NISHANT TRIVEDI

Director, IT QA & Compliance

nitrivedi@gmail.com
https://www.linkedin.com/in/nishant-trivedi-4aa103b/
908-242-7830
Kendall Park, NJ, USA

Strategic and results-driven executive with deep experience leading technology, quality management system and IT QA GxP regulatory compliance for efficient operations. Apply holistic perspective alongside broad technical expertise to create innovative solutions that drive positive organizational change and substantial growth.

Work Experience

Director, IT QA & Compliance Delivery

Aug 2021 - Present

ORION INNOVATION | Edison

- Lead and maintain applicable Information Technology systems in compliance with FDA regulations and ensure Quality Assurance.
- Serve as a Subject Matter Expert (SME) on IT QA & Compliance to senior leadership and technical teams and provide strategic guideline for Global life science regulations including GMP, GLP, GCP, GDP and 21 CFR Part 11.
- Design SOP and training materials within Quality Management System (QMS), IT Quality Assurance and Computer System Validation (CSV) to Computer System Assurance (CSA) transition using GAMP 5 IT risk management based methodology.
- Manage and execute vendor audits / vendor qualification program for GMP, GCP GLP and IT QA regulations while ensuring company systems are audit ready for client and/or health authority audit inspections.
- Identify and report gaps and audit findings for corrective and preventive actions (CAPA) report.
- Establish IT QA and Vendor Audit Center of Innovation for Life Sciences division, while managing multiple clients.
- Coach and manage a team within QA, provide strategic directions and oversee performance management.
- Develop KPI presentations to provide periodic updates to senior leadership.

ITQA & e-Compliance

Aug 2020 - Aug 2021

BRISTOL MYERS SQUIBB | North Brunswick

- Manage and coordinate activities associated with the GxP IT Quality Assurance (QA) program for computerized systems regulatory compliance across the end-to-end product lifecycle.
- Ensure adequate and timely regulatory compliance technical support.
- Review and approve CSV deliverables for assigned projects for global enterprise IT systems.
- Oversight of key Software Development Life Cycle (SDLC) process such as incident, problem, change, release, etc.
- manage multiple projects, create and work within internal timeliness, solve problems, deliver on commitments, and utilize interpersonal skills in a cross-functional team.
- Partner with IT Validation to ensure risk assessments, incident management and oversight are aligned to corporate and data protection standards.
- Provide support to assigned Quality programs, such as Data Integrity Governance, Investigations, Global Quality

Senior IT Validation Analyst

Sep 2018 - Aug 2020

BECTON DICKINSON | Franklin Lakes

- Provide leadership for internal and external validation team members
- Establish global Regulatory Assessments procedure covering regulatory applicability assessment and regulatory impact assessments for global systems used within R&D, Manufacturing, Clinical and reporting.
- Schedule and manage weekly regulatory assessment meetings evaluating General Data Protection Regulation (GDPR), GxP, 21 CFR Part 11, and SOX compliance for system changes.
- Assess change proposals for IT QA compliance and validation, ensuring necessary documentation and procedures.
- Coach technical and business team on applicable FDA and EUMDR regulations for efficient compliance.
- Review and approve changes as part of Change Advisory Board for system production release with focus on quality.

- Spearheaded 600 regulatory assessments of global applications to ensure GxP compliance and CAPA closure.

Software Quality Engineer Consultant
Jun 2018 - Sep 2018

JOHNSON & JOHNSON | Warsaw

- Provide Quality Assurance and compliance guideline for Software As a Medical Device (SaMD) Led system validation activities for SaMD used globally, guiding software upgrade by identifying and eliminating all defects prior to release of version 2. Implemented strategic process to improve software quality.
- Review and approve lifecycle management documentations related to Risk management, Product quality and changes for IED 62304, EU MDR and corporate procedures.
- Liaison with global business and product management team for risk analysis and compliance feedback.

Global Healthcare Software Quality Engineering (SQE) Manager
May 2015 - Jun 2018

SCAPA HEALTHCARE | Knoxville

- Provide strategic thinking leadership to encourage automation, value creation, and global compliance by leveraging cutting-edge technologies.
- Conducted gap analysis and risk assessment to improve processes and quality.
- Establish computer system validation framework for multiple North American and EU manufacturing plants.
- Perform Gap analysis and risk assessment to document risk mitigation as part of audit remediation.
- Reduced paper reliance by implementing digital transformation project within approved budget and timeline saving approximate $600K/year per plant using Lean Six Sigma methodologies.
- Applied problem solving skills for quality data storage and retrieve for external inspections.
- Provide effective training and communication from line manager to C level senior leadership team.
- Successfully closed audit remediation CAPA on computerized system validation audit finding from authority.

Validation Consultant
Sep 2012 - May 2015

Pfizer Pharmaceuticals | Groton

- Create and execute validation test scripts for clinical studies applications.
- Establish testing strategy for custom applications used for patient enrollment to ensure system behaves as expected.
- Ensure drug supply chain system changes are qualified for usage across global drug depot and sites.
- Coach and mentor users for successful execution of user acceptance testings.
- Served as mentor for project team, guiding strategic planning, test automation,
- Ensure all deviations, defect and lifecycle deliverables are recorded in compliance with applicable GxP standards.

Core Skills

Quality Management System (QMS), Software Validation & Assurance, Global Life science Regulations, Enterprise Resource Planning (ERP), Program Management, Lean Six Sigma Black belt, Continuous Improvement, People Management, SaMD, Project Management, GxP audits, IT QA & Compliance, CSV to CSA transition,

Education

Wayne State University
Jan 2005 - May 2007

MS Biomedical Engineering

Awards

Global CEO Awards, Compliance 2016
Scapa Healthcare

CEO Award for establishing computer system validation across multiple manufacturing plants within North America and EU

Global CEO Award, Compliance 2017

Scapa Healthcare

Product Lifecycle Management (PLM) and design controls harmonization across global manufacturing plants while complying with global regulations.

Certificates

Certified Quality Auditor Apr 2022
American Society for Quality (ASQ)

Lean Six Sigma Black Belt Nov 2017
Six Sigma Global Institute

Good Clinical Laboratory Practice Oct 2023
Global Health Network

ICH Good Clinical Practice E6 R2 Oct 2023
Global Health Network

Clinical Research Oct 2023
Global Health Network