Svetlana Greer

(401) 555-2847 svetlana.greer@example.com linkedin.com/example/svetlanagreer Providence, RI 02906

SUMMARY

Verification and validation engineering leader with 10 years of medical device experience across **surgical navigation**, **electromechanical platforms**, embedded systems, and regulated product development. Leads **risk based V&V** strategy, requirements traceability, formal verification, validation, reliability testing, regression planning, and design transfer for Class II and Class III devices. Builds effective engineering teams and coordinates software, hardware, systems, clinical, quality, regulatory, manufacturing, and external laboratory partners. Applies **FDA 21 CFR Part 820**, ISO 13485, IEC 60601, ISO 14971, DOORS, Jama, Python, LabVIEW, MATLAB, automation, statistical methods, and root cause analysis. Brings practical judgment to test scope, sample size, laboratory readiness, nonconformance investigation, technical reporting, audits, and launch support. Ready to contribute disciplined leadership and clear evidence across complex medical navigation programs.

EXPERIENCE

V&V Engineering Manager, Surgical Navigation

June 2022 - Present

Asteron Medical Navigation

Providence, RI

Leads surgical navigation V&V engineering across **system requirements**, risk based test strategy, formal protocols, integration, validation, regulatory evidence, design transfer, and launch support. Manages multidisciplinary engineers while connecting technical decisions with quality, clinical, manufacturing, and business needs.

- Led **risk based V&V** strategy for **surgical navigation** systems, strengthening traceability across release evidence.
- Built master test plans and **formal protocols**, giving engineers clear scope for system verification.
- Directed regression planning after design changes, aligning retesting depth with product risk.
- Coordinated software, hardware, clinical, quality, and regulatory partners through integration failures and **release** decisions.
- Reviewed system reports and subsystem deliverables, improving inspection readiness for **design transfer** and launch.
- Developed engineers through practical reviews, shared laboratory knowledge, and trusted cross company relationships.

Senior Verification and Integration Engineer, Image Guided Devices

March 2019 - May 2022

Meridian Surgical Systems

Hartford, CT

Owned system verification and integration for image guided medical devices, combining DOORS traceability, subsystem reviews, automated testing, failure investigation, and technical reporting. Partnered with systems, software, hardware, clinical, quality, and manufacturing teams during regulated product development.

- Created **DOORS** traceability for image guided devices, connecting **user needs** with system and subsystem evidence.
- Integrated firmware, software, and electromechanical subsystems, resolving interface failures before **formal validation**.
- Automated repeatable test sequences with **Python**, reducing manual effort during regression execution and analysis.
- Investigated **nonconformances** through **root cause analysis**, helping quality partners define focused corrective actions.
- Prepared verification reports and review packages, earning confidence from regulatory and manufacturing stakeholders.
- Built working relationships across engineering teams, turning difficult integration reviews into faster technical decisions.

Verification Engineer, Electromechanical Devices

July 2016 - February 2019

ClearPath Therapeutics Devices

New Haven, CT

Executed verification for Class II electromechanical devices, supporting LabVIEW based automation, manual test methods, reliability studies, statistical planning, technical documentation, and quality system records. Contributed evidence used in design reviews and product release decisions.

- Verified **Class II** electromechanical devices through LabVIEW **automation** and controlled manual test methods.
- Planned **repeatability** and **reproducibility** studies, clarifying method capability before formal test execution.
- Applied **MATLAB** analysis to reliability data, supporting sample size justification and engineering conclusions.
- Reviewed deviations and failures with quality partners, documenting evidence for **corrective action** decisions.
- Coordinated calibrated laboratory equipment and external testing resources, keeping scheduled verification work moving.
- Presented concise test findings to multidisciplinary teams, helping resolve open risks before design review.

Associate Verification Engineer, Embedded Medical Devices

July 2013 - June 2016

Northstar Biomedical Instruments

Cambridge, MA

Supported embedded medical device verification through MATLAB analysis, software and **firmware testing**, requirements review, controlled documentation, and cross functional issue resolution. Built foundational expertise in regulated development, test execution, statistical interpretation, and technical **communication**.

- Tested embedded medical device functions against approved requirements, recording clear results for engineering reviews.
- Used MATLAB analysis to interpret test data and identify performance trends requiring follow up.
- Supported firmware and software verification, linking observed behavior with documented **system requirements**.

- Prepared test records and deviation details, helping senior engineers maintain complete quality documentation.
- Coordinated sample availability and laboratory **schedules**, reducing interruptions during planned verification activities.
- Shared test findings with systems and quality colleagues, building trust through clear evidence and timely updates.

PROJECTS

Surgical Navigation Risk Based V&V Program **2024**

Led a distinct risk based verification and validation program for surgical navigation, aligning system requirements, formal protocols, regression scope, clinical input, and release evidence with product risk and intended use.

Automated Electromechanical Test Methods **2018**

Created and validated automated and manual test methods for electromechanical medical devices, using LabVIEW, MATLAB, repeatability studies, and statistical analysis to support dependable verification evidence.

LEADERSHIP & AWARDS

- Certified Quality Engineer recognition, American Society for Quality, 2024
- Six Sigma Green Belt achievement, applied to regulated device process improvement, 2021
- Engineering leadership recognition for cross functional verification delivery, 2023

EDUCATION

Master's Degree in Biomedical Engineering 2013

University of Connecticut GPA: 4.0 *Storrs, CT*

Coursework: *Medical device design, systems engineering, statistical methods, biomedical instrumentation*

Bachelor's Degree in Electrical Engineering 2011

University of Rhode Island GPA: 4.0 *Kingston, RI*

Coursework: *Embedded systems, control systems, electronics, software testing*

CERTIFICATIONS

- Certified Quality Engineer, ASQ 2024
- Six Sigma Green Belt 2021

TECHNICAL SKILLS

- **Quality Standards:** FDA 21 CFR Part 820, ISO 13485, ISO 14971
- **Safety Standards:** IEC 60601, applicable IEC standards, basic safety
- **Requirements Tools:** DOORS, Jama, requirements traceability
- **Programming and Scripting:** Python, MATLAB, scripting
- **Test Automation:** LabVIEW, automated testing, manual testing
- **Statistical Methods:** Sample size calculation, statistical analysis, repeatability
- **Systems Engineering:** V model, waterfall, Agile
- **Medical Device Domains:** Class II devices, Class III devices, surgical robotics
- **Integration Testing:** Embedded systems, firmware testing, software testing
- **Quality Investigation:** Root cause analysis, corrective action, nonconformance investigation
- **Laboratory Compliance:** NRTLs, EMC laboratories, calibrated test labs

SKILLS

- Medical Device V&V
- Surgical Navigation
- Systems Engineering
- Risk Based Testing
- Requirements Traceability
- Formal Verification
- Formal Validation
- Reliability Testing
- Regression Testing
- Technical Writing
- Statistical Analysis
- Root Cause Analysis
- Design Transfer
- Laboratory Coordination
- Team Leadership

PROFESSIONAL AFFILIATIONS

- American Society for Quality, quality engineering and medical device community member
- Biomedical Engineering professional community, medical device systems participant

LANGUAGES

- English (Native)
- Russian (Proficient)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST