**PROFESSIONAL SUMMARY**

An accomplished transformational leader, proven strategist, skilled communicator, team builder, and adept negotiator who blends expertise in global regulatory affairs and quality management with exceptional skills in business development and operations management. Proven ability to analyze global regulatory and quality trends, products, and services, and develop and deploy solutions that improve compliance, product quality, and competitive performance while aligning with corporate objectives and maintaining budgetary commitments.

**SKILLS**

QMS Implementation Effective Leader

Medical Device Regulation Staff Training/Development

Validation Processing Process Improvement

Risk Management Cost Reduction Strategies

CAPA Implementation Results-Oriented

**PROFESSIONAL EXPERIENCE**

**February 2022– to date: Revital Healthcare (EPZ) Ltd**

**Position: Quality Assurance Supervisor**

# Key responsibilities

**-**Responsible for the direction and implementation of QMS, Quality Policy and Procedural improvement.

-Responsible for the approval of all validated processes; IQ, OQ, PQ per FDA and Medical Device regulations and customer requirements.

-Preparation of SOPs and specifications according to ISO standards.

**-**Enforcing Good Manufacturing Practices, WHO- GMP.

**-**Coordinating routine quality schedules with Production and procurement departments.

**-**Coordinate and performing Audits (internal and external) in compliance with FDA and ISO guidelines.

**-**Writing reports and advising the management body on continuous improvement.

-Responsible for training of the Quality Inspectors and establishing company level of inspection acceptance per industry regulation and company procedures.

**January 2020 – February 2022: Cosmos Ltd**

**Position: Microbiology Section Head**

# Key responsibilities

∙Microbial Analysis and approval of pharmaceutical raw materials

∙Analysis of intermediate and finished products

∙Analysis of water and compressed air

∙Carrying out bioassays

∙Daily Calibration of Instruments

∙Preparation of SOPs and specifications

∙Enforcing Good Manufacturing Practices, cGMP

∙Writing Reports.

**Nov 2017 – Oct 2019: Dinlas Pharma EPZ Ltd**

**Position: Microbiologist In-charge**

# Key responsibilities

∙Conduct water validation and perform microbiological analysis of water to ensure microbiological control of the water systems

∙Perform material and finished product microbiological testing to ensure quality

∙Participate in environmental monitoring through swab, ambient air and compressed air

testing and trending of data.

∙Carrying out Preservative Efficacy Tests according to the stability program.

-Report to the Manager any results deviating from the set specifications or limits and participate in laboratory investigations.

∙Draft and modify SOPs used in QC micro and chemistry lab, and provide the training ∙Carry out calibration checks and routine maintenance on all microbiology lab equipment and instruments.

**April 2015 – August 2017: Universal Corporation Ltd**

# Position: QC Microbiologist

# Key responsibilities

∙Performing Microbial Limit test for finished and raw materials

∙Conducting Bio-assays and disinfectant efficacy tests

∙Performance of microbial and chemical analysis of purified and potable water

∙Environmental monitoring through settle plates, swabs analysis and particle count ∙Draft and modify SOPs used in QC micro and chemistry lab, and provide the training ∙Maintain reference cultures.

# EDUCATION BACKGROUND

# Aug 2008 – Dec 2012: Kenyatta University

Bachelor of Science Biotechnology (Upper 2nd Class Honors)

**2003- 2006: Makueni Boys’ High School**

Kenya Certificate of Secondary Education (KCSE) A- Minus.

**1994 - 2002: Malivani AIC Primary School**

Kenya Certificate of Primary Education (KCPE) 412 Marks

**REFEREES**

Mr. Willy Elbalido

Quality Assurance Manager

Cosmos Limited

P.O Box 41433- 00100

Nairobi.

Cell: 0723126033

Mrs. Leah A. Ambani

Programmes Officer

African Biotechnology Stakeholders Forum

P.O. Box 66069- 00800

Nairobi.

Tel +254720223244

Dr. Mary N. Mwangi

Lecturer

Department of Biochemistry & Biotechnology

Kenyatta University

P.O. BOX 43844─00100 Nairobi.

Cell: 0722646382