ANN NYAKINYUA NDIRITU P.O. Box 27511-00100, Nairobi +254 710 793 800 nyakinyuandiritu@gmail.com

PPB Reg. No. 3607

PROFILE

A dedicated regulatory pharmacist professional with four years' experience in regulatory aspects, quality assurance, product development, supply chain management and clinical pharmaceutical practice. With proven ability to absorb and process new concepts, increase productivity while maintaining the highest standards of pharmaceutical ethics. I have a strong work ethic and I am an advocate of continuous learning.

EDUCATION

May 2011 – June 2017

BACHELOR OF PHARMACY

Jomo Kenyatta University of Agriculture and Technology

WORK EXPERIENCE

Oct 2021 - To Date

QUALITY & REGULATORY AFFAIRS OFFICER, EA BEIERSDORF EAST AFRICA LTD

Key Responsibilities:

- Coordinate the approval, registration of Beiersdorf consumer products by regulatory bodies to ensure fast access to market in all East Africa countries.
- Provide regulatory support and advice for other functions in the achievement of business objectives
- Keep up to date with regulatory policies and procedures for the countries and maintain an understanding of the scientific and technical background of company's products.
- Maintain access to Beiersdorf registration library as the RAO and ensures the generation/sourcing of required regulatory documents for submission to health authorities

Feb 2021 - Oct 2021

REGULATORY AFFAIRS & QUALITY ASSURANCE PHARMACIST PYRAMID PHARMA

Key Responsibilities:

- Carrying out internal audits as the Lead Internal Auditor for auditing of Quality Management System to ISO 9001 2015.
- Preparing and submitting of new pharmaceutical dossiers and submitting of product retentions.
- Preparing and submitting of new registration documents for medical devices and submitting retentions.
- Following up on queries following submission of documents in PPB and laboratory analysis of products.
- Identifying gaps in the QMS, warehouse inspections and following up CAPAs. Handling of quality concerns that may arise from pharmacovigilant activities.

Feb 2020- Jan 2021 **PRODUCT & REGULATORY AFFAIRS PHARMACIST** ZUVAN LIMITED

Key Responsibilities:

- Participating in product development including preparing of artworks, clinical studies and brochures.
- Preparing and submitting of new product dossiers and retentions.
- Following up on queries following submission of documents and lab analysis of products at the pre-qualified labs.
- Ensuring quality assurance, compliance with regulatory requirements and adherence to Good Distribution Practices.
- Developing marketing and promotional mix to meet brand objectives by training of medical representatives.

TRAINING

| TRAINING | CONVENER | DATE |
|---|--|----------|
| PHARMACOVIGILANCE (E-learning) | Mission for Essential Drugs and Supplies | On going |
| INTRODUCTION TO REGULATORY AFFAIRS (E-learning) | Global Institute of Regulatory Affairs | Dec 2020 |

PROJECTS

| TITLE & DATE | PROJECT | |
|--|---|--|
| RESEARCH INTERN Feb 2019 – Aug 2019 | HATUA (Holistic Approach to Universal Antimicrobial Resistance) Project, KEMRI. | |
| EDITORIAL ASSISTANT Nov 2018 - Jan 2019 | 2 nd Edition of the Kenyatta National Hospital Formulary (2013) | |

REFEREES

| Aquatix Pharmaceuticals Ltd Company Pharmacist | Migori County Hospital Hospital Pharmacist | Nakuru County Hospital Hospital Pharmacist |
|---|--|--|
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