

Curriculum Vitae

Personal information **Madira Litedu**

Work experience

Jan 2013 – Present Medicines Registration Officer National Department of Health (SAHPRA) Area, South Africa

Sept 2021 – Sept 2022 Backlog project Co-lead for P&A Pre-reg
South African Health Products Regulatory Authority (SAHPRA), Pretoria, South Africa

May 2011 – Dec 2012 Scientist Research and Development, Chemical Process Technologies Area, South Africa

Jan 2010 – Apr 2011 Lecturer for First Year Chemistry Students Science Foundation Students University of KwaZulu-Natal Pietermaritzburg, South Africa

2009 Tutor for First Year Chemistry Students Science Foundation Students University of KwaZulu-Natal Pietermaritzburg, South Africa

2006 – 2008 Tutor for the Second Year Organic Chemistry Students University of KwaZulu-Natal Pietermaritzburg, South Africa

2007 – 2008 Lecturer for Engineering Students University of KwaZulu-Natal Pietermaritzburg, South Africa

Education and training

EDUCATION

2010 Degree: Ph.D (Organic Chemistry) University of KwaZulu-Natal Pietermaritzburg, South Africa

Supervisor Prof Fanie van Heerden

Thesis Topic: Synthesis and characterisation of biological active bisbenzylisoquinolines.
Specialising in: Multi-step synthesis of macrocyclic compounds from cheap starting materials.
Characterisation of the products by different techniques (e.g. NMR, IR, LC-MS, GC-MS).

2005 Degree: MSc (Organic Chemistry),

Supervisor Dr Irene Kamara University of the Free State Bloemfontein, South Africa

2002 Degree: BSc Honours (Chemistry) University of the Free State Bloemfontein, South Africa

2001 Degree: Bachelor of Science (BSc) University of the Free State Bloemfontein, South Africa

ADDITIONAL TRAINING / EDUCATION / SHORT COURSES

March 2014 GMP for Active Pharmaceutical Ingredients (API) applying international standards hosted by PIC/S and PDA

March 2014 Challenges and solutions for regulatory environment at SARI symposium.

May 2015 Collaboration and convergence of regulatory programs hosted by IGDPR.

June – Oct 2015 Regulatory course at UNW, Potchefstroom Campus.

May 2017 9th Annual training in Assessment of product dossier WHO Prequalification of Medicines Programme.

June 2017 Best Practices for CTD and eCTD Submissions hosted by Pharma Training Company.

Oct 2017 eCTD dossier submissions hosted by Extedo.

Jan 2018 Good Clinical Practice Independent Researchers – Basic Course hosted by Academic Advance, A division of Wits Health Consortium.

Additional information

Publications

1. Moeti L, Litedu M, Joubert J. Common Deficiencies Found in the Active Pharmaceutical Ingredient (API) Section of Non-sterile Generic Products Submitted for Registration by SAHPRA. Ther Innov Regul Sci, 2022;56:276–290. <https://doi.org/10.1007/s43441-021-00359-9>.
2. Moeti L, Litedu M, Joubert J. Common deficiencies found in Generic Finished Pharmaceutical Products (FPPs) submitted for registration by the South African Health Products Regulatory Authority (SAHPRA). J Pharm Pol Prac. 2022;15:1– 21.
3. Moeti L., Litedu M, Joubert J. Bioequivalence Common Deficiencies in Generic Products Submitted for Registration to the South African Health Products Regulatory Authority (SAHPRA). Ther Innov Regul Sci.

2022:56;822–838. <https://doi.org/10.1007/s43441-022-00429-6>.

4. Moeti L, Litedu M, Joubert J. The implementation of a risk-based assessment approach by the South African Health Products Authority (SAHPRA), Pharm Med, 2023;37:71–91.
5. Moeti L, Litedu M, Joubert J. Regulatory registration timelines of generic medicines in South Africa: Assessment of the performance of SAHPRA between 2011-2022. J Pharm Pol Prac. 2023;16(34):1- 13
6. Moeti L, Litedu M, Joubert J. Common Deficiencies witnessed in the regional section, Module 1, on applications submitted to the South African Health Products Regulatory Authority (SAHPRA), S Afr Pharm J. 2023:90(3):16a-j.

Projects

Memberships

Other Relevant Information