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EXECUTIVE SUMMARY

Accomplished pharmaceutical quality executive with over 20 years of leadership experience driving QA, QC, GMP compliance, and QMS governance for leading multinational and regional pharmaceutical organizations. Proven record of leading enterprise-wide quality transformations, strengthening supplier governance, site risk management, and inspection readiness. A strategic leader is adept at aligning quality systems with business objectives to ensure patient safety, regulatory compliance, and sustainable operational performance.

CORE LEADERSHIP COMPETENCIES

- **Executive Quality Leadership:** Quality Strategy & Governance, QMS Transformation, Quality Culture Development, Executive Communication.
- **GMP & Regulatory Compliance:** Regulatory Inspection Readiness (SFDA, WHO, GCC), Data Integrity, Batch Release Governance, Deviation & Change Control.
- **Operational & Risk Management:** Enterprise Risk Management, CAPA Governance, Supplier Quality Management, Validation Governance, Business Continuity.
- **Organizational Excellence:** Cross-Functional Leadership, Budget & Resource Planning, Lean Six Sigma, Operational Excellence, Talent Development.

PROFESSIONAL EXPERIENCE

Quality Director | ARABIO | Feb 2016 – Present
Leading enterprise QA strategy and governance for a major biopharmaceutical manufacturer.

- **Enterprise Transformation:** Designed and implemented a risk-based supplier quality framework, strengthening GMP compliance and vendor oversight across the supply chain. Established a site-level risk management program with structured assessment, mitigation, and escalation protocols.
- **Regulatory Readiness & Patient Safety:** Strengthened product complaint, recall, and mock recall processes, significantly improving regulatory inspection readiness and product quality oversight.
- **Quality Governance Leadership:** Direct all GMP compliance, batch release, and quality decision-making. Lead governance for CAPA, internal audits, third-party audits, regulatory inspections, and management review.
- **Organizational Capability:** Reorganized the QA department to align talent with business needs and introduced monthly governance and visual management practices, enhancing accountability, cross-functional ownership, and daily execution.
- **Strategic Oversight:** Provide executive approval for validation master planning, technical assessments, and critical quality documentation, ensuring lifecycle compliance and readiness.

QC Manager | ARABIO | Oct 2014 – Jan 2016
Managed QC laboratory operations with full accountability for compliance and performance.

- **Laboratory Compliance:** Strengthened laboratory quality systems, including SOP compliance, OOS investigations, deviations, and CAPA, ensuring alignment with cGMP, cGLP, and local regulatory requirements.
- **Performance Improvement:** Drove timely CAPA closure from internal and external audits, improving compliance performance and inspection readiness.

- **Operational Leadership:** Introduced accountability and visual management practices to optimize workload prioritization, analyst productivity, and laboratory execution.
- **Strategic Planning:** Developed a 3-year instrument utilization plan aligned with business demand, testing capacity, and capital planning.

QC Supervisor | GSK Saudi Arabia | May 2009 – Sep 2014
Led stability and quality operations for a global pharmaceutical leader.

- **Stability Governance:** Directed stability protocols and SOP updates in line with regulatory and GCC requirements. Represented the site on the Analytical Leadership Team, contributing to laboratory standardization and best practices.
- **Regulatory Analysis:** Led pharmacopoeia and CAP gap analysis, translating regulatory updates into actionable QC improvements.
- **Operational Excellence:** Advanced lean laboratory practices through audits, 5S, and KPI monitoring, driving a culture of continuous improvement.

Stability Supervisor | Saudi Japanese Pharmaceutical Company | Feb 2004 – Apr 2009

- Managed all stability activities, including protocol preparation, testing, reporting, and documentation.
- Supported regulatory registration for products across SFDA, GCC, Jordan, Egypt, Sudan, Syria, and Libya.
- Performed analytical method transfer, validation, and troubleshooting for HPLC, UV, and dissolution apparatus.

Pharmacist | King Abdul Aziz Hospital and Oncology Centre | 2001 – 2003

- Prepared sterile intravenous admixtures (T.P.N & I.V.F) using aseptic techniques in a biological safety cabinet.
- Managed drug information services, non-sterile preparations, and warehouse inventory controls, including cold chain management.

EDUCATION & CREDENTIALS

- **Postgraduate Diploma in Total Quality Management** | American University in Cairo | 2013
- **Bachelor of Science in Pharmacy** | Virgen Milagrosa University Foundation, Philippines | 2000

CERTIFICATIONS & EXECUTIVE DEVELOPMENT

- **Certified Manager of Quality/Operational Excellence** – Leoron Institute | 2025
- **Leading & Managing Lean Six Sigma (Green Belt)** – GSK Experts | 2013
- **QMS for Pharmaceutical Quality Management** – Quality Compliance Institute | 2019
- **EU-GMP Annex 1: Design & Management of Facilities** – CSV Group | 2023
- **Analytical Method Transfer** – Daiichi-Sankyo, Munich, Germany | 2008
- **Stability of Medicines** – SFDA & WHO, Riyadh | 2007
- **HPLC Software & Troubleshooting** – KI & Partners Co. | 2005

LANGUAGES

- Arabic (Native)
- English (Fluent)