Anudi Sirimanna

✉ anudisiri@gmail.com | 🔗 linkedin.com/in/anudi-sirimanna

Education

University of Waterloo

BASc in Biomedical Engineering, Honors, Co-op   *2020 – 2025*

- Colonel Hugh Heasley Engineering Scholarship | President's Scholarship of Distinction
- **Key Courses:** Human Factors, Biomechanics, Neuroscience, Rehab Engineering, User Experience, Medical Imaging
- **Reg & SaMD foundation:** Design Controls (21 CFR 820.30), ISO 13485, ISO 14971, IEC 62304/62366
- Whitepaper (rs-fMRI & tractography): methods, clinical rationale, limitations

Work Experience

Veeva Systems

Associate QA Engineer   *Jun 2025 – Present*

- Authored risk-based test plans and decision logs with PM acceptance criteria; on-time releases to ≥**98%** and P1 incidents **–35%**
- Expanded Selenium/Postman automation to **~85%** coverage; regression cycle time **–30%** enabling predictable biweekly cadence
- Led UAT for Campaign Manager (5 squads); triage + MTTR tracking cut P1 MTTR **–42%** and escaped defects **–36%**
- Translated field feedback with PM into backlog OKRs; workflow change reduced clinician task time **–24%** and improved CSAT **+11pts**
- Release gates dashboard (coverage, MTTR, escaped defects) informing go/no-go; authored decision logs
- **Instrumented KPI pipeline** with **SQL/Excel** to track **coverage, P1 MTTR, escaped defects**; flagged risk early and improved go/no-go decisions
- **Release retros** with PM/Eng/QA; standardized a **risk-acceptance matrix** tying **severity×likelihood** to release gates

Omniscient Neurotechnology

Systems Engineering Co-op   *Jan 2024 – Aug 2024*

- Maintained **DHF** with **100% traceability** across **5** Quicktome releases; executed compliant **design transfer** & change control per **21 CFR 820.30**
- Investigated nonconformances/complaints and executed **CAPA**; recurrence **–30%**, closure time **–25%**
- Implemented **21 CFR 820.198 complaint handling** workflow; improved **signal-to-CAPA** conversion (**+14pp**), ensured timely **MDR** escalation
- Ran formative/summative usability (IEC 62366); UI updates reached **SUS 95** and clinician task time **–25%**
- Led cross-functional standups + CI reviews; audit findings **–50%** and standardized SOP updates
- Co-authored requirements, risk file (**ISO 14971**), lifecycle docs (**IEC 62304**), usability protocols (SUS study report), trace matrix

Vena Medical

Opto-Mechanical Engineering Co-op   *May 2023 – Aug 2023*

- Prepared MicroAngioscope for **510(k)**: DHF sections, uFMEA/pFMEA, V&V; verification time **–20%** via new fixtures
- Provisional patent (optical throughput); **SolidWorks** prototypes improved optical throughput **+40%** and stabilized tolerances
- Developed optical/mechanical test methods (**ISO 13485**, ISO 8600); created throughput bench scripts and verification fixtures
- Executed **Design Verification Plan & Report (DVPR)** with **GR&R/MSA** checks; validated methods per **ISO 13485**

Intellijoint Surgical

Product Development Support Specialist   *Sept 2022 – Dec 2022*

- Built Jira quality dashboards; backlog **–35%** and surgeon adoption **+20%** post-release
- Authored V&V protocols, req→test trace matrices (**100%** coverage), decision logs, release checklist

Hyivy Health

Design Support Intern   *May 2021 – Aug 2021*

- Designed & tested subsystems; iterated 9 Fusion 360 designs improving reliability **+50%** & BOM cost **–12%**
- Bench testing + early risk inputs; produced usability study SOP draft (critical task focus)

Projects

Peritoneye   *Sept 2024 – May 2025*

- Built high-fidelity prototype for early peritonitis flagging via optical monitoring of WBC concentration
- Validated setup/cleaning/UI workflows; achieved **SUS 95** and reduced steps **–3** (time **–25%**)
- Identified **650 nm** interference-resistant wavelength; authored SOP for WBC standard curve generation
- Drafted **ISO 14971 risk file** with **hazard analysis → mitigations → residual risk**; reduced top **RPNs –27%** and linked controls to **SUS 95**
- Designed optical-sensor circuits (Hamamatsu 12880MA) with **Arduino**, perfboards, 3D-printed housings
- Summative test n=18; SUS study report; critical task success ≥**94%** (95% CI), no residual high-risk use errors

3D Ultrasonic Imaging Device   *Oct 2023 – Dec 2023*

- Implemented hand-gesture detection (**93%** accuracy) demonstrating rapid prototyping & user-facing ML signal flow
- FEA-guided mechanism optimization (rotation-pulley) with iterative **SolidWorks** prototyping
- Generated real-time 3D ultrasound visualization pipeline using **Python** & **Arduino**
- Achieved ≤**85 ms** end-to-end latency at **32 FPS**; packaged a **requirements → tests** trace matrix ensuring **100%** coverage for demo acceptance

Skills

Regulatory & Quality	Design Controls, DHF/traceability, ISO 13485, ISO 14971, IEC 62304, IEC 62366, Risk files, uFMEA/pFMEA, CAPA, 510(k)
Product & Data	Roadmapping, KPI/OKRs, V&V, UAT, SUS, Jira, Confluence, Figma, Excel
Software & Tools	Python, SQL, MATLAB/Simulink, Postman, Selenium, UML, Git, HTML/CSS, JavaScript, C/C++, Java
Mechanical/Imaging	SolidWorks, Fusion 360, FEA, 3D Printing, Soldering, OpenSim, 3D Slicer, Arduino