Jonathan Muteba

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SUMMARY

Results-driven chemical engineer and quality assurance compliance professional with 11 years of hands-on experience in FDA regulated biotech and pharma environments. Proven track record of leading CAPEX projects as a Project Manager, Quality Assurance Supervisor/Manager, and Lead Engineer, identifying operational bottlenecks & compliance gaps, creating excel files to analyze data, recognized data trends, & driving measurable operational improvements, qualifying systems, processes, & equipment, and executing, reviewing, and approving cGxP documents and Quality Management System (QMS) records. Currently transitioning into dedicated auditing practice with Certificated Quality Audition (CQA) certification in progress. Expertise spans from quality control technician to validation engineer, to plant engineer to project manager to quality assurance supervisor/manager. Specialty is CAPEX projects and compliance remediation for startup and large commercial companies. Seeking roles as either internal/external auditor, lead/manager in engineering, validation, or quality assurance departments that are focused on compliance, remediation, and CAPEX projects where problem-solving and system improvement implementation drive results.

EDUCATION

Master of Engineering, Chemical Engineering, December 2021
Northeastern University, Boston, MA

Gordon Institute of Engineering Leadership, Gordon Engineering Leadership Certificate, August 2020
Northeastern University, Boston, MA

Bachelor of Engineering, Chemical Engineering, December 2014
University of Massachusetts - Lowell, Lowell, MA

PROFESSIONAL EXPERIENCE

Quality Process Standards, Training, and Improvement Manager
Vertex Pharmaceuticals (Small Molecule) ***Boston, MA, January 2025- February 2026***

- Managed the Small Molecule documentation, ensured documents were approved in a timely manner.
- Conducted an assessment on Document Control processes, identified bottlenecks, developed and implemented strategies to improve day-to-day operations, and presented findings to senior leadership and team.
- Built and fostered strong cross-functional relationships, enhancing collaboration and serving stakeholders across Small Molecule and Cell & Gene Therapy teams.
- Edited, reviewed, and approved Policies, SOPs, Work Instructions, Forms, and Assessments and ensured documents were compliant with FDA, EU, and ICH regulations.
- Recognized as a fast learner and agile team player, able to quickly adapt to evolving business needs while maintaining high standards of quality and compliance.

Ultragenyx: Senior QAV Contractor (Gene Therapy) ***Bedford, MA, January 2024- April 2024***

- Led CAPEX projects as the QAV lead to ensure project activities were compliant with FDA, EU, and ICH guidelines.
- Worked closely with QAV director to support Year 1 of in-house manufacturing operations.
- Reviewed and approved change control feasibility & SME assessments, action items deliverables, and change plans for pre-execution, execution, and post-execution phases.
- Reviewed and approved Commissioning & Qualification (C&Q) protocols and summary reports to release new process equipment in cGMP environment and support Year 1 Manufacturing Operations.
- Identified and resolved and quality issues or compliance gaps that occurred during execution.
- Supported all Blue Mountain Regulatory Asset Manager (BMRAM) work orders and activities to ensure compliance of the Computerized Maintenance Management System (CMMS) of all equipment in the facility.

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Takeda Quality Systems Specialist (Oncology and Rare Diseases) Lexington, MA, April 2023- August 2023

- Performed commercial batch disposition, approved lot Certificates of Analysis (CoA), product labeling, and archival of batch records and supporting quality documents.
- Conducted thorough reviews of batch records, change controls, deviations, in-process data, Environmental Monitoring (EM) data, and Quality Control (QC) release testing.
- Prepared and assessed cGMP documents and change controls for regulatory market release & restrictions.
- Acquired and integrated information across various departments to ensure accurate material disposition.

Quality Assurance (QA) Manager

Amgen Inc. (Combination Product/Medical Device) *Cambridge, MA, July 2022- April 2023*

- Served as the Quality lead for lab and process equipment design, qualification, and maintenance/calibration.
- Interviewed, onboarded, and mentored senior QA specialists and assisted recruiting CO-OP students.
- Provided QA support for CAPEX projects and test methods executions to help launch and build new facility.
- Reviewed & approved QMS (Change Controls, CAPAs, and Deviations) records, SOPs, risk assessments, summary reports, protocols for combination and medical device equipment and processes and ensured documents were compliant with FDA, EU, and ICH regulations.

Senior Quality Assurance Validation (QAV) Specialist I (Supervisor Level)

Takeda Pharmaceuticals (Cell Therapy and Oncology) *Cambridge, MA, June 2020- July 2022*

- As QAV lead, spearheaded and supported validation and engineering activities during manufacturing shutdown for Alewife facility.
- Reviewed and approved change control feasibility & SME assessments, action items deliverables, and change plan for pre-execution, execution, and post-execution phases for CAPEX projects and ensure all activities were compliant with FDA, EU, and ICH regulations.
- Provided coaching and knowledge transfer to external staff to enhance team capabilities.
- Reviewed and approved QMS records (Deviations, CAPA, Change Controls) to ensure all nonconformities were documented, resolved, and prevented with respect to FDA, EU, and ICH regulations.
- Conducted Audit Trail Reviews (ATRs) to ensure the compliance and data integrity of computerized and electronic systems.
- Supported the implementation of Kneat to transition the documentation of validation executions from paper to electronic.
- Collaborated with cross-functional team to ensure cGxP compliance on engineering & validation projects and documents.
- Received over 10 “Takeda Celebrate Well Done Awards” for excellent work performance & exhibiting Takeda’s core values.

Project Manager / Engineer II

Vericel Corporation (Cell Therapy) *Cambridge, MA, December 2018- June 2020*

- Led an Engineering Leadership Challenge Project as part of the Northeastern University Gordon Engineering Leadership Program for the commissioning and decommissioning of multiple cold storage units.
- As change control owner, initiated, executed, and implemented change control, created feasibility impact assessment, consolidated action items deliverables, and generated change plans for pre-execution, execution, and post-execution phases for CAPEX projects.
- Led weekly & ad-hoc meetings for CAPEX projects with cross-functional team to ensure project deadlines are met and discuss any potential anomalies.
- Executed commissioning test plans, determined optimal processing parameters to ensure equipment, systems, and processes were compliant with FDA, EU, and ICH regulations and ready for cGMP operations
- Supported and oversaw vendors’ calibration and preventive maintenance activities.
- Verified the calibration and preventative maintenance schedule for all equipment were appropriate and up to date in the Computerized Maintenance Management System (CMMS).
- Successfully decommissioned equipment at the end of its life cycle, ensured safe removal and disposal while preventing operational disruptions and maintaining cGMP compliance.

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- Installed, configured, and monitored Building Management System (BMS) to observe and analyze live process data to verify the performance of production equipment and ensure equipment consistently and operated within specification.
- Troubleshooted and investigated production equipment that displayed Out of Specifications (OOS) results, conducted root cause analysis & process/product impact assessment, and determined appropriate resolutions.

Engineer I

Azzur Group (mRNA Therapeutics, Biologics, and Cell Therapy) Waltham, MA, April 2016- December 2018

- As a team lead, helped engineers with executing validation protocol & report, ensured validation project timelines were met and presented weekly updates to management.
- As Validation lead, conducted Instructor-Led Trainings (ILTs) and was point of contact for temperature mapping activities.
- Managed and Oversaw vendors activities and reviewed their documentation to ensure compliance with company policies and procedures, maintaining high standards of quality and regulatory adherence.
- Developed a deviation tracker in excel analyze over 150 deviations that occurred during requalification execution activities. Applied trend analysis and root cause identification to determine 6 common causes accounted for 80% of all deviations. Used findings to drive procedural improvements that resulted in eliminating a backlog of 200-300 overdue Validation reports.
- Executed Design/Installation/Operational/Performance Qualifications (DQ/IQ/OQ/PQ), Factory Acceptance Tests (FATs), and Site Acceptance Tests (SATs) per ISO 9001 & ASTM E2500 to verify Facility, Utility, Systems, and Equipment (FUSE) were fit for GMP operations.
- Validated Manufacturing and QC operations equipment to help company progress to commercial operations.
- Authored, executed, and completed User Requirement Specifications (URS), Failure Mode and Effects Analysis (FMEA) risk assessments, SOPs, protocols, deviations, and summary reports.
- Received 3 “Amazing Azzur Awards” for excellent work performance & exhibiting Azzur’s core values.

Environmental Monitoring QC Technician

Shire Pharmaceuticals (currently Takeda Pharmaceuticals) *Lexington, MA, July 2015- March 2016*

- Executed environmental qualification studies (OQ, PQ, and Recovery studies) per ISO 14644-1:2015 to verify that the cleanroom areas (ISO 5, 7, and 8) and Air Handling Units (AHUs) were in conformance to FDA regulations.
- Performed routine Environmental Monitoring (EM) samples and investigated any EM excursions to ensure the Safety, Identity, Strength, Purity, and Quality (SISPQ) of the manufacturing batches.
- Recognized with 2 prestigious Shire Awards for exceptional work performance during EM qualification studies, demonstrating consistent excellence and commitment to high-quality standards in environmental monitoring initiatives.

TECHNICAL SKILLS

- Certified Quality Auditor (CAQ)- In Progress
- 21 CFR Parts 4, 11, 211. 600, 601, 820, and 1271
- ASTM E2500
- ISO13485
- ISO 14644-1:2015
- PDA TR64
- ISPE BG5
- Qualified Trainer/Instructor
- Kneat (paperless validation software)
- Strategic Planning & Operational Execution
- Engineering Leadership
- Problem-Solving & Decision-Making
- Batch Disposition
- electronic Quality Management Systems (eQMS)
- Commissioning & Qualifications (C&Q)
- Project Management
- Cleaning Validation
- Continuous Process Improvement