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JONATHAN M. MUTEBA

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AREAS OF FOCUS

- cGxP Operations
- cGxP Auditing
- Project Management
- Quality Assurance
- Validation
- Plant & Process Engineering

CASE STUDIES

Shire Pharmaceuticals (Jul 2015 to Mar 2016)

Challenge: Qualification testing was required across multiple cleanrooms (400, 300, 200, L-Wave, and North Reading) under worst-case scenarios (minimum and maximum occupancy) to validate environmental conditions for GMP manufacturing.

Role: Environmental Monitoring Technician responsible for executing viable and non-viable sampling in support of OQ/PQ and recovery studies.

Impact: Ensured cleanrooms met ISO 14644-1 specifications, enabling GMP manufacturing operations to proceed. Played a key role in Alewife PQ recovery studies and ongoing EM support, directly contributing to successful qualification and safe batch production readiness.

Keywords: Environmental Monitoring • Cleanroom Qualification • ISO Classification • Recovery Studies • Viable & Non-Viable Sampling • PQ Support • OQ Execution • GMP Compliance

Shire

Moderna Therapeutics (Apr 2016 to Sep 2017)

Challenge: As Moderna moved from late-stage clinical trials to commercial readiness, the company faced the dual challenge of preparing for FDA licensure and scaling operations to a new commercial facility in Norwood, MA.

Role: Entry-Level Validation Engineer supporting Commissioning, Qualification, and Validation (CQV) efforts. Contributed to equipment qualification, cleaning validation protocol development, and QC specification reviews.

Impact:

- Successfully qualified GMP production equipment, ensuring readiness for commercial operations.
- Contributed to cleaning validation framework critical for facility licensure.
- Reviewed and verified QC material and equipment specs to ensure FDA compliance — reducing risk in tech transfer and batch release readiness.

Keywords: CQV • Cleaning Validation • Equipment Qualification • QC Specification Review • FDA Compliance • Commercial Readiness • GMP Scale-Up • Late-Stage Clinicals • Facility Transition

moderna

Regeneron Pharmaceuticals (Sep 2017 to Dec 2018)

Challenge: Regeneron faced a growing backlog of requalification activities for Control Temperature Units (CTUs), risking potential compliance lapses and delayed batch operations.

Role: Started as an Entry-Level Validation Engineer and quickly promoted to Team Lead overseeing CTU requalification execution and reporting.

Impact:

- Led requalification efforts for CTU protocols and reports, restoring GMP compliance timelines.
- Developed and implemented a Deviation Tracker system to identify root causes and enforce corrective actions — a key tool in eliminating the requalification backlog within 12 months.
- Provided regular performance and status updates to management, coordinating between cross-functional teams to improve throughput and scheduling.

Keywords: CTU Requalification • GMP Compliance • Validation Protocols • Deviation Management • Root Cause Analysis • Corrective Actions • Backlog Reduction • Team Leadership • Regulatory Readiness • Risk Mitigation

Vericel Corporation (Dec 2018 to Jun 2020)

Challenge: Vericel, a smaller biopharma company, operated with aging and overutilized equipment running 24/7. Due to limited resources and long lead times (avg. ~14 months) for replacements and repairs, production capacity was often constrained, directly impacting revenue and scalability.

Role: Mid-Level Plant Engineer / Project Manager supporting daily operations and leading scale-up initiatives.

Impact:

- Spearheaded multiple CAPEX projects to phase out malfunctioning systems and onboard new equipment critical for scaling operations.
- Shortened project execution timelines by revising and streamlining URS and risk assessment documentation, saving 3+ weeks.
- Conducted weekly BMS reviews to monitor equipment specs, ensuring compliance and uptime.
- Led root cause analysis and implemented corrective actions for equipment failures, boosting operational reliability.
- Worked cross-functionally to manage commissioning, change control, and deviation response throughout the equipment lifecycle.

Owner of deviations, CAPAs, and change controls from engineering execution activities.

Keywords: CAPEX Projects • Plant Engineering • Commissioning & Qualification • BMS Monitoring • Root Cause Analysis • Corrective Actions (CAPA) • Deviation Management • Change Control • GMP Operations • Engineering Documentation

VERICEL

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CASE STUDIES

Takeda Pharmaceuticals (Jun 2020 to Jul 2022)

Challenge: .The Alewife facility, one of the oldest in Takeda's network, faced ongoing challenges with aging infrastructure, room repurposing, and modernizing operations. The site was transitioning from paper-based validation systems to KNEAT (paperless execution) while managing multiple shutdown and equipment replacement projects.

Role: Senior QA Validation Specialist / Supervisor providing quality oversight for validation, engineering, and facilities operations.

Impact:

• Acted as QA Lead on all CAPEX and OPEX projects related to the Alewife facility, ensuring equipment changes, mitigations, and shutdown work maintained compliance and validation state.

• Supported transition to KNEAT digital validation platform, helping streamline validation execution and reduce errors and inefficiencies.

• Served as the approver for all deviations, CAPAs, and change controls originating from engineering and validation execution.

• Partnered with execution teams to troubleshoot non-conformances, support timely closure of quality records, and safeguard data integrity during critical system and equipment implementations.

Keywords: Environmental Monitoring • Cleanroom Qualification • ISO Classification • Recovery Studies • Viable & Non-Viable Sampling • PQ Support • OQ Execution • GMP Compliance

Takeda

Amgen INC. (Jul 2022 to Apr 2023)

Challenge: Amgen's Cambridge pilot facility was tasked with supporting the development and scale-up of operations for a new manufacturing site. This required tight alignment between engineering, quality, and project execution teams.

Role: Quality Assurance Manager responsible for supporting engineering-led projects and capital investments

Impact:

• Provided QA oversight for CapEx projects and test method executions tied to pilot plant initiatives.

• Reviewed and approved key QMS documentation, including change controls, deviations, and CAPAs to ensure compliance during the plant's scale-up phase.

• Served as part of the interview panel for QA management hires and mentored senior QA specialists, managers, and co-op professionals.

• Led efforts in onboarding and training new quality staff, strengthening internal capability and compliance culture.

Keywords: Quality Assurance Management • GMP Compliance • QMS Oversight • Change Control • CAPA • Deviation Review • Pilot Plant • CapEx Support • Test Method Execution • Mentorship • Talent Development • Interview Panel

AMGEN

Takeda Pharmaceuticals (Apr 2023 to Aug 2023)

Challenge: The Lexington site faced a significant batch disposition backlog, with some product batches sitting unreviewed and uncertified for over a year. This delay threatened product release timelines, patient supply, and compliance standing

Role: Senior QA Operations Contractor focused on batch record review, certification, and disposition.

Impact:

•Reduced batch backlog, and released legacy product batches.

• Conducted thorough QA reviews of batch records, change controls, deviations, process data, environmental monitoring, and QC release test results to ensure all critical compliance elements were met prior to disposition.

• Reviewed and approved Certificates of Analysis (CoAs) and product labeling to meet both regulatory and internal standards.

• Oversaw batch record archiving and documentation workflows to ensure audit readiness.

Keywords: QA Operations • Batch Disposition • GMP Compliance • Change Control • Deviation Management • Certificate of Analysis • Environmental Monitoring Review • QC Data Review • SAP • Batch Record Review • Product Release QA • Regulatory Documentation

Takeda

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CASE STUDIES

Ultragenyx Pharmaceuticals (Jan 2024 to Apr 2024)

Challenge: Ultragenyx's Bedford facility had just launched its first year of in-house GMP production and batch disposition. As a new site, the challenge lay in navigating novel operations, immature systems, and ensuring all processes were audit-ready and compliant with regulatory expectations from day one.

Role: Senior QA Validation Contractor supporting validation, engineering, and CMMS compliance initiatives.

Impact:

• Served as QA validation lead on CAPEX projects, ensuring alignment between engineering and quality objectives.

• Provided quality oversight for all Blue Mountain Regulatory Asset Manager (BMRAM) work orders, ensuring that the Computerized Maintenance Management System (CMMS) met cGMP requirements across plant and process equipment.

• Actively supported nonconformity investigations, leveraging prior experience to drive resolution strategies and maintain project velocity during critical startup phases.

• Partnered closely with validation and engineering teams to streamline quality workflows during a period of operational ramp-up and internal capability building.

Keywords: QA Validation • New Facility Start-Up • Batch Disposition Readiness • CMMS • BMRAM • Computerized Systems Compliance • CAPEX Projects • Equipment Qualification • Nonconformity Investigation • GMP Startup Support • Quality Oversight • Cross-functional Collaboration

ultragenyx

Vertex Pharmaceuticals (Jan 2025 to Feb 2026)

Challenge: Vertex was facing a high documentation workload due to increased operational demands and a recent transition to the Veeva QMS platform. The team also faced pressure to meet short turnaround times for documentation deliverables while adapting to new systems and evolving stakeholder needs.

Role: Quality Manager supporting document control, stakeholder engagement, and continuous improvement across small molecule operations.

Impact:

• Supported a high-volume documentation backlog, ensuring all records were compliant, properly formatted, and ready for use in execution or periodic review.

• Built strong cross-functional relationships with stakeholders to better understand timelines, priorities, and improve communication.

• Proposed and helped implement process improvement tools, such as:

Document Intake Forms to collect critical request info, allowing for better triage and prioritization.

Training video/tutorial initiatives to help both QA teams and stakeholders understand document control workflows.

"VARK" base learning assessment strategy to educate stakeholders on quality principles while also deepening the QA team's understanding of operational needs.

• Acted as a bridge between quality and operations by promoting mutual understanding and empowering both sides to operate more efficiently.

equipment.

• Actively supported nonconformity investigations, leveraging prior experience to drive resolution strategies and maintain project velocity during critical startup phases.

• Partnered closely with validation and engineering teams to streamline quality workflows during a period of operational ramp-up and internal capability building.

Keywords: Quality Management • Document Control • Veeva QMS • Stakeholder Engagement • Process Improvement • Intake Forms • Training Material Development • Compliance Oversight • Cross-Functional Collaboration • Continuous Improvement • Small Molecule Operations • Root Cause Prevention

VERTEX