



# Dr. Selina Lumadi Musalia

Regulatory Affairs Manager

## KEY AREAS OF COMPETENCE

### CONTACT DETAILS

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### LANGUAGES

- English
- Kiswahili
- German(basic)

### PERSONAL SUMMARY

Experienced Regulatory Manager with vast regulatory experience. Skills include strategy execution, compliance and governance. I am a skilled professional seeking to contribute towards employer's strategic vision for growth and success on a local and international platform.

### EDUCATION

**2019:** Master of Business Administration (MBA) for Executives – Strathmore Business School  
**2018:** Pan African MBA- IESE Business School.  
**2012:** Bachelor of Pharmacy – University of Nairobi  
**2007:** Zertifikat Deutsch – Goethe Institute Nairobi

### ATTRIBUTES

- Team leader
- Good communicator
- Autonomous
- Loyal
- Drives results

- Registration and product maintenance.
  - Preparation, submission and follow up on approval of registrations, renewals, variations, labelling updates for pharmaceutical and consumer products in Eastern African countries.
- Regulatory Compliance.
  - Maintenance of regulatory databases. Ensuring promotional material adhere to regulatory requirements within the country. Compliance with regulator requirements for wholesale dealer's license, medical representative licenses. Prompt application for renewals before license expiry.
- Strategy.
  - Developing strategies to ensure faster regulatory approvals of new registrations.
- Lobbying.
  - Negotiating with health Authorities for faster approval of registrations. Participating in technical committee meetings and pushing for update and change of standards to accommodate new innovation.
- Leadership.
  - Taking initiative and spearheading implementation of various projects. Always willing to take up new roles and responsibility. Providing direction to team members. Mentoring and coaching of new employees.
- Regulatory intelligence.
  - Gathering intelligence information on new regulations within the region. Formulating position papers on the potential impact of certain regulation on the business environment.
- Change management.
  - Handling of product variation from inception to implementation.

## EMPLOYMENT HISTORY

### LOREAL EAST AFRICA

Present

#### Regulatory Affairs Manager-East Africa

Responsible for regulatory compliance, formulating regulatory structures for the organization, claim approvals, lobbying on behalf of L'Oréal and the cosmetic industry.

#### Key Achievements

- Organized for key stakeholder engagements including MD for KEBs, KAM, Head of regulation and policy at the ministry of Health, Cosmetics technical committee, Head of importation TBS.
- Initiated and currently pursuing the change in labeling information on all locally manufactured products to ensure compliance to local labelling requirements and subsequent reduction of tax obligations.
- Reviewed current standards on relaxers and aftershaves to include innovative products.
- Development of position paper on KFDA bill on behalf of the cosmetic industry and sharing with key stakeholders.
- Review of claims, specifically for active cosmetic division to ensure compliance with local regulations.

L'OREAL

## SYSTEMS PROFICIENCY

**BRAIN:** Bayer Regulatory Affairs Information Network.

**SAP(P4S and P2R):**stock management and Artwork management systems.

**Share Doc-**Information archiving system

**SYNAPS-**Consumer Health product Change management tool including regulatory documents request.

## MEMBERSHIPS AND ASSOCIATIONS

### Current

KAM cosmetic sector committee-Member  
KEBs cosmetics technical committee-Member  
Pharmaceutical Society of Kenya-Member.

### Previous

KAPI PR committee-Member  
KNH handwashing area committee-Chairperson  
Bayer Brand Ambassadors-secretary

## BAYER EAST AFRICA

June 2014-June 2019



### Regulatory Affairs Specialist-Middle Africa

My core deliverable was in establishing new licenses in the region and maintenance of the key products. I managed the Anglo East Africa region which includes Kenya, Uganda, Tanzania, Rwanda and Ethiopia. In addition I manage the consumer health business for East Africa, Anglo West Africa (Nigeria and Ghana) and French West Africa countries.

My role involved:

- Registration of 20 products in Kenya, Uganda, Ethiopia, Tanzania and Rwanda including key brands such as Eylea, Xarelto, Ciprobay, Nexavar, Supradyn and Bepanthen which account for 60% of sales in East Africa.
- Maintenance of 233 licenses in the AEA region, and 235 consumer health licenses in FWA.
- Successful transfer of 62 products following acquisition of Merck Consumer Health in the Middle Africa region. Handling of labelling activities for 79 pharma SKUs and 25 consumer health SKUs.
- Prompt update of RA relevant databases and continuous tracking of registration statuses. Providing regulatory support for business in the Kenyan office, representative offices and local contacts within the region
- Formulating regulatory strategies to realize faster registration approvals.
- Creating and maintaining contacts within the various regulatory Authorities and ensuring we have up to date information on regulatory requirements for each individual country.
- Ensuring compliance with industry codes of conduct as pertains to product advertising and regulatory and guidelines.
- Prompt submission and approval of product specific changes to the regulatory Authorities.
- Providing launch support for key brands
- Maintenance of Quality Management Systems (QMS) within the organization.
- Ensuring no interruption of product supply by coordination of product supply, regulatory and change management functions.
- Archiving of all regulatory documents.
- Participation in trade association meetings and regulatory Affairs relevant trainings.

## COMMUNITY SERVICE

- Organized Moon cup project in Baba-Dogo Primary school. The project involved organizing for trainers to speak to girls and boys on Puberty, crime and drugs. Additionally we provided all girls of the appropriate age with moon cups.
- Set up Bayer Welfare program. A program to assist employees financially in case of loss of a loved one.
- Took lead in the implementation of KNH handwashing area refurbishment.
- Actively participated in the endometriosis awareness campaign.

## REFERENCES

Dr. John Mwangi  
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