DWARAKESH RAMESH

Location: Chennai, India | **Ph:** +91-8946086865 **Email:** dwarakesh68@gmail.com

---

EXECUTIVE SUMMARY

Lead Mechanical Engineer with 8+ years of global R&D experience (Canada & India), specializing in product development for regulated industries (Medical Devices & Automotive). Expertise in bridging North American engineering standards (FDA, ISO 13485) with cost-effective manufacturing solutions. Proven track record of leading cross-functional teams, managing full product lifecycles from concept to verification, and securing multiple patents for organ preservation devices. Returning to India with a focus on bringing global best practices in DFM, Value Engineering, and Compliance to world-class engineering teams.

CORE COMPETENCIES

- **Product Development**: New Product Introduction (NPI), Full Lifecycle Management, Rapid Prototyping, DFMEA/PFMEA.
- **Regulatory & Standards**: FDA 21 CFR, ISO 13485 (Medical), GD&T (ASME Y14.5), cGMP.
- **Engineering Software**: SolidWorks, ANSYS (FEA), AutoCAD, Inventor, Catia, Fusion 360, PDM.
- **Process Improvement**: Lean Manufacturing, 5S, Six Sigma Tools, Root Cause Analysis (RCA), CAPA.
- **Leadership**: Cross-functional Team Leadership, Vendor Management, Design Reviews, Mentoring.

PROFESSIONAL EXPERIENCE

TRAFEROX TECHNOLOGIES INC. | Mississauga, Ontario, Canada

Lead Mechanical Design Engineer | March 2021 – June 2025

- **R&D Leadership**: Led a team of 6 engineers through conceptual design, mechanical validation, and verification for Class II medical devices.
- **Clinical Translation**: Collaborated directly with surgeons at the UHN (University Health Network) to translate complex clinical needs into life-saving hardware for organ perfusion and transportation systems.
- **Regulatory Compliance**: Managed full Design History File (DHF) documentation, verification protocols, and risk control activities aligned with FDA and ISO 13485 requirements.

- **Cost & Design Optimization**: Implemented cost-saving initiatives and value engineering through alternative mechanism design and component simplification.
- **Advanced Analysis**: Resolved medium-complexity technical issues utilizing ANSYS (FEA) for structural integrity and CAD-based analysis.
- **Process Innovation**: Drove improvements in PLM systems and served as PDM administrator to ensure efficient engineering data management.

STRONCO | Mississauga, Ontario, Canada

Mechanical Designer | **March 2018 – Feb 2021**

- **Design for Manufacturing (DFM)**: Created comprehensive 3D models, 2D drawings, and complete Bill of Materials (BOM) for mechanical components using AutoCAD and Inventor.
- **Supply Chain Management**: Leveraged procurement expertise to source reliable vendors and identify optimal materials, ensuring timely acquisition of critical components.
- **Production Support**: Collaborated with manufacturing personnel to devise efficient assembly procedures and troubleshoot "fit, form, and function" issues on the shop floor.

ROYAL ENFIELD MOTORS PVT LTD | Chennai, India

Mechanical Design Engineer | **June 2014 – Aug 2015**

- **Component Design**: Managed the design process for engine components, tools, and subassemblies, documenting results including GD&T and prototyping.
- **Prototype Testing**: Procured and tested prototype parts and assemblies, ensuring "do-it-right-the-first-time" quality standards.
- **Efficiency Improvement**: Assisted in developing new assemblies that accelerated production line speed by up to 25%.

EDUCATION

- **Master of Engineering (Mechanical)** | University of Windsor, ON, Canada | **2015 - 2017**
- **Bachelor of Engineering (Automobile)** | SVCE, Anna University, Chennai, India | **2010 - 2014**

PATENTS & KEY ACHIEVEMENTS

- **Patents**: Hold multiple patents with FDA and Health Canada for Organ perfusion and Organ transportation devices used clinically around the globe.
- **Lean Implementation**: Led the implementation of lean methodologies at a Canadian Tire store and warehouse in Windsor, ON (Sep 2015 – Dec 2015).
- **SAE BAJA**: Lead Design Engineering Intern; managed the design and build of small off-road cars for intercollegiate competition (July 2013 – Mar 2014).