

Luis Moreno

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SUMMARY

Principal R&D engineer with 12 years of medical device development experience across **electrophysiology catheters**, **electromagnetically navigated devices**, miniaturized components, **flexible electronics**, advanced materials, and manufacturing transfer. Leads complex programs from feasibility through prototype architecture, design validation, process development, regulatory documentation, commercialization readiness, and **early clinical use support**. Hands on work includes SolidWorks, AutoCAD, Minitab, fixture development, preclinical testing, risk assessment, process characterization, and validation protocol development. Partners with clinical, quality, regulatory, manufacturing, and external teams to resolve high risk technical issues and create traceable evidence. Communicates findings to senior leaders and project teams, mentors engineers, manages priorities, and balances technical decisions with project economics. This background supports disciplined delivery of safe, manufacturable catheter technologies from concept through early production.

EXPERIENCE

Principal R&D Engineer, Electrophysiology Catheter Development

January 2022 - Present

VelaPulse Medical

San Diego, California

Lead regulated catheter and electrophysiology programs from clinical need through prototype development, validation, transfer, and commercialization readiness. Provide technical direction, mentor engineers, and coordinate quality, regulatory, manufacturing, clinical, and external partners.

- Architected miniaturized catheter prototypes in **SolidWorks**, improving fixture readiness for **preclinical testing**.
- Translated clinical needs into flexible assemblies, resolving design risks through rapid iterative experiments.
- Applied **design controls** and **risk assessment**, preserving traceability across validation and commercialization decisions.
- Analyzed verification data in **Minitab**, guiding targeted responses to technical failures and process variation.
- Coordinated quality, regulatory, manufacturing, clinical, and external teams through transfer milestones and evidence reviews.
- Mentored junior engineers through design reviews, **technical reports**, priorities, and knowledge transfer.

Senior R&D Engineer, Catheter Technology Development

April 2019 - December 2021

CardioVector Innovations

Oceanside, California

Advanced regulated catheter technology through prototype architecture, **design validation**, **process development**, and manufacturing readiness. Served as a senior technical contributor while aligning engineering evidence with clinical objectives, resource limits, and regulatory expectations.

- Developed AutoCAD catheter fixtures for preclinical trials, shortening iteration cycles during prototype refinement.
- Evaluated **advanced catheter materials** and flexible electronics against performance and manufacturability requirements.
- Built **validation protocols** addressing safety, performance, manufacturability, and **regulatory readiness**.
- Characterized processes with Minitab, helping manufacturing partners isolate sources of inconsistent test results.
- Prepared technical reports, memoranda, and **design control records** for cross functional review.
- Presented findings and recommendations to senior management, regulatory partners, and project teams.

R&D Engineer II, Miniaturized Device Development

July 2016 - March 2019

AtriaFlex Devices

Irvine, California

Supported miniaturized catheter and flexible device programs from feasibility through verification, **process characterization**, and transfer preparation. Combined CAD development, structured experimentation, risk analysis, and collaborative **problem solving** across engineering and operations.

- Created **SolidWorks** component designs for miniaturized catheter assemblies, supporting repeatable prototype builds.
- Designed test fixtures for preclinical evaluation, connecting device requirements with practical measurement methods.
- Performed risk assessments that clarified failure modes and focused design verification activities.
- Investigated technical failures through controlled experiments, converting findings into actionable design updates.
- Supported **process development** and basic validation activities with manufacturing and quality stakeholders.
- Documented engineering decisions in reports, records, and review materials for transfer planning.

R&D Engineer, Electrophysiology Device Development

June 2014 - June 2016

NovaCath Research

Tustin, California

Contributed to electrophysiology catheter development through early prototypes, flexible component design, verification support, and technical documentation. Worked with senior engineers and cross functional partners to move promising concepts toward manufacturable solutions.

- Modeled catheter components in **SolidWorks**, supporting early feasibility builds and design discussions.
- Refined flexible assemblies for miniaturized devices through hands on prototype evaluation.
- Executed preclinical test preparation using fixtures, defined methods, and documented acceptance criteria.
- Reviewed process data in Minitab, helping engineers separate material variation from design effects.

- Supported design control updates and risk documentation during verification planning.
- Shared technical findings with quality, manufacturing, and regulatory partners during program reviews.

Associate R&D Engineer, Medical Device Prototyping

June 2012 - May 2014

SignalPath Biomedical

Costa Mesa, California

Supported early medical device prototyping, CAD updates, fixture preparation, test execution, and engineering documentation. Built foundational experience in catheter development, design controls, analytical problem solving, and collaborative product development.

- Updated **AutoCAD** layouts for catheter prototypes, improving clarity during engineering build reviews.
- Assisted with fixture assembly and preclinical test setup for early device concepts.
- Recorded test observations and organized evidence for design verification documentation.
- Supported **risk assessment** sessions by tracing potential failures to device requirements.
- Used structured experiments to investigate prototype issues and inform senior engineering decisions.
- Coordinated technical details with manufacturing and quality partners during prototype handoffs.

PROJECTS

Electromagnetic Catheter Navigation Platform 📅 2024

Led prototype architecture for a navigation enabled electrophysiology catheter, combining miniaturization, flexible electronics, advanced materials, fixture development, and preclinical test planning.

Catheter Manufacturing Transfer Readiness 📅 2021

Coordinated process characterization, risk review, validation evidence, and technical documentation supporting transfer of a regulated catheter platform into early production.

LEADERSHIP & AWARDS

- Principal technical contributor recognized for advancing electrophysiology catheter programs from prototype architecture through validation readiness.
- Technical Mentor, Southern California Biomedical Engineering Network, 2021 to Present, supporting practical growth among biomedical engineers.
- Trusted cross functional partner for clear technical communication across quality, regulatory, clinical, manufacturing, and engineering teams.

EDUCATION

Master of Science in Biomedical Engineering

2012

University of Southern California GPA: 4.0

Los Angeles, California

***Coursework:** Medical device development, biomaterials, biomechanics, design validation*

Bachelor of Science in Mechanical Engineering

2010

California State University, Long Beach GPA: 4.0

Long Beach, California

***Coursework:** Mechanical design, manufacturing processes, materials science, engineering analysis*

CERTIFICATIONS

- ASQ Certified Quality Engineer 📅 2018
- Master of Science in Biomedical Engineering 📅 2012

TECHNICAL SKILLS

- **CAD Design:** SolidWorks, AutoCAD, prototype modeling
- **Statistical Analysis:** Minitab, verification data, process variation
- **Catheter Technologies:** Electrophysiology, navigation devices, flexible electronics
- **Materials Engineering:** Advanced catheter materials, biomaterials, material evaluation
- **Design Controls:** Requirements analysis, traceability, design records
- **Validation Engineering:** Design validation, validation protocols, acceptance criteria
- **Process Development:** Process characterization, basic process validation, manufacturing readiness
- **Risk Management:** Risk assessment, failure analysis, design risk
- **Manufacturing Transfer:** Technology transfer, early production, DTV and DTQ
- **Testing Methods:** Preclinical testing, fixtures, verification methods
- **Regulatory Documentation:** Technical reports, memoranda, First In Human materials
- **Project Leadership:** Strategic projects, resource planning, milestone management

SKILLS

- Medical device R&D
- Electrophysiology
- Catheter development
- Design validation
- Process development
- Risk assessment
- Regulatory compliance
- Miniaturization
- Advanced manufacturing
- SolidWorks
- AutoCAD
- Minitab
- Project management
- Preclinical testing
- Technology transfer

PROFESSIONAL AFFILIATIONS

- Southern California Biomedical Engineering Network, Technical Mentor, 2021 to Present.
- Professional collaboration with medical device quality, regulatory, manufacturing, clinical, and engineering communities.

LANGUAGES

- English (Native)
- Spanish (Proficient)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST