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 biopharmaceutical industry encompassing 6+ years of Technical Operations experience, 6+ years of Manufacturing experience along with 2+ years of Quality Assurance experience. Possessing 9+ years of experience in an FDA-regulated CDMO environment.
- 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 stakeholders, 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.
- **Pursuing Collaboration:** Leveraged relationships with internal and external stakeholders in closing quality events related to client-owned allogenic and autologous CAR-T processes, which led to the timely clearance of client IND and BLA applications.

CORE COMPENTICES

- Quality Risk Management
- Audit and Regulatory Support
- 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
- Data and Metrics Management
- Project and Client Management
- 21 CFR Parts 210, 211, 820, ICH, ISO 9001 and ISO 13485

PROFESSIONAL EXPERIENCE

Founder and Principal Consultant / OAAK Biosolutions - Branchburg, NJ (Remote) *12/2025 - Present*

- Leads a healthcare and biopharmaceutical consulting firm focused on advancing technical operations, manufacturing excellence, quality systems, and regulatory compliance across biologics, cell and gene therapy, vaccine, and combination product programs.
- Develops and executes the company's long-term strategic vision, business development initiatives, operational infrastructure, and market positioning to support sustainable growth within the life sciences industry.
- Advises biotechnology and biopharmaceutical organizations on complex manufacturing operations, quality event management, deviation investigations, CAPA effectiveness, risk mitigation, and operational readiness initiatives.
- Leverages 13+ years of industry experience to provide strategic guidance on GMP manufacturing, technical operations, process performance monitoring, regulatory inspection preparedness, and continuous improvement programs.
- Builds strategic partnerships and industry relationships to expand organizational capabilities and deliver scalable solutions supporting clinical and commercial biopharmaceutical operations.
- Drives thought leadership initiatives through industry-focused content, educational programs, and consulting engagements that promote operational excellence, quality culture, innovation, and regulatory compliance throughout the life sciences sector.
- Champions a culture of innovation, collaboration, and operational excellence while advancing industry best practices through thought leadership, training, and professional engagement.

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

- Directed technical oversight for 6 CGT programs by managing the resolution of quality events through 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.
- 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.
- Acted as process steward responsible for evaluating and resolving technical challenges associated with allogenic and autologous CAR-T processes, including supporting tech transfer and process scale-up initiatives.

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, materials readiness, and production scheduling, enabling uninterrupted execution of clinical and commercial CGT production schedules.

EDUCATION

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

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

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)