

ANIL SIVA KUMAR MEKALA

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SUMMARY

Certified SolidWorks Professional with 5+ years of experience in the medical device industry, experienced in taking products from concept through design verification, validation, and manufacturing. Skilled in DFM/DFA, FEA, tolerance analysis, and a range of materials and manufacturing processes. Well-versed in quality systems and regulatory compliance, including ISO 13485, FDA 21 CFR 820, and 510(k) submissions. Passionate about innovation and delivering advanced solutions to improve patient care. Adept at collaborating with surgeons, engineers, and cross-functional teams to translate clinical needs into practical, patient-centric designs.

EDUCATION

University Of Pittsburgh	Dec 2024
Masters in Biomedical engineering and Bioengineering - Medical product Engineering (MPE)	
MVGR College of Engineering	May 2017
Bachelors in Mechanical Engineering	

SKILLS

Technical: SolidWorks, Creo, Ansys, Autocad, GD&T (Geometric Dimension and Tolerance), DFM (design for manufacturability), DFA (design for assembly), and DFU (design for usability)
Prototype & Fabrication: : 3D Printing, Laser Cutting, Rapid Prototype
Programming: Arduino IDE, Python, MatLab
Quality Management: ISO13485, 21 CFR 820, DHF (Design History File), FMEA, Risk Management
Collaboration & Productivity Tools: Microsoft office Suite (Word, Excel, PowerPoint, Outlook), TeamGantt, Slack

EXPERIENCE

R&D Project Engineer	May 2024 – Present
Nvision Biomedical Technologies (SWBC Professional Employer Services I, LLC – PEO)	
<ul style="list-style-type: none">Design and development of orthopedic implants and instrumentation, supporting multiple concurrent R&D programs, including FEA simulation to evaluate performance.Translate clinical user needs and surgeon feedback into engineering design inputs, ensuring implants and instruments support physiological loading, fixation stability, and surgical usability.Develop and maintain Design History Files (DHF) in alignment with FDA QSR, ISO 13485, and biomedical device standards, supporting 510(k) and exempt regulatory pathways.Collaborated directly with surgeons, regulatory, and manufacturing partners to refine surgical techniques, support cadaver labs, and prepare systems for deployment.	
Lecturer (Adjunct) – Biomedical Engineering - BME 4923	Sep 2025 – Jan 2026
The University of Texas at San Antonio (UTSA)	
<ul style="list-style-type: none">Appointed as a non-tenure-track Lecturer to teach Orthopaedic Device Design, a senior-level, project-based course.Evaluated student teams on orthopedic device concepts, providing technical feedback and ensuring adherence to engineering and academic standards.	
Project Manager-Surgical Robotics (Volunteer)	Feb 2025 – Aug 2025
FutureTech Foundation	
<ul style="list-style-type: none">Spearheaded the design and development of a low-cost, 3D-printable surgical robot for training and research purposes; collaborated with engineering teams to prototype robotic arms and end-effectors using CAD tools and open-source components.Led project planning and coordination for a cross-disciplinary volunteer team, including roboticists, clinicians, and educators; established timelines, delegated tasks, and created documentation to align design, training content, and project goals.	
Design Engineer Intern	Sep 2024 – Dec 2024
Innovation and Design Engineering Acceleration (IDEA) Lab @University of Pittsburgh.	
<ul style="list-style-type: none">Designed and prototyped 3+ assistive and medical devices for university clients, applying DFMA principles to reduce part count by 20% and streamline fabrication.Conducted brainstorming sessions, patent research, and root cause analysis using Fishbone Diagrams and 5 Whys to guide concept development and problem-solvingDeveloped iterative prototypes based on user feedback, compiled Design History Files (DHF), and performed FMEA-based risk assessments to support safe, effective handoff.	
Senior Product Design Engineer	Apr 2021 – Jun 2023
Kmedika Solutions Pvt. Ltd.	

- Led multiple R&D projects with full ownership of project management activities, improving project completion efficiency by 20% through structured project planning and stakeholder coordination.
- Mentored junior engineers and managed task assignments, reducing delays by 15% and boosting design quality using DFMEA, tolerance analysis, and cross-functional feedback loops.
- Created DHFs, design protocols, and verification plans aligned with FDA guidelines; communicated project risks and milestones through regular reports to leadership for timely resolution and resource alignment.

Apr 2019 – Apr 2021

Product Design Engineer

Kmedika Solutions Pvt. Ltd.

- Designed and developed various implants and instruments systems and evaluated materials such as Nitinol, titanium, stainless steel, PEEK, and Radel PPSU, optimizing for mechanical performance, manufacturability, and biocompatibility in surgical applications.
- Conducted competitor analysis and market research to identify design gaps and emerging trends, leading to enhancements in implant systems that improved new product adoption by 18%.
- Performed tolerance stack-up analysis, FEA using ANSYS, and supported FDA submission by preparing detailed Design History Files (DHF) and risk documentation.
- Applied anatomical knowledge and manufacturing expertise (CNC, EDM, 3D printing, injection molding) to optimize design-for-manufacturability (DFMA) and ensure clinical readiness.
- Conducted IP and patent searches to ensure design novelty and compliance, and created 3D models and 2D drawings in SolidWorks following ASME Y14.5-2009 GD&T standards for accurate documentation.

PROJECTS

Ankle Fracture and Fusion | Client: Kognitus LLC, Medline Unite

- Designed and developed low-profile plate implants for Ankle fractures. Designed a Plate Inserter that works with all the plates in this system.
- Guided and Designed Ankle Fusion System Consisting of Fusion plates, screws, and respective instruments.
- Designed a Targeting guide for Short talar and Anterior TT plates that precisely places a tibiotalar crossing screw.

Mid Foot Fracture | Client: Kognitus LLC, Johnson & Johnson

- Designed the TriLeap lower extremity anatomic plating system, incorporating a low-profile design promoting easier surgery access.
- Designed locking and non-locking screws for micro, mini, and small plates to ensure secure fixation across various anatomical structures.

Bicortical Fixation | Client: Kognitus LLC, Vilex

- Designed and developed a toggle screw for bicortical fixation, which improves pullout strength and enhances fracture compression.
- Compare the implant with a partially cannulated cancellous screw and perform a 4-point bending analysis using ANSYS to optimize the design for better performance.

Nitinol Staple | Client: Kognitus LLC, Medline Unite

- Designed and developed Staple bone implants, implant insertion mechanism, and instrumentation for Akin procedures for foot bone fusion operations with a minimal amount of surgeon effort.
- Perform a 4-point bending finite element analysis using ANSYS concerning ASTM Testing standards on the implant to determine the worst case and compare it with existing staples in the market. DHF was created for FDA.

Optimotion Blue Implants | Client: Kognitus LLC, Optimotion Implants

- Worked with other engineers on creating knee replacement implants for osteoarthritis.
- Created drawings for instruments and Performed Tolerance Stack analysis to identify the worst-case assembly and functionality.

VOLUNTEER EXPERIENCE

Pennsylvania Robotics and Technology Fellowship | NeuEsse Inc.

Jan 2024 – Mar 2024

- As part of a four-person team, I collaborated on developing a product roadmap and delivering optimal recommendations for enhancing shelf stability through chemical and biomechanical methods for a local biotech startup.

X-Projects | Medical Wire Torque Device

Jan 2024 – Dec 2024

- At the UPitt, collaborated on a project to design and test a wire torque device with two UPMC cardiologists for percutaneous vascular interventions. My role involves literature reviews and IP analysis to ensure product uniqueness. I contributed to human-centered design activities, prototype iterations, and testing phases, working closely with clinicians to bring this invention to life. This experience strengthened my skills in medical device development and interdisciplinary teamwork - Patent Pending.

CERTIFICATIONS

SolidWorks Professional – Mechanical Design (Credential ID: C-J4TKX6CYFN)

SolidWorks Associate – Additive Manufacturing (Credential ID: C-8T8KCHZYS6)

SolidWorks Professional – Advanced Weldments (Credential ID: C-WM49XKTL52)

SolidWorks Professional – Advanced Drawing Tools (Credential ID: C-YVKS8XRH69)

Creo 2.0 – (Credential ID: PTC202-0419)

Human Center Design – Luma Institute

Product Development and Management Association - PDMA Certification