SEAN KEHMEIER

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QUALITY MANUFACTURING | CROSS-FUNCTIONAL ENGAGEMENT | PROBLEM SOLVER

Accomplished manufacturing engineer in product and process development providing leadership, teamwork, and execution to drive the achievement of key operational goals. Skilled at DFSS, lean manufacturing, risk mitigation, and data driven analysis to safely build high quality product on schedule. Passionate about integrating and collaborating with cross-functional teams to drive bottom line results developing and building quality product. Languages: English (Fluent), Spanish (light conversational) and French (light conversational).

TECHNICAL APPLICATIONS

Microsoft Office (advanced), Microsoft Project, Business Planning and Control System (BPCS), EOne, Oracle Agile PLM, NI LabVIEW, NI TestStand, IntraStage, SmartSheet, Mentor Graphics PADS and Schematic Capture, OrCAD Capture, OrCAD PCB Editor, Pro/ENGINEER, Windchill PTC, Boothroyd-Dewhurst DFM/DFA, Timer Pro, Minitab, Associated Research Autoware (I, II, III), IHS CAPS Universe, elliTek Data Commander and Workbench, Git, IBM Rational

EXPERIENCE

Covidien, Energy-Based Devices / Medtronic, Surgical Solutions, New Product Development
Boulder, CO

Senior Product Advanced Manufacturing Engineer | 2008 to 2018

Promoted to Advanced Manufacturing Engineering (AME) as manufacturing core team lead on new project cross-functional teams to establish efficient and cost-effective manufacture of energy-based surgical generators.

- Accomplished year-in-year-out on-time product launch while meeting targeted product COGS, quality, and safety metrics driven by risk-based and Six Sigma (DFSS) product development practices.
- Slashed manufacturing assembly time and labor requirements by 50% for new product over predicate medical devices through employment of DFM, DFA and DFT improvements to product and manufacturing processes while meeting plant efficiency and quality metrics.
- Expanded SPC monitoring and product quality data analysis of manufacturing processes through development and validation of data communication and storage of CRio, PLC, and PXI controller data generation.
- Drove consistency in contract manufacturer (CM) production through standardization of CM specifications and defined standards for device master record (DMR) control within the product life cycle management (PLM) system. Coordinated and implemented deployment and validation of all CM processes including test fixtures, equipment, tooling, instructions, and software, and resolved continuing supplier change requests.
- Achieved and preserved Authorization to Mark and UL or ETL classification for five medical device products through the management of product compliance with IEC 60601-1 3rd Edition by management of affected critical components, product electrical safety test development, and support of NRTL (Underwriters Laboratory, Intertek) follow-up services audits.
- Cultivated project success across all new generator and instrument projects by managing the AME laboratory through timely equipment and material procurement, project work cell layout for trial builds, management of facility/utility modifications and expansions, equipment calibration control, enforcement of lab safety rules to achieve a zero RIR year-in-year-out, maintenance of GMP areas, and creation of ESD area compliant systems and

audits.

- Established domestic and international product service by deploying and training service centers on product assembly and test processes and by developing supply chain conduits between suppliers, distribution centers, and worldwide service centers.

Tyco Healthcare Group LP, Valleylab Inc / Covidien Operations Engineering Boulder, CO
Product Manufacturing Engineer / PCB Designer | **Component Engineer** 2001 to 2008

Hired to integrate acquired suite of RF Ablation product BOMs and component stock with resident PLM and MRP system, implement component obsolescence tracking and resolution program, and to revise, maintain, and verify changes to all commercialized product PCB schematics and board layout designs.

Promoted to oversee manufacturing assembly and test processes, complaint investigation, product and process change validation and implementation, medical device safety regulatory compliance, resolution of material non-conformance, and to implement material and process cost savings of energy-based surgical generators using Six Sigma DMAIC strategies.

- Evaded production line down and reduced supply chain risk of using obsolete components by tracking ten thousand parts for part End-of-Life (EOL) and Part Change Notifications (PCN),
- Led cost reduction team saving $500K annually in component costs through alternate source verification and approval.
- Enabled continued market retention and penetration of flagship electrosurgical generator by redesigning its controller PCBA for a replacement FPGA and orchestrating the original part's lifetime-buy prior to its stock-out.
- Increased rolled throughput yield (RTY) of manufacturing processes to 95% by promotion and implementation of upstream PCBA testing through redesign of PCBAs for ICT at board house manufacturer.
- Attained continued worldwide product penetration through creation, management and implementation of the company's RoHS compliance transition project for ten thousand components spanning company energy-based surgical generators and changed internal production processes to meet the 2006 WEEE mandate.
- Created Standard Operating Procedures (SOPs) for the approval process and documentation requirements for control, verification, and validation of component approved source of supply within the Agile PLM System to maintain component quality control.
- Guided and assisted supplier Quality Engineers in component inspection, defect analysis, and failure resolution to reduce MRB backlogs and increase incoming material quality.

EDUCATION

University of Colorado Boulder, CO, **Bachelor of Science in Electrical Engineering**
University of Colorado Boulder, CO, **Bachelor of Science in Civil Engineering**

PROFESSIONAL DEVELOPMENT

Six Sigma (DMAIC & DFSS) Blue-belt and Green-belt Training (Covidien OpEx), Sample Size Calculation (Covidien OpEx), Design of Experiments (Covidien OpEx), Analysis of Variance (Covidien OpEx), IEC 60601-1 3rd Edition Part 1, ISO 13485, ISO 14971, FDA Quality System Regulation 21 CFR Part 820, CAPA (Medtronic), PPAP (Medtronic), Project Management (Kepner Tregoe), GD&T, Electrostatic Sensitive Device (ESD) Program Management (Dangelmayer Associates L.L.C), Agile software development environment, LabVIEW Core 1 & 2 (NI), Developing Test Programs Using TestStand (NI), Using LabVIEW and TestStand in Regulated Industries (NI), IPC-A-610 and IPC-J-STD-001 (Blackfox),

COMMUNITY ENGAGEMENT

Leadville 100, Crew	2018
Run Rabbit Run 100, Crew and Pacer	2018
Medtronic Pack to Plate with Feed My Starving Children, Volunteer	2018
A Precious Child, Volunteer	2015
Habitat for Humanity, Volunteer	2001 - 2017
Colorado Bike to Work Day, Participant	2001 - 2018
Society of Manufacturing Engineers (SME), Member	2011 – 2013