LEE S. MOORE

Education:
BSE, Automobile Technology, Bolton Institute of Technology Bolton, UK
HND, Electrical & Electronic Engineering, Liverpool John Moore's University Liverpool, UK

Professional Licenses and Certifications:
- Project Management Professional (PMP)
- Certified Lead Auditor. AS9100, ISO 13485
- Six Sigma Master Black Belt (SSMBB)
- Lean Champion Trainer
- Danaher Business System Leader (DBSL)

Experience with System Engineering Lifecycle:
15+ years of extensive experience with all the system engineering lifecycle including all the capabilities Risk Management, design analysis, verification & validation. Hands on experience with designing analysis, product architecture and testing.

Experience with Product Development:
15+ years of experience working in product development, product introduction, Product designing and Product quality remediation. Improved overall Divisional performance reducing product field issues. Managed the auditing, monitoring, assessing and selection of suppliers supporting product lines.

Experience with Medical Device:
15+ years of hands on experience working in medical device industry with Global standards and requirements of ISO and FDA regulations. MDR and IVDR remediation for leading Fortune 500 medical device and In-Vitro Diagnostic manufacturers.

Experience with Quality Assurance:
15+ years of extensive experience as a multi site Quality Director at global operations. CAPA, NCMR, field material review, verification and validation and testing and management of global quality projects.

Experience with Supplier/Contract Manufacturing:
15+ years in leading global supplier teams for aerospace, automotive, medical device and In-Vitro Diagnostics. Experienced in biologic, and aseptic manufacturing processes, electromechanical, ESD, cold chain, regulatory and investigative audits for low and high volume product lines

Experience with Operational Excellence:
15+ years extensive lean six sigma experience. Lean six sigma master black belt. Expert in implementing and training on Danaher DBS tools, as well as Toyota Production Systems: Kaizen, SPC, VSM, Kanban, Root Cause Analysis, Hoshin Kanri, Policy Deployment etc

Summary
- Result driven and collaborative leader, with an accomplished record in creating value and growth across businesses, with an unwavering passion to exceed customer expectations.
- Technical expertise in high volume IVD, Medical Device and Biologic Manufacturing. Lean Six Sigma, Quality, Supply Chain Management implementations both domestic and globally in compliance with Global standards and requirements (ISO 9001, AS9100, TS16949, ISO 13485
- 21 CFR 820, 21 CFR 1020, RoHS, IVDR, CE Mark, MDSAP).Developer of successful global strategies and roadmaps to improve short and long term operational and quality performance and profitability and multi-million dollar cost savings

Skills

- Global/Divisional Quality Leadership
- Global (QMS) development
- Lean/Six Sigma Champion
- Root Cause Analysis
- Continuous Improvement
- Global Supplier Management
- FDA remediation
- New Product Introduction
- Site Relocation/remediation
- IT agile implementation
- Proficient in French, Spanish, Italian

Professional Experience

Lee S Moore Consulting, San Marcos, CA **2011 - Present**
Consultant Director

- QMS IVDR and MDR remediation for leading global toxicology screening manufacturer. Including technical file remediation, updates and preparation for IVDR submissions
- Consultant at floral customer including managing cold chain distribution center, exceeding operational targets by 30%, and increasing operational output.
- Implemented new temperature control shipping process resulting in 34% YOY savings ($200K) and increasing incoming material throughput by 40%, and reducing customer complaints by 25%.
- Restructured medical device customer supplier management and evaluation process in accordance with FDA regulations. Resulting compliance to 21 CFR 820, with a 30% improvement in supplier rejections, and manufacturing defect costs, and updates to Master Control QMS software

Biotelemetry Inc., San Diego, CA **2018 – 2019**
Director R&D Project Management Office

- Oversight of R&D Project Management Office, providing strategic and tactical plans for R&D PMO support
- Management of global R&D projects for leading Heart, Blood glucose and Clinical research medical device company.
- Financial responsibility for Department budgets and projects.
- Strategic and tactical roadmaps for R&D PMO departments
- Management of domestic and offshore 3rd Party software developers and agile scrum teams
- Developed and implemented Structured Agile Framework (SAFe) pilot

Danaher Corporation, Brea, CA **2016 – 2018**
Danaher Business Systems Leader and Project Management – Global Quality

- Management of global quality projects and Kaizens including, MDSAP, ISO 9001:2015 13485:2016 evaluation, and successful recertification with no major findings
- Rectified REACH, GLP projects to ensure projects to deliver on time and under budget resulting in $6M savings
- IVDR due diligence and remediation planning of all CEIVD products, participation in BSI pilot resulting in proactive risk management and resolution
- Reduction of IVDR 953 products to 53 families resulting on $25M saving
- Established Global Infrastructure QMS IT implementation, Metrics, PMO, and Global Quality Communications utilizing agile software processes
- Developed ‘QMS with DBS’ strategy and processes resulting in proactive quality management.
- Danaher Business Systems (DBS) champion and practitioner, with 24 month cost saving exceeding $35M

Quality Systems Integrated Corporation, San Diego, CA **2014 – 2016**
Director Quality and Regulatory

- Product quality remediation, and resolve customer dissatisfaction
- Global Quality oversight for quality systems and compliance in accordance to ISO 13485, AS9100, NADCAP, and ESD2020.
- Implemented RTY and single piece flow, improving production throughput from 85% to 98%
- Multisite management (US and Vietnam) resulting in 57% improvement in manufacturing yields and 47% reduction in RMA's within 6 Month period.
- Reduced supplier related defects by 40%, improving RI throughput by 60%, and implementation of PPAP, APQP supplier part and production performance practices.
- Obtained Northrop Grumman Platinum Supplier Status, 1st time in company history (25 years) for Global Hawk Program

DJO Global, Vista, CA **2013 - 2014**
Director BU Quality – Vascular, Bracing and Support

- Quality department reorganization and FDA 483 remediation including 30,000 complaints
- Managing a division of 5 orthopedic manufacturing sites, with an overall team exceeding 130 personnel in accordance to 21 CFR 820 for Class II-III medical devices
- Improved overall Division Quality performance reducing product field issues and customer complaints by 30%.
- Aligned and implemented Unipoint QMS throughout division within 4 months using agile scrum practices and processes
- Resolved legacy manufacturing yield issue due to worn tooling, resulting in improving yields by 50%, and implementing internally developed shop floor management system
- Improved internal PM processes using SPC to minimize tool wear by 30% and improved product quality by 60%

Rapiscan Systems, Los Angeles, CA **2012 - 2013**
Director Global Supply Chain Quality, and Commercial Security Division

- Green field creation of Global Supplier Quality Department, and TSA remediation
- Divisional QA leadership of 3 global manufacturing sites and global Supplier Quality Division with an overall workforce exceeding 40 personnel.
- Established APQP, PPAP and OEM supplier management program, in alignment with TS16949 practices
- Site product design and manufacturing transfer from East Coast to West Coast with no interruptions on product delivery, quality or customer impact
- Implemented global QMS processes and Agile QMS software system in accordance with 21 CFR 1020, ISO 9001 including supplier selection, qualification. CAPA, NCMR, field material review, verification and validation and testing.
- Championed supplier qualification and scorecards, resulting in 20% reduction incoming rejections, and improved material throughput and supplier performance
- Value stream mapped, and 5S MRB area resulting in reducing Divisional in MRB inventory by 95% ($700k) in 3 month period

Life Technologies Corporation, Carlsbad, CA **2008 – 2011**
Quality Assurance Manager

- QA lead for NPI's, redesigns and upgrading of NPI quality polices, process, and procedures to cGMP and CEIVD. MDD requirements for Life Technologies instruments, improving instrument design quality by 20%
- Management of Global 3rd party vendors and contract manufacturers including: Technical transfer of instruments, supplier sourcing and qualification, DHF compilation, DMR transfer, product and software V&V activities, SCAR, CAPA investigations and training.
- 15% improvement in Genetic Analyzer Field Acceptance & 20% MTBF improvement with a 22% cost saving in 6 months, through comprehensive root cause analysis, and manufacturing improvement.
- Managed site relocations, and remote sites post M&A due diligence, quality remediation, and established global QMS, and Agile QMS software implementation
- Created reports and metrics for VP Global Quality & Regulatory, and CEO monthly review

Rockwell Collins Optronics, Carlsbad, CA **2006 – 2008**
Senior Supply Chain Quality Engineer

- Site Lead responsible for the creation and management of site supply chain quality department including AVLs, IPT, Supplier scorecards, and SCAR management
- Proactive management 300 suppliers, reducing DPPM by 73% in 12 months
- Championed Lean Manufacture and Six Sigma training program, VSM, SPC etc
- Championed black belt OLED project reduction scrap rates by 40%, and $1.5M saving
- Single point of contact for customer complaints and FRACAS database reporting
- Design and manufacturing reassignment and transfer to internal manufacturing sites.

SAIC, San Diego, CA **2003 – 2006**
Supplier Quality Engineer

- Managed the quality auditing, monitoring, and assessing of suppliers supporting 10 product lines and New Product Integrations (NPI), Integrated Product Teams (IPT) and launches to ISO 9001 standard, and NRC requirements
- Created and managed supplier classification program for all Key Suppliers.
- Established APQP, PPAP and OEM supplier management program, in alignment with TS16949 practices

Professional Memberships

- Member of the Project Management Institute (PMI)