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| EXPERIENCE | **Deputy Responsible Pharmacist**Company: International Pharmaceutical and Medical Device CompanyMay 2018 – PresentDuties: * 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 GroupNovember 2017 – March 2018Duties: * 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 GroupJanuary 2015 – February 2017Duties: * 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 TissueSeptember 2002 – December 2014Duties: * 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, 2005SAPICS Total Quality Management, 2002UNISAManagement Advancement Programme, 1997University of Witwatersrand Bpharm Degree, 1986University of the North Limpopo Matric, 1981Tembisa 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
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