

ROHITH SHAIK

Product Development Engineer

(B.Tech - Mechanical Engineering)

Address: 4-86, Leguntapadu (v),
Kovur (m), Nellore (district),
Andhra Pradesh – 524137

Phone : +918897971158

Email : rohith.3.786@gmail.com

CORE COMPETENCIES

- 21 CFR Part 803, 820 and ISO 13485: 2016
- Risk management ISO 14971
- Packaging and labelling ISO 15223
- 2D Drafting as per ASME 14.5Y 2009.
- California prop 65 and REACH (EC 1907/2006)
- 3D modelling, Assembly in Solid Works
- Product life cycle management SAP ECC 6.0
- Production planning and control (DV, DV Protocol, Test report and DTM)

SOFTWARE SKILLS

- Solid works 2016
- SAP 6.0 (Everest)
- Minitab 2018
- Microsoft Office
- CATIA V5
- Creo and Auto Cad

PROFESSIONAL SUMMARY (5 YEARS OF EXPERIENCE)

- A creative professional with zeal to make a winning career in Engineering.
- Possess a flair for working hard and contributing towards achievement of organizational goals.
- Ability to evaluate and interpret unique problems with a combinations of training experience and logical thinking to find the right solutions.
- An effective communicator with strong analytical, logical thinking and problem solving abilities.

WORK EXPERIENCE

September 2019 – Present

- Member of Technical Staff – Product Development (Medical Device)
- HCL TECHNOLOGIES LIMITED, Chennai
- Client – Becton Dickinson and Company

January 2017 – July 2019

- Junior Design Engineer – Product Development (Automobile)
- BCARD SOLUTIONS INDIA PVT. LIMITED, Hyderabad
- Client – OEM service based Company

RESPONSIBILITIES

- Requirements / response gathering from cross functional team for the project.
- Redline the packaging documents as per the requirements and coordinating with cross functions to freeze the inputs.
- Developing ECR/O strategy and creating / updating graphics as per project requirements and standards.
- Create Technical documents (Design verification plans, Protocols, Reports) to conduct design verification studies.
- Performing content reviewer on technical documents (Design verification documents, Technical memo and Rationales).
- Maintaining Design History Files (DHF) and records for traceability purpose.
- Designing and creating 3D solid works models for the graphic general specification, components, sub-assemblies and final assembly of the desired product or test fixtures.
- Creating detailed design documents (2D drawing) for the part and assemblies.

EDUCATION

B.Tech, Mechanical: 2011-2015

SANA Engineering College, (Affiliated to JNTU-Hyderabad), Kodad, Telangana with an aggregate of 77.8%

Higher Secondary: 2009-2011

Sri Bharathi Junior College, Nellore with an aggregate percentage of 91.1%

PROFESSIONAL SKILLS

- Good team worker
- Quick learner
- Good communication skills

LANGUAGES KNOWN

- English
- Telugu
- Hindi
- Tamil
- Urdu

DATE OF BIRTH

10 July 1994

NATIONALITY

Indian

MARITAL STATUS

Married

- Creating / updating design control documents and supporting documents owned by R&D.
- Performing Tolerance and stack up analysis for the drawings.
- Supporting the change release management (Engineering change order or Engineering change master preparation for document release / product change / new release / obsolete).
- Creating / updating TSR and ACR to close the design changes via ECROs or ECMs.
- Sound knowledge on ISO 13485 (ISI standards for Medical Device), FDA regulation 21CFR Part 803, 820 and ISO 17025.
- Preparing the statement letters and declarations in order to support Stewardship team activities.
- Sound knowledge on California prop 65 and REACH (EC 1907/2006) and other chemical hazardous regulations.
- As Defect Preventive Analyst (DPA) for the team, creating CAPA (Corrective Action and Preventive Action) for the defects happened on the documents / drawings.
- Experience in using CATIA V5 part design, shape design, sheet metal design, assembly and drafting.
- Knowledge on design table, GD&T application and preparing presentations for client review.
- Studying the inputs, modeling and detailing the components as per the standards of the client.
- Strong ability to create/ read/ interpret engineering drawings.

ACCOMPLISHMENTS

- Successfully completed the value creation for the Technical specification release in SAP which is enabling the saving of 81K USD per year.
- Being received 5/5 in all parameters like Quality, Oversight, Project management and Timeliness from client in all quarters from the day joined. Owning the achievement of most 5/5 in one quarter from client.
- Received appreciations from client and Team leads for the dedication and hard work towards the responsibilities.

DECLARATION

I hereby declare that all details furnished above are true to the best of my knowledge.

Rohith Shaik