

MICHAEL C. CLARK

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PROJECT MANAGER

Driven engineering professional who leverages a high-energy work ethic, leadership skills, and diligence in following up and following through. Adept at communicating across global functions and language barriers to manage risk and deliver prioritized results.

Project Management | Sourcing | Supply Chain | International Liaison | Auditing | Automotive | Stampings
Aluminum Die Castings | Springs | Injection/Blow Molding | Quality | Biomedical Engineering | Biomaterials
Biotechnology | Cell Culture | Clinical Trials | Drug Delivery | Life Sciences Manufacturing | Medical Devices
Neuroscience | Quality Control | Start-up | Tissue Engineering | Document Control | New Product Development

EDUCATION

Master of Engineering (M. Eng.) with Highest Honors in Biomedical Engineering GPA 3.874 / 4.0
J.B. Speed School of Engineering, University of Louisville Louisville, KY

Bachelor of Science (B.S.) with High Honors in Biomedical Engineering GPA 3.733 / 4.0
J.B. Speed School of Engineering, University of Louisville Louisville, KY

PROFESSIONAL EXPERIENCE

Haldex Brake Products (Kansas City, MO) June 2018 – Present
Global Project Supplier Quality Engineer

Liaison for all supplier quality and sourcing activities for four NPD projects (budgeted approx. \$2M USD)

- Manage reporting and execution of sourcing project toll gate deliverables for engineering, quality, regulatory compliance, and operations departments.
- Develop and onboard new suppliers while continuously improving or phasing out others based on sourcing strategy.
- Cultivate relationships with overseas suppliers (China, India, Turkey, Europe) for Advanced Product Quality Planning (APQP) activities including tooling design, construction, and part validation
 - NPD for \$6M USD per year sales project on a \$0.6M capital investment for 22 tools (28 different part numbers).
 - \$1.4M USD per year savings on a \$0.5M capital investment for 29 tools (41 different part numbers).
 - 1.8M Euro per year savings on a 0.3M Euro capital investment for 12 different tools for Hungary facility.
- Collect and manage supplier compliance criteria for Conflict Minerals, IATF 16949 and ISO 14001 compliance, and corporate social responsibility utilizing the Market Dojo and NQC online platforms
- Outline and complete AIAG compliant supplier part qualifications (PPAPs) for purchased parts
- Collaborate with program managers to align sourcing and program management processes and streamline efficiency
 - Co-author of Haldex prototype part submission warrant form to expedite prototype approvals.

Harley-Davidson (Kansas City, MO) March 2017 – June 2018
Senior Supplier Quality Engineer

Ensured quality and regulatory compliance of motorcycle body and powertrain products

- Outlined and completed AIAG compliant supplier part qualifications (PPAPs) for purchased parts
- Ensured the quality of product and compliance of documents for multiple major supplier moves
 - Qualified all fasteners over to a new supplier
- Managed supplier quality nonconformance and defective parts per million (PPM) reduction through 8 disciplines root cause analysis (8D) and corrective action request (CAR) completion
 - Decreased supplier PPM by 30% within 9 months and 70% over 18 months, achieving the lowest PPM rate ever for the site.
- Ensured continuity of the supply chain utilizing SAP enterprise software to track inventory
- Trained backup for Material Review Board to analyze and provide disposition for reported nonconformances

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Hill-Rom (Batesville, IN)

December 2015 – March 2017

Supplier Quality Engineer

Ensured quality and regulatory compliance of purchased metal, plastic, electronic, and architectural products

- Outlined and completed supplier part qualifications for purchased parts
- Utilized Gage R&R, capability study analysis, and Minitab control charts
- Conducted ISO9001 and ISO13485 supplier audits across the USA
- Trained a quality manager to become the main Hill-Rom lead internal auditor
- Ensured the quality of product and compliance of documents for multiple major supplier moves
 - Drafted and executed a quality plan for transitioning all blow molded components to a new supplier, managing supplier onboarding, technical reviews, and supplier new part approval.
- Managed supplier quality nonconformance and complaint reduction through corrective action/preventative action (CAPA)
 - Increased the supplier scorecards by 25% for top 3 commodity contributors
 - 25% reduction of confirmed supplier non-conformance reports.
- Ensured continuity of the supply chain
- Analyzed trending data for purchased product complaints
 - Implemented supplier change to eliminate complaints for hardness of Affinity® maternal line calf supports
 - Coordinated cross-functional meetings with architectural products suppliers, marketing, sourcing, and engineering to resolve color mismatches between wood and high-pressure laminates.

Hill-Rom (Batesville, IN)

June 2014 – December 2015

Advanced QA/RA Engineer

Product quality engineer for the Affinity and Surfaces Assembly lines in the Batesville Operations facility

- Ensured quality and regulatory compliance of finished products
 - Managed RoHS implementation via creating and executing a pilot protocol with my manufacturing engineer
- Reviewed and approved engineering changes pertaining to each assembly line and corresponding products
- Assisted with the review and closure of engineering complaint investigations for assigned products
- Collaborated in the reduction of product nonconformances with the manufacturing engineers and operators
 - Implemented master samples in the Surfaces welding department along with improving product workflow in the cutting department (via lean principles) to improve first pass yield and reduce nonconformances.
- Analyzed trending data for product complaints using Excel and Minitab
- Activities supported the closure of an FDA 483 warning letter
- Managed three direct reports: monitored activities, completed APEX performance reviews and set employee goals
- Conducted internal audits to ISO9001, ISO13485, and 21CFR820 standards as an auditor and as a lead auditor
 - Obtained certification as a Biomedical Auditor through the American Society for Quality

Advanced Solutions Life Sciences (Louisville, KY)

June 2013 – June 2014

Biomedical Engineer / Project Manager

- Project Manager of the Tissue Structure Information Modeling (TSIM™) software product
 - Aided in the development and design of the functional specifications for the TSIM™ software product
 - Drafted the initial functional specifications document for TSIM™
 - Planned lab tests and ensured quality of TSIM™ build cycles
 - Partnered in the advancement and incorporation of the science of 3D printed constructs in TSIM™
- Project Manager of the BioAssemblyBot (BAB) workstation product
 - Collaborated with the design engineer to design the BAB prototype and Version 1
 - Managed parts procurement and vendor contracts for BAB workstation components
 - Assembled BAB workstations and tested functionality
- Managed TSIM™ and BAB timelines as well as key milestones to ensure projects are delivered on time and on budget
- Interacted with prospective customers to demonstrate the capabilities of TSIM™ and the BioAssemblyBot

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Neuronetrix (Louisville, KY)

June 2010 – May 2012

Co-op Student

- Traveled as an ambassador for the company to the Cognitive Neuroscience Society annual meeting of 2012 with the Executive Vice President of Business Development to interact with potential customers and generate sales opportunities
- Reviewed and archived clinical study documents under the tutelage of the Clinical Study Coordinator
- Worked with Director of Production and Development to generate a user manual for the medical device as well as solutions for manufacturing optimization, software/electrical components debugging, and ergonomics
- Assembled and tested multiple design iterations of the COGNISION® headset, now the first FDA approved ERP/qEEG device.

CERTIFICATIONS

Haldex Six Sigma Green Belt

May 2020

Haldex

Exemplar Global ISO9001:2015 Lead Auditor / IATF 16949:2016 Supplier Auditor)

July 2018

Automotive Industry Action Group (AIAG)

Project Management Excellence (PMX)

November 2017

Harley-Davidson

Hill-Rom Internal Lead Auditor

August 2015

Hill-Rom

Certified Biomedical Auditor (March 2015 – June 2019)

March 2015

American Society for Quality

INTERNATIONAL TRAVEL VISAS

China

April 2019 – April 2029

Valid for multiple entries