Anudi Sirimanna

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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, Computational Neuroscience, Rehab Engineering, User Experience, Medical Imaging

Work Experience

Veeva Systems

Associate QA Engineer *Jun 2025 - Present*

- Authored risk-based test plans with PM acceptance criteria, supporting timely releases and reducing P1 incidents
- Expanded Selenium/Postman automation to **70%** coverage, shortening regression cycles by **18%**
- Built KPI pipeline in **SQL/Excel** to track coverage, MTTR, and escaped defects, flagging release risks early and informing go/no-go decisions

Omniscient Neurotechnology

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

- Maintained the DHF with full traceability across 5 Quicktome releases; executed compliant design control per **21 CFR 820.30**
- Maintained compliance with **IEC 62304 and ISO 14971** through design reviews, risk/requirement analyses, and **SOP** management
- Led the Continuous Improvement Program with dashboards and monthly reviews, streamlining lean practices and reducing audit findings
- Investigated nonconformances and customer complaints, performing root cause analysis to identify systemic issues and drive corrective actions
- Supported **CAPA** initiatives, minimizing recurrence and reducing closure times by **15%** through cross-functional collaboration
- Performed **formative/summative** usability testing per **IEC 62366**; authored a risk-based critical task file, mitigating high-severity hazards
- Collaborated on user & software requirements and contributed to risk management and usability plans for a new medical software product
- Developed a whitepaper on the viability of rs-fMRI and tractography for treating disorders of consciousness, supporting product strategy

Vena Medical

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

- Prepared the Vena MicroAngioscope for **510(k)** submission by enforcing design controls, developing **uFMEA/pFMEA**, and **V&V** documentation
- Drafted a provisional patent outlining engineering designs; designed mechanical drawings & prototypes in **SolidWorks**
- Developed optical & mechanical test methods compliant with **ISO 13485 and ISO 8600**; designed fixtures reducing verification time by **20%**
- Executed the **Design Verification Plan & Report (DVPR)** with GR&R/MSA checks, validating test methods in alignment with **ISO 13485**

Intellijoint Surgical

Product Development Support Specialist *Sept 2022 - Dec 2022*

- Built **Jira** quality dashboards that reduced backlog by **30%** and increased surgeon adoption post-release
- Developed and executed **V&V** protocols with comprehensive requirements-to-test coverage, supporting compliance

Hyivy Health

Design Support Intern *May 2021 - Aug 2021*

- Modeled and iterated through 9 **Fusion 360** designs of a pelvic health device subsystem, improving reliability and lowering BOM cost
- Conducted bench testing and provided early risk inputs, drafting a usability study **SOP** focused on critical tasks

Projects

Peritoneye *Sept 2024 - May 2025*

- Designed a high-fidelity prototype for early peritonitis detection by optically monitoring WBC concentrations
- Streamlined nurse workflows by integrating a direct cycler-to-waste container connection, improving overall system usability
- Organized stakeholder meetings and validated setup, cleaning, and UI workflows, achieving a **95** on the **System Usability Scale**
- Led lab procedures by developing a **SOP** for WBC standard curve generation and spectrometer calibration
- Designed optical sensor circuits for a Hamamatsu 12880MA spectrometer using **Arduino**, perfboards, and 3D-printed housings
- Packaged a requirements-to-tests trace matrix with comprehensive coverage, ensuring demo acceptance

3D Ultrasonic Hand Imaging Device *Oct 2023 - Dec 2023*

- Implemented hand-gesture detection with **93%** accuracy, demonstrating a user-facing ML signal flow
- Optimized a rotation-pulley mechanism through FEA-guided **SolidWorks** prototyping and rapid iteration
- Built a real-time 3D ultrasound visualization pipeline in **Python/Arduino**, achieving ≤85 ms latency at 32 FPS

Skills

Quality & Regulatory	Design Controls, DHF, FMEA, CAPA, ISO 13485, ISO 14971, IEC 62304, IEC 62366, FDA 21 CFR 820
Product & Data	V&V, UAT, SUS, KPI/OKRs, Jira, Confluence, Figma, Excel, Agile, Scrum
Software	Python, Java, C/C++, SQL, MATLAB/Simulink, HTML/CSS, JavaScript, Postman, Selenium, UML, Git
Mechanical	SolidWorks, Fusion 360, FEA, 3D Printing, Soldering, OpenSim, 3D Slicer, Arduino