Sarang Shah

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Professional Summary

Engineering leader with 14+ years of experience developing, commercializing, and sustaining FDA-regulated medical devices, including molecular diagnostics, hematology, and automated urinalysis platforms. Proven track record leading cross-functional engineering teams through product development, design transfer, verification, post-launch reliability improvements, lifecycle management, and global manufacturing support. Successfully contributed to multiple commercial product launches while driving quality, risk reduction, operational excellence, and customer-focused innovation.

— Key Competencies —

Medical Device Development: Design Controls • Design Transfer • Design Verification & Validation • Product Lifecycle Management
Quality & Regulatory: FDA 21 CFR 820 • ISO 13485 • ISO 14971 • CAPA • Root Cause Analysis (RCA) • Risk Management
Engineering Methods: DFMEA • Statistical Process Control • Reliability Engineering • Lean Six Sigma
Tools: Minitab • Azure DevOps • SAP • Power BI • SolidWorks • Microsoft Visual Studio

Experience

Waters Corporation (Formerly Becton Dickinson) **Sparks Glencoe, MD - 21152**
Staff Engineer (Process) – R&D Molecular **November 2024 - Present**

Engineering Lead responsible for sustaining engineering, post-launch product support, and continuous improvement of the BD COR and legacy BD MAX Molecular Diagnostic platforms. Lead multidisciplinary initiatives spanning product reliability, design verification, CAPA investigations, lifecycle management, manufacturing support, and engineering change implementation for FDA-regulated diagnostic systems.

- Drive engineering execution for the BD COR Molecular Diagnostic platform, leading hardware and software design improvements through failure investigations, field performance analysis, verification testing, and cross-functional execution.
- Collaborated with the BD COR Failure Investigation Team (FIT) to resolve complex hardware and system-level failures across PX and MX platforms through structured root cause investigations, verification testing, engineering evaluations, and implementation of corrective actions improving field reliability. Applied structured failure analysis methodologies (Fault Tree Analysis, Fishbone, SPC) to identify failure mechanisms within the BD COR MX microelectrode PCR heater assembly, enabling targeted design enhancements.
- Partnered with Technical Services to develop and implement service solutions for BD COR PX/MX platforms, improving field support effectiveness while reducing service cost and improving customer experience.
- Developed an enterprise Power BI dashboard integrating field performance data from 105 deployed BD MAX systems, providing Technical Service teams with real-time visibility into instrument health, recurring failure modes, service trends, and predictive maintenance opportunities that improved troubleshooting efficiency and supported proactive reliability initiatives.
- Serve as CAPA Owner for complex engineering investigations, leading root cause analysis, corrective actions, effectiveness verification, and documentation supporting FDA Quality System requirements.
- Manage End-of-Life (EOL) engineering projects to mitigate component obsolescence through qualification of alternate materials and hardware while minimizing product risk and maintaining manufacturing continuity.
- Lead qualification and implementation of replacement components including pump seal assemblies and pipette tip materials through engineering evaluation, verification testing, supplier collaboration, and change control activities.
- Spearheaded optimization efforts for the BD MAX Tuberculosis (MDR-TB) PCR assay by enhancing the customer workflow for TB sample preparation, resulting in a 25% increase in PCR target sensitivity.

Staff Engineer – R&D Molecular - Design Transfer Team Manager **September 2021– November 2024**

Led engineering execution for design transfer, process development, and commercialization of BD COR molecular assay consumables, ensuring scalable manufacturing, regulatory compliance, and successful product launches.

Selected Contributions:

- Led cross-functional engineering activities supporting successful commercialization of five BD COR molecular diagnostic assays (i.e. BD COR CTGCTV2, Vaginal Panel, Enteric Bacterial Panel, Respiratory Viral Panel Suite) through design transfer, manufacturing readiness, verification activities, and supply chain coordination over a 3-year period.
- Improved design transfer process efficiency by 35% through an in-process materials tracking system, incorporating performance measures into daily meetings, establishing weekly gap analysis and leading R&D and Ops leadership reviews.
- Managed three R&D Scientists across four laboratory operations while providing technical leadership, project prioritization, and execution support for new product development and commercialization activities.
- Led risk analysis, functional testing, and verification for End-of-Life raw materials and vendor changes. Performed material data sheet analysis to identify equivalent material as second source supply.
- Partnered with Medical Affairs to ensure consumable readiness supporting clinical trial execution.
- Served as the primary R&D representative for raw material strategy, supplier qualification, and lifecycle management, partnering with Supply Chain and Product Management to ensure uninterrupted product development and manufacturing corrective actions.
- Utilized Design for Six Sigma methodologies to reduce defects and variations during manufacturing equipment improvements. Equipment managed: Despatch Conveyor Ovens, 96 Well Plate Automated Spotter, Bag/Plate Sealers, Automated Liquid/Reagent Filling Line.
- Planned and executed IUO/RUO/Verification/Validation/Stability/IVD Builds for various molecular assay reagent consumables utilizing R&D and/or validated Manufacturing equipment.
- Directed engineering activities supporting global transfer of BD COR assay manufacturing from Baltimore to Quebec, ensuring manufacturing readiness, process scalability, and successful knowledge transfer.

Danaher Diagnostics - Beckman Coulter, Inc. **Miami, Florida - 33196**
Staff Mechanical Engineer – R&D Hematology **February 2020 – August 2021**

Technical Lead responsible for systems engineering, product development, design controls, risk management, and cross-functional execution supporting Beckman's next-generation Hematology and automated urinalysis diagnostic platforms.

Selected Contributions:

- Core team member on Beckman’s flagship product, DxH 900 Hematology Analyzer. Maintained over 90% on time delivery through oversight of project budget, resource, and schedule.
- Partnered with Product Management for scoping and identified 30 customer pain points for workflow improvements during DXH 900 Analyzer development. Oversaw Voice of Customer sessions internally at Beckman’s Education Center and with clinicians at external hospital sites.
- Leveraged experience and skills to create product development plans, risk management plan, quality and regulatory management plan, and master schedule in collaboration with program management and core team members.
- Led hardware development activities for a multidisciplinary engineering team, reducing development timelines by 30% through implementation of Visual Project Management and accelerated design review methodologies.
- Improved customer workflow during DXH 900 development and obtained US patent for magnetic tubing holder.
- Conducted hands-on modification and testing of instruments in Beckman’s lab and presented prototype instrument concepts to the L1 leadership team during a DBS Kaizen event.
- Proficient in Particle Characterization and Chemical Compatibility Analysis. Executed numerous materials and chemical compatibility test protocols and reports. Qualified new tubing for Hematology blood analyzer as part of reliability improvement initiative.

- Updated and maintained Design History File for DXH 900 Hematology Blood Analyzer.
- Well-versed in Design Controls, including Human Factors, Design Input & Output Documentation, Design Verification & Validation per 21 CFR, Design Transfer and System Risk Assessment/Risk Analysis.
- Developed product road map using Azure DevOps and defined module level requirements in JAMA.

Danaher Diagnostics - Beckman Coulter, Inc. **Miami, Florida - 33196**
Senior Mechanical Engineer – R&D Hematology **September 2012 – January 2020**

- Led CAPA investigations for manufacturing and field quality issues, driving root cause identification, corrective actions, process optimizations, and documentation compliance.
- Led engineering initiatives contributing to a 300% improvement in DxH 800 analyzer reliability, generating approximately $2 million in annual service cost savings while significantly improving instrument uptime and customer satisfaction.
- Conducted multiple root cause failure analyses on field-returned parts to identify reliability improvement opportunities and assisted in reliability investigations and mechanical design optimization using disciplined problem-solving methodologies.
- Performed Design and Analysis using CAD Tools for DXH 800 analyzer reliability improvement efforts.
- Supported design and development of DxU Iris 850m/840m Automated Urinalysis Line of Products.
- Drove FDA 483 warning letter – Remediation efforts for IRIS International/Beckman Coulter Chatsworth facility from 2017 to 2020.

Education Background

Master of Science in Mechanical Engineering – FY2010 to FY2012
Florida International University, University Park, FL
Specialization – Design & Manufacturing

Bachelor of Science in Mechanical Engineering – FY2004 to FY2008
Sardar Patel University, Gujarat, India

Certifications & Training

Design For Six Sigma Foundation Training – BD | PMP (Project Management Professional) Training – Danaher Diagnostics | Lean Kaizen Training & Workshop (2018) | Risk Management Specialist Workshop (2019)

Awards & Recognitions

DS Innovation Fest- Outside-the-Box Thinking Award – BD | STAR of Excellence Award – Beckman Coulter | Grad School Non-Residential Tuition Differential Scholarship – Florida International University

Published Patent

Magnetic Tubing Holder – US-11596491-B2 (Patent Link)