



Curriculum Vitae

Personal information **Martha Mandale**

Work experience

- Pharmacy and Poisons Board March 2016 - Present
Principal Regulatory Officer, Pharmacovigilance
- Support the African Union's Smart Safety Surveillance (AU-3S) Joint Signal Management Secretariat in signal management activities for regulatory decision-making across Member Countries.
 - Implement risk management recommendations from the National Vaccine Safety Advisory Committee and the Pharmacovigilance Experts Review and Advisory Committee to enhance patient safety in Kenya.
 - Lead in the review and approval of safety variations to ensure compliance with regulatory requirements.
 - Evaluate individual case safety reports (ICSRs), periodic safety update reports (PSURs), periodic benefit-risk evaluation reports (PBRERs), and risk management plans to support informed regulatory decisions on the safety of health products.
 - Assess the safety profiles of health products during the registration process, providing essential input for market authorization.
 - Timely submission of safety reports to the WHO-Uppsala Monitoring Centre VigiBase under the International Drug Monitoring Program
 - Inspect clinical trial sites to ensure compliance with Good Clinical Practices and PPB regulatory requirements
 - Collaborated with the Uppsala Monitoring Centre in the signal management for Dolutegravir and sexual dysfunction for Kenya-reported cases
 - Participated as a Regional Centre of Regulatory Excellence in Pharmacovigilance in hosting other National Regulatory Authorities such as Malawi, Ethiopia, Somalia, South Sudan, Zambia for a learning experience.
 - Collaborated as a member of the Expert Working Group for Pharmacovigilance (PV) within the East African Community (EAC), contributing to the development of an EAC Compendium of Guidelines for the Safety and Vigilance of Medical Products and standard operating procedures (SOPs) to facilitate standardized PV practices across Member States.
 - Led the review of the National PV guidelines to domesticate the EAC Compendium of Guidelines for the Safety and Vigilance of Medical Products in Kenya.
 - Participated in the capacity building of 30 participants from the South Sudan Drug and Food Control Authority on the domestication of the EAC Compendium of Guidelines for Safety and Vigilance of Medical Products.
 - Collaborated with the IGAD Member states in the development and implementation of the Harmonised Pharmacovigilance Indicator Based Assessment and Monitoring tool at selected cross-border sites.
- Webuye District Hospital
Pharmacist-in-charge Sep 2012 - Sep 2013
Hospital pharmacist Jan 2008 - Sep 2012
- Spearheaded the improvement of pharmaceutical services, resulting in a 300% increase in revenue, ensuring consistent availability of essential medicines, and improving patient access to care.
 - Led the department to become the best-performing unit with the highest revenue and significantly reduced patient waiting times.
 - Introduced and streamlined the use of electronic stock management systems, reducing stockouts and expiries, thus improving overall operational efficiency.
 - Expanded the hospital's service capacity by implementing round-the-clock pharmacy services, enhancing patient access to essential health products.
 - Co-developed protocols for managing hypertension and diabetic emergencies, contributing to improved patient outcomes.
 - Collaborated with AMPATH and Moi Teaching and Referral Hospital to strengthen the management of non-communicable diseases, improving patient outcomes in Western Kenya.
- Mac's Pharmaceuticals Limited Oct 2007- Dec 2007
Pharmacist intern
- Gained hands-on experience in the production of oral formulations, including tablets, capsules, and suspensions.
 - Participated in in-process quality control and ensured compliance with Good Manufacturing Practices (GMP), contributing to high-quality pharmaceutical production.
- Batian Peak Pharmacy July 2007 - Sep 2007
Pharmacist intern
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- Provided patient counselling and medication information, supporting informed patient decision-making.
- Participated in the procurement of medicines and maintained accurate records for opioids and prescriptions, ensuring regulatory compliance
New Nyanza Provincial Hospital Jan 2007 - Jun 2007
Pharmacist intern
- Actively participated in medication reconciliation and ward rounds as part of a multidisciplinary healthcare team, ensuring the safe and effective use of medicines.
- Monitored drug therapy safety and provided critical medication information to healthcare professionals and patient

Education and training

University of Nairobi 2013-2015
Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance

University of Nairobi 2001-2006
Bachelor of Pharmacy Degree

CERTIFICATIONS

2008 Effective Management for Antiretroviral Therapy in Primary Health Care Settings training course
2009 Malaria Case Management for the implementation of the National Guidelines for the Diagnosis, Treatment, and Prevention of Malaria
2011 Senior Management for Health Systems Strengthening Course by the Kenya Institute of Administration, currently the Kenya School of Government.
2014 Clinical Chronic Diseases Management Course-Diabetes and Hypertension
2017 Training of Trainers on vaccines, medicines and Medical Supply Chain Management
2019 Training on Assessment of the quality part of a medicinal product dossier 2019 Training on Pharmacovigilance in Africa beyond spontaneous reports by the International Society of Pharmacovigilance
2019 Strategic Leadership Development Program at the Kenya School of Government 2020 Signal Detection and Management training by PROFORMA Consortium /Lareb (Netherlands Pharmacovigilance Centre 2020 Pharmacovigilance and risk assessment training-US FDA

Additional information

Publications

Projects

Memberships

Member of the Pharmaceutical Society of Kenya (MPSK).
Member of the International Society of Pharmacovigilance (ISoP) and the Africa chapter
Member of the International Society for Pharmacoepidemiology (ISPE)

Other Relevant Information

I am a patient representative

PROFESSIONAL SUMMARY

Dynamic and results-driven Pharmacovigilance Specialist with 16 years of experience in patient safety, public health, and regulatory oversight. Skilled in safety data evaluation, signal management, and implementing risk management strategies to enhance public health. Experienced in guiding regulatory decision-making, ensuring compliance, and contributing to effective pharmacovigilance frameworks at national, regional, and continental levels.

Skills: Project implementation and oversight, Regulatory systems strengthening, Safety surveillance, Risk management, Capacity building, Excellent analytical and communication skills, Microsoft Office (Excel, Powerpoint, Word), Collaboration and teamwork, cultural sensitivity
Interests: Travel, making ornaments, crocheting, learning different cultures.