OA

OLAWALE AKINTUNDE, MBA

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PERSONAL SUMMARY

- Self-motivated forward-thinker with a patient-first mentality possessing a proven track record of striving for excellence, pursuing collaboration and teamwork, executing results, and driving innovation. Possessing 13+ years of GMP experience in the field of biotechnology in the of Technical Operations, Manufacturing, and Quality Assurance plus 9 years of CDMO experience.
- Proven leader with expertise in interfacing and collaborating with internal and external stakeholders to achieve business, manufacturing, technical operations, process development, regulatory, and quality initiatives.
- Strategic partner skilled in executing and managing manufacturing operations, technical operations activities, as well as providing technical analysis expertise in quality risk management and quality compliance resolution initiatives. Possessing expertise in driving process improvement initiatives while delivering reliable outcomes for clinical and commercial manufacturing programs.

SIGNATURE ACHIEVEMENTS

- **Executing Results:** "Executing Results" Bravo Award recipient for leading the completion of manufacturing-related tasks to support a client's first allogenic clinical CAR-T GMP run, which minimized quality risks, enhanced customer satisfaction, ensured compliance, generated revenue, and ensured patient treatment.
- **Striving for Excellence: "**Striving for Excellence" Bravo Award recipient for identifying 4 moderate issues during the Papillon audit and implementing corrective actions in collaboration with internal partners, thereby reducing internal failure costs related to quality investigations by $40,000.
- **Driving Innovation:** Pioneered a process for collecting, analyzing, and reporting process performance data related to CAR-T processes, which improved quality investigations review and closure rates by 30% and 35%, respectively.

CORE COMPENTICES

- Quality Risk Management
- Batch Release and Disposition
- CAPA and Quality Event Management
- Leadership, Management, and Training
- Documentation Control and Management
- Aseptic and Drug Product Manufacturing
- Six Sigma Methodology
- Quality System Management
- Technical Writing and Review
- Project and Client Management
- 21 CFR Parts 4, 210, 211, 820, and ISO 9001
- Quality Audits, Inspection, and Regulatory Support

PROFESSIONAL EXPERIENCE

Technical Operations Supervisor/Manager / WuXi Advanced Therapies - Philadelphia, PA *04/2022 - 04/2025*

- Directed technical oversight for 6 CGT programs with the primary responsibility of managing the resolution of quality events by coordinating cross-functional triage, interfacing with internal and external stakeholders, as well as providing root cause analysis, technical analysis, and risk mitigation expertise resulting in a ~25% reduction in investigation cycle time and improved client satisfaction.
- Led and developed a team of 7 Technical Operations Specialists (I–III) through structured coaching, workload prioritization, and performance management, coupled with driving the on-time closure for deviations, CAPAs, NCEs, OOS, and complaints.
- When complex GxP investigations required senior-level technical judgment, served as Technical Operations SME, authoring and approving investigations in alignment with 21 CFR Parts 210/211 and FDA expectations, thereby strengthening compliance adherence.
- Identified risks and communicated gaps associated with quality and GMP processes/systems, as well as served as Technical Operations SME on technical matters involving quality investigations, manufacturing operations, risk assessments, quality audits, quality systems management, and documentation management.
- Supported cross-functional senior and executive leadership in the day-to-day management and oversight of cell and gene therapy drug product manufacturing operations.

Technical Operations Specialist II-III (Lead) *03/2019 - 04/2022*

- Identified recurring deficiencies in investigation quality and led 2 Quality Improvement Projects (QIPs) with Senior QA leadership, improving technical writing consistency and reducing investigation rework by ~30%.

- Delivered site-wide GMP and investigation training to 50+ employees to address root cause analysis gaps, strengthening deviation quality and improving audit readiness across manufacturing functions.
- Maintained 90% on-time NCE closure and 96% on-time deviation closure along with authoring and reviewing SOPs, CAPAs, complaints, OOSs, and manufacturing support documentation in compliance with site quality systems.

Lead Manufacturing Associate *02/2016 - 03/2019*

- Executed CAR-T GMP manufacturing runs in a patient-first environment requiring strict adherence to aseptic technique and data integrity, ensuring right-first-time execution and sustained product quality.
- Improved batch documentation accuracy by reviewing and approving batch records and manufacturing instructions, increasing batch record right-first-time rates by ~15%.
- Supported manufacturing leadership with resource planning, quality audits, materials readiness, and production scheduling, enabling uninterrupted execution of clinical and commercial CGT production schedules.

Shop Floor Quality Assurance Specialist (Short-term Contract) / Seqirus - Holly Springs, NC *10/2015 - 01/2016*

- Provided real-time shop floor QA oversight during aseptic fill/finish operations, ensuring compliance with cGMP, sterility assurance, and contamination control requirements.
- Resolved on-the-floor quality issues through rapid collaboration with Manufacturing and Engineering, preventing batch impact and supporting 100% batch disposition success during assignment.
- Partnered with QA Batch Release to complete release activities for 3 commercial vaccine combination products, meeting regulatory timelines and supply commitments.

Quality Assurance Specialist (Short-term Contract) / Medtronic – Monmouth Junction, NJ *12/2013 - 01/2015*

- Collaborated with suppliers to drive the resolution of identified GMP materials non-conformances.
- Served as process steward and SME for the inspection, labeling, and packaging of 2 combination products, as well as for resolving technical and compliance issues associated with the aforementioned processes.
- Served as process steward for the receipt, inspection, and release of raw materials and consumables, as well as for resolving technical and compliance issues associated with the aforementioned processes.

EDUCATION

Master of Business Administration (MBA)
The Pennsylvania State University (PSU) - Malvern, PA

B.Sc. Biology (Major: Biotechnology)
Kean University - Union, NJ

PROFESSIONAL SKILLS

- **Systems**: LIMS, MasterControl, Agile, Novatek, Oracle ERP Systems, REES, TrackWise, ELPRO, and BMRAM
- **Applications**: Microsoft Office (Word, Excel, PowerPoint, and Visio), Minitab, Tableau, Zoom, and Teams
- **Investigational Tools**: Fishbone Diagram, Pareto Chart, 5 Whys, FMEA, Control Charts, and Scatter Diagrams
- **Business Skills**: Negotiation, SWOT Analysis, Porter's 5 Forces, 5S, DMAIC, Brainstorming, and PEST Analysis

CERTIFICATIONS & PROFESSIONAL DEVELOPMENT TRAINING

- Six Sigma Green Belt Certification – Villanova University
- Quality Risk Management & Documentation Control Training – CfPA
- CMC Biopharmaceutical Development Training – ISPE
- Pharmaceutical Technology Transfer & Project Management Training – Cobblestone
- Train-the-Trainer Certification – Dendreon Corporation
- Diversity, Equity & Inclusion Leadership Certification – Penn State University

HONORS & AWARDS

- Beta Gamma Sigma Honor Society (Associated with Penn State University for MBA Academic Excellence)
- Penn State Great Valley Quality Enhancement Award (Penn State University)
- Joseph P. & Marilyn H. Henry Graduate Scholarship (Penn State University)
- James Nemes Educational Equity Scholarship (Penn State University)
- Executing Results and Striving for Excellence Bravo Awards (WuXi Advanced Therapies)
- Dean's List (Kean University)