

VINIT TALELE

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Mechanical Engineer with experience in machine design using CAD and process validations.

AREAS OF EXPERTISE

- Installation/Equipment Qualification (IQ/EQ)
- Operational Qualification (OQ), Performance Qualification (PQ)
- Design of Experiments (DOE)
- MS Office
- Minitab
- Product Design
- Certified SolidWorks Professional
- 3D, 2D CAD
- Bill of Materials (BOM)
- Geometric Dimensioning and Tolerancing (GD&T)
- ANSYS
- MATLAB
- Finite Element Analysis (FEA)

PROFESSIONAL EXPERIENCE

Self Employed (Family Business), Pune, India

Mechanical Engineer

April 2019-Present

- Conceptualize the **product design** of various Ayurvedic personal healthcare products.
- R&D of products through **prototypes**, trials and **testing**.
- Design product and required components using SolidWorks for 3D, 2D, **plastic mold design** etc.
- **Manufacture and source** components and parts from multiple vendors.
- Design, manufacture or solder electronic and electrical components required for the machinery.
- **Assemble** complete product and perform **quality check** under stress and long durations.
- Survey potential customers and identify effective marketing strategies.

Zimmer Biomet, Warsaw, IN, USA

Process Validation Engineer

March 2017 – January 2019

- Ensured compliance with **FDA 21 CFR 820** and **ISO 13485** through Validation, Verification & Remediation.
- Wrote and performed validations **IQ, OQ, PQ** for sterile packaging heat sealers, used for Class II and Class III medical devices.
- Validated and designed tools for heat sealers and vacuum heat sealers.
- Executed **DOE** to establish parameters for new processes.
- Used **Minitab** for normality, **capability study** and DOE surface response analysis.
- Reviewed sealer tool designs/layouts with tolerance analysis.
- Reviewed CAD drawings and models for new/existing packages, performed **feasibility studies** and first article layouts.
- Created, searched and investigated equipment maintenance work orders in **SAP** system.
- Co-ordinated with cross functional teams for **Electronic Change Notifications** (ECN) and releasing validations for production.
- Designed any parts required for validation such as poly simulants using CAD software and maintained database in **PLM software**.
- Supported CAPA personnel with any required data and perform **root cause analysis**.
- **Managed** individual projects by **leading a team** of one to two juniors.
- **Financial Award**

Managed and executed the project to re-validate an FDA Class III device package after a downtime of more than two months due to monitoring failures. Since the products in this package were extremely high demand and critical products for knee implants, this was highly escalated. Project was completed well before target deadline.

University of Texas at Arlington, Arlington, TX, USA

Graduate Teaching Assistant (Part-time semester contract)

February 2016 – May 2016

- Assisted professor with **Computer Aided Engineering** (CAE) course for senior year undergraduate students.
- Assisted with grading homework, classroom activities and exams.
- Managed online student class database including class homework scores, attendance and projects.
- Conducted office hours to help guide students through the course.
- Helped students with final class projects.
- Taught lectures on **Finite Element Analysis** using **ANSYS** software.

Mechatronic Technologies, Pune, India

Mechanical Design Engineer (Part-time)

October 2013 – March 2014

- Created 3D CAD models for parts using **SolidWorks** of complex machines utilizing electrical, pneumatic and PLC components.
- Drafted 2D drawings with **GD&T**, owned and maintained a database of all drawings.
- Suggested improvements where necessary.
- Supervised over **assembly** and ensured proper working of the machines.

Aquatret Pipe Lining (Family Business), Pune, India

Mechanical Engineer (Part-time)

January 2009 – January 2014

- Converted paper drawings to CAD drawings and organized them based on the size of the cement mortar lining machines.
- Aided in the design and created **3D CAD** models using **Creo** for new parts.
- Identified machine parts and created **Bill of Materials (BOM)**.
- Overlooked the assembly and testing of machinery by sampling small pipe portions.
- Assisted with inspection of pipelining sites for pipe condition and resource availability.

NPT & Co., Pune, India

Mechanical Design Engineer Intern (Part-time)

July 2012 – September 2013

- Designed concepts for machines or parts per client requirement with the help of supervisor.
- Created 3D CAD models for parts using **SolidWorks/Creo** of all parts including **sheet metal, fixtures, dies**, etc.
- Drafted 2D drawings with **GD&T** of all individual parts and exploded view of assembly with Bill of Materials.
- Checked all parts after manufacturing and aided in assembly as well as testing of machines.
- Created **simulations** of moving parts in SolidWorks and presented concepts to clients.

EDUCATION

Master of Engineering - Mechanical Engineering

August 2014 – May 2016

The University of Texas at Arlington
Arlington, TX, USA

Bachelor of Engineering - Mechanical Engineering

July 2007 – November 2012

University of Pune
Pune, India

CERTIFICATIONS

- **Six Sigma Green Belt Certified** January 2017
Management and Strategy Institute
- **Certified SolidWorks Professional (CSWP)** September 2016
Dassault Systèmes
- **Certified SolidWorks Professional Advanced – Sheet Metal (CSWPA-SM)** September 2016
Dassault Systèmes
- **Certified SolidWorks Professional Advanced – Drawing Tools (CSWPA-DT)** September 2016
Dassault Systèmes

AFFILIATIONS

- **American Society of Mechanical Engineers (ASME)** October 2016 to Present
Professional Membership