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| EXPERIENCE | **Portfolio leader: Regulatory Affairs** Company: Well-known Generic ManufacturerSeptember 2017 – CurrentDuties: * Due diligence of new dossiers
* Compilations of dossiers
* Responses to MCC pre-registration phase, and life cycle management for registered products.
* Conversions of MRF1 to CTD dossiers
* Annual product reviews
* Change control reviews
* New product development and launch of registered products

**Regulatory affairs manager and Responsible Pharmacist** Hetero Drugs South Africa (Pty) LtdMay 2014 – August 2017Duties: * As pertained in Regulation 25(3) and 28 of the Pharmacy Act 53 of 1974
* Due diligence of new dossiers
* Compilations of dossiers
* Responses to MCC pre-registration phase, and life cycle management for registered products.
* Applying for Nappi codes and SEP pricing (initially and annually).
* Audits and inspections of third-party suppliers, and self-inspection.
* Quality control and release of pharmaceutical stock to the SA market
* Proofread and approving artwork and advertising material.

Reference: Kevin Moodaley, former COO, 082 876 7572 **Quality assurance and Pharmacovigilance pharmacist** B Braun Medical (Pty) Ltd, North riding, Randburg June 2013 – April 2014Duties: * As quality assurance pharmacist, I am responsible for:
* Ensuring GWP compliance.
* Ensuring GMP compliance, accurate record keeping, SOP compliance and review.
* Provide training on SOP’s for staff
* Offering support to warehouse staff when required.
* Liaising with 3rd party providers – manufacturers, distributors, printers, suppliers of raw materials, etc.
* Manufacturer/packer/laboratories audits and contracts with third parties.
* Assist with investigation of technical complaints and trend analysis.
* Finished product releases.
* Arranging for post-importation testing with local laboratories.
* Liaising with local laboratories on post-importation testing.
* Ensure the quality of products out in the market.
* Storage and control of retention samples.
* Management of deviations and investigations.
* Ensuring stability test results are within specifications as stipulated by the dossier.
* Assist in control of Product Returns Process - SAP
* Assist in control of Section 21 Products
* Liaising with MCC and assisting Regulatory when needed.
* Pharmacovigilance management
* Communication with medical professionals in case of an adverse drug reaction.

Reference: Jana Potgieter, Regulatory Manager, 082 854 4615**Pharmacy manager** Mooimed private hospital, PotchefstroomJuly 2012 - May 2013Duties: * Management of the Pharmacy and pharmaceutical stock
* Implementation of stock control systems and follow-up thereof
* Administration functions including the month-end reports
* Assisting with the financial aspects of the pharmacy, including the preparation and interpretation of reports
* Controlling the budget and purchasing expenditures of the pharmacy
* Personnel management
* Building relationships with doctors, nursing staff and patients
* Planning, organizing and co-ordination of the dispensing function
* Responsible for the quarterly stock-take and continuous stock control
* Dispensing in patient prescriptions
* Provision of in-service training to nursing staff
* Provision of a drug information service and patient counseling
* Assisting in weekly surgical stock ordering
* Implementation of controls to enforce GPP and SOP’s to minimize the risks

Reference: Mrs. Gene Putter, RP, 082 788 5922**Senior regulatory affairs pharmacist** DI consultants, PotchefstroomJuly 2010 - June 2012Duties: * Ensure compliance of the Act and Regulations in accordance to guidelines of the South Africa Regulatory Authority to register medication:
* Create and amending registration dossiers as necessary for legal requirements for submission to the regulatory authorities in the South Africa.
* Monitor, collect and interpret regulatory issues and trends that will impact products, policies and procedures in the South Africa.
* Interface with government agencies (i.e. SA Pharmacy Council) and industry associations to assess the impact and implementation of required company compliance with all regulations, laws and industry policies that affect the ingredients, packaging, marketing, advertising, labeling and production for our products.
* Ensure compliance with guidelines and procedures of the Medicine Control Council of South Africa.
* Provide regulatory and product expertise in the development and clearance of advertising and label copy for existing and new products in South African markets. Maintain the filing of approved artwork and advertising copy.
* Ensure the required dossier updates are affected for the South African market at appropriate, regular intervals, in line with regulatory and internal standards.
* Ensure the alignment between manufacturing documentation and the latest approved regulatory documents.

Reference: Dr Charmaine van Eeden, Manager, 018 297 4072**Chief Pharmacist and Responsible Pharmacist** Steve Biko Academic Hospital August 2003 - June 2010Duties: * Position required management of 60 staff members in the pharmacy, clinical and quality assurance matters, strategic management as member of top management of the hospital, managing the finance of the Pharmacy, training, HR related matters including labour relations issues, public relations and security matters.
* Committees involved in:
	+ Top Management & Budgeting
	+ Medical advisory Committee
	+ Cluster meetings
	+ Quality Assurance
	+ Infection Control
	+ Committee member of Pharmaceutics & Therapeutics committee (PTC) of Pretoria Academic Hospital and province.
	+ Committee member of the Executive committee, Pharmaceutical services, Gauteng Health
	+ Committee member of SAAHIP, Northern Branch
	+ Advisory meeting of Tshwane University of Technology

Reference: Leonie Deysel, Pharmacy Manager, 012 354 4227 /  083 286 8180  |
| EDUCATION | Master’s in Public Health- Management and policy track, (Dissertation not finalized)University of Pretoria BPharm Degree, 1992North West UniversityMatric, 1984President High School, Johannesburg, Gauteng |
| ACHIEVEMENTS: | Won **Gauteng Health Khanyisa Service Excellence Awards** for Manager of the Year (2008/9), awarded by Mr. Brain Hlongwane (former MEC, Gauteng). |

**PRESENTATIONS:**

* Rational antibiotic use – Emperors Palace 2005 (invitation by Gauteng department of Health)
* To Nurses on Prescriptions for old age (invitation Tshwane Region.
* To other pharmacy managers on ways to remain in their budgets
* Various presentations at SAAHIP (chairperson) and pharmacist managers conferences

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**PUBLICATIONS:**

* An article on Methicillin Resistant Staphylococcus Aureus and Peptic Ulcers in the SA Pharmaceutical Journal (March 2005) –
* Special interest: Cost impact on the pharmaceutical budget due to antibiotic resistance in ICU’s. The Hospital hence implemented an empirical use of antibiotics to reduce resistance.
* “Guidelines for administrating medication to patients with swallowing difficulties” (July 2007)
* “Guidelines for Pharmacists conducting trails” (August 2007)
* “Guidelines for Palliative Care to assist nursing staff with the terminally ill”

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