**Quality management executive, who blends twenty-five years of experience in production and supplier quality with a strong background in the sciences, seeks an executive position in an quality management function requiring an individual with extensive experience in quality operations, quality auditing and customer service.**

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**Qualifications:**

 • Twenty-five years of experience in pharmaceutical Quality Assurance and management

 • Practical working knowledge of pharmaceutical production processes (Dry Powders, Aerosols, Solid Dose, Bulk Actives and Sterile products)

 • GSK “Certified Quality Auditor”

 • GSK certified as an OE/Lean Sigma “Greenbelt”

 • ASQ certified as a “Certified Quality Engineer” and “Certified Quality Auditor”

 • Sound communication skills (verbal and written)

 • Good negotiation and influencing abilities

 • Excellent technical writing expertise

 • Proficient in budgeting and planning

 • Extensive internal and external audit program and auditing experience

 • Strong understanding of business and science disciplines

 • Experience with regulatory interaction in a regulatory audit environment

• Project team/project leadership/project management experience (OE projects/facility start up/regulatory audit preparation, quality systems implementation, acquisition integration, internal team integration, etc,).

• Extensive experience with integration of supplier management programs of acquired companies.

• Practical working knowledge of regulatory expectations, supplier quality management, quality systems, statistical trending and industry best practice

**Accomplishments:**

 • Successfully lead integration of supplier audit teams from multiple company divisions into one cohesive, aligned and supportive team working under same processes, procedures and standards

 •Effectively recruited, staffed, trained and implemented a new team of 10 auditors and specialists to support supplier management and audits located in South America and Latina regions

 • Directed team of auditors to successfully implement a business performance turn-around and close a longstanding and significant gap in audit coverage in the Mexico region

 • Lead team that successfully integrated a large acquisition, as well as several smaller acquisitions, into the global supplier quality management and audit program

 • Lead OE project team that reduced batch record review cycle times by 40+%

 • Successfully directed and coordinated the revision of all quality related SOPs impacted by the implementation of new quality documentation system

 • Effectively managed the full application and implementation of Production QA-related systems and processes during start-up of a new manufacturing facility

 • Developed and put into practice a system to categorize quality notifications generated for trending purposes

**Professional** **GlaxoSmithKline, Aug 2013 - Present**

**Experience:** **Supplier Quality Audit & Compliance Hub Head NALA / Regional Director EUNALAMEA / SQAC Head NALA**

• Direct a team of approximately 40 geographically dispersed supplier quality professionals responsible for coordinating, managing and auditing a complement of approximately 3200 material and service suppliers supporting Consumer Health, Pharma, Biological, Dermatological and Vaccines divisions in a geographical region covering Europe. Middle East and Africa and the Americas
• Ensure that appropriate supplier quality management systems are in place and in use within team and at audited suppliers (corrective actions, change controls, quality agreements, complaints, etc.) to support customers (global GSK user sites and GSK CMOs)

• Develop and manage multiple regional budgets to support business objectives and projects (contract auditors) and allocate external and internal resources as well as finances effectively

• Communicate results of investigations and/or identified risks to ensure stakeholders understand the technical, regulatory and quality risks

• Develop a diverse global team and provide coaching and mentoring to ensure individual development as well as engaging them around a common goal to achieve the desired business outcome

**Professional GlaxoSmithKline, Feb 2009 - Aug 2013**

**Experience (cont.)** **Audit Operations Manager**

• Lead a team of seven supplier quality professionals responsible for coordinating, managing and auditing a complement of approximately 800 material and service suppliers supporting Consumer Health, Pharma and Biological divisions

• Identified improvement opportunities for supplier quality management, auditing and CAPA management processes using quality/OE tools, customer feedback, and statistical analysis

• Performed or supported investigations into significant quality incidents arising at suppliers through for cause audits and ensuring that root causes were identified and appropriate corrective and preventative actions are implemented.

 **May 2006 - Feb 2009**

 **GlaxoSmithKline, May 2006 - Feb 2009**

 **Quality Consultant / Senior Quality Consultant**

• Coordinated, managed and executed supplier quality audits for a complement of approximately 100 suppliers

• Ensured that appropriate corrective actions were identified and implemented for all audit findings related to supplier audits performed

• Identified improvement opportunities for supplier quality auditing and CAPA management processes using quality/OE tools, co-worker feedback, and statistical analysis

• Performed or supported investigations into significant quality incidents arising at suppliers through for cause audits and ensuring that root causes were identified and appropriate corrective and preventative actions are implemented.

 **GlaxoSmithKline, Aug. 2003 - May 2006**

 **Product Release Leader**

• Coordinated and managed the release of components, raw materials, intermediates and finished products

• Provided oversight to the batch documentation review process by addressing any potential Quality or Regulatory issues (e.g., stability, integrity, safety issues or NDA deviations) observed during batch documentation review/release

• Coordinated and managed production and laboratory deviation investigation teams to ensure thorough investigations and adequate CAPAs

• Reviewed and approved investigations, batch documents, SOPs, specifications, etc. for compliance to internal QMS and regulatory requirements

• Presented Product Release QA documentation and systems during internal and external regulatory inspections and prepared responses as needed

**GlaxoSmithKline,**

 **Senior Process Auditor/Lead Process Auditor Jan. 2001 - Aug. 2003**

• Provided quality compliance support for manufacturing and packaging operations

• Evaluated production processes, operations and proposed process changes to assure cGMP and regulatory compliance

• Performed internal compliance audits of manufacturing and packaging

• Performed production deviation/lab OOS investigations and was responsible for coordinating and investigating exceptions and authoring investigation reports

• Authored, reviewed, edited and approved critical documentation items for cGMP compliance including batch documents, SOPs, and specifications

 **Catalytica Pharmaceuticals, Inc., Aug. 1997 - Jan. 2001**

 **GlaxoWellcome Inc.,**  **April 1997 - Aug. 1997**

 **QA Compliance Specialist I/II**

•Reviewed and approved batch documentation and test data for batch release

•Provided quality complaince support for Bulk Active Production Operations

•Led process deviation and customer complaint investigations and authored associated investigation reports

•Performed trend analysis of non-conformance events for the APR program

•Assisted in coordination of production, QC, QA and Planning to expedite the release and shipment of products to internal and external clients.

**Education: Master of Science 2003**

**School:** East Carolina University, Greenville, NC

 **Major:** Biology **Concentration:** Cellular Biology

 **Bachelor of Science**, **1996**

**School:** East Carolina University, Greenville, NC

 **Major:** Biology **Concentration:** Anatomy and Physiology

 **Associate of Science** **1994**

**School:** James Sprunt Community College, Kenansville, NC