validation Scientist (Contract position)***

- Writes manufacturing process qualification/validation protocols (Process and Cleaning Validation) for execution.
- Knowledgeable of production instructions and processes as well as processes for QC tests
- Interacts with internal and external subject matter experts (SMEs) to efficiently develop documents
- Supports laboratory personnel in executing written protocols
- Assists with data interpretation and leads preparation of summary reports
- Prepares documents that conform with the QMS.
- Maintains standards and documentation practices that allow for consistent execution of documents
- Collects input from various departments to ensure efficient communication and understanding.
- Completes document control steps for protocols and reports

**Roche (Sequencing Solutions), Cape Town****September 2016-June 2018*****QA Specialist***

- Implemented and served as key Business Administrator and local Subject Matter Expert on DiaDoc, a Roche Electronic Document Management System platform for use at RSS Cape Town.
- Successfully drove the transition and migration of the document control system from the existing system to the Roche document management platform.
- Managed document and record types in line with cGMP requirements, managed internal turnaround times for eg. deviations, CAPAs and change requests.
- Compilation, review, approval and training of QA QMS documents.
- Initiation, investigation, implementation and guidance of teams involved in deviations, change requests and CAPAs.
- Validation and qualification processes.
- Participated in Internal Audits and Notified Body Audits and facilitated and conducted Risk Assessments.
- Facilitated the document control process regarding new or existing QMS documents, non-QMS documents, and company records; tracking the status of documents during the draft and approved, effective, obsoleted, etc.
- Facilitated document control workflow and document archiving/retention in Laserfiche and DiaDoc.
- Assisted with document formatting, ensured required metadata and other applicable data inputs for compliance were provided; tracking and trending.
- Technical writing and review of QMS documents prior to formal review process to ensure accuracy and readability in accordance with ISO9001, ISO13485 and Roche Divisional Standards.
- Identified QMS gaps, provided guidance to document authors regarding how to create, remediate or correct documents prior to their finalization.
- Managed the creation of QMS documents and best practices procedures and policies.
- Trained RSS Cape Town employees on document, record and change control processes, including DiaDoc.

**Pick 'n Pay, Cape Town****February 2016 – August 2016*****Trainee Store Manager***

- Managing the Fresh Produce Department at the Pick 'n Pay and making sure it runs smoothly, cleanly and meets budget or sales goals.
- Planning and promoting the daily schedule of employees and the department.
- Driving department turnover to ensure achievement of targets
- Controlling expenses
- Managing stock losses to ensure shrinkage is in line with the department, store and company standard.
- People management including training of staff employee relations and performance management
- Able to retail hours, and sales and target driven
- Ensuring a superior customer service at all times.

**Lathitha Wines****February 2015 – February 2016*****Business Development Manager***

- Responsible for the overall management of all strategic and operational Marketing and Customer Relationship activities.
- Planning and coordinating the implementation of business plans and the penetration of new markets.
- Provide market feedback to the company managing director regarding competitive offerings, prospect needs and new market penetration ideas.
- Manages the sales and marketing functions of the business.
- Plans and manages promotional events (like wines tasting, product launch, special events) as to increased revenue and profit in order to achieve the Company`s ambitious growth.
- Manages a team of people (freelancers and temporarily employees) on marketing related operations and events.

**The Biovac Institute****April 2009 – January 2015*****QC Analyst: Microbiology and Immunology***

- Compilation and writing of SOP, test methods, specifications and environmental monitoring metrics, trending and reports.
- Testing of raw materials, in-process/bulk and finished products, eg. total protein concentration, antigen identification, potency using ELISA test method, TVC and endotoxin tests on purified water, environmental monitoring.
- QC Micro and Immuno Test Method Development and Validation.
- Testing and Implementation of environmental monitoring, and cleaning validation program.
- Setting up sterility test procedure, calibration and verification of equipment.
- Involved in the validation of processes and equipment.
- Developed SOP MS Word templates for the for use to write SOP, Work Instructions, Test Method and Final Product Specification for QA QMS.
- Designed and developed a Data Trending Analysis System on MS Excel for monitoring all QC Test Results.
- Developed and implemented the use of electronic lab reports, assessment reports and validation protocols and validation reports into the IT Document systems QC for easy access and use within QC department or by external departments (especially Production).

**Tygerberg Academic Hospital****February 2008 – March 2009*****Senior Administrative Officer: Gatekeeper***

- Co-ordination and implementation of different types cost effectiveness strategies to reduce the cost on diagnostic laboratory tests.
- Researching and analysing (using Microsoft excel statistical data tool) the number of laboratory tests that are required for each patient per day to avoid unnecessary testing.
- Analysing the laboratory tests and costs data, and reports andcheck for discrepancies from either the lab or requesting doctors.
- Import data from MS Access to MS Excel and analyse it using pivot tables and generate reports.
- Present monthly reports to hospital management meeting and department superintendents.

**NON-PROFIT ACTIVITIES****Arethusaneng Foundation NPO****May 2017 – Current*****Board Member: Treasurer***

- Serves as Chair of the Finance Committee.
- Manages the review of the Board's action related to, the Board's financial responsibilities.
- Works with the Chairperson and Deputy Chairperson and an Accountant to ensure that appropriate financial reports are made available to the Board, SARS and Social Development on a timely basis.
- Assists the Chairperson and Accountant in preparing the annual budget and presenting the budget to the Board for approval.
- Works with the Chairperson and Deputy Chairperson to develop Fiscal Policies for recommendation to the Board to ensure the financial integrity and sustainability of the organization.

## EDUCATION / TRAINING

### University of Cape Town

Year completed: Current

#### ***Postgraduate Diploma in Management in Marketing (Online-Part-time)***

**Subjects:** Business Research and Communication, Consumer Behaviour, Digital Marketing, Effective People, Management and Practices, Event Management, Integration Marketing Communication, Managerial Information System, Organisation and Management, Service and Retail Marketing, Strategic and International Marketing

### University of Cape Town-Graduate School of Business

Year completed: 2013

#### ***Associate in Management (AIM)***

**Subjects:** Business Government and Society, Business and Technology, Business Numeracy, Economics; Entrepreneurship, Financial Management and Accounting, Management Communication, Management of Human Resources and Organisations, Marketing, Strategy, Operations Management

### University of Cape Town

Year completed: 2007

#### ***Bachelor of Science (Honours) in Medical Biochemistry***

**Subjects:** Technique Course, Bioinformatics, Transcriptional Regulation, Signal Transduction, Metabolism of foreign compounds (Pharmacology), Cell aging and cell death, and Research Thesis

### University of Free State

Year completed: 2005

#### ***Bachelor of Science (BSc) in Biochemistry***

**Subjects:** Biochemistry, Microbiology, and Human Physiology

### Tlhomelang Senior Secondary School (Kimberley)

Year completed: 2001

#### ***Matric - High School Matric / Grade 12***

**Subjects:** Afrikaans, Biology, English, Mathematics, Physical Science, and Setswana

## ADDITIONAL TRAINING

Qualified Group Exercise Instructor (2015), Microsoft Office 2010: Excel Data Analysis (2012), Sterile Product, Manufacturer (Certificate of Attendance) (2011), Practical Microbiology Level 2 (Certificate of Competency) (2011)

## REFERENCES

### **Luan Webber**

Improvements and Quality Manager  
Roche Diagnostics (Nederland)  
Previously QA Manager (RSS, Cape Town)

### **Michael Morad**

Quality Operations: Director  
Roche Sequencing Solutions  
(RSS)

### **Nana Gule**

Validation Manager  
Adcock Ingram (Clayville)

### **Ms Corne' Kleyn**

QC Manager  
The Biovac Institute (Cape Town)