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| EXPERIENCE | **Deputy Responsible Pharmacist**  Company: International Pharmaceutical and Medical Device Company  May 2018 – Present  Duties:   * Oversee Regulatory Affairs and Quality Assurance for South Africa & Sub-Saharan region * Ensure compliance with the legislative requirements as we as all applicable statutory & regulatory requirements * Driving the development, implementation and maintenance of a QMS which Integrates Pharmaceutical Quality System, ISO 13485:2016 and cGMP * Provide all relevant Quality and Regulatory affairs training e.g. cGMP, ISO 13485:2016; Medical Device Code, CAPA and Root cause analysis. * Managing all QMS events vis CAPA, deviations, non-conformances, recalls, the change control system * Provide RA/QA advice in New Product Introduction (NPI) projects * Preparation of Third Party/CMO Quality Agreements * ISO 13485:2016 Management Representative and Lead Auditor for the organization. * Management of all tasks related to dossiers, within the guidelines and regulations * Preparation, compilation, submission and management of all dossiers requirements, applications and amendments for both medicines and medical devices. * Compilation of due diligence reports on potential and new dossiers as and when requested * Process owner and quality leader for Enovia Product Lifecycle Management (PLM) system * Compilation of registration submissions in neighboring countries as and when required * Responsible for Final Product Release   Notable Achievements:   * Successful preparation of the organisation for ISO 13485:2016 Certification * Registration of Medical Devices in Ghana     **QA Locum Pharmacist**  Litha Healthcare Group  November 2017 – March 2018  Duties:   * Final Product Release in accordance to applicable cGMP requirements. * Updating Batch Manufacturing masters and specifications in line with registered information * Managing the change control system * Participate in annual quality and product reviews. * Preparation of Quality and Investigation reports * Auditing and Improvement of the Quality Management System   Reference: Nanda Redmond, QA Manager, 082 886 9264  **National Strategic QA Manager**  Twinsaver Group  January 2015 – February 2017  Duties:   * Defined QA strategy/plans and established vision for Quality Assurance team in line with organizations vision, customer expectations and relevant regulatory requirements * Planned and provided expertise throughout the entire product development life cycle making sure that quality is built in from the start. * Remediated any adverse reaction reporting and management deficiencies found during regulatory or internal audits. * Developed and preserved company data sheets, procedures and activities to ensure compliance with applicable quality standards and statutory/regulatory requirements, * Provided Scientific and Technical expertise in Risk Management and Value engineering projects. * Set annual quality KPIs and continuous improvement initiatives * Prepared internal and corporate quality documentation and reports by collecting, analyzing, and summarizing trends for failed processes, stability studies, recalls, and corrective actions * Compiled Self-audit inspections/supplier audit schedule and monitored effective execution * Developed and executed strategies in pursuance of an effective Supplier Relationship and Quality Management program. Management of Third-Party manufacturers/Contractors * Setting the QA department budget and ensuring costs kept within budget * Company representative - CGCSA champions committee, SABS TC committee, SAQI and PAMSA   Key Accomplishments:   * Provided technical and quality leadership that managed efficient transition to new company. * Conducted risk assessments in preparation for ISO 9001:2015 transition and multisite listing * Headed Supplier improvement initiative which saved the Company R5m+ * Achieved a high-performance rating and Identified as one of the Talented Manager to earn an Incentive bonus and included in the Company Share Scheme   Reference: Simon Ndimande, Supply Chain Director, 082 807 1979  **National Quality Assurance Manager**  Nampak Tissue  September 2002 – December 2014  Duties:   * Designed, developed and implemented quality management system in line with ISO 9001, ISO 13485; FSSC 22000 standards, cGMP guidelines and relevant statutory/regulatory requirements. * Implemented Total Quality management initiatives to improve product quality, promote safety, increase production efficiency, and improve customer satisfaction. * Established and implemented a New product development approach to ensure that quality and safety is built into products and processes * Ensure regulatory compliance and safety throughout trial. * Developed and implemented supplier system-level quality-assurance plan, monitored and analyzed reports on quality performance trends * Reported and managed Pharmacovigilance within the business units. Managed customer and consumer complaints, ensured complaints are investigated, identified root causes, formulated solutions and remedial actions. * Directed and implemented hazard analysis critical control point (HACCP) studies, and prepared reports on quality performance, * Developed internal audits and an audit schedule compliant with relevant standards * Coordinated the collections of information for Item Master data requirements, i.e. raw materials, ancillaries, etc. to ensure that Bill of Material is accurate * Conducted external and supplier audits to ensure compliance to Tissue requirements, adherence to applicable GxPs, and created reports on the audit findings. * Identified Potential suppliers, approved new suppliers, set quality agreements and monitored service delivery performance. * Management of Suppliers/Third party manufacturers quality program * Liaised with Nampak R & D (Epping) and SCA R & D (Sweden) on any new Innovation and Product improvement. * Technical Member of project team that oversaw the acquisition and installation of 2 new diaper machines, Paper Machines and Tissue Converting lines   Key Accomplishments:   * Achievement of ISO 9001 and 14001 on first attempt without any major nonconformities * Improved product development effectiveness across company by deploying design for Six Sigma methodology and tools * Reduced consumer complaints from 20/million units sold to 1/million units sold over a 10year period * Introduced Supplier Performance Rating system across the 80% spent * Saved the business over R60m in Value engineering initiatives * Nominated amongst best performing managers an awarded a week stay in Cape Town * Member of a high-performing team which won the “Nampak division of the year” award in 2009/10 * Successfully represented the Company during Paper Tissue De-regulation debate * Diaper Improvement initiatives led to low Cost of material, advanced efficacy and increased Market Share from 6 to 12%   Reference: Mike Dennis, Supply Chain Director, 082 800 8937 |
| EDUCATION | Diploma in Supply Chain Management, 2005 SAPICS Total Quality Management, 2002 UNISA Management Advancement Programme, 1997 University of Witwatersrand Bpharm Degree, 1986 University of the North Limpopo Matric, 1981 Tembisa High School |
| ACHIEVEMENTS | * Led successful registration of Company with SAPC and pharmaceutical products with MCC * Appointed Responsible Pharmacist - Biocide (Pty) Ltd (1996) * Achieved ISO 9001:2000/2008 and ISO 14001:2004 certification. * Audited and assisted Unilever Companies (Africa, Middle East and Turkey), and obtained “A” status with respect to Quality and Consumer Safety systems/HACCP. * Invited to present Topics such as * GMP Implementation “Starting from Scratch” at Vodaworld in 2002 | * ISO 9001:2000 – Johannesburg International 2003 * Management difficulties – MDP 2003 * Leadership that gets results – Tomorrow Leaders Course (TOM) * Created and Implemented a program that effectively improved adverse reaction reporting and management and reduced customer complaints * Provided technical expertise in Value engineering and cost saving projects * Directed Employment Equity Committee for Nampak Tissue 2006-2010 and achieved targeted status * Consistent high-performance reviews and recognized as being one of the best performing managers |