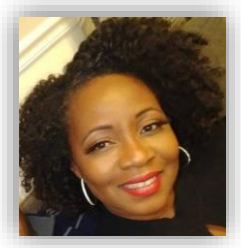

Curricula Vitae

Janice P. Thompson

GMP Analyst V –
Pharmaceutical Industry

Janice.akaxco@gmail.com
914-539-1181
11 Field Street Peekskill, New York
www.linkedin.com/in/JanicePThompson

Twenty-three combined years of experience in Software Quality Assurance in the Life Science Industry. Thirteen years as Internal/External IT Auditor within regulatory environment. Fifteen years of experience creating technical documentation. Areas of expertise include: Validation, Auditing, Design Controls, Requirements Analysis, and Hardware/Software Testing.

EXPERTISE

IT/Vendor Audits | Root Cause Analysis | CAPA Management | Quality Assurance | Software Testing | Training
Computer System Validation | GAMP 5 | cGxPs | Inspection Readiness | Risk Management | SOP development
System Development Lifecycle | ITIL | Quality Systems | Validation Master Plans | Website Design | Consulting

PROFESSIONAL EXPERIENCE

Boehringer Ingelheim– Ridgefield, CT (Pharmaceutical Industry) **09/2010 – Present**

Q&RM Analyst V, Computer Systems Compliance & Development Empowerment Ambassador- 05/2019 – Present

- Analyze and provide empowerment strategies and discussions for employees that leads to innovation.
- Act as compliance advisor and provides hand on support to the Development functions in the areas of computer and/or equipment validation and/or qualification
- Leading Risk Based Approach brainstorming sessions within teams
- Lead and conduct computer and/or equipment validation audits
- Review/audit compliance documentations
- Identify compliance gaps in computer and/or equipment validation and/or qualification and participate in the implementation of process improvements related to computer and/or equipment validation and/or qualification across the Development Department.
- Organize and host inspections and audits by regulatory agencies, BI compliance groups and consultants.
- Manage programs designed to ensure regulatory compliance of Quality Systems and foster an environment for R&D QA personnel to initiate improvements.

IT Quality & Compliance; Computer Systems Quality, IT Auditor, IT Training Lead - 09/2010 – 04/2019

- Identify, coordinate and develop annual global IT Training Curriculum
- Created a Validation Manager Certification Training program for IT colleagues which was successfully piloted in Germany and will be kicked off in 2018.
- Developed and designed a global IT Audit Framework that is available to all IT colleagues. This IT Audit Framework keeps tracks of all audits (i.e. regulatory, internal, supplier, clients) that are being conducted globally. The Framework also maintains the IT Audit contact list with escalations for particular topics. This framework also provides training, support, etc.
- Currently supporting Research & Development Clinical Trial system team members with revalidation and CAPA management.
- Manage/conduct internal/external supplier assessments/vendor audits for computer-related systems (Trackwise, Documentum, Call Center, CSOs) included SaaS vendors.
- Track CAPAs/investigations/commitments for IT related issues, determine root cause analysis and complete closure of corrective actions taken.
- Implemented a self-serve Audit Framework on Internal Audits, Supplier Audits and CAPA Management.
- Developed and conducted FDA/GxP inspection readiness training seminars/workshops for IT/Business organization
- Created and trained global IT employees on GxP related topics (i.e., GDP, Data Integrity, Data Protection & Management)
- Defined and implemented the compliance and validation oversite for the first Global implementation of "cloud" Customer Record Master System (CRM) *SalesForce* Platform for Prescription Medicines, CHC and Oncology area resulting in receiving the President's Award the highest award within Boehringer Ingelheim.
- Partner with Legal and IT Security to conduct risk assessments on "Cloud Vendors" determining the impact to GxP data
- Site Computer System SME responsible for the site-wide policies and procedures around Computer System Validation and Infrastructure Qualification
- Represents IT on the Research & Development Standard Operating Procedure Advisory Board
- Computerized Systems Subject Matter Expert during Regulatory Inspections to Regulatory Agencies
- Developed KPI metrics (CAPAs, Training, Change Controls) for management review and implemented process improvement measures for those areas deficient
- Business Quality Approver for GxP systems within Prescription Medicines, Sales and Marketing, HR, Legal, Ethics & Compliance

Pfizer – Pearl River, New York (Pharmaceutical Industry) 06/2004 – 09/2010

Liaison between Biotech/CHC/Vaccines Research QA departments, Biotech/CHC Technology departments, Engineering and IS for IS compliance related issues including changes. Represented the facility during FDA inspections for IT related systems.

Provided recommendations to site wide senior management regarding appropriate IT related risks. Represent Biotech (Andover, Grange Castle, Algete, Pearl River and Sanford) on a Corporate initiative for global computer validation SOPs. Managed the IS *Consent Decree* Inspection Readiness activities and coordinate the Enterprise Computer System communications for Site System Owners.

Associate Director, IS Compliance 01/2008 – 09/2010

- Responsible for directing a total of 15 Computer validation group, IS Compliance personnel and validation consultants across the Pearl River Manufacturing Facility
- Lead team during the Consent Decree 2009 FDA/Lachman Audit Follow-up resulting in zero (0) computer-related observations
- Computerized Systems Subject Matter Expert during Regulatory Inspections to Regulatory Agencies.
- Developed metrics to determine where the greatest need of improvement is required.
- Validation Lead for developing the $5M site-wide validation approach and strategy for Manufacturing Execution System (MES).
- Tracked investigations/commitments for IS related issues, determine root cause analysis and complete closure of corrective actions taken.
- Conducted external supplier assessments/vendor audits for computer-related systems

Manager, IS Compliance 03/2006 – 12/2007
QA/Technology Relationship Manager

- Managed 6-computer validation group and IS Compliance personnel and 5 validation consultants.
- Defined and developed the site-wide validation approach and strategy for 1st automated Manufacturing Execution System (MES). This strategy became the model for other sites.
- Implemented three new lifecycle (Process Control System, Laboratory Computerized Systems and Enterprise Computer Systems) to streamline the validation process on site.
- Gained QA agreement on a new strategy for Disaster Recovery using VMWare technology. Also established a new Application Disaster Recovery process based on process re-engineering techniques.
- Assisted Biotech QA in Operational Excellence project focusing on reducing the QA review cycle time.
- Developed metrics to determine where the greatest need of improvement is required. Created a commitment to streamline the current validation SOPs and training.
- Responsible for establishing and tracking the 2007 Validation Master Plan for Computer Systems.
- Tracked MIR/Commitments for IS related issues, determine root cause analysis and complete closure of corrective actions taken.

Manager, Computer Validation Group
QA/Technology Relationship Manager 11/2005 – 03/2006

- Responsible for managing 6-computer validation group and 10 validation consultants (Part 11/Remediation activities)
- Managed $9M Part 11 remediation projects. Reduced the number of consultants needed to complete remaining workload.
- Validation Lead for developing the validation approach and strategy for site-wide Building Management Systems.
- Implemented a site-wide spreadsheet validation lifecycle that eliminated the need for 3 SOPs.
- Defended the non-traditional testing approach for the custom-built Reference Standard Database System that resulted in a change in how Quantic views simulated environments.
- Responsible for establishing and tracking the 2006 Validation Master Plan for Computer Systems to project completion. Projects include, prospective, re-validation, remediation, decommissioning and periodic reviews.

Manager, Application Development (IS Computer Validation Consultant) 06/2004 – 11/2005

- Responsible for managing 1 IS Compliance personnel.
- Provided computer system validation support for site and manage the 2005 computer system validation master plan.
- Rewrote 14-computer validation SOPs to remove ambiguity and ensure alignment with Conformance Standards.
- Conducted internal audit of computer information services department to comply with FDA expectations and determine Consent Decree Readiness.
- Subject matter expert (SME) for computer system validation procedures and supervise SOP training team.
- Established 2 boot camp training programs for internal IS staff.

Schering-Plough (Merck)– Kenilworth, New Jersey (Pharmaceutical Industry) **11/2002 – 06/2004**

WRQA (Worldwide Research Quality Assurance) Manager – Computer Validation Unit

- Responsible for independently performing QA reviews/internal audits/inspections on computerized systems, which ensure compliance to the FDA, worldwide health authority regulations/guidelines, site SOPs, and/or industry standards.
- Audited five (5) areas such as: GCP Change Control/Configuration Management, cGMP §211.192, 211.180 computerized system, GxP Data Center, Training, and participated on vendor audit for GxP adverse events system
- Audited vendor's COTS applications such as: TrackWise, ISOTrain, ClinPro, Millennium, and Documentum
- Informed departmental and senior management, in-house and/or at contract facilities, of compliance findings/concerns.
- Provided recommendations for corrective action and tracks correction action commitments until closure.
- Established a training program for team members and conducting a seminar on "How to Write Audit Findings"

Hill-Rom, Inc. - Cary, North Carolina (Medical Device Industry) **09/2000 – 11/2002**

Design Assurance Engineer Lead/Internal Auditor

- Audited eight (8) internal processes based on FDA Quality System Regulations resulting in multiple corrective actions such as revising existing procedures or re-qualification of individuals to maintain compliance.
- Audited specialized areas such as: Production & Process Controls, Process Validation, Control of Quality Records, Identification, Traceability, Device Labeling and Device Packaging.
- Conducted validation on medical devices based on FDA's 21 CFR Part 820 cGMP, 21 CFR Part 11, UL 1069, and FCC Part 15.
- Performed verifications, qualifications, and validations , which included IQ (installation qualification), OQ (operational qualification) and PQ (performance qualification) for Class II medical devices.
- Created and revised Verification and Validation (V&V) Plans, Reports and Standard Operating Procedures.
- Performed V&V in Windows NT and AIX UNIX environments, which included: unit, component, integration and systems testing on hardware and software components.
- Created Requirements Analysis and Traceability Matrices templates and tool for the Design Assurance department.
- Created Test Case Point Analysis tool for test schedule estimation for projects.
- Implemented Test Plans, Test Procedures and Test Cases and documented Test Results on multiple projects.

Trading Edge, Inc. – New York, New York (Financial Industry) - **Acquired** **04/2000 – 08/2000**

Software Quality Assurance Engineer

- Introduced Requirements Based Testing and created requirement traceability matrices.
- Established test processes based on CMM from Level 1(initial) to Level 2 (repeatable).
- Responsible for all test case generation of Bond application.
- Created Data validation, algorithms and daily database feeds test cases.
- Created Build acceptance checklist for entry into testing.
- Maintained change control of scripts, results, regression/build acceptance test cases using Perforce.
- Implemented SQL scripts for developers to validate daily data loads.
- Implemented test case point analysis for determining the length of time to generate test cases and systems test.

Bovis, Inc. – New York, New York (Construction Industry) **8/1993 – 8/1999**

Software Quality Assurance Manager/Technical Writer

- Technical traveling team member and developer's liaison of a client's application rollout throughout the United States.
- Maintained and monitor product defect and project system.
- Verified technical design, requirements and functional documents for requirement's testability.
- Developed test documentation (test plan, test procedures, and test summary reports).
- Developed QA documentation (service level agreements, functional descriptions, design specification, installation procedures, system specifications, maintenance manuals, and user manuals).
- Performed systems, functional and user acceptance tests.
- Created test result reports.
- Researched reported errors to determine severity and possible causes and solutions.
- Verified product manuals and technical design.
- Provided customer support.
- Developed HTML Help systems for application using RoboHelp.
- Administrator to SQL Server and Oracle Database Server.

EDUCATION

M.S. with Distinction in Organizational Leadership & Technology, May 1999, Mercy College, Dobbs Ferry, NY
B.A. in International Relations, December 1991, Syracuse University, Syracuse, NY
A.A.S. in Computer Information System, May 1989, S.U.N.Y. Cobleskill, Cobleskill, NY

PROFESSIONAL EDUCATION

- Implications of the FDA's NEW Guidance for Industry on Part 11, Electronic Records and Electronic Signatures, August 25, 2003 – RCWG, Parsippany, NJ
- Auditing Computerized Systems to Pass FDA Regulatory Inspections, August 26, 2003 – RCWG, Parsippany, NJ
- Internal Auditor Training Program – Nov. 14, 16 & 30, 2000 – Hill-Rom, Inc., NC
- Red Belt Certified – 2008 – Wyeth Pharmaceuticals, Inc.
- ITIL Foundation Certification in IT Service Management #GR750267264JT
- Boehringer Ingelheim's Management Development Program - 2014