Elena Rodriguez

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PROFESSIONAL SUMMARY

Senior Biomedical Engineer with over 10 years of experience in cardiovascular device design and regulatory submissions. Proven track record of leading R&D teams to successful FDA Class III approvals. Expert in 3D modeling, biocompatibility testing, and multidisciplinary project management aimed at improving patient outcomes.

WORK EXPERIENCE

Senior R&D Biomedical Engineer | Medtronic | Boston, MA
May 2018 - Present

- Spearheaded the design and development of a next generation implantable cardioverter defibrillator (ICD) resulting in a 15% increase in battery longevity.
- Directed a $2.5M research project focused on biocompatible coating applications for vascular stents.
- Managed a multidisciplinary team of 15 engineers and researchers to meet aggressive product launch timelines.
- Achieved FDA Class III approval for two flagship products by streamlining the clinical data documentation process.
- Reduced prototype production cycles by 30% through the implementation of high precision 3D printing workflows.

Biomedical Systems Engineer | Boston Scientific | Marlborough, MA
Jun 2014 - Apr 2018

- Optimized signal processing algorithms for neurostimulation devices, improving therapeutic efficacy for patients by 22%.
- Conducted comprehensive Finite Element Analysis (FEA) on structural components of endoscopic tools to ensure durability.
- Facilitated over 50 risk assessment workshops following ISO 14971 guidelines to identify and mitigate potential failure modes.
- Collaborated with global manufacturing sites to transfer design specifications, reducing waste by $400,000 annually.
- Authored technical white papers and patent applications for three unique medical device innovations.

Junior Biomedical Engineer | Johnson & Johnson | Raynham, MA
Sep 2011 - May 2014

- Assisted in the development of orthopedic joint replacement systems using CAD software for precise component modeling.
- Performed rigorous mechanical testing on biomaterials to verify compliance with industry safety standards.
- Documented experimental results for 10+ clinical feasibility studies used in regulatory filings.
- Maintained and calibrated laboratory equipment, ensuring 100% uptime for critical R&D operations.
- Supported Senior Engineers in the troubleshooting of post market device performance issues.

EDUCATION

Massachusetts Institute of Technology (MIT) | Master of Science | Biomedical Engineering
Sep 2009 - May 2011

Georgia Institute of Technology | Bachelor of Science | Biomedical Engineering
Aug 2005 - May 2009

SKILLS

AutoCAD & SolidWorks, MATLAB & Simulink, Python & C++, Finite Element Analysis (FEA), LabVIEW, Biocompatibility Testing, Medical Imaging (MRI/CT), Signal Processing, Materials Science, Biomechanics, FDA 510(k) Submissions, ISO 13485 Standards, Quality Management Systems (QMS), Clinical Trial Design, Risk Management (ISO 14971)

CERTIFICATIONS

Certified Biomedical Auditor (CBA) | American Society for Quality (ASQ) (2019)
Project Management Professional (PMP) | Project Management Institute (2016)

LANGUAGES

English (Native)
Spanish (Fluent (C2))

ACTIVITIES

Science Fair Mentor
Volunteering as a mentor for local high school students interested in STEM and medical technology careers.

Biomedical Engineering Society (BMES)
Active member and regular attendee of annual conferences to stay updated on emerging biomechanical research.