



MARIE WANJA NYAGA

REGULATORY AFFAIRS MANAGER

Profile

I am an experienced and self-motivated Regulatory Affairs professional in the FMCG and Pharmaceutical Industries with an education in Pharmacy and Human nutrition and dietetics. In my eleven years experience in regulatory affairs, my passion is in policy making, advocacy and ensuring favorable regulations are put in place that encourage industry growth while putting the health of consumers at the fore-front. My work includes analyzing the impact of proposed new global standards and seeking opportunities for regulatory alignment to remove barriers to business growth.

Employment History

REGULATORY AFFAIRS MANAGER-EAST AFRICA, COLGATE PALMOLIVE (EAST-AFRICA) LTD, Nairobi

SEPTEMBER 2017 – PRESENT

Presently, I engage my services as a Regulatory Affairs Manager where I bear full charge and responsibility for the management of regulatory matters related to products sold within the East Africa cluster.

I cover the following countries: Kenya, Uganda, Tanzania, Rwanda, Ethiopia and Zanzibar. I also offer support for Somalia, Eritrea and South Sudan.

My achievements include:

- I have successfully registered various new and innovative products in the East Africa market on time hence ensuring timely market launch
- I have ensured that the company's marketing authorization is valid and compliant to local regulations by ensuring timely renewals and variations submissions are made.
- I have ensured that the business strategies for East Africa are successful by actively making regulatory assessments, checking label compliance and ingredients review.
- I have built strong relationships with key competent authorities in the region in my regular engagements which comes in handy during business advocacy and crisis solving whenever regulatory issues arise
- I have managed to reduce by 90% noncompliance to regulations in importation and marketing of our products by training logistics and marketing team on regular basis.
- As a member of the technical committee at KEBS, I have succeeded in drafting and reviewing several standards that concern our products hence ensuring harmonization of our internal processes and those set by the regulator.
- I am a member of a local advocacy team that is working with the Kenya Association of Manufacturers (KAM), Africa Organization for Standardization (ARSO), Personal Care and Products Council (PCPC), Cosmetic, Toiletry & Fragrance Association (CFTA) and Cosmetics Europe (EC) on harmonization of African Standards and ensuring that standards encourage innovation with an incline towards consumer safety.

REGULATORY AFFAIRS , VARIOUS PHARMACEUTICAL INDUSTRIES IN KENYA, Nairobi

FEBRUARY 2010 – AUGUST 2017

Details

Nairobi

Kenya

+254 721 914 607

mariewanja@gmail.com

NATIONALITY

Kenyan

Links

[LinkedIn profile](#)

Skills

Communication Skills

Team player with strong
engagement skills

Analytical and strategic thinking

Coordination and organisation

Advocacy

Languages

English

Swahili

Hobbies

Hiking, Travelling, Working Out,
Reading

I have an experience of seven years in regulatory affairs having worked in four pharmaceutical companies in Kenya.

These are:

1. Regulatory Affairs & Quality Assurance Associate at Abbott Laboratories (EPD) Ltd-June 2015 to August 2017'

Responsible for English and Portuguese speaking Africa.

2. Regulatory Affairs Head at Laboratory & Allied Ltd -Feb 2012 to May 2015.

As a manager I was responsible for a team of 5 as well as overall responsibility for the East and Central Africa region.

3. Regulatory Affairs Officer at Dawa Ltd-Sep 2011 to Jan 2012

Covered East, Central and some English speaking West Africa countries.

4. Regulatory Affairs Officer at Universal Corporation -Feb 2010 to August 2011

Covered East, Central and some English speaking West Africa countries.

My major achievements in the pharmaceutical industry were:

- Successful registration of many products in the region in all the companies
- While at Abbott Laboratories EPD, I successfully ensured set-up of the new Nairobi office and new registration of products in the region. This led to massive growth of the company within the three years that I worked at the company.
- While at Laboratory and Allied, I was part of the team that worked with the Pharmacy and Poisons Board in drafting CTD guidelines .
- Having been a member of the GMP and Pharmacovigilance teams, I was successful in ensuring that the companies passed external quality audits.
- I helped develop and implement best-practice standards aimed at ensuring compliance with Local FDA regulations and accreditation programs for the company and its partners in the market.

Education

BSc Human Nutrition and Dietetics, Kenya Methodist University, Nairobi

Diploma in Pharmacy, Kenya Polytechnic University College, Nairobi

Kenya Certificate of Secondary Education, Kyeni Girls High School, Embu

Internships

Short-Time Assignment, Colgate Palmolive North America

APRIL 2021 – AUGUST 2021

A short Term Assignment to Support the Oral Care Team in:

- I supported the North America team in Claim Tracker, Regulatory Assessment, ensuring process work flow and provided other regulatory assistance and support to the hello, Tom's of Maine and Toothbrush.

Qualification Internship with the Pharmacy and Poisons Board , PPB-Kenya

JANUARY 2009 – NOVEMBER 2009

1. Embu Provincial General Hospital

2. Njeru's Pharmacy

3. Universal Corporation Ltd

Short-Time Assignment at Hills Pet Nutrition, Nairobi

FEBRUARY 2022 – PRESENT

Hills Pet Nutrition is an affiliate of Colgate Palmolive company that is working to penetrate the East-Africa region.

I am currently their contact person and working with Hill's Pet Nutrition team to on their products launch in the East Africa market. This includes label review, checking products compliance to standards, registration and also making assessment on other regulatory requirements.

Membership and Associations

Member, Kenya Pharmaceutical Association

JANUARY 2014 – PRESENT

Technical Committee Member, Kenya Bureau of Standards

SEPTEMBER 2017 – PRESENT

A member of the cosmetics, surface active and Oral Care technical Committees.

Technical Committee Member, Kenya Association of Manufacturers

SEPTEMBER 2017 – PRESENT

A member of the Chemical Sector Technical Committee at

Personal Care Products Council Member, PCPC

SEPTEMBER 2017 – PRESENT

A member of the PCPC-Sub Saharan Africa Advocacy Team

Achievements and Competency

Lobbying

1. I was part of the cosmetic industry through KAM in negotiations with the Pharmacy and Poisons Board(PPB)regarding new proposed regulations for cosmetics. The PPB thereafter acknowledged they do not have sufficient resources to regulate cosmetics and would maintain their focus on products with medical claims only.
2. Actively participated in the PCPC led Sub-Saharan initiative that engaged stakeholders from KEBs, MOH, US embassy, AmCham, European Chamber of Commerce, Ministry of Trade and Cooperatives regarding TBTs in the cosmetic industry and proposed alignment to global regulatory practices.
3. Successfully proposed the review of the toothpaste standard for the East Africa region hence ensuring harmonization of standards for the East Africa region which ensured a better marketing environment for Colgate Palmolive toothpaste.

References

References available upon request