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| EXPERIENCE | **Responsible Pharmacist/Head of Regulatory Affairs**  Company: Multinational Pharmaceutical Company  Jan 2015 - Current  Duties:   * Ensure continuous supervision of the company, and employees who provide services forming part of the scope of pharmacy practice. * Ensure compliance of the company in line with the responsibilities of a Responsible Pharmacist as contemplated in regulation 25 (3) of the Pharmacy Act and the relevant sections of the Medicines Act. * Legal   + Maintenance of license and its requirements   + SOP compilation, review, approval and maintenance   + Record maintenance   + Regulatory Inspections   + Staff training- Marketing code of practice, GMP requirements, Pharmacovigilance * Regulatory Affairs   + Overseeing submission of dossiers according to annual product submission plan to SAHPRA and regional Medicines Regulatory Authorities within SADC.   + Continuous liaisons with SAHPRA to ensure new product registrations are received timeously ,to satisfy the requirements of business.   + Co-ordination of Zazibona application to facilitate faster registration/evaluation processes.   + Oversee updates are made to the Registration Dossier according to latest requirements of the Medicine Regulatory Authorities, including conversion of dossiers to the ZA-CTD, pre-registration responses and post-registration amendments.   + Ensure adherence to SAHPRA and GMP guidelines by all relevant personnel.   + Providing training and support to Regulatory Affairs Pharmacists and Assistants.   + Co-ordinating GMP/GCP inspections of parent company’s manufacturing facilities with inspectors from the various Regulatory Authorities.   + Controlling correspondence with other pharmaceutical companies and pharmaceutical consultants with regards to regulatory activities.   + Finalizing agreements and Customer relationship management with any 3rd party partners.   + Ensuring compliance to departmental targets by the various personnel of the Regulatory Affairs Department and ensuring deadlines are met by consultants.   + Planning and delegating of monthly targets to staff members/consultants   + Responsible for all budgets relating to the department – monthly/quarterly/annual budgets for regulatory submissions to South Africa, as well as the general departmental budget.   + New Business Development: Advise on regulatory pathways for the purposes of new dossier development, packaging development and marketing thereof (Cosmetics, Scheduled medicines, Complementary and Medical devices).   + Oversee of SEP update and submission applications for the company.   + Marketing – Worked closely with the marketing department to meet company objectives. Reviewed, advised on compliance and approval of all Promotional marketing material * Production   + Compilation, review and approval of Masters for local manufactured products   + Liaise with local and overseas manufacturers on technical issues   + Old medicines/complementary medicines – CAPA analysis on the manufacturing of old medicines/ complementary medicines * Quality Assurance   + Release of finished product – Review and release of inspection and finished product release forms to third party distributors. Co-ordinating sampling and testing of imported finished product between third party distributors and third-party laboratories   + Conducting audits of Third party overseas/local manufacturer’s facilities   + Vendor audits   + Review / compilation and approval of Annual product reviews * Pharmacovigilance   + LPVRP for the affiliate   + Underwent successful PV audits by Global PV (MHRA compliant)   + Investigation and record maintenance of ADRs, customer complaints, MIE’s   + Facilitated Pharmacovigilance training to all staff and 3rd party partners   + Submission of Aggregate reports to Global PV   + Established a Local Pharmacovigilance database   **Regulatory Affairs Consultant/Director**  Regworks Consulting CC  2005 - 2014  Duties:   * Management of product registration process i.e. sourcing of dossiers, preparation of CTD/MRF1 Dossiers, preparation of committee responses (pharmaceutical, clinical, Post-registration and inspectorate); compilation of package inserts and patient information leaflets * Management of Post-registration variations i.e. identifying variations, preparation and submission of applications and the implementation of approved variations * Review and approval of printed packaging and marketing materials * Compilation of SOP’s for manufacturers and Dear Doctor Healthcare letters * GMP Inspections/audits of 3rd party manufacturers: Analytical testing laboratories and distribution facilities * Batch release/Rejection of products * Budgeting for costs related to client, MCC/SAHPRA fees and consulting rates * On-site training of Regulatory staff- MCC/SAHPRA circulars, skills development with regards to dossier evaluation and compilation of CTD dossiers * On-site training of Sales team- Product training – Pharmacology and Package insert Aspects, Adverse/Product complaints and recall procedures and SOP’s * Pharmacovigilance- on-site regulatory work * Maintained effective communication with all internal and external customers.   **Regulatory Affairs Manager**  Cipla Medpro (Pty) Ltd  February 2000 - 2005  Duties:   * Co-ordinated and managed the registration process and the product life cycle for all products including the compilation of dossiers for the business, while providing regulatory, scientific, medical, technical and marketing support * Established a regulatory department – implementation of tracking systems for the registration of products and management and training of staff and projects * Ensured maintenance and compliance of existing products in accordance with the requirements of the relevant Regulatory Health Authorities * Submitted dossiers in African Countries- Uganda. Kenya, Namibia, Botswana * Liaised with various departments within the company:   + Marketing: Screened promotional and advertising material to ensure compliance with local regulatory/legal requirements and company policy   + Compiled promotional material for distribution in African countries   + Assisted the training department, particularly with regard to product knowledge   + Liaising with Quality Assurance and Production on projects which affected or could affect the registration of products * Maintaining and building of Relationships: * Liaising with Medicine Control Council/SAHPRA key personnel in various departments * Liaising with registration consultants to track and finalize registrations * Liaising with overseas affiliates on various projects * Attended ITG meetings with MCC: (a member of the NAPM, attended SAPPRA meetings) * Played an important role from industry side by attending the workshops to establish the guidelines for the registration of orthodox medicine * Have attended the international bioavailability and bioequivalence symposium * Performed site inspections audits of third-party manufacturers (focusing on GMP/GLP)   **Regulatory Affairs Pharmacist**  Abbott Laboratories (Pty)Ltd  Jan 1999 – February 2000  Duties:   * Preparing, submitting and obtaining registration of new products * Maintaining existing product registrations in line with current legal and in-house requirements * Liaising with various departments within the company * Pharmacovigilance officer   **Pharmacist Intern**  Abbott Laboratories (Pty) Ltd  Jan 1998 – Dec 1998  Duties:   * Departmental rotations in order to gain practical experience and knowledge in the practical setting.   **Pharmacist Assistant**  Plaza Pharmacy  1995 – 1996 (Part time)  Duties:   * Counselling, Dispensing, Stock Control * Performing primary screening and monitoring services (blood pressure, cholesterol and glucose testing) |
| EDUCATION | Business Management Course, 1999 Damelin Bpharm Degree, 1997 University of Witwatersrand |