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To Whom It May Concern:

I am a Quality Assurance Professional with 7+ strong years of progressively responsible experience at Cardinal Health, Inc.

In my current role I am a Quality Systems Analyst with 2+ years of extensive experience in auditing and project management and Lean Six Sigma. In this role, I manage Field Corrective Actions for Cardinal Health, Inc. and various vendors from project execution to completion of moderate or large projects. In this role I perform internal audits related to Field Corrective Actions. Additionally, my project management experience includes financial recovery and reporting, and web site management.

My role as a Documentation Specialist within Cardinal Health, Inc. afforded me five solid years of invaluable opportunities to gain and polish my skills in audit processes, practices and project management. I ensured records, methods, and practices were consistent with corporate standard operating policies and business unit procedures, as well as regulatory requirements and external certifying agency requirements. I facilitated audits of local businesses within the company and also assisted in the preparation of audit inspections by sponsors, regulatory authorities, and certifying agencies. I conducted systems audits and issued reports assuring compliance and ensured the local policies and practices were in alignment with the standard operating procedures and regulations. I reviewed reports, source documents and other data ensuring compliance and made recommendations and implemented changes as necessary. I also conducted effectiveness checks of corrective / preventive actions ensuring the corrective actions were implemented and that they were effective in correcting and preventing nonconformance's. Additional project management experience in this role included, document control center management, policy and procedure implementation, document change control, orientation training facilitation and training records management, financial reporting, and web site development.

Due to the high visibility of these roles I communicate effectively with a wide range of people at various levels. In addition, I have obtained valuable computer skills from my career path as well as from my academic studies.

I feel that my auditing skills, project management skills, my valuable verbal and written communication skills, and my organization and planning skills would be great assets to this organization.

Thank you for your time and consideration. I hope that you will find my auditing and versatile skills an asset and welcome my enthusiasm. Feel free to contact me at (847) 406-7322 so that I may discuss this job opportunity with you.

Sincerely,

Michelle Emery

SUMMARY

Quality Assurance professional, experienced in providing global support to corporate, research and product development teams in diverse, manufacturing / distribution operations. A goal-oriented performer with proven contributions to productivity, driven to obtain a leadership role that will provide growth in technical areas and opportunities to make significant contributions to an organization. Expertise in project management, document control center management, audit processes, policy/procedure change control and implementation, orientation training facilitation and training records management, financial analysis, web site development and web authoring.

ASSETS

- Exceptional organizational & analytical skills, with excellent verbal and written communication skills
- Strong computer skills in applications, database mainframes, and website development
- Working knowledge of regulating agencies

BUSINESS EXPERIENCE

CARDINAL HEALTH, INC., McGaw Park, Illinois **2000 – Present**

The undisputed leader in medical products and services employs more than 55,000 people on six continents and produces annualized revenues upward of \$81 billion. Formerly Allegiance Healthcare Corporation, \$4.5 billion spin off from Baxter, acquired by Cardinal Health in 1999.

Quality Systems Analyst, Quality and Regulatory Management **2005 – Present**

Manage Field Corrective Action projects for a variety of domestic and international self-manufacturing / distribution businesses and associated customers in support of the Quality and Regulatory Management group (Regulatory and Quality Assurance, Sales / Marketing, Corporate Legal Department, Manufacturing / Distribution facilities, Alternate Distributors and Cardinal Health customer base.)

- **Performs** internal audits relating to Field Corrective Actions.
- **Initiates / maintains** product Recalls, Holds, Market Withdrawals, and Advisories in accordance with internal / external regulations.
- **Initiates / prepares** over label procedures and protocols maintaining available product base for customers.
- **Prepares** monthly billing of Field Corrective Action charges for business segments with a realization of annual revenue of \$40,000+ and cost recovering of approximately \$200,000.
- **Manages** recall web page for business clients.

Documentation Specialist, Quality Operations

2000 - 2005

Established and maintained Document Control Center activities in adherence to regulatory pathway requirements, assisted international manufacturing facilities and a variety of contract manufacturing sites for Cardinal Health, Inc. business units. Ensured records, methods, and practices were consistent with corporate and business unit standard operating procedures / policies as well as regulatory requirements and external certifying agency requirements.

- **Reviewed** reports, source documents and raw data assuring management that they accurately reflected standard operating procedures, policies and regulations.
- **Conducted** systems audits and issued reports to management assuring standard operating procedures, policies and regulation compliance.
- **Facilitated** local audits and performed effectiveness checks to assure corrective / preventive actions were taken and were effective in preventing reoccurrences of nonconformances.
- **Assisted** with audits by sponsors and regulatory authorities regarding quality processes to include standard operating procedures, training, document review, document change control, etc.
- **Key individual** responsible for transitioning business units to align with Quality Operation's standards.
- **Created** a paperless documentation system by transitioning documentation to electronic form across all business units for global access.
- **Created** web sites to facilitate electronic access to controlled documents.
- **Systems Implementation** – implemented a database (Microsoft Access) for electronic tracking process of annual review cycles and mainframe (AS/400) for electronic documentation and tracking of training requirements.
- **Developed, implemented and delivered** orientation training plans/materials to all business units.
- **Created** monthly and adhoc reports utilizing Business Objects, Excel and SAP R/3.

ROY F. WESTON, INC., Vernon Hills, IL

1998 – 2000

Leading employee-owned environmental and redevelopment firm provides comprehensive solutions to complex problems for industry and government worldwide.

Administrative Assistant, Environmental Consulting

Key individual responsible for internal audits, coordination, preparation and submittal of monthly / annual reports, drafted contract / subcontract agreements and maintained document control center activities under the Remedial Action Contract (RAC) regulated by United States Environmental Protection Agency.

RECOGNITIONS

Recipient of Cardinal Health's Chairman's Award, 2003 & 2005

SPECIALIZED MEMBERSHIPS & TRAINING

ASQ Member; Lean Six Sigma; ISO 9000; ISO 9001:2000; ISO 13485; 21 CFR, Part 820; 21 CFR, Part 11

EDUCATION

Pursuing Bachelor of Science degree, Columbia College