Ingrid Vasquez-Thornbury

Biomedical Engineer

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SUMMARY

Biomedical engineer with 5 years of experience in diagnostic devices and catheter-based systems, working across design verification, risk analysis and FDA submissions. Led the verification testing that supported a 510(k) clearance for a point-of-care glucose monitor and cut a catheter failure rate from 4% to 0.6% through a redesigned tip geometry. Comfortable moving between CAD, bench testing and regulatory documentation.

EXPERIENCE

Biomedical Engineer II — Northline Diagnostics

Minneapolis, MN · Apr 2022 – Present

- Led design verification testing for a point-of-care glucose monitor across 6 environmental conditions, supporting a successful 510(k) clearance.
- Redesigned a catheter tip geometry using SolidWorks and finite element analysis, cutting the field failure rate from 4% to 0.6%.
- Wrote and executed 45 test protocols under IEC 60601-1 and ISO 10993 biocompatibility requirements for 3 device submissions.
- Ran a design FMEA with cross-functional reviewers that caught a seal failure mode before pilot production, avoiding an estimated $180K rework.

Biomedical Engineer I — Harrowgate Medical Devices

St. Paul, MN · Jun 2020 – Mar 2022

- Built bench test fixtures for catheter burst-pressure and kink-resistance testing, used across 8 product lines.
- Supported design history file documentation for 2 Class II device submissions, reviewed and approved by regulatory affairs.
- Analyzed 300 units of field return data to trace a connector failure to a supplier tolerance issue, leading to a spec change.

SKILLS

Design & Analysis: SolidWorks, Finite Element Analysis (ANSYS), MATLAB, risk analysis (FMEA)

Testing: Bench test fixture design, biocompatibility testing (ISO 10993), environmental testing

Regulatory: 510(k) submissions, Design History Files, IEC 60601-1, ISO 13485

Documentation: Design controls, verification/validation protocols, risk management files

CERTIFICATIONS

Certified Quality Engineer (CQE), ASQ, 2023

EDUCATION

B.S. Biomedical Engineering, University of Minnesota, 2020

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