DR. TERESIA W. WAITHAKA

Regulatory and Scientific Affairs Manager – Nestlé Kenya Limited

Public relations | Partnerships & Stakeholders Engagement | Community Engagement | Coalition coordination | Law | Creative and innovative problem-solving skills | Policy Formulation & Advocacy | Negotiations | People Management | Culture Champion

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PROFESSIONAL PROFILE

A strategic thinker, innovative problem solver and passionate Pharmacist accomplished in driving standards of excellence in the pharmaceutical industry and the fast paced FMCG world. I have a good understanding and awareness of direction of government policies, legislative and regulatory requirements. I also claim Excellent interpersonal and influencing skills with both external and internal stakeholders; Strong customer service skills and solid operations expertise of over 10 years are underpinned with broad ranging functional experience that builds trust and lends authenticity to any leadership role. With a proven record in training, energizing and motivating teams, known for creating positive workplace cultures, lifting team productivity and building collaborative relationships with internal and external customers, regulatory authorities and business associations at all levels.

Professional strengths:

- ☑ Strategic management: refined through a *dynamic 9-year career* in diverse assignments including *product design & development*, *operations management, Regulatory and scientific affairs management,* and *stakeholder management.*
- ☑ Problem Solving skills: *Conceptual ability to assess and create roadmaps—prioritizing, planning, and executing with discipline and passion.*
- ☑ Result oriented: Committed to relevant and sustainable solutions. *Drive for tangible results is balanced by an equal drive for quality and First Time Right.*
- ☑ Communication: astute communicator accomplished in *both written and spoken language including expertise in giving presentations to a variety of audiences.*

PROFESSIONAL EXPEREINCE

Regulatory and Scientific Affair Manager and Corporate Communication and Public Affairs Manager – East African Cluster | October 2019 – To date.

Nestlé Kenya Limited

Management of regulatory matters related to products sold by or within the East Africa cluster. This includes management of regulations, compliance of products, labels and all related consumer communication material with local regulations, support for innovation and renovation, participation in elaboration and revision of local regulations in the countries of responsibility and co-ordination of Shared Regulatory Services. My role covers Kenya, Uganda, Tanzania, Rwanda, Burundi, and South Sudan. I also offer support for Ethiopia, Eritrea and Djibouti.

Key contributions:

- ☑ Facilitating timely product registration, marketing authorization and Pre-Export Verification of conformity as required by regulatory authorities in East African Countries and part of the Horn of Africa.
- ☑ Driving advocacy in key agenda to facilitate trade in a dynamic business environment. I am the regulatory lead in:
    - Advocacy towards harmonization of Standards in the EAC through KAM, COMESA business Council and EABC.
    - Advocacy towards process registration as opposed to product registration including mutual recognition of registration in EAC.
    - Contribution towards the revision of Kenya Legislations impact the industry to reduce technical barriers to trade.

- ☑ Developing and maintaining documentation to support decision making in labeling, claims and advertising of infant foods and foods for general populations.
- ☑ Supporting the Ideation to Launch process with regulatory insight for labeling, claims and other aspects of product development.
- ☑ Provide Regulatory Early Warning by ensuring that emerging issues are communicated in a timely manner, assessing the potential impact on business and putting in place risk mitigating action plans.
- ☑ Key Stakeholder mapping and designing strategies and action plans for meaningful engagement. Providing regulatory expertise in supporting different functions in engagement with external stakeholders. I have achieved key successes in Tax dispute resolutions, Pre-market approvals, License to operate, reduction of technical barriers to trade among others.
- ☑ Enhancing the corporate image and positioning of Nestlé through effective networking and public relations with our key stakeholders, and increase our visibility through mainstream, digital and social media.
- ☑ Managing Nestlé's existing CSV Creating Shared Value (CSV) projects and other sustainability projects.
- ☑ Spearheading consumer engagement services and management of the customer and consumer complaints handling process. Streamlining consumer engagement services in East Africa Cluster to reduce the percentage of dissatisfied contacts.
- ☑ Developing and implementing the internal communications plan. Managing internal communication and supporting the business by informing, engaging and motivating employees in pursuit of a shared strategic vision and goals.

Regulatory and Medical Affairs Manager-East and Southern Africa | Nov 2014 – Sept 2019
Mega Lifesciences Public Company Limited.

Ensured the Mega Lifesciences complies with all the regulations and laws concerning the company's pharmaceutical operations in Kenya, Uganda, Tanzania, Ethiopia, Sudan, Zambia, Rwanda and Burundi. Additionally, served as a medical affairs and quality compliance professional, to meet service and business needs via strategic planning, innovative resource allocation and change leadership.

Selected achievements:

- ☑ Advised on regulatory restraints and requirements to be considered when drafting the pharmaceutical development plan.
- ☑ Guided drug development strategy by advising on the best processes to follow and enabling structured interactions with regulatory authorities.
- ☑ Maintained marketing authorizations including application for annual retentions, re-registrations, variations, and appeals.
- ☑ Strengthened the understanding of local medical practices and patient needs and derived relevant insights. Maximized the medical benefits for customers by serving as the primary medical voice of the patient on all internal strategy discussions.
- ☑ Integrated relevant medical information into a central knowledge repository that includes internal medical data, publications and external knowledge from physicians and medical institutions.
- ☑ Presented educational information and training on the company's products in internal medical trainings and external CMEs.
- ☑ Supported research initiatives for off label indications.
- ☑ Developed and implemented SOPs aimed at ensuring compliance with regulations in the selling markets and accreditation programs for the company and its distributors in the market.
- ☑ Conducted internal and partner audits of regulatory documents and processes.

Company Pharmacist and Quality Head | June 2013 – October 2014
Oss-Chemie (K) Ltd

Selected achievements:

- ☑ Ensured implementation of the company's Quality Management System, and oversaw the Quality Control and Production Functions
- ☑ Directed the identification and procurement of capital assets necessary for the efficient operation of the Plant and QA/QC functions
- ☑ Developed and motivated plant and QA/QC staff
- ☑ Resource application and development
- ☑ Recruitment and training of technical staff.
- ☑ Liaised with various departments as regards development and introduction of new products (and old products in new markets) in the region
- ☑ Conducted regular reviews of complaint history with a view to establish trends in product quality.
- ☑ Participated in vendor quality audits and to ensure that any service likely to impact on product quality, is procured from approved vendors.

Site Pharmacist | May 2012 – June 2013
Elys Chemical Industries Ltd

Selected achievements:

- ☑ Oversaw the transfer of technology from the Beta-lactams department in Elys Unit I to the new Beta-lactams department in Elys Unit II and facilitated regulatory approvals for manufacturing in the new site.
- ☑ Set up and implemented quality assurance management systems in Elys Unit II.

- ☑ Approval of production and release of finished products.
- ☑ Conducted personnel training.

Quality Assurance Manager | Feb 2011 – Apr 2012

Ivee Aqua EPZ Ltd.

Selected achievements:

- ☑ Quarterly production planning, product costing, raw material and packaging material procurement, and Production Budgeting.
- ☑ Set up and implemented quality management systems.
- ☑ Qualification of equipment and Validation processes and analytical procedures.
- ☑ Oversaw Pharmacy and Poisons Board GMP and external audits and implementation of CAPA.

Intern Pharmacist | Aug 2010 – Dec 2010

DAWA Pharmaceutical Limited

Selected achievements:

- ☑ Conducted tests to determine identity, purity and assay of raw materials in relation to specified standards and current pharmaceutical manufacturing practices.
- ☑ Assisted in development of SOPs for Good Manufacturing Practices.
- ☑ Involved in determination of the most suitable packaging material for medicinal substances to avoid deterioration and facilitate distribution.
- ☑ Assisted with qualification testing and production equipment and validation of analytical methods.
- ☑ Assisted Compounded liquid dosage forms, ointments, and sterile powders for injections, tablets and other medications.

EDUCATION

Master's in Business Administration (MBA) –Strategic Management | 2013-2015
University of Nairobi, Nairobi – Kenya

Bachelor of Pharmacy | 2003-2007
University of Nairobi, Nairobi – Kenya

PROFESSIONAL AFFILIATIONS

Registered Pharmacist

Member | Pharmaceutical Society of Kenya

Board Member | Nestlé Pension Fund Trustee Board

REFERENCES

Dr. Peris Kibandi | Quality Assurance Head-EEA - Novartis Pharma Services
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Dr. John Mureithi | Head of Regulatory Affairs and Local Quality Representative- Middle Africa, Bayer Healthcare Ltd
Tel: +254 726 396 098

Stella Macharia | Former HRBP- East and Southern Africa Region, Nestlé ESAR
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