

MAYA CHEN

BIOMEDICAL ENGINEER

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PROFESSIONAL SUMMARY

Biomedical engineer with 6+ years of experience developing Class II electromechanical and wearable medical devices from concept through design transfer. Combines hands-on prototyping and test-method development with rigorous design controls, risk management, and cross-functional leadership. Delivered three product launches, reduced verification cycle time by 28%, and supported successful FDA 510(k) submissions and ISO 13485 audits.

PROFESSIONAL EXPERIENCE

Senior Biomedical Engineer

Jan 2022 – Present

Helix Medical Systems

Cambridge, MA

- Lead systems engineering for a portable infusion platform, translating 120+ clinical and user needs into traceable inputs, subsystem requirements, and verification protocols for a Class II device.
- Designed benchtop fixtures and automated Python data pipelines for flow accuracy, occlusion, and battery testing, cutting execution and analysis time by 28% across 1,500+ test runs.
- Drove ISO 14971 risk activities, including hazard analysis, FMEAs, and risk-control verification; closed 34 high-priority risks before design freeze with no unresolved unacceptable residual risk.
- Coordinated firmware, mechanical, quality, clinical, and manufacturing teams through design reviews and transfer, enabling pilot production at 96% first-pass yield and an on-time 510(k) submission.
- Mentored four engineers and standardized verification templates, calibration practices, and statistical acceptance criteria across two product programs.

Biomedical Engineer II

Jul 2019 – Dec 2021

VitaSense Technologies

Waltham, MA

- Developed and verified a wearable cardiorespiratory monitor using ECG, PPG, and inertial sensors; improved motion-artifact rejection by 22% through signal characterization and algorithm tuning.
- Created test methods in MATLAB and LabVIEW, performed Gage R&R and correlation studies, and authored 40+ protocols and reports under ISO 13485 design controls.
- Investigated field and manufacturing failures using fault-tree analysis, 5 Whys, and DOE; corrective actions lowered sensor-related nonconformances by 31% in six months.
- Partnered with clinicians on formative usability studies and converted findings into ergonomic and interface changes that increased successful task completion from 82% to 97%.

Biomedical Engineering Co-op

Jan 2018 – Jun 2019

Northeastern University Center for Translational NeuroImaging

Boston, MA

- Built a synchronized EMG and force-sensing acquisition system for upper-limb rehabilitation research, reducing experimental setup time by 35% and improving signal repeatability.
- Designed SolidWorks enclosures and 3D-printed fixtures, validated sensor calibration, and maintained IRB-compliant test documentation for studies involving 60+ participants.

SELECTED ENGINEERING PROJECTS

Low-Cost Prosthetic Hand Controller

Embedded Systems, Signal Processing

Designed an eight-channel EMG acquisition board and real-time gesture classifier on an STM32 microcontroller; achieved 93% classification accuracy across six grasp patterns with sub-100 ms response time.

MRI-Compatible Respiratory Phantom

CAD, Instrumentation, Validation

Developed a programmable motion phantom for validating image-registration algorithms; characterized displacement accuracy to within ± 0.6 mm over clinically relevant breathing profiles.

EDUCATION

M.S. Biomedical Engineering, Northeastern University

2019

Concentration: Biomedical Devices and Bioinstrumentation; GPA: 3.86/4.00

Boston, MA

B.S. Biomedical Engineering, University of Connecticut

2017

Minor: Electrical Engineering; *magna cum laude*

Storrs, CT

TECHNICAL SKILLS

Medical-device development: Design controls, V&V, requirements traceability, design transfer, CAPA, DHF, usability engineering, ISO 13485, ISO 14971, IEC 60601, FDA 21 CFR 820

Engineering and analysis: Python, MATLAB, LabVIEW, Minitab, JMP, statistical analysis, DOE, Gage R&R, signal processing, test automation

Design and prototyping: SolidWorks, Altium Designer, GD&T, tolerance analysis, PCB bring-up, sensors, microcontrollers, 3D printing, machining