Leigha N. Wilson

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513.253.9694

Desired location: Atlanta, GA

Education:

Master of Science, Industrial Engineering — Clemson University, Clemson, SC
Bachelor of Science, Electrical Engineering — Clemson University, Clemson, SC

Experience:

February 2017 - Present

GE Healthcare – Maternal-Infant Care, Laurel, MD
Engineering CAPA and Change Management Leader

Responsible for creating and supporting a quality culture by driving activities around the engineering CAPA program, managing engineering quality and process improvements, and leading the change control board working with cross-functional leadership teams to ensure effective change implementation for MIC products and processes.

- Manage engineering investigations and CAPAs to completion, ensuring clear, accurate, and timely execution, with emphasis on patient, customer, and business risks
- Manage regulatory responses with the complaint handling organization
- Provide inputs to the risk management process based on customer experience and external audits
- Provide engineering inputs to the regulatory organization for country specific product registrations
- Serve as subject matter expert on the change management process for internal and external audits
- Maintain site metrics on investigation and CAPA performance and report out to leadership on a quarterly basis
- Successfully on-boarded and trained 10 engineers on the CAPA system and MIC business as part of the current site closure and transfer plan
    - Worked hands-on for ~3 months training on the MIC processes, products, and requirements

October 2014 – February 2017

GE Healthcare – Maternal-Infant Care, Laurel, MD
Supplier Quality Lead Engineer

Worked closely with the GEHC supply base and engineering organization to ensure purchased components met GEHC requirements, including drawings and quality agreements, in addition to the necessary regulatory requirements.

- Maintained approved supplier list (ASL) in accordance with GEHC selection and qualification procedures
- Resolved supplier-caused issues via the supplier corrective action request (SCAR) process, in compliance with the CAPA process
- Collaborated with engineering, quality, materials, and manufacturing to resolve supplier-caused issues and provided input on process or product improvements for the MIC business
- Served as subject matter expert for internal and external audits, representing the SQ organization
- Served as site representative for purchasing controls change review board and CAPA review board
- Successfully managed ECO implementation for CSA regulatory issue, working with the MIC materials team and supplier to expedite rework, alleviating ~$200k in revenue risk
- Completed CAPA investigation ahead of schedule, allowing the business to recover ~$35k from the supplier

September 2013 – March 2015 **Beretta USA Corporation,** Accokeek, MD

Supplier Quality Engineer

Managed suppliers and component qualifications for various gun models, including the M9, primary sidearm of the U.S. Military.

- Lead supplier quality engineer for first article submission of M9 sidearm
    - Managed PPAP submissions of approximately 50 components ensuring all government requirements were met
- Conducted supplier approval and surveillance audits
- Managed component qualification from concept to release, ensuring suppliers followed standard production approval process (PPAP)
- Conducted capability studies to understand existing processes and determine required improvements
- Developed receiving inspection plans based on historical data

January 2008 – August 2013 **Philips Electronics North America – Home Healthcare Solutions,** Kennesaw, GA

Supplier Quality Engineer

Managed suppliers to ensure purchased components met the necessary requirements as specified per purchase orders, drawings, and quality agreements

- Responsible for reporting quality metrics of global suppliers across various commodities which included electronics, electromechanical, hardware, and injection molded plastics
- Responsible for both new product introductions and sustaining products, including writing and ensuring the execution of validation protocols
- Conducted supplier approval and surveillance audits in accordance with ISO 9001, ISO 13485, and 21 CFR 820 of global suppliers for the Philips corporation
- Conducted surveillance audits of factory authorized service centers (FASCs)
- Maintained procedures, work instructions, and quality forms as they pertained to the supplier quality organization
    - Lead on Quality Systems Improvement Project for Supplier Selection
        - Streamlined quality system by reducing the number of procedures and work instructions by 80%
        - Aligned supplier audit process with current ISO auditing practices
- Lead supplier quality engineer for transfer of work (TOW) project, achieving an annual cost savings of $450K
    - No negative impact to the quality levels of this product occurred as a result of this transfer, as evident in final line yield and field service data

May 2007 – August 2007 **Johnson & Johnson – Ethicon Endo-Surgery, Inc.,** Cincinnati, OH

External Operations Intern

- Engineering Testing Development
    - Developed test methods and work instructions to aid in diagnosing field failures
- New Supplier and Process Validations
    - Responsible for validation protocols for 2 external manufacturers, 1 of which was a new supplier to J&J

Training:

Six Sigma Green Belt Training, Philips Healthcare
Working knowledge of FDA, Medical Device Directive (MDD), EN ISO 14971:2012 and ISO 13485:2016 regulations
ISO 9001:2008 Lead Auditor – TPECS version, RAB/QS Certified Training
ISO 13485:2003 Internal Auditor Training Course, TQS, Inc.
Software: Minitab, SAP, Agile, Oracle, TrackWise

Recognition:

Empower and inspire, GE Healthcare
Customers determine our success, GE Healthcare