

ROHITH ADDAGATLA

MECHANICAL DESIGN ENGINEER

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Present role :

Senior Design Engineer | Research & Development | Sensa Core Medical Instrumentation Pvt. Ltd. |

Software Skills:

• Creo	• ISO 13485:2016 Medical Devices Quality Management
• Solid works	• Medical Devices Rules – 2017
• AutoCAD	• Device History Files and Design Dossiers
• Ms office	• 21 CFR (Code of federal regulations)

Academics:

Bachelor of Technology

in Mechanical (2018) : 67 %

College: St. Mary's Engineering college science & technology, Hyderabad.

Diploma in Mechanical (2015) : 66%

College: TRR Polytechnic college, Hyderabad.

Personal Details

Date of birth : 25 August 1994

Languages Known : English, Hindi and Telugu,

Marital Status : Unmarried

Present location : Hyderabad

Professional Summary

Extremely reliable on Product designing, design controls and regulatory affairs with handful of experience on Medical Devices manufacturing (in-vitro Diagnostics). As an Innovative Mechanical Designer driven to bring customized design concepts to life in order to guarantee complete customer satisfaction. As a multi-tasking handling and maintained Design documentation in stage wise. Able to perform Learning by Doing in every task and correlate multiple work tasks simultaneously to achieve optimum results. `

Organisation: Sensa Core Medical Instrumentation Pvt Ltd.

Duration: February 2018 - Present

Work Experience:

Roles & Responsibilities:

- 3D modelling (Plastics & sheet metal) & 2D drafting in Creo, Solidworks and AutoCAD software
- Preparation of Bill of material
- Jigs & fixtures designing to mitigate time consumption
- Responsible to maintained the Design Controls documents, Risk Management File and DHF for Blood Gas Analyzers, Electrolyte Analyzers and Blood Glucose Measuring System manufactured by Sensa Core Medical Instrumentation Pvt. Ltd
- Preparing and submitting the product transfer documents from R&D to Technology Transfer team.
- Review of document required for **Regulatory Bodies (Process Validation reports & protocols, Stability data** and coordination with other departments like Validation, QA, QC and Engineering and Project Management for various regulatory documents requires for dossier submissions.
- Experience with filing **CE, CDSCO and DCA** files submissions and technical files for In-Vitro Medical Devices.

Project: Arterial blood gas analyser (ABGEM).

- Responsible to maintain design & document files from initial stage to end of the project
- Designed various mechanical plastic & metal components modules for ABGEM analyzers such as ISE-Electrode, Flip mechanism, Pinch valve flow system, Tab enclosures in **Creo, Solid works & AutoCAD software's**.
- Provided detail mechanical General Assembly design and individual part design for each module including Tolerances. For instance, converting 3D modelling into 2D drawing to manufacture the product.
- As per the requirement initiated new proposal designs for the clients with aesthetical looks. Moreover, designed multiple parts to meet functional requirement with the consideration of Die feasibility.
- Prepared **mechanical Bill of Materials (BOMs)** which fits in the product to support manufacturing, testing and assembly, and support components to assist with assembly
- Responsible for product designs for manufacture ability, cost and quality. (e.g.molding, turning, machining,)
- Manage all stages of the mechanical design process for electronic medical devices.
- Investigate production problems related to parts design, fit, function and/or process design. Recommend counter measures and improvements.

Project: Blood Glucose Meter:

- Initiated number of proposal designs with the respective of user needs and reporting to customer for the approval of any modifications and revisions in design like **Dr.Trust , Control D and Nureca** .
- Designed & developed numerous models of portable type Glucometer for handy use and compatible for measuring.
- Chosen different types of plastic material as per the consideration of application and plastics materials shrinkage tolerances.
- Collaborated with R&D electronics team to develop the PCB design according to
- Meters were designed as per **the ISO 14385 to meet the Medical regulatory standards**.
- Conducting internal meetings weekly to know the status of the projects with production team, material management team and the quality team.

Project: Hemaglobin Meter:

- Designed Hemaglobin meter that suitable for Reflectance photometry principle which measures results with the source of light.
- Meter had been designed with snap lock for easy to assemble and for production productivity.
- Chosen multiple types of plastic material Such as ABS, Acrylic, Nylon.
- Disposable Strip design (POCT) has made for measuring Hemaglobin in human body.
- Initiated automation process for hemaglobin strip manufacturing right from raw material to finished goods.
- Collaborated with manufacturing team to create liquid dispensing, row cutting and Individual strip cutting.

Hematology analyzer

- Sheet metal chassis has been designed to mount the various module such as (**Vacuum chamber, Horizontal & vertical Slider, and Sample syringe module, Pinch valve, Hemoglobin Flow cell chambers**).
- Providing sheet metal bending drawings and Laser cut drawing to vendor.
- Developed with assist of various mechanisms and Accomplished the Hematology product with high precision in the medical results.
- Maintained **version control for every design change**, also maintained **Standard operating procedure** (SOP'S) to assembly the individual parts.
- Acquired wide range of knowledge in terms of mechanism development and designing complex parts with draft angles for Mold releasing purpose.
- Discussion with vendors while manufacturing and segregating weekly report of development stage to accomplish product within the timeline.
- Provided necessary fixing parts & jigs arrangements for electronic components, such as Mother board, Temperature sensors, grounding connections.
- Responsible for preparing mechanical Bill of material as per the Assembly and General assembly drawing.

DECLARATION:

I hereby declare that particulars given above are true to the best of my knowledge.

Place: Hyderabad

Date:

(Rohith Addagatla)