MEENAKSHEE K MISHRA, PMP®
93 Riverbend Dr., North Brunswick, NJ 08902
Ph: (732) 754-0691; minumishra@gmail.com

SUMMARY:

- Results-driven, innovative leader with **expertise in QA** Project/Program Management, thought leadership, and mentoring skills with over 15 years of experience in **Medical Device Manufacturing/Biomedical /Biotech, Pharmaceutical, health care**, **Consumer Products,** and **Financial** Industries.
- Design and develop the QA Test from the beginning of the Business Simulation Test from the Scenarios of the User stories/Requirements to the Production readiness Test.
- Managed System in compliance with 21 CFR 820 and ISO 13485:2016, communication with regulatory bodies, conducting audits, and supporting compliant execution of quality-related processes.
- Implemented and transferred the QMS into the organization and ensured that it is lived in everyday life.
- Proficient in **Resource Planning, Budgeting, Risk Management, and Successful Stakeholder Management.**
- Highly experienced in diverse **ERP** Systems (SAP, ORACLE, PEOPLESOFT, and SIEBEL, etc.), **Supply Chain Management**, **LIMS** (Labware, Empower), **Pharmacovigilance, Quality**, and **Compliance.**
- **Led and managed Global CSV** (**Computer System Validation**) teams ensuring compliance with GxP (GMP, GLP, GCP, and GDP) protocols, GAMP as set forth by USFDA, and international regulatory bodies (EU Annex 7, 11, EMA, MHRA, PMDA, QSR, PIC/S, ICH Q10, EudraLex Vol 4, etc.).
- **SME in the use of structured methodologies for certified testing including Automation Testing** using various tools (QTP / UFT, SAP Solution Manager, Rational Suite, etc.), Quality Assurance of Mainframe, and Distributed Environment including Cloud Based applications.
- **Led GxP Auditors, managed testing and validation as per FDA Regulations; CFR 21 Part 11, 50, 56, 203,210, 211, 218, 312, 820, 821, and 822(a) & (b).**
- Supervised Management of outside vendors and ensured on-time deliverables.; it's leadership in action.
- Pictured translating this skill into an achievement-focused narrative that compels employers to take notice.
- Managed Quality Assurance, Quality Control, and Sterility Assurance resources effectively.; it's strategic management. Imagine illustrating how to be led teams through challenges and triumphs, proving mettle as a dynamic manager. – **Management.**
- Managed and led Quality Assurance and Compliance teams, overseeing various aspects of GxP activities and regulatory compliance...; it's mentorship and leadership. Imagine portraying myself as a guide who doesn't just teach but empowers others to excel – **Leadership.**
- Worked with Global Cross-functional teams to determine Product Line Readiness
- Possess excellent organizational, managerial, and interpersonal skills.
- **Experienced in project management in multi-project and multi-cultural setups.**

Core Competencies:

- GxP Regulation, FDA, EU, Annex, GAMP 3, 4 & 5 standards
- Supply Chain & ERP systems – SAP ECC, FI, S4/ HANA, WMs, Oracle EBS
- Computer System Validation
- Laboratory Information Management System – (LIMS), Labware, Empower
- Change Control, CAPA Follow up / Investigation / Closure, Deviation
- Product Quality Complain Management System
- Document Management System (Documentum, Veeva, LiveLink)
- End to End Test management
- Risk Assessment & Mitigation
- Quality Systems and Standards
- Project Management.
- Organization Change Management
- Process Excellence
- Training Management System
- Technical writing
- Defect Management

PROFESSIONAL EXPERIENCE

AMERICAN REGENT INC., **SHIRLEY, NY**

SR. MANAGER (QA, GXP) **11/2020 TO PRESENT**

Managed the American Regent's Quality Assurance, Quality Control, and GxP activities for the New York and PA sites. Oversees GxP compliance initiatives and effectively manages Quality Assurance, Quality Control, and Sterility Assurance resources, acting as Site Head of Quality. Partners with the Manufacturing Department to ensure all standards, regulations, and guidelines are followed in manufacturing company products. Interacts with all areas and levels of the company in addition to regulatory agencies, vendors, consultants, suppliers, and other intended parties. Managed quality and validation for **Human and Veterinary Medicines**. Also responsible for QA and Validation of **Consumer Products** and **Combo Products** as per FDA rules and regulations. Also, I worked on **SAP S/4 HANA** for OTC (Order to Cash) Project.

- Responsible for QA testing for SAP S/4 HANA OTC project.
- Developed, managed, and maintained the **project schedule**, budget, and **financial tracking**.
- Led **project reporting activities**, including **regular updates to stakeholders** on **project status, risks, budget adherence, Monthly schedule and cost reporting incl. cash flow curves and resource utilization (mobilization)**
- **Facilitated communication between IT, Business, and validation teams.**
- **Managed project changes, ensuring documentation and approvals align with company standards.**
- **Implemented risk management processes to mitigate project delays or cost overruns.**
- **Effectively managed projects to deliver on time, on cost and according to client quality expectations**
- **Ensured a strong understanding of and ability to leverage Customer project management standards across the PM lifecycle**
- **Ensured assigned project proposals are positioned for cost/benefit analyses, business case diligence and alignment with technology, business and other appropriate strategies.**
- **Demonstrated a firm dedication to the project Sponsors goals and objectives relative to the project.**
- **Ensured definition and approval of project scope, deliverables, desired quality and measures of success.**
- **Developed project plans that effectively align scope, time, cost, quality, resources, risk, communication and procurement in a manner that enables highly coordinated execution and control.**
- Also responsible for the QA Testing of Sand Box and Validation in secure environment for OTC project.
- Currently leading and managing the implementation, deployment, and rollout (Globally) for end-to-end QA testing and Computer System Validation (CSV) of Veeva Vaults, Labware LIMS, and Empower (CDS Tool).
- Liaised as a trusted advisor to bridge business partners and Quality groups to champion world-class innovation, Quality, and accountability.
- Involved in equipment, utility, and facility qualification/validation protocol review and approval including both pre and post execution.
- Supported closure of exceptions and approval of final reports.
- Developed the capabilities of the team to support the CDMO business.
- Accountable for the quality activities related to all clinical phases of production generated at our CDMO Sites by providing strategic direction, setting clear expectations, goals and metrics.
- Maintained positive relationships to support strong organizational change.
- Managed definition and delivery of experiments to grow innovative ideas to develop concepts that drive value-based solutions.
- Partnered with cross-functional teams to design and implement purposeful solutions through technology and artificial intelligence-based data analytics strategies to uncover deep insights to pre-clinical, clinical, and pharmacovigilance compliance.
- Identified customer needs and system landscape for R&D Quality, Quality Analytics, and Business Partners.
- Supported department head in bringing the culture of Innovation and data integrity outward to the organization.
- Identified and nurtured new capabilities and/or technologies in support of data, platforms, analytics, statistics, and modeling.
- Managed process improvement initiatives or system initiatives, serving as the data integrity advisor and/or analytics translator.

- Pursued developing a deep understanding of the data model, interconnections, and downstream impacts.
- Supported teams in creating user communication, user account management, and training materials.
- Managed Quality & Compliance exercises to explore data integrity scenarios within their area of expertise.
- Provided business partner requirements to Quality Analytics team members as to specific ways that data from their area of expertise can be leveraged and visualized.
- Developed the definition and documentation of business problems, requirements and business rules with identified key stakeholders.
- Managed a pivotal role in the planning, execution, and management of clinical trials.
- Overseen and coordinated all aspects of clinical research activities, ensuring compliance with regulatory requirements and study protocols for Clinical Trials.
- Had exceptional organizational skills, attention to detail, and the ability to collaborate with various stakeholders to facilitate the successful completion of clinical trials.
- Managed the day-to-day operations of clinical trials, including protocol implementation, participant recruitment, and data collection.
- Ensured that trials were conducted according to study protocols and regulatory standards.
- Made sure that all clinical trials adhere to regulatory guidelines, including IRB (Institutional Review Board) submissions, informed consent processes, and documentation.
- Responsible for maintaining up-to-date knowledge of regulatory requirements and incorporating them into trial procedures.
- Responsible for ensuring data integrity and accuracy throughout the trial process, and for maintaining detailed records of trial progress.
- Worked closely with research teams, including principal investigators, research nurses, and other clinical staff.
- Coordinated team meetings, provided updates on trial progress, and ensured that all team members are aligned with trial objectives.
- Also worked to ensure that trial resources are used efficiently and that budgetary constraints are adhered to. Implemented corrective actions as needed to address any deviations from the study protocol or operational challenges.
- Liaised with specific process improvement initiatives or system initiatives as appropriate – serves as the data integrity advisor and/or analytics translator for such initiatives.
- Executed processes to identify, document, and implement cross-platform data flows and dependencies.
- Partnered across our R&D Quality analytics, data and platforms to adopt best practices to create sustainable measures to adapt with our evolving business partner solutions to improve organizational efficiencies.
- Managed critical process and system interfaces and connections and worked with IT and systems project teams to ensure that these interfaces and connections were considered.
- Executed user communication, user account management, and training materials as necessary.
- Supported critical system business administration tasks as necessary.
- Also experienced as Senior Business Analyst with QA background.
- Conducted in-depth analysis on business operations and identified process improvements.
- Facilitated cross-functional team meetings to gather requirements for a new Datahub system, leading to a successful implementation project completed on time and under budget.
- Managed the creation of customized reports and dashboards for executive leadership resulting in improved decision-making and increased visibility into key performance metrics.
- Collaborated with IT teams to develop and execute user acceptance testing plans and Performance Qualification Validation, ensuring software releases are bug-free and meet business and Regulatory requirements.
- Learned about new platforms, analytics, data, systems, and emerging technologies capabilities, evaluated and informed end user group within the organization of new capabilities.
- Responsible for E2E testing, System Testing, and UAT along with Validation of the S/4 Hana system, Validating the software as per the FDA Regulation, and Perform Risk assessment.
- Worked on analytical method development and validation; stability and release testing; testing to support pharmaceutical development efforts.

- Led the Vendor Quality Management function to develop and implement an effective and phase appropriate vendor quality oversight program in accordance with domestic and international regulations, including 21 CFR, EudraLex Volume 4 and applicable annexes, USP/EP compendia, ICH and ISO standards and principles.
- Developed and implemented vendor qualification and audit processes for external vendor oversight.
- Performed virtual and on-site audits for GCP and GxP vendors.
- Managed a team of audit consultants who will schedule and perform GMP vendor qualification audits,
- Developed qualification plans via risk analysis and criticality of GxP vendors.
- Develop process to track audit observations and ensure implementation of corrective actions at vendor Sites.
- Supervised Management of outside vendors and ensured on-time deliverables.; it's leadership in action.
- Pictured translating this skill into an achievement-focused narrative that compels employers to take notice.
- Responsible for quality and sterility assurance of sterile products at the Center for Breakthrough Medicines, while adhering to applicable regulatory (CFR 21 part 4) requirements and industry best practices.
- Provided technical leadership to manufacturing facilities in regard to environmental monitoring and sterile product terminal sterilization requirements.
- Directly interacted with project team members, including presentation of data; critical review of data; preparation of technical reports; and evaluation of new instrumentation or analytical techniques.
- Authored and certified Validation Plan, /Validation Protocols, (IQ, OQ, PQ), Requirement's traceability matrix, and related documents.
- Managed and monitored programs daily to track progress against the schedule, resolve risks/issues, and manage program changes.
- Provided input to outsourcing decisions by performing make versus buy analysis.
- Formed Materials Core Team and coordinated product development process deliverables through matrix management of buyers, planners, and production control.
- Collaborated with engineering team to interpret engineering requirements.
- Accountable for leading the design and validation of terminal sterilization processes for new products manufactured globally both in-house and by external manufacturers.
- Supported the sterilization portion of the integration of new products or modifications to existing products into designated plants or external manufacturers.
- Migrated QMS system from TrackWise to Veeva Vault.
- Managed the entire life cycle of CSV & SQA for the Veeva Vault.
- Responsible for GxP and Non-GxP testing.
- Oversee all phases of the implementation. Lead cross-functional workstreams, establish project plans, track issues, manage deadlines, and drive on-time execution for strategic and tactical business initiatives
- Ensured that delivery of each implementation has appropriate levels of quality, is timely, within budget, and in line with the Leadership Teams expectations.
- Responsible for the tracking and reporting of all changes with regards to delivery and associated budget implications as well as benefits and escalating issues and risks as appropriate.
- Provided responsive, competent service and information to company management.
- Performed ad-hoc query for Data Lake and web applications which are radically different than regular queries, e.g. most big data queries often gather data from columnar storage because they attempt to do projections on a few columns and get massive datasets on a date range with some aggregations.
- Responsible for managing All Equipment's CSV-related activities for Laboratories (QC Chemistry, Stability, Microbiology, Environmental Monitoring, Material Quality Management, QC Particulate, and Method Validation) R&D/Technologies.
- Provided technical assistance on new and existing products to other departments,
- Also responsible for Audit Trails and Periodic Review of the Systems.
- Maintained and enhanced data integrity compliance throughout laboratories.
- Responsible for direct management and utilization of laboratory (analytical and microbiology), water treatment, syrup blending, sanitation, microbiological equipment, raw materials, and all quality processes.
- Optimized resources while ensuring raw materials and finished products meet specifications and manufacturing standards by FDA, GxP, HACCP, and all other governmental policies, procedures, and regulations.
- Managed and maintained a stability program under supervision.

- Overseen daily Quality Assurance inspections to ensure all products are meeting compliance.
- Managed quality assurance activities for all in-house GLP regulated studies and manage GCP Quality audit program for Investigational sites, CROs, and third-party service providers.
- Experienced in planning, executing, reporting and publishing clinical studies.
- Strong understanding of Pharmaceutical Development processes, specifically clinical trial protocol development.
- Executed regulatory tasks for product development projects including health authority interactions (e.g., EMA, FDA), regulatory submissions (e.g. IND, CTA, MAA, BLA, NDA), and other regulatory requirements in line with corporate objectives, timelines, and budgets.
- Applied skills to assure management that nonclinical studies are conducted by applicable regulations.
- Provided recommendations for corrective action and tracks corrective action commitments until closure.
- Communicated critical compliance risks noted to senior management.
  Scheduled, overseen, and/or performed routine and non-routine GCP audits.
- Defined and managed the annual GCP audit program using a risk-based approach and fulfilling all contractual obligations.
- Oversee the approved Clinical Research Vendor list and coordinates qualification/requalification audits per policy
- Managed CAPA follow-up and effectiveness.
- Tracked GCP commitments from internal audits, regulatory inspection findings, CAPAs, and other regulatory commitments.
- Served as the GCP subject matter expert for the audit staff and client areas.
- Managed qualification and provides quality oversight of service providers contracted to perform any functions in support of GCP-regulated studies.
- Planned and conducted GCP and as applicable GPV regulated service providers to assess compliance with all pertinent regulations as well as the company's SOPs.
- Collaborated with R & D, non-clinical and Clinical Operations staff to identify, evaluate and recommend solutions to issues identified in the performance of GCP audits.
- Managed the internal audit program for GCP and was responsible for scheduling, tracking, and metrics.
- Led or support GCP inspection readiness, conducted, and follow-up activities for clinical programs.
- Assisted during FDA inspections.
- Also responsible for design, development, implementation, and testing of life sciences compatible MES (SAP ME) solutions.
- Collaborated with Clinical Operations, Research and Development/Non-clinical, and other relevant departments and Quality to determine the acceptability of GCP Service Providers for potential engagement as well ongoing evaluation of overall compliance performance of Service Providers.
- Provided technical assistance on new and existing products to other departments.
- Provided guidance and leadership for staff and all departments to facilitate the Change Management and Document Control processes.
- Reviewed weekly Change Control Board meetings to review all change controls for the site.
- Reported monthly on the status of the Change Management system as a member of the Quality Council.
- Provided support for regulatory inspections and client audits related to pharmaceutical products.
- Provided additional support as needed for the management of the Annual Products Review (APR) process and to support the completion of deviation investigations.
- Managed staff and guided departmental representatives for the following processes:
    - deviation investigations,
    - product complaint investigations,
    - CAPA, and Internal Auditing.
- Acted as a host for regulatory inspections and ISO certification audits in support of both pharmaceutical and medical device products in compliance with 21 CFR 211, Health Canada, 21 CFR 820, and ISO 13485 requirements. Achieved the company's first ISO Certification according to ISO 13485 standards and first successful Regulatory Inspection according to 21 CFR 820.

AMERISOURCEBERGEN CORP. –AMERICAN HEALTH PACKAGING **COLUMBUS, OHIO**

Quality & Compliance Project Manager **09/2019 to 10/2020**

Working on **Business Technology Transformation in** a Supply Chain Management Program. Involved in the implementation of the Enterprise Resource Planning (ERP) solution on SAP S/4 HANA (On-premises edition) platform and **Warehouse Management for Open System (WMOS)** as part of the **AHP Business Technology Transformation (BTT)** program. Currently working on a site named **American Health Packaging (AHP)** located in **Columbus Ohio.**

- Developed quality goals based on business strategies that align with other functions in the organization as well as with the corporation.
- Developed, implemented, and maintained quality policies, processes, systems, and technology to ensure our products are safe, meet customer expectations, and comply with all applicable quality standards.
- Managed the Quality and Validation team for **pharmaceutical products, Combo Products,** and **Consumer Products**.
- Effectively and consistently managed project status reporting updates on project accomplishments against milestones
- Worked effectively with onshore/offshore process and delivery teams
- Created and manages constructive relationships with Virtual Team Members, Subject Matter Experts, Sponsors, etc.
- Demonstrated interest in and accountability for personal and professional development.
- Understand Organizational culture; recognize resistance points to outsourcing and negotiate/recommend approaches to resolving conflicts etc.
- Worked closely with other Enterprise Services and Business Group organizations to effectively align project resource requirements and work package leadership in support of project objectives.
- Led and managed the QMS team to ensure adequate quality systems are implemented and maintained across the business to meet quality requirements.
- QA responsibilities included but were not limited to GxP documentation review and approval for procedures related to QMS and process controls.
- Interfaced with the Compliance management to implement quality system strategies and plans to facilitate continuous improvement of the QMS.
- Also responsible for the quality of QMS documentation approved to support GxP activities for sponsor-related projects.
- Interfaced with other areas of the organization to provide sound QA decision-making in areas that impact the QMS.
- Supported release readiness, Test script development, execution & data validation, metric tracking, reporting, AWS cloud migrations, and assisting in the development, implementation, and maintenance of Quality Assurance best practices and FDA and international regulatory standards.
- Provide quality oversight and input regarding discrepancy reporting such as non-conformances, and deviations related to sponsor projects and/or QMS; and provide final disposition of discrepancies that impact QMS.
- Ensure adequate QMS infrastructure is maintained for sponsor projects; this includes meeting regulatory, international, and industry standards related to GxP activities.
- Establish and report quality metrics related to the QMS and sponsor projects
- Led and managed CSV Team for IQ, OQ & PQ followed by GAMP 4 & 5 Categories.
- Established standards/metrics to monitor key product quality and quality system performance indicators, identify trends and assure appropriate corrective & preventative actions. (i.e. Deviations, Customer Complaints, CAPAs, etc.)
- Also developed and implemented strategies, goals, and direction of the QA/QC functions to align with corporate strategies, meet the needs of the business, and applicable quality standards.
- Investigated deviation and CAPA and mitigated, escalated, and resolved them.
- Responsible for developing, implementing, and training facility workers on a quality plan to comply with quality regulations.
- Developed plans that effectively support commercial needs in conjunction with Quality Systems Regulations.
- Conducted regular Quality Management Reviews with senior managers to assess overall quality system health, identify trends, define corrective actions, and track completion/effectiveness.
- Was accountable for effectiveness and continuously improving core Quality Systems.
- Responsibilities included direct oversight of the following functions and accountabilities:
    - **Quality control,**
    - **Investigations, and analysis.**

- **Quality Assurance**
- **Validation & Verification**

- Interacted with customers in addition to other departments to main product supply and help introduce a new product.
- Implemented and followed AHP's quality procedures.
- Educated visually and personally employees at all levels on quality systems, results, issues, and focus areas to drive continuous improvement.
- Lead Inspection Readiness (IR) activities for AR(American Regent) entities covering GxP, including Regulatory Affairs, and Medical Affairs.
- Lead Pre-Approval Inspection (PAI) activities, identify Quality Risks and provide strategic solutions for continuous improvement across the concerned activities.
- Attended Requirement review meetings and was responsible for Initial Risk Assessment (IRA) Plan.
- Lead the validation and testing activities involved in the Validation, QA, and UAT teams.
- Prepared and performed **GxP** and **Non-GxP** related Functional Requirements' Functional Risk Assessment of **WMOS.**
- **Monitored, Reviewed, and Approved IQ, OQ,** and **PQ Test Protocols** for **WMOS.**
- Managed several GxP Regulated system implementations and change controls.
- Ensured execution of Corrective and Preventive action plans
- Monitored performances of the resource (Consultants).
- Wrote technical and management systems reports
- Represented the company in FDA regulatory inspections and customer compliance audits
- Author, review, and approved Master Validation Plan, Validation Strategy, Risk Management Plan, etc.,
- Currently Working on Training the Products' SOPs, Work Instructions, Processes, and Policies.
    - Developed a plan for the revision of current Processes/ SOPs
    - Developed roadmap for Skillset training
    - Revised or authored new SOPs
    - Tracked all the deliverables as per Validation Plan.
    - Prepared and submitted Validation Summary Reports along with Deviation forms if any.

Johnson & Johnson **Bridgewater, Somerset, NJ**
Quality Compliance Project Manager **01/2019 to 09/2019**

Worked on a project called **Depuy Spine Rainbow** a **Supply Chain Management Project**. The application provides functionality to manage and record regulatory license information for the multi-variant product and provides controls to allow shipment of variants from ERP systems (SAP S/4 HANA) defined to receive can ship data from the RAD. The system was implemented as part of Project Rainbow and has been enhanced regularly since the initial implementation. The RAD **receives product information** from **MDM** to verify that the product added to the system has been registered and exists within the organization. Also, work on Manhattan's WMOS 2019.

Responsibilities include:

- Effectively managed projects to deliver on time, on cost and according to client quality expectations
- Ensured a strong understanding of and ability to leverage Customer project management standards across the PM lifecycle.
- Ensured that all planned and unplanned quality & compliance issues were addressed.
- Ensured assigned project proposals are positioned for cost/benefit analyses, business case diligence and alignment with technology, business and other appropriate strategies.
- Demonstrated a firm dedication to the project Sponsors goals and objectives relative to the project.
- Ensured definition and approval of project scope, deliverables, desired quality and measures of success.
- Developed project plans that effectively align scope, time, cost, quality, resources, risk, communication and procurement in a manner that enables highly coordinated execution and control.
- Monitored appropriate risk management practices throughout the project lifecycle
- Ensured that change, acceptance and approval management is proactively and effectively on all projects.
- Participated in the creation of the Project Plan, Test Plan, Test Strategy, and Compliance report.

- Identified and managed risks associated with a project and implemented strategies to reduce those risks; enforced project standards across the project teams and performed project reviews, including quality assurance and risk reviews.
- Involved in the Development and management of project timelines with adherence to agreed-upon milestones
- Contributed to Budget tracking and bi-weekly estimate-to-actual reconciliation.
- Allocated resources and maintained an online tasking system.
- Overseen planning and execution of a very large & critical MES(Siemens) project/implementation for a J&J Manufacturing site.
- Performed IQ, OQ, and PQ (including the Siemens CAMSTAR / OpCenter MES System integration with SAP PAC and other L3/L2 systems).
- Implemented Veeva for the QMS and EDMS.
- Managed the entire end-to-end CSV for Veeva.
- Supervised Management of outside vendors and ensured on-time deliverables.
- Responsible for leading Clinical quality oversight within the Quality System to ensure compliance with cGMP and cGCP requirements, SOPs, and regulatory standards for product portfolio across generics and biosimilars, including combination products.
- Planned and Executed Test Protocols (Test Scrips) and prepared reports for Clinical Validation for Clinical Studies.
- Attended Daily leadership of team status meetings and ongoing knowledge of all project statuses.
- O**perated a team of 10 testers.**
- Lead the validation activities involved in a group of three.
- Managed several GxP Regulated system implementations and change controls.
- Defined the validation strategy, activities, and deliverables folllowed by GAMP 4 & 5 Catagories..
- **Managed and helped in the creation of UAT Scripts, and E2E Scripts for Various modules** like; **WMS (Warehouse Management System from Manhattan Assoc.), OTC (Order to cash), BOM (Bill of Materials), P2P (Procure to Pay), RTR (Record to Report),** etc.,

Celgene
Summit, NJ
Sr. Global QA Specialist **07/2018 – 12/2018**

Collaborated closely with cross-functional team members as a Sr. Global Quality System Specialist. Also reviewed Deviation, Change Request, and CAPA. Worked on Oracle **SCM/EBS/MES** and **CAR-T** projects.

- Established and oversaw continuous improvement initiatives for worldwide commercial QA functions.
- Managed team to perform CSV using HPALM.
- Performed gap assessment against Quality SOP/WP/WI to identify the process gap.
- Developed and maintained Deviation and CAPA for GxP and Non-GxP Regulations.
- Performed Root Cause Analysis.
- Collaborated with other functions at the global and site level to ensure MES projects are successfully implemented.
- **Reviewed software UAT Scripts and defect reports daily at the time of new releases or enhancements of the system.**
- **Led and performed an audit for Oracle SCM/ EBS/MES Training for GxP.**
- Involved in Change Control Management Process.
- Reviewed and approves SOPs and Work Practice Documents.
- Well-versed in working with Veeva Vault ETQ and eQRMS Tools.
- Used **Veeva** as **Electronic Document Management System (EDMS)** including SOPs, Work Instructions, Policies, Deviation, CAPA, etc.
- Drove continuous improvement in the Root Cause Investigation Process.
  Also responsible for HPALM implementation.
- Helped in training to obtain Traceability Matrix.

Johnson & Johnson **New Brunswick, Bridgewater, Piscataway, and**
Raritan, NJ ***Quality & Compliance Project Manager*** **09/2015 - 07/2018**

Smith Medical **Keene, NH**
QA / Validation Manager **03/2013 - 07/2015**

BioArrays Solutions/Immucor Inc. **Warren, NJ**
Sr. BA / QA Project Test Manager (AVP) **01/2011 - 03/2013**

KeySoft Consulting Inc. **City/Bridgewater, NJ**
Sr. QA / BA Engagement Manager **10/2008 - 01/2011**

Johnson & Johnson **Raritan, NJ**
Sr. QA Program / Engagement Manager **05/2007 - 10/2008**

Organon USA **Roseland, NJ**
Global Integration System Test / UAT Manager **03/2005 - 12/2005**

Pfizer Inc. **Groton, CT /St. Louis, MO** ***QA Manager***
06/2004 - 03/2005

GMAC Insurance, St. Louis, MO: ***Lead Tester*** 08/03-05/04
Pfizer Inc., NYC: ***QA Lead*** 07/02-08/03
TBCT, Inc., NJ: ***QA Test Manager*** 12/98-06/02
Merrill Lynch Inc, NJ: ***QA Test Leader*** 04/98-11/98
PaineWebber, Inc, NJ: ***Lead QA Analyst*** 01/97-03/98

EDUCATION

- Bachelor of Science in Chemistry & Biology (Dual Major), Bhagalpur University, INDIA
- PMP Certified from PMI.