John Middleton
Oceanside, CA | 714-476-4967 | middletonjohn474@gmail.com | linkedin.com/in/john-middleton-data

Master Resume

Methodical Leadership | System, Process, & Quality Engineering | Lean-Six Sigma
Product Development & Commercialization | Team Building | Assay & System Integration

A scientific and bioengineering professional with proven results delivering exceptional business growth by steering product and process development and introducing innovation through risk-balanced strategies. Spearhead operational excellence by applying data insights that improve processes and integrating best practices to accelerate output, cut costs, and ensure quality. Employ analytical thinking and deep industry expertise to solve high-value technical problems adeptly.

A patented inventor and trusted SME embodying professionalism and a positive attitude while driving crucial enterprise change. Build high-performing teams by mentoring staff in career skills aligned with organizational objectives and leading with logical approaches and a strong work ethic. Consistently exceed expectations by uniting cross-functional stakeholders in achieving common goals and fostering collaborative and supportive cultures of open idea sharing.

Product Verification & Validation • Requirements Development • Technical Writing • Experimental Design
Medical Device Regulations• Production Support • Cybersecurity • Process Improvement
Technical Issue Resolution • Project & Program Management • Data Analysis • Strategic Planning
Cross-Functional Collaboration • Risk Management • Stakeholder Communication

Career Experience

Amprion, Inc., San Diego, CA 02/20-06/24
A start-up biotechnology company developing and commercializing novel technologies for diagnosing neurological disorders.
Director of Design Controls & Data Analytics (2022-2024) **& Senior Systems Engineer** (2020-2022)
Spearheaded strategic initiatives in project management, system engineering, analytics, technical documentation, and quality system development with a team of six. Directed critical design reviews across development phases and secured stakeholder consensus for project advancement. Garnered a promotion through exceptional performance.

Architected and implemented comprehensive FDA-compliant design controls, risk management, and software validation frameworks and established project management processes. Led mission-critical data transfers supporting leading pharmaceutical corporations and top academic research institutions. Reported to the EVP of regulatory and laboratory operations

- **Unveiled and advanced realization of multi-million dollars of commercial potential by**
  1. Managing the development project from laboratory transfer to market readiness for SYNTap® qualitative α-synuclein assay, the first commercially available test in the clinical laboratory.
     - Secured 100% stakeholder accord on project progress, conducting critical stage-gate design reviews.
  2. Contributing to neurology publications regarding movement disorder and dementia diagnostics.
  3. Leading the development of quality management procedures key to organizational success, such as design controls, risk management, software validation, business continuity, and project management.
- **Cultivated a 10X efficiency increase** and dramatically enhanced project agility by designing and deploying assay data analysis software. The instrumental tool enabled the efficient study of assay reaction parameters to support business-critical validation and transfer studies.
- **Attained 100% regulatory compliance and** maintained zero audit findings by directing the formation of validation documentation and overseeing clinical laboratory cybersecurity functions that safeguarded patient and client privacy, providing the foundation for business growth.
- **Achieved 90 + % assay accuracy**, an industry-leading benchmark, by engineering a sophisticated patient classification algorithm for the SYNTap assay and enhancing business development by further developing related scientific literature and publishing performance data.

Qualigen, Inc., Carlsbad, CA 09/07-06/19

A medical equipment manufacturer offering diagnostic tests for cancers, men's health, hormone function, and vitamin D status.

Systems Development & Continuous Improvement Manager

Demonstrated leadership and scientific acumen in next-generation product development and process improvement. Integrated efforts of internal teams and external resources. Solved business critical issues in assay and instrument performance. Directed next-generation device development from viability through verification. Led a staff of engineers, R&D, customer support, quality assurance, and operations personnel.

Formed comprehensive design input requirements incorporating human factor engineering principles, key hardware features, and software specifications for advanced assay mathematics and statistical analysis. Drove assay standardization for vitamin D, total PSA, free T4, and testosterone using calibrator value assignment, reference material development, and comprehensive quality control protocols. Answered to the CEO.

- **Prevented ~$100,000 in monthly revenue losses** by resolving PMT dark current issues in collaboration with engineering by isolating a label design problem. Resolved instrument shipment delays through the development of VBA software to analyze critical magnet face dimensions.
- **Ignited ~$2 million in external investment** by inventing and securing technology-pillar patents for innovative quantitative, lateral flow-based blood separation technology and a real-time image analysis system for positive sample verification.
  - Piloted next-generation system development by aligning external resources and internal technical teams to create and optimize software, hardware, and disposable designs.
- **Protected $100,000s in yearly revenue** via reaction algorithms to reduce instrument-to-instrument variation for top-selling tPSA assay 25%, innovating a signal adjustment model for FT4 assay stabilization that doubled shelf life, marshaling FDA 510(k) TSH submissions and testosterone sample-type projects.
- **Eliminated 100s of hours of overhead** by **automating** internal data collection and installing statistical process control tools for reagent and instrument QC release testing.
  - Innovated calibrator and control formulation processes via nonlinear concentration modeling, introduced Excel-based CLSI evaluation, and wrote software that automated instrument burn-in test data analysis.
- **Took ~$150,000 out of instrument costs** by engineering a PMT transformation model that cut per-unit production costs $500+.

Earlier Experience

Staff Scientist, Beckman Coulter, Inc., Brea, CA

Product development and production support for multiple flagship platforms such as Astra, CX3, CX4/5, CX7, LX20, and DxC. Established organizational authority on calibrator and control value assignments and advanced data analytics. Served as project manager for important Immage Cystatin C immunoassay. Developed calibrators and associated value assignment processes for the Synchron prealbumin and microalbumin assays. Reported to a senior development manager.

- **Cut $10,000 plus from yearly operational costs** by blueprinting an original control value assignment process that qualified for a US patent.
- **Ensured 100% compliance and traceability with an in vitro diagnostic directive** by framing a thorough compliance process and developing advanced S-PLUS programs and Monte Carlo simulation tools for calibrator uncertainty characterization, enhancing the company's profile in EU markets.
- **Gained a ~30% improvement in assay precision**, sheltering $100,000^{+} in annual sales by shepherding a high-sensitivity, c-reactive protein standardization initiative and pioneering a spectroscopic parameter optimization process implemented for Valproic acid assay.
- **Elevated the company's image as a medical device innovator** by publishing groundbreaking research on analytical error impacts on cardiac risk assessments and specialized value assignment methodologies for the Synchron prealbumin assay.

Education

California State University Fullerton College of Natural Sciences & Mathematics
Master of Science in Chemistry *(coursework complete, thesis incomplete)*

The University of California Riverside
Bachelor of Science in Chemistry

Licenses & Certifications

ASQ, **Certified Quality Engineer (CQE)**

ASQ **Certified Six Sigma Black Bel (CSSBB)**

Technical Proficiencies & Industry Standards

Microsoft Office Suite, Atlassian Jira, SPLUS, MATLAB, Python, VBA, RStudio, Pre-Market Studies (510(k), CLIA Waiver, LDT CAP accreditation), 21 CFR Part 820, ISO 13485, 14971, & 27001, dFMEA, pFMEA, Measurement System Analysis (Gauge R&R), GDPR, HIPAA, IEC 62304, CAPA, cGMP, CLSI Method Evaluations, DOE

Professional Associations & Publications

Association for Diagnostics & Laboratory Medicine, Member

American Society for Quality, Member

Alzheimer’s & Dementia, 2025, “Misfolded α-synuclein co-occurrence with Alzheimer's disease proteinopathy.”

Neurology, 2024, “Association of CSF alpha-synuclein-SAA seed amplification results with clinical features of possible and probable dementia with Lewy bodies.”

Journal of Neurology, 2023, “Seed amplification assay results illustrate discrepancy in Parkinson’s disease clinical diagnostic accuracy and error rates.”