

Curriculum Vitae

Personal information Margaret Malatji

Work experience

November 2015 - present

Medicine Registration Officer

South African Health Product Regulatory Authority

South Africa

Main Activities:

- **Evaluation of Generic Medicine Applications:** Conduct thorough assessments of applications for the registration of generic medicines, ensuring compliance with regulatory standards and guidelines to ensure the safety, quality, and efficacy of the products.
- **Risk Management:** Identify, assess, and mitigate potential risks associated with medicine registration processes to safeguard public health and align with regulatory frameworks.
- **Audit Management:** Address and respond to audit findings from internal and external audits, ensuring corrective actions are implemented and compliance is maintained.
- **Technical Screening and Monitoring:** Perform detailed technical reviews of medicine registration applications, allocate applications to appropriate teams, and oversee the capturing and tracking of responses to ensure timely processing.
- **Leadership and Supervision:** Lead and supervise the clinical evaluations unit, providing guidance and support to team members, monitoring performance, and fostering professional development to enhance operational efficiency.
- **Facilitation of Clinical Committee Meetings:** Organize and manage clinical committee meetings, ensuring productive discussions, decision-making, and adherence to objectives related to medicine evaluations.
- **Peer Reviews and Performance Management:** Facilitate peer review processes to ensure consistent application of evaluation standards and oversee performance management activities to drive team accountability and alignment with organizational goals.

May 2012- October 2015

Drug Utilization Review Pharmacist

Sechaba Medical Solutions

South Africa

Main activities

- **Promotion of Rational Medicine Use:** Oversaw and implemented strategies to ensure the safe, effective, and appropriate use of medicines in alignment with clinical guidelines and best practices.
- **Departmental Leadership and Supervision:** Managed the daily

operations of the Drug Utilization Review (DUR) department, providing oversight and guidance to team members to ensure optimal performance and adherence to goals.

- **Chronic Medicine Authorization:** Reviewed and authorized patient applications for chronic medication, ensuring alignment with medical necessity and regulatory requirements.
- **Medicine Formulary Updates:** Regularly reviewed and updated the medicine formulary to incorporate new evidence-based treatments and maintain relevance to healthcare needs.
- **Compliance with Policies and Guidelines:** Ensured strict adherence to Standard Operating Procedures (SOPs), organizational policies, and regulatory guidelines to maintain high standards of practice.
- **Collaboration with Healthcare Professionals:** Acted as a key liaison between the DUR department and external healthcare providers, including doctors and medical personnel, to facilitate seamless communication and decision-making.
- **Staff Training and Capacity Building:** Designed and delivered training programs to educate staff on medicines guidelines, regulatory compliance, and best practices, fostering a knowledgeable and skilled team.

May 2008 - April 2012
Responsible Pharmacist (RP)
Gauteng Department of Health
Nokuthela Ngwenya Clinic
South Africa

Main Activities:

- **Dispensing and Quality Assurance:** Dispensed medications to patients with a focus on accuracy and adherence to prescriptions, while conducting thorough quality checks to ensure compliance with pharmaceutical standards.
- **Inventory Management:** Oversaw the ordering, receipt, and distribution of pharmaceutical stock, maintaining optimal inventory levels to prevent shortages or overstocking while ensuring proper storage conditions.
- **Data Collection and Reporting:** Gathered, analyzed, and reported on pharmaceutical data and statistics to inform decision-making and improve operational efficiency.
- **Staff Supervision and Work Allocation:** Managed and supervised pharmacy personnel, ensuring the efficient allocation of tasks, monitoring team performance, and fostering a productive work environment.
- **In-Service Training and Professional Development:** Designed and delivered training programs for pharmacy staff to address in-service training needs, enhance skills, and ensure up-to-date knowledge of pharmaceutical practices and regulations.
- **Leadership and Oversight of Pharmacy Operations:** Provided leadership and operational oversight to ensure the pharmacy's compliance with statutory requirements, internal policies, and industry best practices.

May 2005-February 2008
Pharmacist
Netcare Clinton Hospital
Alberton , South Africa

Mainactivities:

- **Dispensing and Quality Assurance:** Dispensed medications to patients with a focus on accuracy and adherence to prescriptions, while conducting thorough quality checks to ensure compliance with pharmaceutical standards.
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March 2002 - April 2005

Pharmacist

Life Springs Hospital (Parklands Hospital)

South Africa

Duties & Responsibilities

- **Dispensing and Quality Assurance:** Dispensed medications to patients with precision and care, ensuring prescriptions were accurately filled and medications met safety and quality standards.
- **Inventory Management:** Managed the ordering, storage, and distribution of pharmaceutical inventory, ensuring the availability of essential medicines while minimizing wastage and maintaining optimal stock levels.
- **Regulatory Compliance:** Ensured full compliance with statutory regulations and guidelines established by pharmaceutical regulatory bodies, safeguarding the integrity and legality of pharmacy operations.
- **Supervision and Mentorship:** Provided supervision and mentorship to Pharmacist Assistants and interns, guiding their professional development and ensuring adherence to best practices and operational standards.
- **Participation in Ward Rounds and Audits:** Collaborated with multidisciplinary healthcare teams during ward rounds to provide pharmaceutical expertise, assess patient needs, and make medication recommendations. Conducted audits to evaluate and improve medication management practices.

February 2001 -February 2002

Responsible Pharmacist

Gauteng Department of Health

Randfontein hospital Complex

South Africa

Main Activities

- **Dispensing and Quality Assurance:** Ensured accurate dispensing of medications to patients, adhering to prescriptions and safety protocols, while conducting quality checks to maintain the highest standards of pharmaceutical care.
- **Comprehensive Inventory Management:** Oversaw the procurement, storage, and distribution of pharmaceutical inventory, ensuring uninterrupted availability of medicines and compliance with storage requirements to maintain drug efficacy.
- **Regulatory Compliance:** Ensured all pharmacy operations complied with the standards and regulations set by statutory bodies, maintaining the integrity and legality of practices within the facility.
- **Supervision and Leadership:** Managed and supervised pharmacy personnel, including assigning tasks, monitoring performance, and fostering a collaborative work environment to enhance team productivity.
- **Data Compilation and Reporting:** Collected, analyzed, and compiled pharmaceutical data and statistics, preparing detailed reports to support decision-making and improve operational outcomes.
- **Committee Participation:** Actively contributed as a member of the Pharmaceutical and Therapeutic Committee, providing expertise in developing and implementing medication policies and guidelines to optimize therapeutic outcomes for patients.

January 2000 - January 2001
Pharmacist
Limpopo Department of Health
WF Knobel Hospital
South Africa

Main Activities

- **Stock Procurement and Management:** Oversaw the end-to-end process of pharmaceutical stock ordering, receiving, and distribution. Ensured accurate record-keeping, proper storage, and adherence to inventory control measures to maintain optimal stock levels and prevent shortages or wastage.
- **Dispensing and Quality Control:** Dispensed medications with precision, ensuring prescriptions were accurately filled and provided patients with appropriate counselling on medication use. Conducted thorough quality checks to uphold the safety and efficacy of dispensed medicines.
- **Participation in Ward Rounds and Audits:** Collaborated with healthcare teams during ward rounds to provide pharmaceutical expertise, review patient medication regimens, and make recommendations for optimized therapeutic outcomes. Conducted regular audits to ensure compliance with best practices and identify areas for improvement in medication management.
- **Pharmaceutical Compounding:** Prepared customized pharmaceutical formulations tailored to patient-specific needs, adhering to compounding protocols to ensure product safety, efficacy, and quality.

January 1999- January 2000
Pharmacist Intern
Limpopo Department of Health
Polokwane Provincial Hospital

Main Activities

- **Stock Ordering, Receiving, and Control:** Managing the procurement process for pharmaceutical supplies, including placing orders based on stock levels, ensuring the timely and accurate receipt of medications and supplies, and maintaining an organized inventory.
- **Distribution of Stock in the Hospital:** Coordinating the effective distribution of pharmaceutical products throughout the hospital to various departments, wards, and clinics.
- **Dispensing and Quality Checks:** Ensuring that prescribed medications are accurately dispensed to patients in compliance with medical guidelines and patient-specific needs.
- **Compounding of Medicinal Preparations:** Preparing customized medicinal formulations to meet individual patient needs.
- **Small-Scale Manufacturing:** Overseeing the production of small batches of pharmaceutical products, such as medications or medical devices, in a controlled environment.

Education and training

January 2022- present

Clinical Assessment on medicine for registration

The Federal Institute for Drugs and Medical Devices (BfArM)

Bonn, Germany

Skills learned:

- Lifecycle of a medicinal product
- Legal framework of marketing authorisation of medicinal products in Germany and Europe
- European Union as a model of regulatory reliance
- Clinical/statistical aspects of bioequivalence studies
- Evaluation of efficacy and safety studies
- Principles of Biostatistics in clinical studies
- Assessment of the product information
- Didactics and methods of teaching (online and face-to-face)

September 2021 - December 2021

Clinical Assessor course

Pharmacometrics Africa

Certificate

South Africa

Skills learned:

- Lifecycle of a medicinal product

- Evaluation of efficacy and safety studies
- Principles of Biostatistics in clinical studies
- Assessment of the product information

2021

Introduction to Biostatistics/ Bioequivalence

Competency certificate

Medicines Control Authority of Zimbabwe

Zimbabwe

Skills learned:

- Basic concept of statistics and data presentation.
- Descriptive and inferential statistics and statistical tests.
- Probability and distributions.
- Correlation and regression.
- Basic concepts of pharmacokinetics, bioavailability and bioequivalence.
- Study design in BE studies.
- Statistical analysis of BE studies.

2017

Good Clinical Practice

Competency certificate

South African Health Product Regulatory Authority

South Africa

Skills learned:

- Ethical conduct of clinical research
- Protocol adherence
- Accurate documentation and data integrity
- Informed consent process
- Safety reporting
- Quality Management

January 1993 - December 1998

Bachelor of Pharmacy

University of the North (now University of Limpopo)

South Africa

Courses covered:

Pharmaceutical Chemistry
Pharmaceutics
Pharmacy Practice
Pharmacology

Additional information

Publications

Projects

Memberships

Other Relevant Information