JULIAN MERCER

BIOMEDICAL ENGINEER

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PROFESSIONAL SUMMARY

Biomedical Engineer with 7+ years designing, testing, and sustaining Class II and Class III cardiovascular devices under FDA design controls. Strong in verification testing, risk management, and root-cause analysis with clinical and manufacturing partners. Writes clear design history documentation that passes audit.

CORE SKILLS

FDA design controls (21 CFR 820) | ISO 14971 risk management | ISO 13485 | Verification and validation testing | SolidWorks | Design of experiments | Root cause analysis and CAPA | Test method validation | Statistical analysis (Minitab) | 510(k) documentation | Process validation | Bench and fatigue testing | Design transfer

PROFESSIONAL EXPERIENCE

Senior R&D Engineer Mar 2023 - Present
Medtronic, Minneapolis, MN

- Lead mechanical design and verification for a catheter delivery system component through bench testing, risk analysis, and design transfer.
- Designed and ran a fatigue and tensile test protocol on 120 samples, showing the design exceeded its requirement by 30 percent.
- Maintained the ISO 14971 risk file and reduced the number of unmitigated high-severity hazards from 6 to 1 through design changes.
- Prepared design history file sections and technical files for FDA 510(k) support, with no deficiencies noted in internal review.
- Partnered with manufacturing to cut assembly scrap on the component from 7 percent to 3 percent by adjusting a bonding fixture and process window.
- Supervise two engineers and a technician on verification builds and train new hires on design controls.

R&D Engineer Jun 2020 - Feb 2023
Boston Scientific, Maple Grove, MN

- Developed prototype components for an electrophysiology catheter in SolidWorks and tested them against design inputs.
- Authored 14 test method validations and reports for a verification package, all accepted on the first review.
- Investigated 20 field complaints with quality, finding a recurring adhesive cure issue and implementing a corrective action that stopped recurrence.
- Supported animal lab studies with physicians, collecting handling feedback that led to two design changes.
- Ran design of experiments to tune a heat-shrink process, widening the process window and improving yield by 9 points.

Quality Engineer Jul 2018 - May 2020
Abbott, St. Paul, MN

- Reviewed process validations for implantable device manufacturing lines and approved IQ/OQ/PQ protocols for six processes.
- Led nonconformance investigations and CAPA actions that closed in an average of 38 days against a 45-day goal.
- Performed supplier audits for two component vendors and tracked corrective actions to closure.
- Trained line technicians on inspection methods and measurement systems analysis.

EDUCATION

Bachelor of Science in Biomedical Engineering, University of Minnesota, Minneapolis, MN

CERTIFICATIONS

Engineer in Training (EIT), Fundamentals of Engineering Exam, NCEES | Certified Six Sigma Green Belt (CSSGB), ASQ