

**CURRICULUM VITAE**  
**KIRUI ENID CHELANGAT**

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**PERSONAL DETAILS**

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**NATIONALITY:** Kenyan  
**SEX :** Female

**Date of birth:** 17<sup>th</sup>/09/85  
**Religion:** Christian

**PROFILE**

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I am an ambitious Regulatory Affairs Professional with unwavering resolve. I am determined to do well in my job and have a successful career, as well as to make the organisation I work for more competitive. I pride myself in being strongly reliable and focused regulatory affairs professional with a great depth and breadth of experience in pharmaceutical and cosmetics product review and evaluation with over 5 years of experience.

I am someone who believes that learning is a process that never stops and to be productive one has to always be ready to improve their skills

**KEY SKILLS**

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- Regulatory Knowledge
- Excellent Organization skills
- Working effectively with diverse group of people
- Business acumen
- Pro-activeness and Results oriented
- Strong communication skills

**EDUCATION**

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April 2006- May 2009: **Jomo Kenyatta University of Agriculture and Technology**

- Undergraduate degree in BSc. Medical microbiology,  
(Second class, lower division)

2000- 2003 **Buruburu girls' secondary school**

- Grade B-(Minus) in Kenya certificate of secondary Education (KCSE).

1994-1999 **Tengecha girls boarding primary school**

- Kenya certificate of primary Education.

## **EXPERIENCE**

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**June 2017 to Current: Beiersdorf East Africa Limited**

**POSITION: Regulatory affairs & Quality Assurance Officer**

### **RESPONSIBILITIES**

- Ensuring the regulatory compliance for all Beiersdorf client's consumer products for all countries in the Management Unit (MU) CEWA (Central East and West Africa).
- Working closely with R&D and Marketing departments during product launch and relaunch.
- Advising the business in case of regulatory developments that might affect the business positively or negatively.
- Coordinating the approval, registration, listing or notification of Beiersdorf client's consumer products to ensure fast access to market in the CEWA countries.
- Development of MU Quality Management Systems (QMS).
- On shelf assessments and reporting of results to relevant stakeholders
- Management of VAS (Value Added Services) activities and LSP (Logistics Service Providers) to include monitoring of warehousing of products from other countries

**September 2013 to June 2017: Bimeda Limited**

**POSITION: Regulatory affairs Coordinator (AMEA)**

### **RESPONSIBILITIES**

- Facilitating new product registration for Africa, Middle East and Asian (AMEA) market and update any product registrations, in line with change requests, so as to safeguard business continuity.
- Ensure high quality collaboration between headquarters Regulatory (Global Regulatory Affairs) and development functions; Area Regulatory Head and local Regulatory teams to deliver the fastest regulatory approvals.
- Identifying as early as possible, the required documentation and any content, quality and/or timeline issues. Negotiate the delivery of approved technical source documents in accordance with project timeline.
- Support AMEA Commercial objectives for new and existing products. Ensure alignment of Regulatory objectives with global development strategies and commercial plans
- Evaluating key issues for discussion and negotiated with Health Authority experts to clarify questions.
- Coordinating with Bimeda colleagues in various countries to ensure that all the documentation and samples requirements of each country is obtained and delivered.
- Requested data from the manufacturing site and submitted the updated version of the dossier to Competent Authorities.
- Putting requests to KEBS for approval
- Arranged and indexed correspondence and approved documentation on drug products, archiving copies of submitted files

- Assist in the continuous improvement of departmental systems to support the regulatory function.
- Ensuring all legal and regulatory documents concerning the company and products are up to date in all drug regulatory registration.
- Represent the company in various forums e.g. KAPI, PPB, AAK, PCPB.
- Assist in managing product incidents and support product recalls.
- Report and follow-up on product complaints with manufacturing sites, customers, commercial teams and conduct analysis of product complaint trends in conjunction with the Medical department.
- Review, update and finalize all distributor quality agreements at renewals.

**August 2012 to August 2013: Surgilinks Limited**

**POSITION: Professional Medical Representative**

**RESPONSIBILITIES**

- Recommended and created awareness of the company's products and services to existing, new and potential customers i.e. Doctors, Pharmaceutical products' wholesalers and retailers and institutions such as hospitals
- Carried out market survey by gathering information of trends of the company's products as well as those of the major competing products in the market
- Formulated the marketing strategies to employ in order to fit and dominate the market.
- Maintenance and built of strong customer relationships
- Managed budgets and keeping detailed records of all contacts visited
- Responsible for overall account management, account development, relationship and sales development
- Sourced for suppliers and undertaking systematic negotiations on products and prices and ensure transparency in the procurement of product supplies
- Determining customer requirements and expectations in order to recommend specific prescriptions for products
- Conducting continuous medical education meetings to educate the practitioners about terminology, features and benefits of products in order to improve product related sales and customer satisfaction
- Proactively recommending items needed by customers to increase customer satisfaction and improve transaction profitability
- Ensuring prescription records and inventories of medications and pharmaceutical products were accurate
- Conclusively managed all customer queries and complaints and continually monitored on clients satisfaction and requirements

**Jan 2010 to June 2012: Current: Laboratory and Allied limited.**

**POSITION: Drug Registration Officer.**

**RESPONSIBILITIES**

- Timely Preparation of dossiers for registration in Kenya and other countries as per the outlined format and guidelines

- Maintaining progress reports for all RA operations for presentation at meetings and to the management.
- Ensuring that the formulation is consistent with that in Batch Manufacturing record (BMR).
- Ensuring that all legal requirements are adhered to.
- Ensuring that any change after registration is reported to the registrar.
- Assist in responding to queries raised by various regulatory bodies on drug product registration.
- Making sure that follow-up is made in order that re-registration is not delayed.
- Ensuring that there is coordination of registration dossiers with QA and QC department.
- Proper record keeping of all Regulatory documents assigned in a manner that they are retrievable whenever required.

## **INTERESTS**

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Reading, travelling, listening to music and doing community volunteer work (Member of Kenya Red Cross society)

## **REFEREES**

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### **1. Dr. George Wafula**

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