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| EXPERIENCE | **Responsible Pharmacist**  Company: Wholesale Division of a well-known Pharmaceutical Company  Jul 2017 – present  Duties:   * Management of the documentation systems - control and retention including SOPs, Training records, Validation records and Site Master File * Coordination of the Training programme – procedures, on-the-job and annual GDP/GWP training programme * Management of on-site Validation and Calibration requirements – ensuring facilities, utilities & equipment are qualified * Management and implementation of transportation and container validation studies. * Management of the Quality Management System – Hosting Management reviews, monitoring initiation of deviations, Change control and CAPA. * Management of the Self-inspections and internal audits programme * Management of the vendor management programme. * Management of the Credit Returns Department for receipt of customer returns, product complaints and ultimate destruction * Management and control of Schedule substances, Section 21 and Cold chain product operational activities. * Management of onsite product recalls & mock recalls as initiated by the Registered Applicant * Implementation of Quality risk management and continual improvement projects * Management of onsite permanent contracted service providers * Management of required Regulatory Licence compilation and applications * Responsible person for regulatory and supplier audits   **Key Achievements:**  Successful relocation of premises and licensing with the Medicine control Council license to act as a wholesaler of pharmaceutical products and medical devices. This included the coordination of the validation of the HVAC system including Cold Rooms and freezers, the cold chain shipping containers and the transport vehicles.  Cost saving project initiative successfully implemented was tracking of reverse logistics due to customer returns, with the aim of eliminating the major cause thereof.  **Quality Assurance Manager & Responsible Pharmacist**  Aspen Pharmacare Centralised Distribution Warehouse  Oct 2014 – Jun 2017  Duties:   * Operational Activities   + Ensuring compliance with all the provisions of the Act 101 of 1965; Pharmacy Act, Act 53 of 1973 and all regulations and guidelines pertaining to the Wholesale license for medicinal products and Good Wholesaling/Distribution and Good Housekeeping Practices and Good Pharmacy Practice.   + Ensuring maintenance of the quality management system through the effective implementation and maintenance of systems, processes and procedures that are in keeping with the Quality Assurance Department objectives. Management and Control of the Quality Management System and all it encompasses.   + Responsible Pharmacist activities responsible for the licensing, certification and continual supervision and control of the wholesale/distribution pharmacy relating to the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, supplying or selling of any medicine or schedule substance medical devices * Managerial Activities (Financial and Human Resources)   + Managed the QA departmental staff performance, financial and budgetary performance, SHE, HR and GM-WP responsibilities and activities   **Key Achievements:**  Successful application of the business unit’s Medicine Control Council license to act as a wholesaler.  Coordinated the validation of the HVAC system servicing the warehouse to completion as this was a critical MCC outstanding finding.  Continuous improvement project currently successfully implemented was to improve the cost for destruction of pharmaceutical products. This included achievement of more than 50% cost saving, an environmental aspect for zero to landfill and zero residue as well as a 20% reduction in the amount of stock required to be sent for destruction.  Reference: Winston Delport, Distribution Manager, 079 509 5550  **Quality Assurance Systems Manager**  Aspen Pharmacare Outsource International Division, Port Elizabeth  Nov 2011 – Jul 2014  Duties:   * Operational Activities   + Established, implemented and maintained Quality Assurance Management Systems that comply with International requirement (cGMP and ISO 9001) Department activities are developed from the divisional strategy. Responsible for the ERP - BaaN Item Master and Bill of Material implementation and maintenance and Control of all QA related BaaN sessions. Compiled and provided input into Annual Product Review, Quality Systems Management Review and Mock Recall actions and Reports * Managerial Activities– Financial and Human Resources   + Assisted QAM with management of the QA department financial, SHE, HR and GMP responsibilities and activities.   **Key Achievements:**  Assisting the QAM in establishing the Outsource International quality systems for maintaining GMP standards for the importation of final products to South Africa and well as South America and Sub-Saharan Africa.  Stabilising the change control, deviation, CAPA and Customer complaint management and reporting system for the Outsource department. Provided formal training to staff involved on the correct way to define and describe a quality issue, conduct a root cause analysis, identify corrective and preventative actions and monitoring effectiveness after implementation as appropriate.  Involved with and assisted OSI staff during the implementation of new Quality Management systems including QUMAS and TrackWise® for reporting of Change controls, deviations, customer complaints.  Establishing an improved process for maintaining of final product item masters in the company’s Baan ERL system. Ensuring that no products are purchased and sold without a QA failsafe.  Reference: Tracey Marais, OSI Unit Head, 041 407 1809  **Director of Operations Quality Management, Early Phase**  PAREXEL International Clinical Research Units – George & Port Elizabeth  Jan 2009 – Oct 2011  Duties:   * Head of Quality Management for both Port Elizabeth and George Clinical Research Units   + Managed the quality management systems and entrenched the ISO 9001:2001 Quality Management System to ensure highest quality clinical research services are provided to sponsors and continual improvements are implemented. * Managerial Activities:   + Managed, coached and developed the personnel and administrative issues within the department and optimised resources. Manage routine department activities and complex Quality initiatives.   Key Achievements:  Initiated a project to have the units more than 50 expired SOPs reviewed and updated with 9 months. This included creation of additional process map flows which were new to the staff. Coordinated the training that was then provided in these crucial procedures which played a role in clinical quality assurance and ensured that all units’ staff (especially new ones) understood their importance and that they must be followed by all during a clinical trial to ensure that the validity of data generated is not compromised, which may lead to warning letters being issued and delays in the trial process and that Auditors and inspectors see SOPs as essential and following them is crucial.  Successfully had the George and PE units certified according to ISO 9001:2001 Quality Management Systems and thus entrenched the standard to ensure highest quality clinical research services are provided to sponsors and continual improvements are implemented. This was then adopted by PAREXEL Global Quality Management for implementation throughout all their units world-wide.  Reference: Anne Smith, Unit Head, 082 467 1284  **Director of Quality Assurance & Regulatory Affairs**  Ferlot Manufacturing & Packaging – Jeffrey’s Bay  Oct 2002 – Dec 2008  Duties:   * Operational Activities   + Accountable for the effective deployment of policies, procedures and programs that maintain quality standards for company products; develop and execute programs and policies that ensure regulatory compliance; adherence to manufacturing guidelines; analyze and write test standards and procedures and provides Q.A./Q.C. and regulatory compliance to the facility.   + Managed the Quality Assurance, Quality Control & Regulatory aspects of manufacture and packaging and formulation development of new and existing product lines. * Managerial Activities:   + Lead and effectively delegated tasks and activities of a staff of production leaders and staff to set, review, and execute the Q.A. plan.   **Key Achievements:**  Using my pharmaceutical manufacturing background, I improved the company’s processes and SOPs as well as training the staff in GMP and GLP allowing this complementary medicine company to become a GMP licensed Manufacturer and Packer with the local regulatory agency.  I set-up and validated their QC laboratory saving this small company more than 2 Million rand a year in laboratory test fees for their raw materials and final products.  I formulated and assisted in launching several new products for the company which are now big sellers in the local market as well as some parts of central Africa.  Reference: Johann Lottering, Managing Director, 042 293 1278  **Regulatory Affairs Pharmacist**  MeyerZall Laboratories - Saasveld George  Apr 2000 – Sept 2002  Duties:   * Regulatory Affairs & Quality Assurance responsibilities   + Information gathering from the different sections of the Development laboratory, QC department and manufacturing division for the compilation and submission of product registration dossiers to local (South African) and internationally (incl. UK, USA, Canada, Italy, Malaysia, India, Australia and Sub-Saharan Africa) Regulatory Authorities.   + Responsible for maintenance of the Quality Management System for the company.   **Key Achievements:**  Submitting dossiers to South Africa, Italy, Malaysia, Australia and Canada for a new product launched by the company successfully to registration and then to market.  Assisting in the initiation and then implementation of a Tuberculosis clinical trial using the company’s Emzaloid technology for use in Human volunteers and then in TB patient. Assisting with the formulation, Protocol compilation and then conduct of the study as IP Pharmacist.  Reference: Ansie Savrda, Manager Director, 082 442 8557  **Formulations Pharmacist**  Adcock Ingram Pharmaceuticals RD&I – Aeroton, Johannesburg Apr 1999 – Mar 2000  Duties:   * Formulation Pharmacist   + New & existing product formulation development and project implementation.   Reference: None  **Production Pharmacist (Internship year)**  Universal Pharmaceuticals, Johannesburg  Jan 1998 – Dec 1998  Duties:   * Pharmacist Intern   + Oversight of the manufacturing and packaging processes under the Supervision of the Pharmacist   Reference: None |
| EDUCATION | Diploma in Programme in Business Leadership, 2001 UNISA Business School Bpharm Degree, 1997 University of Port Elizabeth, South Africa |