

[Full Name]

[City, State] | [email@example.com] | [Phone Number] | [LinkedIn URL] | [Portfolio/Website]

PROFESSIONAL SUMMARY

Results-driven **Biomedical Engineer** with [X]+ years of experience in designing, validating, and optimizing medical devices and diagnostic systems in regulated environments. Proven track record in **cross-functional collaboration**, requirements definition, and verification/validation aligned with FDA and ISO standards. Skilled in translating clinical needs into robust engineering solutions using **CAD modeling, data analysis, and systems engineering**. Adept at communicating complex technical concepts to clinicians, stakeholders, and non-technical audiences.

PROFESSIONAL EXPERIENCE

[Senior Biomedical Engineer] | [Medical Device Company Name]

[Month Year] – Present | [City, State]

- Led the design and development of [Class II implantable/diagnostic device] from concept through verification, using [SolidWorks/Creo/MATLAB] to reduce design iterations by [X]% while meeting [ISO 13485/IEC 60601] requirements.
- Authored and executed comprehensive **V&V protocols** (IQ/OQ/PQ, bench testing, biocompatibility assessments), achieving [X]% first-pass success rate and supporting on-time regulatory submissions to [FDA/CE].
- Collaborated with clinicians, quality, and manufacturing teams to perform **risk management (ISO 14971)**, FMEA, and design-for-manufacture reviews, reducing post-launch complaints by [X]% within [Y] months.

[Biomedical Engineer] | [Hospital/Research Institute/MedTech Startup]

[Month Year] – [Month Year] | [City, State]

- Developed and validated prototypes for [patient monitoring/rehabilitation/imaging] systems using [LabVIEW/MATLAB/Python] for signal acquisition, filtering, and data visualization, improving measurement accuracy by [X] percentage points.
- Performed **clinical workflow analysis** and usability studies with [N] clinicians and patients, translating feedback into design requirements and user interface improvements that reduced setup time by [X] minutes per procedure.
- Supported **regulatory documentation** by generating design history files, test reports, and traceability matrices, ensuring alignment with [21 CFR 820/ISO 13485] and internal quality system procedures.

EDUCATION

[Master of Science in Biomedical Engineering] | [University Name]

[Month Year] – [Month Year] | [City, State]

- Relevant coursework: [Medical Device Design], [Biomaterials], [Biomechanics], [Biomedical Signal Processing], [Regulatory Affairs].
- Thesis: "[Thesis Title Related to Biomedical Devices/Imaging/Signals]," focusing on [brief description of topic, methods, and outcome].

[Bachelor of Science in Biomedical Engineering] | [University Name]

[Month Year] – [Month Year] | [City, State]

- Senior design project: [Project Title] – designed and tested a [device/system] addressing [clinical problem], achieving [quantified performance metric] in bench/clinical simulations.

SKILLS

Technical: [Medical Device Design], [CAD (SolidWorks/Creo)], [Finite Element Analysis], [MATLAB], [LabVIEW], [Python/R], [Signal & Image Processing]

Regulatory & Quality: [ISO 13485], [ISO 14971], [21 CFR 820], [Design Controls], [Risk Management (FMEA)], [Verification & Validation], [GMP/GDP]

Laboratory & Clinical: [Biocompatibility Testing], [Mechanical & Fatigue Testing], [Sensor Integration], [Clinical Data Collection], [Protocol Development]

Soft Skills: [Cross-Functional Collaboration], [Technical Communication], [Problem Solving], [Project Coordination], [Stakeholder Engagement]

SELECTED PROJECTS

[Wearable Physiological Monitoring System] | [Academic/Industry Project]

[Month Year] – [Month Year]

- Designed a wearable device to monitor [ECG/SpO2/respiration] using [sensor type, microcontroller platform], implementing real-time data acquisition and wireless transmission to a mobile application.
- Developed algorithms in [MATLAB/Python] for signal filtering, feature extraction, and basic anomaly detection, achieving [X]% sensitivity and [Y]% specificity in pilot tests with [N] subjects.

[Rehabilitation Device / Assistive Technology Prototype] | [Capstone/Independent Project]

[Month Year] – [Month Year]

- Created a low-cost [exoskeleton/assistive device] for patients with [condition], integrating [actuators/sensors/microcontrollers] and designing mechanical components using [CAD tool].
- Conducted usability testing with [N] participants and iterated design based on comfort, range of motion, and safety feedback, improving user satisfaction scores by [X]% between prototype iterations.