

Jonathan Muteba

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SUMMARY

Results-driven AI engineer and life sciences professional with 11 years of hands-on experience in GxP-regulated environments. Proven track record of leading teams and capital projects and streamlining compliance and operational processes. I specialize in building and shipping commercial-grade products powered by AI systems — identifying operational bottlenecks, performing root-cause analysis, and implementing corrective actions that eliminate inefficiencies. In one case, that approach traced 80% of deviations to six root causes and cleared a backlog of 200–300 overdue validation reports. Open to engineering, quality, and remediation roles where I can leverage my leadership, problem-solving, and technical expertise to improve systems, drive results, and strengthen production.

SELECTED AI ENGINEERING PROJECTS

Adversarial AI Security Platform | Python, LangGraph, Multi-Agent Systems, LLMs, Langfuse- [Click Here to View Live Demo](#); Token for Launch Token: af-launch-9k3mx7qp2w

- Built an autonomous multi-agent platform that red-teams LLM applications, orchestrating four Claude-based agents (attack generation, dual evaluation, orchestration, reporting) against a live AI target.
- Discovered a critical prompt-injection vulnerability — a poisoned document caused the target to report fabricated clinical data as fact — proven with an A/B control and mapped to the OWASP LLM Top 10.
- Engineered a deterministic evaluation harness with an independent LLM cross-judge, a versioned exploit database with regression testing, and full per-agent cost/latency observability.

Clinical Co-Pilot — AI Clinical Decision-Support Assistant | Python, RAG, LangGraph, LLMs, OpenEMR, FastAPI- [Click Here to view Live Demo](#); Username: admin Password: ClinicalCoPilot2026!

- Built a retrieval-augmented clinical assistant that answers physician questions grounded in patient chart data and clinical guidelines, integrated with an OpenEMR backend.
- Engineered a multi-agent LangGraph pipeline (intake extraction, evidence retrieval, answer synthesis) with hybrid BM25 + semantic reranking and source-cited, scope-controlled responses.
- Implemented safety guardrails — patient-scope enforcement, refusal handling, and grounding checks — to keep the assistant within a decision-support role rather than making clinical decisions.

PROFESSIONAL EXPERIENCE

AI Engineer Fellow

Gauntlet AI

Remote / Austin, TX, July 2026- July 2026

- Designed and shipped production-grade AI systems — not prototypes — measured against real benchmarks for performance, cost, reliability, and security.
- Architected a multi-agent clinical co-pilot (LangGraph) embedded in OpenEMR: hybrid RAG retrieval, vision-based (VLM) document ingestion, PHI redaction, and a deterministic evaluation gate that blocks any deploy failing the benchmark.
- Built an autonomous multi-agent adversarial red-team platform that continuously discovers, evaluates, and documents vulnerabilities in live LLM applications — running the co-pilot as a black-box target across five attack categories mapped to the OWASP LLM Top 10.
- Engineered the reliability stack behind both: deterministic evaluation harnesses, end-to-end observability with cost instrumentation, prompt-injection and AI-safety defenses, and Railway deployment on Git CI.

Process Engineer III

Moderna Therapeutics (mRNA)

Norwood, MA, May 2026- July 2026

- Used Maximo to create and manage work orders for new processing equipment entering production use, and to manage assets across their lifecycle.
- Investigated and troubleshoot equipment failures, determining root causes and resolutions.

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Quality Process Standards, Training, and Improvement Manager

Vertex Pharmaceuticals (Small Molecule)

Boston, MA, January 2025- February 2026

- Identified operational bottlenecks in the document-control process and presented improvement strategies to senior leadership and the broader team.
- Designed and implemented a document intake form — driving 60 completed submissions across 20 document owners — that streamlined the review-and-approval workflow and shortened document turnaround.
- Reviewed and approved a range of document types supporting Small Molecule operations, establishing rapport with document owners to surface feedback and drive process improvements.

Senior Quality Assurance Validation (QAV) Contractor

Ultragenyx (Gene Therapy)

Bedford, MA, January 2024- April 2024

- Leveraged QA expertise to identify and resolve quality and compliance gaps in support of Year 1 in-house manufacturing operations.
- Reviewed and approved BMRAM (Blue Mountain Regulatory Asset Manager) work orders supporting engineering and facilities activities — ensuring equipment failures were resolved with no product impact and returned to production.
- Served as QA lead on capital projects and the point of contact for quality issues during production, supporting day-to-day engineering and facilities operations.

Quality Systems Specialist

Takeda (Oncology and Rare Diseases)

Lexington, MA, April 2023- August 2023

- Performed commercial batch disposition, ensuring the quality of finished product before release and shipment.
- Worked with the batch disposition team to clear an outstanding product backlog.

Quality Assurance (QA) Manager

Amgen Inc. (Combination Product/Medical Device)

Cambridge, MA, July 2022- April 2023

- Served as QA lead on capital projects and test method executions to support the launch of a new combination-product and medical-device facility, acting as the primary point of contact for quality issues throughout execution and approving the QMS records, SOPs, and risk assessments that kept the build compliant.
- Contributed to building out the QA team — sitting on interview panels, onboarding and mentoring QA specialists, and recruiting co-op interns.

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

Takeda Pharmaceuticals (Cell Therapy and Oncology)

Cambridge, MA, June 2020- July 2022

- Served as QA lead across 10 facility-shutdown projects, spearheading validation and engineering activities for the entire Alewife site.
- Reviewed and approved GxP documents, change controls, deviations, and CAPAs across capital projects and day-to-day operations, keeping the facility compliant through pre-execution, execution, and post-execution phases.
- Helped implement Kneat, leading the facility's transition from paper-based to electronic validation — a then-emerging paperless approach — and conducted audit trail reviews to safeguard data integrity across computerized systems.
- Coached and transferred knowledge to external staff, strengthening team capability and execution.

Project Manager / Engineer II

Vericel Corporation (Cell Therapy)

Cambridge, MA, December 2018- June 2020

- Led an Engineering Leadership Challenge Project to replace aging cold storage units and expand production capacity — analyzing equipment utilization to quantify potential lost revenue, forecasting ROI and payback period on the replacement, and presenting the business case to a Northeastern review board.

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- As project manager, led and executed the commissioning and decommissioning of process equipment to support manufacturing production.
- Installed, configured, and monitored building management systems (BMS) to continuously analyze live process data and verify equipment stayed within specified operating parameters.
- Investigated, troubleshot, and resolved nonconformities that occurred during production.

Engineer I

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

- Validation consultant contracted to biotech manufacturers — conducted instructor-led trainings for engineers, served as SME for temperature-mapping activities, and authored company SOPs across engagements.

Regeneron (Cell Therapy) —

Rensselaer, NY | Sep 2017 – Dec 2018

- Built a deviation tracker consolidating 160 protocol deviations across the requalification team; applied trend analysis to determine average close-out time and identified six root causes driving 80% of all deviations. Presented findings to senior management, driving procedural improvements that eliminated a backlog of 200–300 overdue validation reports within a year.
- Served as team lead — guided engineers through validation protocol execution, report generation, and deviation resolution, and delivered weekly progress updates to senior management.

Moderna (mRNA Therapeutics) —

Cambridge, MA | Apr 2016 – Sep 2017

- As part of a three-person validation team, executed DQ/IQ/OQ/PQ and cleaning validation activities supporting Moderna's progression toward commercial manufacturing.
- Qualified warehouse operations end-to-end — controlled-temperature units, cold-storage units, the QC sampling room, and the warehouse itself — performing temperature mapping under worst-case summer and winter conditions to verify performance across both temperature extremes.
- Authored, executed, and completed URS, FMEA risk assessments, SOPs, protocols, deviations, and summary reports; supported QC operations including raw-material specification documentation.

Environmental Monitoring QC Technician

Shire Pharmaceuticals (currently Takeda Pharmaceuticals)

Lexington, MA, July 2015- March 2016

- Performed routine environmental monitoring (EM) and executed environmental qualification studies — OQ, PQ, and recovery studies — to verify cleanroom manufacturing suites met FDA compliance and classification requirements.
- Investigated EM excursions to determine impact and safeguard product safety across production batches.
- Offered a full-time role to join Shire at the end of my contract, in recognition of strong performance, work ethic, and collaborative team contribution.

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

RECOGNITION

- 10+ Takeda Excellence Awards • 3 Azzur Core Values Awards • 2 Shire Performance Awards

TECHNICAL SKILLS

- **Leadership:** Engineering Leadership · Project Management · Strategic Planning & Execution · Problem-Solving & Decision-Making

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- **AI & Software:** Artificial Intelligence (AI) · Large Language Model Operations (LLMOps) · Multi-Agent Orchestration (LangGraph) · RAG (Retrieval-Augmented Generation) · Adversarial Testing & Red-Teaming · Prompt Engineering & AI Safety · Software Architecture · Observability & Cost Instrumentation · CI/CD · SaaS
- **Quality & Validation:** Certified Quality Auditor (CQA) Candidate — expected Q4 2026 · Batch Disposition · Commissioning & Qualification (C&Q) · Cleaning Validation · electronic Quality Management Systems (eQMS) · Deviation & CAPA Management · Data Integrity (ALCOA+) · Continuous Process Improvement
- **Systems & Tools:** Claude · Codex · Cursor · LangGraph · Railway · Vercel · Supabase · GitHub · GitLab · SAP · Kneat · TrackWise · Maximo · Veeva · Blue Mountain (BMRAM) · Kaye Validator · Ellab Data Loggers · Sensitech Data Loggers · Building Management Systems (BMS)