CURRICULUM VITAE
KIRUI ENID CHELANGAT

P.O. Box 9387 - 00200 NAIROBI, Cell: 0725990978, E-mail: enidkirui@gmail.com

PERSONAL DETAILS

NATIONALITY: Kenyan **Date of birth**: 17th/09/85
SEX : Female **Religion:** Christian

PROFILE

I am an ambitious Quality and 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 organization I work for more competitive. Pride myself in being strongly reliable and focused quality assurance and regulatory affairs professional; with a great depth and breadth of cross regional experience in pharmaceutical and cosmetics product review and evaluation with over 9 years of experience.

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

KEY SKILLS

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

EDUCATION

April 2006- May 2009: **JomoKenyatta 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

Aug. 2021 to Current: L'Oreal East Africa Limited
POSITION: Regulatory and Public Affairs Manager
RESPONSIBILITIES:

June 2017 to July 2021: Beiersdorf East Africa Limited
POSITION: Regulatory affairs &Quality Assurance Specialist
RESPONSIBILITIES

- Ensuring the regulatory compliance for all Beiersdorf products for all countries in the Management Unit (MU) CEWA (Central East and West Africa).
- Working closely with global R&D and Marketing departments during product launch and relaunch to ensure market regulations are met.
- 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 consumer products to ensure fast access to market in the CEWA countries.
- Support in label development to ensure compliance with each country regulations.
- Coordinating samples submissions from various manufacturing sites to approved laboratories as per importing country requirements.
- Maintained and indexed correspondence and approved documentation on drug products, archiving copies of submitted files.
- Representing the company in various forums such KAM and KEBs technical committee influencing regulatory decision that will affect the company's business.
- On shelf products 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.
- Support documentation requirements of various quality, compliance, certification and accreditation programs such as ISO 9001
- Review gap analysis and reviews of Product and Process requirements, Non-Conforming product / process Handling process; set controls and tracking throughout the cycle.
- Track corrective and preventive actions for manufacturing problems & gaps.
- Keep a track on Continual Improvement projects from project identification, risk assessments, implementation to post implementation evaluation.
- Coordinating internal and external audit and follow up of findings to ensure closure and ensuring sustained improvements.
- Supplier management on quality aspects.
- Supporting the supply chain team in setting up procedures and guidelines for effective Quality Management Systems
- Coordinating change management
- Complaints management

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 clarity 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.

Jan 2011 to Aug. 2013: 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

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

REFEREES

1. **Dr. George Wafula**

   Pharmaceutical Supply Chain Manager
   AAR Health Care,
   Head Office 4th Ngong Avenue, Williamson House
   Cell Phone: 0722-360951
   Email: gwangasa@gmail.com

2. **Rashid Sheik**
   Senior Laboratory Scientist Centre for Respiratory diseases
   Cell phone: +25472159616
   P.O.Box 14984-00100, Nairobi

3. **Dr. Castro Wanjoya**
   Regulatory Affairs Manager (AMEA)
   Bimeda
   Cell phone: +254721685287
   Email: cwanjoya@bimeda.com