ROSANA, BEATRICE
Curriculum Vitae

Name: ROSANA, Beatrice Mokeira
Gender: Female
Date of birth: 19th April 1975.
Marital status: Married
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Summary

I am an excellent leader with wide experience in a pharmaceutical Quality control and quality assurance. I have great people management skills and currently assist in managing a team of 35 personnel in the KEMSA Quality Assurance department. Proven to work well as part of a team as well as on individual assignments with great achievements in both GLAXOSMITHKLINE where I worked as a laboratory analyst, in-process chemist and Product and process development technologist and in KEMSA where I worked as a Quality Assurance officer and later promoted to the Assistant Quality Assurance Manager. I have excellent auditing skills and currently I coordinate the internal ISO 9001:2015 and the ISO 17025:2017 audits in KEMSA. I aspire to expand on these skills and enhance my career in competitive organization.

Key Achievements

- Competently overseen the testing and inspection of products in KEMSA in the last 10years
- Successfully set up a fully-fledged laboratory at KEMSA and continued to lead the activities of the lab.
- Successfully steered the KEMSA laboratory in attaining ISO 17025:2005 accreditation and the transition to ISO 17025:2017 in 2019.
- Successfully assisted in maintaining the ISO 9001:2015 Certification in KEMSA.
- Implemented a document control system through unique numbering of KEMSA documents.
- Competently manage the departmental budget.
- Successfully audited most of the major local suppliers to ensure that they qualify to supply KEMSA with drugs.
- Played a key role in validation of laboratory and production equipment and new product development processes in GSK with great success in development of the Hedex local granulation in kenya
- Successfully validated the HVAC system in GSK.
- I am an Operational excellence green belt

Key Competencies

- 20 years' experience in Quality Assurance and Quality Control
- Excellent knowledge on quality management systems (QMS)-Trained as a lead auditor in ISO 9001:2015 and ISO 17025:2017 lead assessor. Currently I coordinate the Quality

Management Activities in KEMSA and oversee the inspection and testing of products in KEMSA.

- Management of the Quality assurance and Quality control systems
- Skills on GMP/GLP training and GMP/Supplier Audits.
- Vast Knowledge on product development.
- Knowledge on Operation Excellence (OE) tools with Excellent analytical and problem-solving skills and process improvement.
- Vast knowledge on Equipment validation and process review..
- Experience in handling of customer complaints-Currently I am the chair of the Public complaints' resolution committee in KEMSA.
- Experience in risk management. I am the risk champion in KEMSA
- Knowledge on developing dossiers for product registration

Education

Year	Institution	Qualification
2015	Moi University	MBA-Strategic management
2010	Moi University	MPH-Pending project
1995–1999:	Moi University	Bachelor of Science Degree, Upper class (Chemistry Major)
1990 – 1993	Alliance Girls High school	Kenya Certificate of Secondary Education (K.C.S.E)
1982 – 1989	Itierio Girls Primary School	Kenya Certificate of Primary Education (K.C.P.E)

Work Experience

January 2017 todate: Kenya Medical Supplies Authority (KEMSA)-Assistant Quality Assurance Manager.

- Oversee the day to day Quality Assurance and Quality control activities.
- Ensure reliability of the results obtained by the laboratory by reviewing the analytical results
- Prepare the department's budget and ensure implementation
- Ensure that product procured meet expected quality requirements through Inspections and analysis:
- Investigate and respond to quality related complaints ensuring customer satisfaction
- Ensured staff competency through appraisal and schedule for trainings based on need analysis
- Maintenance of the ISO 17025:2017 Accreditation
- Implementation of Quality management systems(QMS) by Reviewing and Implementing standard operating procedures, systems, and documentation related to procurement, warehousing and distribution of Pharmaceutical, non-Pharmaceutical and medical equipment in compliance with ISO 9001:2015 standards. Coordination of ISO 9001:2015 internal audits

Key Achievements

- 2018-Set up the chemical testing laboratory and Led the lab in transitioning from ISO 17025:2005 to attaining ISO 17025:2017.
- Steered the organization in transitioning from ISO 9001:20008 to ISO 9001:2015.

May 2011 to January 2017: Kenya Medical Supplies Authority (KEMSA)-Quality Assurance Officer

- Ensured that product procured met expected quality requirements by enhancing the Inspections and analysis processes. Set up an inspection station at the receipt bay.
- Liaised with WHO prequalified labs in undertaking laboratory analysis of products procured by KEMSA in addition to in-house testing.
- Ensured implementation of Quality management systems(QMS) by reviewing and implementing standard operating procedures, systems, and documentation related to procurement, warehousing and distribution of pharmaceutical, non-pharmaceutical and medical equipment in compliance with ISO 9001:2015 standards. Coordinated the ISO 9001:2015 internal audits.
- Maintained the stock master file ensuring traceability of commodities through unique identification
- Investigated and responded to customer complaints relating to drug quality enhancing customer satisfaction
- Carried out GMP/supplier audits of all the key local manufactures ensuring compliance with Good Manufacturing Practices and Good Distribution Practices.
- Ensured that good warehousing practices were maintained by coordinating the temperature monitoring and mapping activities.

Key achievements

- 2011-2014 Led in setting up the quality Control laboratory through identifying the Laboratory requirements, procurement of equipment and building personnel capacity
- 2016-Led the lab in attaining ISO 17025:2005 accreditation
- 2013-Review of the organizational SOPs to a standard format

July 2005 to April 2011: GlaxoSmithKline-Product and Process development Technologist
Specific Duties

- Installation and operation qualification of utilities,
- Validation of manufacturing and analytical equipment.
- Validation of processes and products and risk analysis in processes.
- Product development: Facilitated trial production runs of new products and prepared registration dossiers for new products in conjunction with the regulatory officer.
- Carried out analytical and cleaning validation.
- Coordinated process capability studies to ensure the machines and processes are operating in a state of statistical controls.
- Coordination of stability samples to the lab and retained references samples.

- Evaluated trended data retrospectively for the purpose of process improvement.
- Preparation and review of batch Records.
- Environment Health and safety representative; Ensuring that ISO 14001 and OHSAS 18001 standards were maintained within the company.
- Carried out self-audits

Key achievement

- 2006-Sucessfully led the development of the Hedex extra granulation process
- 2010-Successfully validated the HVAC project

April 2004 – June 2005: GlaxoSmithKline-In-Process Chemist

Specific Duties

- Production startup qualification, assuring quality by performing continuous in-process checks, ensuring all parameters of the product were within specification during production run and that all production documents were filled as per GMP requirements.
- GMP training and online GMP training to ensure that entries in batch documents were correct and right first time
- Sampling, inspection and testing of semi finished and finished products, physical release, approval, issuance of control numbers, manufacturing and expiry dates for the same and obtaining retain reference samples and samples for on-going/accelerated stability programs.
- Investigating and responding to quality related customer complaints.
- Supervision of all production processes and personnel while on night shift.

June 2001 – Mar-2004 GlaxoSmithKline - Laboratory analyst

- Analysis of raw materials intermediates and finished products using high precision analytical equipment such as High liquid performance chromatograph(HPLC),UV spectrophotometer, FTIR Spectrophotometer, Gas chromatograph, Atomic Absorption Spectrophotometer(AAS) Karl Fischer. Kjeltec distillation apparatus, Etc
- Chemical analysis of water for production
- Preparation and reviewing of Standard Operating Procedures(SOP's)
- Preparation and standardization of test /volumetric solutions.
- Calibration of Equipment
- Carrying out stability studies, both accelerated and on-going for the purpose of shelf life determination of products.
- Environment and safety awareness.
- Posting of analytical data for trending monitoring

Feb 2000- May 2001: **Laboratory and allied**

Carrying out same responsibilities as in GlaxoSmithKline as a laboratory analyst

May 1998 to Aug 1998: **East African Portland cement, Athi River.**

Industrial attachment in the laboratory carrying out the following;

Determination of sulphur dioxide, heavy metals, insoluble residue in clinker and cement

May 1997 to Aug 1997 Amasago secondary school

Attachment as a chemistry Teacher

Trainings

Date of Training	Training	Trainers/Institution
May 2019	Laboratory Management systems	KEBS
August 2018	ISO 17025:2017 Internal Auditor	KENAS
April 2018	ISO 17025:2017 Implementation course	KENAS
Mar-2017	ISO 17025:2015 Method validation and uncertainty of measurement	KEBS
Dec-2015	Lead Auditor Training-ISO 9001:2015	Bureau of Veritas
8-10th Oct-2012	International workshop on GMP Audit and self-inspection	WHO, GIZ in Arusha
13-14th April-2012	ISO 9001:2008 internal auditors training	Bureau Veritas
28th Nov to 1st Dec 2011	Patient Safety with a focus on Non-pharmaceutical Commodities	Strathmore business school
9-12 May-2011	Workshop on GMP for manufacturers and GMP inspectors	WHO, GIZ
Oct-2010:	Internal/GMP audit	GlaxoSmithKline
August 2010	First line leadership	GlaxoSmithKline
August-2009:	Leading and managing Lean Sigma-Operational excellence green belt certification	GlaxoSmithKline
April-2008	Quality Leadership edge- Developing a quality mind set	GlaxoSmithKline
Dec-2007	Quality management systems	GlaxoSmithKline
May 2006	Training on Quality Leadership Edge	GlaxoSmithKline

Hobbies:

Interacting and helping the less fortunate in society, Reading and traveling

Referees

1. Tom Ouma Estec Tel:0733700773	2. Esther Githathu GlaxoSmithKline P.O BOX 78392 Nairobi. Tel:020-6933565,	3. Dr. John Aduda, Kenya Medical Supplies Authority (KEMSA), P.O. BOX 47715, NAIROBI. Tel:0733607680