



Resume of Verdad Systems Consultant Paulette Hamilton – FDA Validation Specialist

Achievements:

- Implementation and Validation of OpenText Livelink ECM/Reg Docs. Author, review and execute validation protocols and validation summary reports.
- Upgrade of ERP system (Oracle Financials 11.5.10) within SOX 404 guidelines.
- Conduct IT Audit planning, testing and documentation for SOX 404 compliance; write quarterly reporting for General Computing Controls, security policies and procedures.
- Planned and directed the relocation of Vical's corporate offices and Data Center.
- Installed, implemented and validated Oracle Clinical Data Management system.
- Managed installation and implementation of ERP system.

Professional Summary:

Fourteen years of success as an Information Technology professional with extensive experience planning, implementing and validating applications in a GMP environment. Proven ability defining business processes and designing automated solutions using various workflow applications, Manage projects from start to finish including functional requirements, risk assessment, ROI analysis, project milestone definitions, project timelines. Manage external consultants. Recruit, coach, motivate and develop a diverse team of skilled IT staff that deliver customer service, technological results and cost savings.

Areas of Expertise

Computer Systems Validation, Information Systems Auditing, IT Project Management, Systems Implementation, Budgeting and Financial Reporting, Team Building, Strategic Planning, Decision Making & Problem Solving, Multi-Platform & Multi-site Technology, 21 CFR Part 11, GMP, SOX 404, COBIT, COSO, GCC.

Technical Summary:

OpenText Livelink ECM/Reg Docs, Oracle Financials 11.5.10, , SQL Plus, Access, ADP, Discoverer, Microsoft Office, Microsoft Project, Windows 2000/XP, EMC SAN.

Experience:

1996 - 2008

VICAL, Incorporated

San Diego, CA

DIRECTOR INFORMATION TECHNOLOGY

Lead the company's IT providing strategic direction in all aspects including technology acquisition, project planning and management, governance and risk management. Budget, design and support all technology projects. Oversee and manage systems and applications conformance to regulations and standards like cGMP, GLP, 21 CFR Part 11, HIPPA and SOX 404. Present written, audio-visual and verbal reports to Senior Management, Board of Directors and Audit Committee

- Write, review and execute validation documentation including protocols, IQ, OQ, PQ and functional SOPs for various applications including OpenText Livelink, Oracle Clinical, Oracle Financials and AKTA.
- Manage all Information Technology projects including project management, requirements gathering and status reports to IT Steering Committee and Senior Management.

- Author and implement policies and procedures for the IT environment including change management, data security, data backup and recovery, user setup, system acquisition, incident response and remote access.
- Responsible for development and implementation of Information Technology long-range strategic planning.
- Responsible for planning, staffing, budgeting and operational efforts of all IT and communications functions.
- Responsible for implementation, planning and maintenance of company's multi-site interconnected infrastructure.
- Plan and manage IT budget.
- Hire and manage diverse and dedicated technical staff. Developed cross-training system that enables IT to deliver cost effective system support.
- Successful conversion of payroll system to Ceridian Source 500; currently involved in conversion from Ceridian to ADP.
- Define strategies, methods and approaches for improvement of internal controls in order to meet and comply with regulations for Sarbanes-Oxley Section 404.
- Identify technology risks and ensure that mitigating controls are implemented.
- Direct Technical Support, Customer Support, System Administration, Development and Infrastructure for multi-platform environment supporting Oracle Financials, Oracle Clinical, Livelink, AKTA and various other clinical applications.
- Communicate audit findings to senior management and to the Audit Committee via written and oral reports.
- Facilitate and conduct internal training for IT staff on security and change management policies, procedures and best practices.

1989 - 1996

Laboratory Corporation of America

La Jolla, CA

MANAGER PC & LAN SUPPORT SERVICES

- Responsible for implementation, design, expansion and maintenance of multi-platform mission-critical information systems environment including mainframe and client/server.
- Managed information technology projects including 1) the interconnection of LAN servers and the Mainframe system 2) movement of an 8000-employee payroll system to new corporate site.
- Recommended and evaluated new technology for 2 local sites and for over 23 remote sites nationwide.
- Increased information technology assets by 200%.
- Supplied hands-on leadership, training and supervision.

Education:

Excelsior College, Albany, NY

MBA w/emphasis on Information Technology Management – in progress

Baruch College, City University of New York

Bachelor of Business Administration, Business Management, cum laude

Certifications:

CISA – Certified Information Systems Auditor

Organizations:

NAFE, ISACA, SDOAUG