**Thriveni Tellagorla**

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**Quality Assurance Document Control Specialist**

**Quality Assurance | Validation | Quality Docs**

Experienced Quality Assurance Specialist with over five years of expertise in the pharmaceutical industry, delivering impactful support to quality and documentation initiatives within rigorous cGMP environments. Adept in the meticulous review and approval of essential GMP documents, including deviations, change controls, work orders, protocols, SOPs, and batch records. Recognized for strong communication abilities, meticulous attention to detail, and the capacity to collaborate effectively across cross-functional teams to support organizational objectives.

**SKILLS**

**Quality Assurance:** cGMP, GLP, GCP, FDA Quality Systems Regulations, Pharmacovigilance, 21 CFR Part 11/50/58/210/21, Validation, IQ/OQ/PQ, ALCOA, Medical terminology, Deviation and Change Control,

Root Cause Analysis, CAPA, Risk Assessment, Audit Support, ISO Standards, SME.

**Technologies:** Veeva Vault QMS, EDMS, LIMS, SAP R/3, MS Visio, Track Wise, Share Point, MDR, Excel, Data Metrics, Lean Six Sigma, AWS, Statistical Machine Learning, Predictive Modeling.

**Programming:** SQL, Python

**Database & Visualization:** Tableau, Power BI

**WORK EXPERIENCE**

**Moderna -** *Norwood, MA, USA* 08/2021- PRESENT

**Quality Assurance Specialist**

Responsible for managing Whole ModernaTx Inc., Doc Control activities during Weekends.

* Directed a specialized project to develop comprehensive Standard Operating Procedures (SOPs) for the formatting, analysis, and validation of SOPs, FRMs, MBRs, WIs, Policies, and other critical documents, establishing a foundational framework for the implementation of new Veeva Vault in 2024.
* Implemented advanced document management systems that enhanced accessibility and reduced processing time, optimizing workflow efficiency by 20%.
* Partnered with management and supervisory personnel form Operations, Quality Control, and Quality Assurance to proactively resolve challenges affecting product quality, conducting meticulous investigations and diligent follow-ups to address non-conformance issues effectively.
* Spearheaded validation activities and adeptly managed the Change Control process for computer systems, ensuring compliance with regulatory standards while expertly formatting validation protocols, deviations, and documentation to align with client specific templates and standards.
* Responsible for identifying deviations in the processes that ensure all activities are cGMP compliant, identifying corrective actions, assisting with RCA, establishing path forward activities and appropriate documentation is complete.
* Evaluated QA performance by leveraging Lean Six Sigma methodologies to extract and analyze data, pinpointing root causes of performance gaps and QA issues; conducted comprehensive final QA reviews, delivering decisive dispositions for investigations, deviations, and corrective action plans (CAPs).
* Executed comprehensive periodic reviews of seventeen Quality GxP systems, ensuring robust maintenance and compliance within a validated state of control.
* Orchestrated the development and management of comprehensive change control documentation, including Change Request Forms, Change Control Implementation Plans, and Change Control Summary Reports, ensuring precise tracking and flawless execution.
* Established and verified rigorous quality standards and testing procedures, adapting quality assurance programs to meet specific user requirements and data inputs.
* Exemplified exceptional project and process management skills by independently leading multiple complex initiatives and cross-functional process, consistently achieving established deadlines.
* Conducted thorough audits of change management systems to verify adherence to SOPs and maintain process integrity.
* Ensured strict compliance with 21 CFR Part 11 and cGXP regulations, safeguarding process reliability and regulatory alignment.

**AM LOGIC Corporation** *– Edison, NJ, USA* 04/2021- 08/2021

**QA Validation Analyst**

* Performed Risk Assessment for different tools following GAMP5 procedures.
* Executed Comprehensive risk assessments for various tools, adhering strictly to GAMP5 standards to ensure process control and compliance.
* Analyzed batch records and cGMP documentation, ensuring completeness, accuracy, and seamless archiving, reviewed and executed IQ/OQ/PQ test scripts to maintain validation standards.
* Utilized HP Quality Center for efficient bug tracking, reporting, and resolution follow-up with development teams.
* Maintained and updated Requirement Traceability Matrix (RTM) after completing Functional Verification and User Acceptance Testing.
* Documented all phases of the Computer System Validation (CSV) lifecycle, strictly following 21 CFR Part 11 for electronic records and signatures compliance.

**EDUCATION**

**Indiana University -** *Indianapolis, IN, USA*

Master of Sciences **-** Bioinformatics, December 2020 Compliance, Regulatory, product release, COA, Customer audits, agency Inspections, Quality management review, controlled document system, medical devices, corrective actions, safety regulations, FDA, GLP, ICH Q7, OQ, PQ, NPI, AMS, CSR and QRM

**JSS University -** *Mysuru, KA, India*

Master of Sciences **-** Pharmaceuticals, June 2016

**JSS University -** *Mysuru, KA, India*

Post-Graduation Diploma **–** PharmaceuticalNanotechnology, June 2016

**CERTIFICATIONS:**

* Lean Six Sigma Green Belt
* AWS Certified Cloud Practitioner

**PUBLICATIONS**

* **Thriveni Tellagorla, Importance of Lean Six Sigma in the Pharmaceutical Industry: Relevance in an AI-Driven World; Harmonizing Efficiency of Lean Six Sigma and AI. In WJPPS World Journal of Pharmacy and Pharmaceutical Sciences, 2024.**
* **Thriveni Tellagorla,** Formulation and Evolution of Sustained Release Effervescent Floating Tablets of Nataglinide. *IOSR Journal of Pharmacy, 2018.*