Curriculum Vitae

Personal information

Sandra Tuhairwe

Work experience

Continental Dossier Evaluator **June 2024- Present**

African Medicines Regulatory Harmonisation (AMRH) program-AUDA NEPAD

- Evaluation of medicinal products in support of the listing of human medicinal products under the evaluation of medicinal products technical committee (EMP-TC).

External Dossier Evaluator **July 2024-October 2024**

Rwanda Food and Drug Authority, Rwanda

- Assessed quality and clinical sections of 10 product dossier and provided assessment reports.

Regulatory Officer **August 2017-Present** ***National Drug Authority (NDA), Uganda***

- Assessed the quality and efficacy (bioequivalence studies, where applicable) sections of over 200 chemical product dossiers for marketing authorization approval, written assessment reports, raised queries where necessary, and reviewed the query responses.
- Assessed over 50 biological product dossiers for marketing authorization and over 40 renewal of registration applications for biologicals.
- Assessed over 400 applications for renewal of drug registration and 30 variations for medicinal drug products.
- Participated in the joint assessment of drug dossiers and query responses under the East African Community Joint Assessment program.
- Inspected 8 drug manufacturing sites for compliance with Good Manufacturing Practices (GMP), wrote inspection reports, and presented to the GMP peer review committee.
- Developed and revised drug registration regulations, guidelines, and Standard Operating Procedures.
- Trained intern pharmacists, NDA staff and dossier assessors from the East African Community on different aspects of dossier assessment.
- Spearheaded a project for the digitalization of drug registration processes and liaised with the other departments leading to the successful automation of some drug registration functions.
- Maintained a database of registered medicines and managed customer inquiries.

Process Performance Analyst **February 2023- September 2023**

Launch and Innovation (Project Management Office), Boehringer Ingelheim, Germany

- Reviewed drug development and manufacturing SOPs and guidelines for New Chemical Entities(NCEs), New Biological Entities(NCEs), and medicine-device combination products to understand the procedures currently in use.
- Engaged drug development and manufacturing personnel to understand the current drug development and manufacturing processes critical to product launches and identify areas for improvement to be addressed in the Launch Readiness project
- Visited drug development laboratories and medicine and medical device manufacturing facilities for an enhanced understanding of pharmaceutical/device development and manufacturing processes.
- Attended workshops and trainings on the development and manufacture of NCEs, NBEs, and medicine-device combination products.
- Supported in the planning of the Launch Readiness Project workshops
- Compiled weekly reports on the outcomes of the project workshops and the final project report.

Volunteer teaching assistant **July 2016-August 2017**

Department of Pharmacy, Makerere University, Uganda

- Planned lectures and taught undergraduate students different topics in Pharmacognosy.
- Supervised tutorials and practical laboratory sessions.
- Set, supervised, and marked examinations.

Trainer **December 2016-February 2017**

Trainer in a Project on "Increasing Availability of Children's Medicines in Uganda."- Joint Medical Stores, Uganda

- Attended the training for trainers on Essential Medicines and Health Supplies management.
- Trained dispensing staff and store managers from 20 health facilities on good medicine management practices
- Conducted supervisory visits to 20 health facilities and provided technical assistance leading to an improvement in medicine management by 40%.
- Prepared comprehensive reports about the training and the supervisory visits

Data Consultant **August- November 2016**

Trade Mark East Africa (TMEA), Nairobi Kenya

- Engaged in drug registration data migration to the NDA Management Information System (NDAMIS) and provided technical guidance to the system developers on areas for improvement

Intern Pharmacist **April-May 2016**

National Drug Authority (NDA)

- Screened medicinal registration dossier submissions for completeness.
- Assessed registration dossiers for herbal products, chemical medicines, and supplements and submitted weekly reports to the supervisor

Intern Pharmacist **August 2015- August 2016**

Lubaga Hospital, Uganda

- Provided pharmaceutical care including identifying drug-related problems, participating in ward rounds, advising prescribers, and dispensed medicines to inpatients and outpatients.
- Participated in inventory management (ordering and receiving supplies, stock counting, and record-keeping using stock cards, goods received notes, and dispensing logs)

Medicines Dispenser **September 2014- July 2016**

Qure Pharmacy, Kibuli, Uganda

- Implemented pharmacy-initiated care for patients and initiated referral of patients requiring further hospital management
- Dispensed prescription medicines, over-the-counter medicines, and supplements
- Participated in the procurement of medicines and store management

Industrial Placement (Pharmacy Student) **May 2014**

Abacus Parenteral Drugs Limited, Uganda

- Participated in the dispensing of raw materials, in-process sampling, and temperature mapping activities in the warehouses
- Reviewed different documents including the Standard Operating Procedures, Batch Manufacturing Records, Validation protocols, and Validation master plan among others.

Education and training

Master of Business Administration, Uganda Management Institute, Uganda
August 2018-Present

Subjects: •Management and Organizational Behavior • Research Methods for Business Decisions • Quantitative Methods in Business Management • Business Law and Ethics • Operations Management •Supply Chain Management • Human Resource Management • Marketing Management • Financial Accounting • Financial Management • Public Sector Management • Corporate Strategy & Decision Making • Consultancy Skills Development • Public Private Partnerships • Entrepreneurship & Innovation • Projects and Programme Management

Master of Science in Pharmaceutics, University College London, United Kingdom (Distinction)
August 2020-August 2021

Subjects: Analysis and Quality Control, Preformulation, Formulation of Small Molecules, Personalised Medicine, Pharmaceutical biotechnology, Research Project (*Development of a tablet formulation of ibuprofen-loaded layered terbium hydroxide*)

Analytical methods used: IR, XRD, DSC, UV, HPLC

Bachelor of Pharmacy, Makerere University, Uganda (CGPA: 4.23/5)
August 2011-January 2016

Subjects: Anatomy, Physiology, Biochemistry, Microbiology, Pharmaceutical sciences, Industrial Pharmacy, Clinical Pharmacy, Community Pharmacy Practice, Veterinary Pharmacy, Pharmacy management, Pharmacy law and Ethics, Pharmacy entrepreneurship, Public health pharmacy, Research Projec *(Formulation of an antifungal ointment using Eucalyptus Essential oil)*

Advanced Certificate of Education, Uganda Martyr's Secondary School Namugongo, Uganda 2009-2010

Subjects : Physics, Chemistry, Biology, Mathematics

Additional information

Publications

Projects

Memberships

- Member of the Pharmaceutical Society of Uganda.

Other Relevant Information

TRAININGS AND CERTIFICATES

- Introductory Course for Standard Practice (GxP) by the International Vaccine Institute (IVI), Seoul, South Kore **October -November 2024**
- Training on ICH Q5A-Q5E Quality Evaluation of Biotechnological Products by EAC Regional Centre of Excellence for Vaccines Immunization and Health Supply Chain Management (EAC RCE-VIHSCM), Rwanda **September - October,2024**
- Development and Characterization of Monoclonal Antibody Therapeutics **Feb 2024**
- EDQM inspections program by EDQM Council of Europe **July 2023**
- Certificate of Attendance for Vaccinology in Africa – A Virtual Master's Level course by the University of Oxford **October 2021**
- WHO Prequalification of Medicines Programme (PQTm) Virtual Quality Assessment Training **October 2020**
- Training course on Review of Drug Master File in reference to EMA guidelines held at Mulund Mumbai, India by Institute of Pharmaceutical Management **2019**