DANA FRAIJ

SUMMARY

A recent Biomedical Engineering graduate with honours, with hands-on experience in product development, operations support, and medical device prototyping. Skilled in Design Controls, Verification & Validation (V&V), risk management (FMEA), and regulatory compliance (ISO 13485, IEC 60601-1). Adept at collaborating across multidisciplinary teams, preparing technical documentation (SOPs, SRS, DHF), and implementing process improvements. Dedicated to applying engineering expertise to advance innovative healthcare solutions.

TECHNICAL SKILLS

Product Development & Operations: Design Controls, Requirements Management, Verification & Validation (V&V), Risk Management (FMEA), Product Lifecycle, Documentation (SOPs, SRS, DHF).

Regulatory Standards: ISO 13485 (QMS), ISO 10993-1 (Biocompatibility), IEC 60601-1 (Electrical Safety), FDA QSR.

Technical Tools: MATLAB, Arduino IDE, C, C++, ESP32, Biomedical Signal Processing, Circuit Prototyping.

CAD & Design: SolidWorks (Stress Simulation, Mechanical Design), AutoCAD, 3D Printing.

Collaboration & Tools: Agile (Scrum), Excel (Data Visualization), MS Project, PowerPoint, Word.

WORK EXPERIENCE

Product Analyst | Prep Doctors Corporation, Mississauga, ON
May 2024 - Aug 2024

- Formulated detailed SRS/PRS documents based on stakeholder requirements, aligning deliverables with industry standards.
- Liaised with cross-functional Agile teams to facilitate daily stand-ups, sprint planning, and milestone tracking within the product development lifecycle.
- Prepared comprehensive user guides, SOPs, and technical documentation, enabling smooth product deployment, user adoption, and ongoing operations support.
- Conducted validation testing and system troubleshooting, enabling reliable rollout and ongoing operational stability.

PROJECT EXPERIENCE

Capstone: Smart Rehabilitation Glove - Osteoarthritis (Medical Device Prototype)| Sept 2024 – Sept 2025

- Developed glove prototype under Design Controls in compliance with ISO 13485, ISO 10993-1, and IEC 60601-1, ensuring safe material use and circuit integration.
- Designed and implemented ESP32-based integration of flex/force sensors and servo motors, achieving real-time hand motion replication validated via MATLAB signal analysis
- Co-authored clinical feasibility manuscript (under review, MDPI Sensors).

Automated Goniometer Calibration System | Jan 2025 - Apr 2025

- Designed and automated a servo-driven calibration device with ±0.5° accuracy, reducing manual errors and enabling single-user operation.
- Completed verification studies using Vicon motion capture; confirmed reproducibility and linearity of system response.
- Achieved cost reduction of $33.37 CAD per unit, on a batch of 1000 units; addressing market needs in biomechanical research tools.

SleepSync - Wearable Sleep Monitoring Device | Sept 2024 - Dec 2024

- Prototyped a wearable with accelerometer, heart rate, and temperature sensors, programmed algorithms for real-time feedback.
- Validated sensor functionality through controlled test scenarios, confirming reliable detection of user movement, heart rate changes, and temperature fluctuations.
- Evaluated hardware feasibility for consumer deployment, recommending upgrades such as wrist-based optical heart rate sensing, compact PCB integration, and medical-grade temperature sensing.

EDUCATION

Bachelor of Engineering, Biomedical Engineering (Honours) | University of Guelph, ON
Sept 2021 - Oct 2025 graduation class.

Coursework: Biomedical Devices, Product Development, Quality Systems, Signal Processing

CERTIFICATIONS

Dassault Systèmes - Mechanical Design| Feb 2023
CORE (Course on Research Ethics)| Sept 2024

EXTRA-CURRICULAR ACTIVITIES

Vice President, Logistics - CALE & Professional Development Conference| (100–200+ attendees)
Co-Founder & Co-President - Clash of Concept| (STEM club on ethics, innovation, and technology)