

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, Neuroscience, Rehab Engineering, User Experience, Medical Imaging

Work Experience

Veeva Systems

Associate QA Engineer

Jun 2025 - Present

- Authored risk-based test plans and decision logs with PM acceptance criteria, supporting on-time releases to **95%+** and reducing P1 incidents by **20%**
- Expanded Selenium/Postman automation to **70%** coverage, shortening regression cycles by **20%**
- 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 transfer and change control per **21 CFR 820.30**
- Investigated product nonconformances and complaints, performed root cause analysis, and supported **CAPA initiatives**, reducing recurrence and closure times by 15%
- 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 QMS practices and reducing audit findings
- 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 new medical software products
- Developed a whitepaper assessing the viability of **rs-fMRI and tractography** for treating disorders of consciousness

Vena Medical

Opto-Mechanical Engineering Co-op

May 2023 - Aug 2023

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

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 validation and verification protocols with comprehensive requirements-to-test coverage, supporting regulatory 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 cyclor-to-waste container connection, improving overall system usability by 25%
- 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
- Conducted summative testing with n=8; demonstrated a high critical task success rate with no residual high-risk use errors
- 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