MAANAS MYLAVARAPU

SENIOR VALIDATION AND DIGITAL QUALITY PROGRAM LEADER

WORCESTER, MA

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PROFESSIONAL SUMMARY

Senior validation and digital quality leader driving enterprise system validation strategy, system implementation, data integrity, and GMP commercialization readiness in biotech. Known for leading cross-functional programs, enabling inspection success and compliant digital transformation across QA, IT, Manufacturing, and Supply Chain.

SKILLS

- **Validation and Compliance:** CSV, CSA, GAMP5, risk-based validation, system lifecycle management, data integrity (ALCOA+), DI governance, audit readiness, change control, CAPA, aseptic process simulation, fill parts cleaning validation, sterility
- **GMP and Commercialization:** GMP manufacturing, commercialization readiness, inspection readiness, regulatory compliance, process validation support
- **Digital Systems and Implementation:** eLogbook, Serialization (Antares, TraceLink), eQMS (Veeva, MasterControl), LIMS, ELN, BOX, Genedata, TrackWise, Kneat, Val Genesis, ValSuite, System Integration, Digital Validation Strategy
- **Program Leadership:** Cross-functional leadership, program execution, stakeholder alignment, vendor management, Agile delivery, GMP environments, navigating ambiguity, ownership of delivery and outcomes
- **Enterprise Systems and Digital Platforms:** Oracle Fusion Cloud (SCM, PLM, Quality), SAP, ERP, MES, BMRAM, CMS, eLogbook, Serialization (Antares, TraceLink), BOX, SQL, Cohesity, Acronis, system integration, digital validation strategy
- **Laboratory, Quality, and Validation Systems:** eQMS (Veeva, MasterControl), Track Wise, Kneat, Val Genesis, ValSuite LIMS, ELN, Genedata, SoftMax, Empower, MiniSeq, electronic batch records (EBR)
- **Manufacturing, Processing, and Analytical Equipment:** Autoclaves, chromatography skids, TFF skids, isolators, automated vial labelers, automated visual inspection, HPLC, plate readers, plate washers, force testers, Endosafe, Keyence image dimensional analysis, GelDoc Go, balances, scales, aseptic process simulation, electronic Bowie-Dick testing

WORK EXPERIENCE

REPLIMUNE, Framingham, MA 04/2022 – 04/2026

Senior Validation Engineer, Facilities, Engineering and Validation (04/2024 – 04/2026)

- Led validation strategy and execution for enterprise systems (Oracle Fusion Cloud SCM, Serialization (Antares, TraceLink), MasterControl EBR, Veeva eQMS), enabling on-time commercialization readiness for GMP operations.
- Directed cross-functional program delivery across QA, IT, Manufacturing, Supply Chain, and Engineering, reducing validation rework by 20-30%, and accelerating system implementation timelines by 15%.
- Owned Data Integrity (DI) program maturity, implementing ALCOA+ controls, audit trail governance, and risk-based validation approaches to strengthen inspection readiness and reduce compliance risk.
- Established validation sequencing and system dependency frameworks, eliminating execution bottlenecks and improving program delivery predictability.
- Executed validation in high-pressure, resource-constrained environments, maintaining inspection-ready state

with zero critical validation observations across systems supporting over 20 users and six GMP processes.

Validation Engineer II, Facilities, Engineering and Validation (04/2022 – 03/2024)

- Executed validation and qualification of eight GMP systems and equipment, including ULT packaging, automated vial labeling, inspection systems, analytical platforms (HPLC, GelDoc), and LIMS, ensuring compliant and scalable manufacturing operations.
- Supported end-to-end system lifecycle activities across more than four cross-functional groups (QA, Manufacturing, Engineering, QC), strengthening system reliability and audit readiness.
- Advanced Data Integrity (DI) initiatives, contributing to ALCOA+ assessments and governance efforts, improving compliance across multiple QC and manufacturing systems.
- Supported shipping validation and process qualification, enabling validated processes critical to product release and compliant product distribution.
- Executed concurrent validation activities across multiple systems, improving execution efficiency and reducing validation gaps in fast-paced GMP environment.

SANOFI PASTEUR, Swiftwater, PA 09/2020 – 04/2022

Lab Manager, Quality Control

- Led lifecycle management of QC analytical systems and data platforms, including upgrades, configurations, and validation support, reducing system downtime by 15-20% and improving operational reliability.
- Managed SoftMax system upgrades and method lifecycle processes, ensuring system stability and minimizing disruption to critical QC operations.
- Drove Data Integrity (DI) governance initiatives, including DI master planning, ALCOA+ assessments, CAPA, and change control, reducing audit observations and strengthening inspection readiness.
- Selected to DI Governance Board, influencing site-wide data integrity strategy and compliance standards across QC operations.

NEW YORK GLOBAL CONSULTANTS INC. (NYGCI), Uniondale, NY 12/2017 – 09/2020

Contractor for clients, including Regeneron in Rensselaer, NY, and Sanofi in Swiftwater, PA.

Quality Assurance Engineer (Consultant)

- Delivered validation for six complex GxP systems and analytical platforms, including Genedata, Illumina MiniSeq (NGS), QIA Symphony, and SpectraMax (SoftMax), ensuring reliable data generation across R&D and manufacturing environments.
- Performed data integrity assessments (DIAs) and risk evaluations, identifying compliance gaps and supporting remediation efforts to strengthen audit readiness and regulatory compliance.
- Led process mapping and data flow analysis initiatives, improving end-to-end data visibility and enabling better control of data integrity across system interfaces.
- Partnered with cross-functional stakeholders and vendors, supporting system validation, configuration alignment, and issue resolution in regulated environments.

GLOBAL PHARMA TEK – SANOFI PASTEUR, Swiftwater, PA 10/2015 – 11/2017

Validation Specialist (Consultant)

- Executed Analytical Instrument Qualification (AIQ) and validation lifecycle activities for GMP systems, ensuring compliant system performance and data reliability.
- Supported inspection readiness and data integrity assessments, contributing to successful audit outcomes in regulated environments.
- Managed decommissioning and change-control activities, reducing system risk and maintaining validated state across system transitions.

EARLY CAREER

MEDICINES 4 U LTD, Cambridge, UK

Oracle Data Warehouse Manager

CARE HOSPITALS, Hyderabad, India

Research Data Analyst

NRR LABORATORIES, Hyderabad, India

Quality Analyst

EDUCATION

Master of Science (MS), Health Services Administration, CENTRAL MICHIGAN UNIVERSITY, Mount Pleasant, MI
Master of Arts (MA), International Business, ANGLIA RUSKIN UNIVERSITY, Cambridge, UK
Bachelor of Science (BS), Pharmaceutical Sciences, JNTU, Hyderabad, India

CERTIFICATIONS

PDA 593 – Fundamentals of Automated Visual Inspection, PDA (2023)
Certified Quality Improvement Associate (CQIA), ASQ (2020)
Data Integrity Level 3 – Advanced Auditing, GMQA (2020)