Marcus Suber

Sr Program Director - Independent Contract- Human Resources Command

MetroWest
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As a Senior Project Manager, I will create and maintain an information technology project plan that communicates tasks, milestone dates, and status and resource allocation, utilized Waterfall and Agile PMO life-cycle methodology, coordinate delivery of development and production releases that meet quality assurance standards, assist technical team in design and development tasks and assist test team in creating test plans and testing efforts to ensure proper coverage for DoD, Pharmaceutical, Biotechnology, Biomedical, CRO, CMO and Fuel Management clients.
Willing to relocate: Anywhere
Authorized to work in the US for any employer

WORK EXPERIENCE

Sr Program Director

Independent Contract- Human Resources Command - Fort Knox, KY - February 2016 to Present

Responsibilities:
• Planned, managed and lead multiple complex IT Infrastructure and/or Application Development projects of small to medium size and wide variety of complexity and length
• Provided in-person and remote medical software support to end-users, guiding them through the challenge of new system adoption
• Provided in-depth knowledge of the Microsoft Dynamics CRM platform and evaluate customer's business processes against the standard CRM functionality
• Developed Extract, Transform, and Load (ETL) Specifications to support data conversion and integrations
• Utilized gated Waterfall methodology
• Experience in developing and supporting on Microsoft Azure or other cloud based technologies
• Overseeing the full life-cycle development and implementation program for Citrix Winframe, Legacy LMS, LIMS and EDMS systems and technical activities to ensure successful project execution and meeting of requirements
• Managed activities of subcontractors utilized to deliver the technical solution
• Created and communicated detailed requirements, solution proposals, business process designs (BPD) and business system designs (BSD) that meet the business needs
• Lead validation and integrity of ASP.NET, VB.NET, JavaScript, Ajax, Html, CSS, Visual Studio 2008/2010, Embedded VB Scripting within the Excel environment, Stored Procedures and T-SQL statements
• Planned, lead, organized and controlled multiple project initiatives according to agreed upon scope, schedule and budget targets surrounding the new EMR Rollout
• Developed testing, reviewed and implementation plans with the business groups, user groups and MS Dynamics CRM VAR (implementation partner)
• Delivered end-user application training for go-lives, new hires, and optimization
• Lead and direct the successful delivery of infrastructure design, systems integration, and product installation/ customization services while ensuring that assigned projects adhere to the approved life

Sr. Project Manager

TelaPoint - Louisville, KY - March 2011 to February 2016

Responsibilities:

• Directly responsible for managing the project budget working closely with the PMO and/ or project sponsor to manage and report on the project financials - including the estimates created during the funding process, the ongoing allocation of financial resources and the regular reporting of the state of the project financials.
• Developed and maintained custom applications and interfaces using VB.NET, ASP.NET, Ajax, Html, CSS, VB Scripting, and SQL Server development tools to support the efforts of the Strategic Pricing Group
• Lead a variety of projects including implementing new systems and services, application development, systems integration, operational efficiency improvements, process re-engineering, and infrastructure upgrades and deployments
• Utilized MS Azure and other PaaS technologies on a very large-scale environment
• Utilized Agile(for revenue generating projects) and Waterfall methodology
• Lead the process improve initiative for Epic Healthcare Data Management System and EHR Systems.
• Managed the harmonization and implementation of SharePoint 2012 on enterprise level
• Lead team is responsible for developing and managing next-generation EDA & Automation solutions, utilities & tools that supports high quality & accelerated Time-to-Market
• Lead the implementation of Subrogation application for P&C Claims Review.
• Lead analysis of EPIC model content and negotiation of any user requested modifications
• Used with elastically scalable, fault tolerance and other cloud architecture patterns
• Managed the development and implementation of the ERP customer service, engineering & operations, sales and marketing and financial applications systems - including testing, process re-engineering, training, documenting and maintaining systems
• Proactively manage changes in project scope, schedule and cost, identify risks, and establish contingency plans
• Drove agile development methodology including test driven development.
• Coordinated and conducted a review of the ICD-9-CM/PCS and ICD-10-CM/PCS coding chapters for potential coding and physician education via a team approach.
• Provided in-depth knowledge of the Microsoft Dynamics CRM platform and evaluate customer's business processes against the standard CRM functionality
• Developed Extract, Transform, and Load (ETL) Specifications to support data conversion and integrations
• Lead and managed the project plan, process, and tasks throughout the SDLC process of Siebel CRM sales force automation systems, which tracked sales activity for pharmaceutical sales reps and calls to physicians.
• Managed IT team's effort in developing CarePath, Epic training system
• Monitored guidelines and any new information on the potential ICD-10 implementation.
• Supported and/provided training and education of Coding Staff on ICD-10 and clinical aspects, as well as coordinating education sessions for other departments, hospital-based clinics and physicians.
• Developed and tracks to detailed project plans, including schedules, cost estimates, resource plans, communication plans, risk mitigation plans and issue resolution plans
• Ensured project implementations and deployments are through the Project Management Office (PMO).
• Arranged, prepared and conducted meetings, workshops and presentations as required for a wide variety of audiences, demonstrating consistently high qualities of communication skills and plans and organizes the giving of presentations or training sessions to all levels including senior management
• Responsible for all aspects of application Validation and Verification testing, including requirements analysis, creation and management of Test Plans and Test Cases and the execution of the Test Cases for SmartBuy 4.0
• Managed project deliverables, scope & expectations and coordinates project progress with sponsors, project boards, sponsors and key stakeholders
• Validated financial forecasts and provides on-going reconciliation of resources and other related project expenditures
• Drove collaboration for System Integration with Development and SE
• Developed, documented and implemented improved processes that support overall sales effectiveness. Understand critical business need to drive productivity, document process workflows and implement solutions

to support those workflows. Evaluated and improved programs, communications, systems and reporting requirements based on evolving business needs
• Developed and tracks to detailed project plans, including schedules, cost estimates, resource plans, communication plans, risk mitigation plans and issue resolution plans
• Assisted the development of security measures and policies for Team Foundation Server (TFS) to prevent unauthorized access
• Made project decisions and recommendations to management about schedules, prioritization, and resource allocation with input from others as needed
• Arranged, prepared and conducted meetings, workshops and presentations as required for a wide variety of audiences, demonstrating consistently high qualities of communication skills and plans and organizes the giving of presentations or training sessions to all levels including senior management
• Set strategic direction for a team which implements Quality Assurance industry best practices
• Financial Management of project technical consultancy budget (including budget analysis)
• Define test project schedule for moderate to large projects, as well as test strategy for all test phases in the complete project lifecycle
• Developed Test Strategy for small to medium complexity testing efforts by investigating the context of a testing effort
• Provided systems implementation oversight and leadership for the development, enhancement and/or implementation of healthcare software systems, application programs and databases
• I facilitated critical meetings for project kick-off, status reports, and steering committee meetings with senior leadership. I provided strategic and tactical leadership to successfully implement technology and service projects for the implementation of SFA project
• Conducted risked back approach to harmonize ICD-10 impact to enterprise subjugation applications.
• Identified and managed project dependencies and critical path
• Verified changes to equipment, finished products and processes
• Prepare impact analysis against scope, schedules and budget
• Create, maintain and report against a cross project schedule and resource management plan
• Worked with SD module to help project revenue figures based on product sales assumptions via DSS
• Controlled the version migration process as each software build moves from the development to testing environment and assisted implementation of software versioning control.
• Arranged, prepared and conducted meetings, workshops and presentations as required for a wide variety of audiences, demonstrating consistently high qualities of communication skills and plans and organizes the giving of presentations or training sessions to all levels including senior management
• Establish metrics baselines and perform analyses to identify and eliminate systemic process issues

Sr. Project Manager

Watson Laboratories - Corona, CA - January 2010 to October 2010

Responsibilities:
• Coached, mentored, motivated and supervised project team members and contractors, and influence them to take positive action and accountability for their assigned work
• Worked with Senior Management and other Quality staff to oversee the development and implementation of an FDA compliant Quality System for GCP/GAMP5/GLP activities, provided periodic updates to Senior Management regarding the Quality Systems, LIMS, and collaborated with Clinical Research / Clinical Operations personnel to ensure that clinical trials comply with SOPs, FDA regulations, ICH/GCP, 21CFR11, and international guidelines, as applicable
• Lead sales incentive plan design processes with input from leadership team. Designed commission plans based on business needs, market practices and competitive requirements

• I facilitated critical meetings for project kick-off, status reports, and steering committee meetings with senior leadership. I provided strategic and tactical leadership to successfully implement technology and service projects for the implementation of SFA project
• Supported the creation and maintenance of a complex system being built on the Microsoft Dynamics CRM platform
• Created and communicated detailed requirements, solution proposals, business process designs (BPD) and business system designs (BSD) that meet the business needs
• Followed Agile and Waterfall methods
• Managed Automation team to design, develop and deliver small, mid and large sized technical projects
• Utilized Clarity in toolbox
• Conducted process improvement initiatives on Veeva
• Coordinated automation control system integration between Manufacturing, R&T, IT, and the control system vendors
• Developed and tracks to detailed project plans, including schedules, cost estimates, resource plans, communication plans, risk mitigation plans and issue resolution plans.
• Supported Compliance Program by demonstrating adherence to all relevant compliance policies and procedures as evidenced by in-service attendance and daily practice; notifying management when there is a compliance concern or incident; demonstrating knowledge of PII/HIPAA Privacy and Security Regulations as evidenced by • Performed and evaluated costs analysis and vendor comparisons for projects to ensure cost-effective and efficient operations.
• Performed complex analysis, design, development, testing and support services for Epic HB (Hospital Billing) and EMR Systems.
• Measured feasibility of various approaches and make recommendation(s).
• Helped implement Team Foundation Sever security measure in line with regulatory guidelines
• Lead Software test automation experience using Java and .NET with a distinguished track record on technically demanding projects
• Lead implementation of SharePoint 2007
• Translated the business functionality into Epic system configuration and workflow validations.
• Provided expert GCP compliance and general QA support;
• Acted as liaison between product automated development teams and QAU
• Served as a bridge between end users and vendor implementation staff to tailor the Epic system to the organizational needs
• Arranged, prepared and conducted meetings, workshops and presentations as required for a wide variety of audiences, demonstrating consistently high qualities of communication skills and plans and organizes the giving of presentations or training sessions to all levels including senior management
• Conducted extensive end of year analysis of product line
• Provide corrective feedback to Allen-Bradley DCS automation groups to meet project goals
• Developed and improved quality systems to facilitate business and quality objectives and compliance review and resolution process to ensure the organization is alerted to issues in time to resolve potential adverse affects on the customer, company or business utilizing Trackwise repository.
• Developed and managed quality assurance metrics for performance improvement
• Reviewed every batch, every 'major' and some moderate complaints, reviewed every recall and investigation.
• Managed testing team compliance with existing measures for reporting testing efforts and defect management process and track/monitor defects to closure.
• Responsible for all test execution, test tools development and configuration management activities
• Incorporated performance risks into existing risk management processes
• Managed resources, milestones and inter-dependent deliverables to ensure successful project delivery

• Developed and improved quality systems to facilitate business and quality objectives and compliance review and resolution process to ensure the organization is alerted to issues in time to resolve potential adverse affects on the customer, company or business
• Identified and managed project dependencies and critical path
• Performed product design, bug verification, release testing, and beta support on application reports written using Crystal Reports, SQL Reporting Services, and Microsoft Transact SQL and reviewed product release data for PeopleSoft database
• Created, revised, reviewed, and approved quality-related documents, including procedures, memoranda, protocols, and reports
• Planned, coordinated and conducted internal and external (domestic and international) GxP-related audits, including Investigator Site Audits, System/Process Audits, Vendor Audits (CROs, Labs), Data Audits, Trial Master File (TMF) Audits, Document Audits to ensure templates are followed, identify potential discrepancies, etc. (e.g. protocol, ICF, IB) in concert with DSS

Sr. Project Validation Manager(R&D/Biopharmaceutical/CRO/CMO)

Boston Scientific - Natick, MA - October 2006 to October 2009

Responsibilities:
• Employed project management best practices as governed by Program Management Office's based project management framework including its process definition, templates and tools
• Maintained complicated schedules, develop project timelines, and manage people and materials to complete jobs on schedule and within budget guidelines
• Lead the migration of data to LIMS, CTMS
• Utilized Waterfall methodology and Agile
• Develop, deploy and test automation solutions in support of commercial biotechnology based Drug Product (DP) aseptic fill and finish operations
• Lead implementation of ERP/Workday
• Performed assigned documentation tasks with computer aided design tools (AutoCAD) in accordance with project guidelines
• Analyzed and validates organizational and/or operational requirements and user acceptance testing
• Reviewed consultants and QA employees' test plans and test cases and provides feedback and coaching where applicable to ensure delivery against IT QA department goals and objectives
• Lead the implementation of Epic Ambulatory EMR and Epic Practice Management
• Provided technical guidance and leadership to the team members to deliver on organization and product goals
• Participated in the development and delivery of internal training programs.
• Lead performance of complex DBA tasks including data migrations, replication, troubleshooting, Always ON, clustering and performance optimization
• Lead commissioning and qualification validation efforts on the Emerson Delta V System and other automation systems
• Arranged, prepared and conducted meetings, workshops and presentations as required for a wide variety of audiences, demonstrating consistently high qualities of communication skills and plans and organizes the giving of presentations or training sessions to all levels including senior management
• Designed and specified DCS and other process control needs in the production area that meet regulatory standards
• Supported the preparation, coordination, and management of regulatory agency inspections. During inspection, played lead role as facilitator and communicator.
• Supported 'for cause' audits, as necessary and performed onsite and virtual inspections of installations and service repair work; Citrix Mainframe, DOORS, PeopleSoft7, SharePoint 2007, Clarity and Trackwise were utilized as the document repositories.

• Defined, lead and implemented quality and validation engineering in designing and development of products, during product transfer, and in steady state phases of manufacturing operations; ensured timely independent quality assessment of systems, reports, internal/external facilities and documents that meet the company standards for quality, content, and format
• Ensured adequate allocation of resources to projects being managed through constructive negotiations with functional resource managers
• Utilized DSS to serve the management, operations, and planning levels of an organization and help to make decisions, which may be rapidly changing and not easily specified in advance
• Implemented ongoing quality improvement processes working with interdepartmental teams
• Developed and managed quality assurance metrics for performance improvement
• Functioned as the authority on validation strategy, procedures and techniques and regulatory compliance. Provided leadership and participated in validation protocol development, review and approval.
• Directed the conduct of product performance and manufacturing process experiments, studies and tests.
• Directed the analysis trending and interpretation of experimental data and the preparation of technical reports
• Participated in all phases of development life-cycle by providing input during definition and design meetings, functional and technical walkthroughs, and software testing; worked collaboratively with team members and other departments to identify and resolve issues, implement test strategies and respond to Quality related questions
• Worked with the client to gather reporting requirements and design the reports in Crystal Reports and developed Crystal Reports for use in a large scale IT/PMO Modernization effort
• Applied analysis concepts, techniques, tools and standards to support assigned projects

Sr. Systems Manager(Biotech/CMO)

Millipore Corp - Billerica, MA - June 2005 to October 2006

Responsibilities:
• Authored Validation Master Plans, and lead the execution of concurrent projects at multiple sites.
• Maintained domain and technology expertise by keeping current with evolving testing methodologies and healthcare standards
• Lead review of performance against expectations, highlighting good results, and developing action plans to address concerns
• Utilized Waterfall and Agile methodology
• Lead the GAMP validation compliance directive for Software Engineered Product Group, inclusive to their automated M-ERP II system, Sales Force Automation, Laboratory Equipment, Processes, Allen Bradley, Legacy Labware LIMS and Empower Systems
• Managed and lead Quality Assurance Engineering in support of new product development, ensure Quality Systems and programs supporting these functions comply with company policies and procedures, and industry regulations and standards, including 21CFR part 11, GAMP4/5, FDA QSR, ISO 13485:2003, ICH QA7, QSR and MDD 93/42/EEC, ICD-9.
• Coordinated and aligned management of PLCs and SCADA systems at the plant sites in a consistent and repeatable process approved by Process Engineering group and the Research and Technology
• Verified maintenance of Epic applications and facilitates updates, new releases and system enhancements
• Provided DCS controls support to Capital projects(using DSS) for testing and startup assistance as well as assisting in daily troubleshooting, gathering data and analysis of available information
• Utilized serialization to detect longitudinal changes to data in adherence to 21CFRPart 11
• Managed the validation program for existing and new products, manufacturing processes, testing, packaging, facilities and utilities. Ensured compliance with Federal Regulatory requirements
• Developed and improved quality systems to facilitate business and quality objectives and compliance review and resolution process to ensure the organization is alerted to issues in time to resolve potential adverse effects on the customer, company or business

• Provided overall direction and expertise for administration of validation/revalidation policies and change control system in compliance with Quality System Regulations and corporate policy.
• Under limited supervision assume primary responsibility for problem solving, support and maintenance of multiple Tier 1, Tier 2, and Tier 3 incidents and projects
• Evaluated proposed changes to products, manufacturing processes, and environment to determine validation or re-validation requirements and defines qualification strategy.
• Approved and authorized implementation of product, manufacturing process, and environment changes based on review of information, test data and reports completed in accordance with the defined strategy
• Reviewed SOPs to ensure compliance with applicable regulatory and corporate standards

Associate Director, Manufacturing ERP (Pharmaceutical/CRO/CMO)

GlaxoSmithKline - Research Triangle Park, NC - June 2003 to April 2005

Responsibilities:
• Collaborated with Clinical Research / Clinical Operations personnel to ensure that clinical trials comply with SOPs, FDA regulations, ICH/cGCP/GMP, and international guidelines, as applicable
• Maintained daily/weekly/monthly reports regarding projects, activities, and status of open requests and problems
• Functioned as the Quality Subject Matter Expert and leveraged that knowledge to steer non-conformances into compliance
• Utilized Waterfall and Agile methodologies
• Assisted the Principal Investigator in laboratory oversight of clinical and pre-clinical bioanalytical studies as an Associate Study Director/Associate Principal Investigator per GxP requirements on LIMS
• Created and maintained project plans to ensure timely completion of tasks, major project milestones, and resource allocation utilizing SDLC methodology.
• Lead the migration of SFA systems track sales activity for pharmaceutical sales reps and calls to physicians
• Worked closely with users/laboratory colleagues to resolve issues in a timely manner and managed the performance routine documentation of change control activities for the lab systems with a focus on GMP compliance
• Lead data migration into Salesforce.com for objects including but not limited to accounts, contacts, campaigns, leads and opportunities
• Functionally lead a development team in a .NET environment and assisted in definition, development, documentation and maintenance of quality .NET code
• Managed project cost estimates
• Created and maintained project plans to ensure timely completion of tasks, major project milestones, and resource allocation utilizing SDLC methodology
• Participated in the testing of disaster recovery processes
• Provided overall direction and expertise for administration of validation/revalidation policies and change control system in compliance with Quality System Regulations and corporate policy.
• Adherence to established best practices for systems application development, deployment, monitoring, security, disaster recovery, and backups
• Arranged, prepared and conducted meetings, workshops and presentations as required for a wide variety of audiences, demonstrating consistently high qualities of communication skills and plans and organizes the giving of presentations or training sessions to all levels including senior management
• Evaluated proposed changes to products, manufacturing processes, and environment to determine validation or re-validation requirements and defines qualification strategy.
• Approved and authorized implementation of product, manufacturing process, and environment changes based on review of information, test data and reports completed in accordance with the defined strategy and ERES policies
• Experienced working in a large Global Enterprise level multi-release software project.

• Maximized trending of P/E ratio using DSS.
• Researched changes and/or enhancements to software product line for multiple existing or new features
• Provided technical oversight for .Net projects/development
• Maintained PVCS and PATHDATA global integrity schedule, prepare for, conduct, report, and close out all audits undertaken, and maintained Global Program Project validation matrix
• Completed product review documentation to access needed changes to product line

Sr Manager, Inhaled Toxicology(R&D Pre-clinical, Inhaled Toxicology & Animal Biology)

RJ Reynolds - Winston-Salem, NC - October 2001 to May 2003

Responsibilities:
• Researched and advised senior management on latest software test trends as well as market needs
• Conceived, lead, planned, executed, and interpreted research in inhaled toxicology, physiology, and derma-toxicology studies.
• Provided harmonization of Labware LIMS and acted as the primary liaison between the laboratory and IT group for the development and implementation of new systems, and enhancement of existing systems
• Performed and evaluated costs analysis and vendor comparisons for projects to ensure cost-effective and efficient operations.
• Followed Waterfall methodology
• Measured feasibility of various approaches and make recommendation(s
• Tested and verified system and database models to ensure quality and integrity
• Documented defects that do not successfully meet expected results and communicates results to development and leadership teams
• Accountable for meeting deadlines and budget requirements
• Reviewed COC information against information entered into LIMS; communicate discrepancies and sample anomalies to client
• Confirmed systems control and access calibration*validation needs
• Plan projects, determine technical objectives, make recommendations for the selection of proper staff, and organize the R&D effort to meet protocol objectives
• Defined and tracked QA milestones while developing, maintaining, and reporting on an overall integrated delivery plan
• Participated in continuous process refinement and improvement
• Assisted in the development, execution, and documentation of system and integration test plans
• Communicated products and process status to Senior Management
• Wrote comprehensive application quality assurance test plans
• Created technical specifications and software prototypes used as datasets for system testing
• Prepared detailed analysis and design artifacts using modeling tools
• Conducted annual product reviews
• Lead the QAU test strategy and compliance directives
• Conducted retrospective evaluation of Legacy Oracle/ LIMS/MY SQL database

RegulatoryManager/QA Manager

LabCorp - Research Triangle Park, NC - November 1999 to September 2001

R&D/Clinical Trials Division)
Responsibilities:
• Implemented software testing processes and best practices as well as implemented the test strategy (architecture, framework, tools, etc).
• Adhered to Waterfall methodology.
• Determined the scope of projects, the timeframe, and the resources required; developed and reviewed project and work plans

• Maintained daily/weekly/monthly reports regarding projects, activities, and status of open requests and problems and Updated Salesforce reports and dashboards when necessary and sales territory changes, tier changes, or changes in opportunity definitions may affect reporting results for the organization.
• Lead implementation of EpicCare Quality System and databases to ensure optimum performance
• Conducted internal audits laboratory audits and trained computer validation staff.
• Lead and performed SQE activities, through every phase of the Software Development Life Cycle, for developing new applications and in support of the legacy applications.
• Identified, recommended, and implemented Change Control to enhance the effectiveness of quality assurance strategies. Developed risk and cost analysis
• Coordinated activities of the project team and assist in monitoring project schedules and costs
• Lead and Directed design and code reviews
• Created and maintained project plans to ensure timely completion of tasks, major project milestones, and resource allocation utilizing SDLC methodology
• Lead the overall compliance of 21CFR part 11
• Lead randomization and serialization of aliquots, bathes, lots and data of LIMS/EDMS/LCMS.
• Participated in design sessions and serves as a department representative
• Responsible for managing the multiple phases of the project across multiple on-going projects to meet project timelines
• Ensured test execution is completed within agreed time tables and estimates
• Researched changes and/or enhancements to software product line for multiple existing or new features
• Provided Technology Solution Development and Integration across the SDLC including requirements, functional specs, design, custom development, integration, system testing and deployment
• Prepared detailed project status reports as assigned

Regulatory Compliance Officer/ QA Analysis Manager

General Electric - Raleigh, NC - 1997 to 1999

Biomedical Division/Biotech)
Responsibilities:
• Conducted SDLC life cycle coordinated projects.
• Managed 3 wave implementation of LMS.
• Identified opportunities for testing automation and facilitates creation of standardized test suites
• Served as business analyst for several pharmaceutical divisions.
• Adhered to established best practices for systems application development, deployment, monitoring, security, disaster recovery, and backups
• Worked with internal stakeholders to ensure that the Salesforce.com configuration supports business requirements. As required, managed Salesforce.com enhancement projects to support business needs
• Lead and promoted end-user computing environment and support systems which extend computing capabilities directly to the end-user in terms of software tools, computer
hardware, development/maintenance guidelines, training and consulting
• Conducted a wide range of quality control tests and analyses with full competency to ensure that software meets or exceeds specified standards and end-user requirements
• Supervised a QA team of seven, plus an administrative assistant and a desktop support person. Member of General Electric's regulatory compliance team.
• Lead PEOPLESOFT COTS verification/configuration project.
• Mentored QA team utilizing proprietary software, UNIX, Citrix, and SecurID.
• Helped establish timelines for rollout projects. Ensured compliance as per FDA QSR regulation. Maintained and supported LAN and WAN connectivity, remote access, GE Extend, Mainframe AS400, SQL*LIMS, Telnet, and 3270 Emulator.

• Expected to follow strict change control management policies designed to ensure that proper planning, execution, and meticulous documentation for projects of all systems supported
• Provided Cost Analysis for Support Team.
• Ensured SDLC was followed. Initiated team-building program. Member of GE's morale team.

Pharmaceutical Training Stream Lead(Biotechnology)

Technical Resources Group - Raleigh, NC - 1996 to 1997

Responsibilities:
• Mentored System Engineers. Performed quarterly internal audits. Managed support teams for Johnson and Johnson, Glaxo Wellcome, Schering-Plough, and Norvartis, and ensured regulatory compliance was maintained.
• Single accountable party for defining, planning, orchestrating, and delivering a given initiative
• Supported Sales Development team with ongoing maintenance such as setting up new hires with leads, and managing lead ownership when reps are promoted to other groups
• Performed configuration management duties for PEOPLESOFT/SIEBEL. Trained new analysts. Supported intranet/internet clients. Performed business analyst function for team. Ensured group adhered to SDLC.
• Initiated team-building program, and managed a team of nine quality professionals.
• Conducted training sessions about inbound lead routing & assignment, inbound lead follow up process and expectations, opportunity creation, defining Salesforce list views, tagging campaigns, etc
• Performed quality audits on BMSP, Odyssey, Sonic, and other proprietary software
• Provided FDA compliance recommendations and GxP training to executive committee

Compliance/ Training Supervisor(Pharmaceutical)

QMD, Inc - Raleigh, NC - 1995 to 1996

Responsibilities:
• Created and maintained Project Master Plan and individual Project Quality Plans
• Responsible for workload analysis and the appropriate resource distribution.
• Lead international compliance initiatives and established company-wide quality guidelines, SOPs, and work instructions
• Ensured R&D departmental adherence to SDLC principles
• Performed internal audits
• Mentored new team members.
• Audited lab systems against cGxP requirements.
• Acquired specifications and requirements from user group, and met with Development to construct functional specifications.

EDUCATION

Project Management Methods Boot-Camp

State Farm's Automated Business Process Management Graduate
2003

B. S. in Psychology

University of Maryland
1995

Naval Soldering School Graduate
1994

ADDITIONAL INFORMATION

Technical Skills Summary:

- Agile/Waterfall methodologies and tools
- MS Project/ MS Project Web/Clarity/Primavera
- MS SharePoint 2007, 2010, 2012/ Visio
- Project/Process Management/Quality Assurance/ Regulatory Compliance
- Sales Force Automation, Oracle/PeopleSoft/Siebel CRM, SFA.com, Veeva
- Computer Systems Validation/ Retrospective Evaluation
- Enterprise Resource Planning/ Manufacturing Resource Planning II/MES/MS Dynamics
- Pre-Clinical and Clinical Expertise, Phase I-IVa
- LEAN Manufacturing and 5S
- Documentum, MS Azure, One Drive, MS Office 365, Drop Box, Remedy, PDM, JIRA, DOORS and TrackWise
- ICD-9 and ICD-10 training
- Automated (Rational Suite, Mercury Suite, Selenium) & Manual Testing Tools (Delta V, UCA, SCADA, CAD, PLC)
- LIMS, EMDS, CTM, MS Dynamics CRM, EPIC and LMS implementations, migration and harmonizations