**Current location:** Bangalore

**Phone:** +917259902717

**Mail ID:** shridevimdmbr@gmail.com

**Experience Summary**

* I have overall experience of 4 years 11 months in which 1 year of experience in CAE automotive, 3 years 11 months of experience in Medical domain.
* Good leadership quality, good communication skills, quick learning ability, adaptability to change, hardworking, good team player, committed to honesty and responsibility.

**Professional Summary**

* Working with **HCL** as **Member technical staff** from AUGUST 2019 to JULY 2023.
* Worked as a **CAE Engineer** with **NOVA GLOBAL TECHNOSOFT Pvt. Ltd.,** since NOVEMBER 2016 to NOVEMBER 2017.

**Significant Projects:**  **2019 - 2023**

**Company: HCL technologies**

**Project Title:** RAD Support

**Client:** Johnson and Johnson

**Environment:** MDRIM & RAD (Regulatory Approval Database)

**Designation:** Member Technical Staff

**Project Description:** The main purpose of the RAD is torelease product codes across the globe. Maintaining database for regulatory approvals for all the products affiliated with Depuy, Synthes, & Ethicon BU’s of Johnson and Johnson.

**Roles:** Support on completion of back orders & new license by verifying the license details for the existing products and its variant codes and complaint handling.

**Responsibilities:**

* Releasing product codes across the globe. Maintaining database for regulatory approvals for all the products affiliated with Depuy, Synthes, & Ethicon BU’s of JnJ.
* Collecting licenses for medical products from country RA’s across the globe through Email and MDRiM.
* RAD RA Team will review country requirements and request the local country RA Management to confirm the appropriate Country Level assignment and country regulation requirements.
* Investigating the licenses received from country Regulatory Affairs associate and performing processing based on respective country regulations.
* Validating licenses processed by the investigator and lifting the restrictions created by RAD environment in the ERP’s.
* Releasing licenses for required variants conforming to respective country’s required regulations.
* RAD RA Team will review country requirements and request the local country RA Management to confirm the appropriate Country Level assignment and country regulation requirements.
* Review Country requirements, including but not limited to, Legal and Physical Manufacturers, and Made in information.
* Reaching out to country RA’s for issues in the licenses and maintaining country level changes.
* If there is a stop shipment notification sent to the RAD RA team via the RAD inbox, this will be treated as an urgency to resolve the block in the system.
* Maintaining the regulatory data as new information becomes available from the country affiliates.
* Compliant handling will be done whenever the assigned licenses come up with some complaints like product licenses are wrongly released with wrong variants, will release for required variants conforming to respective country’s required regulations.
* Receiving and recording complaint and feedback information ensuring all complaints are documented upon receipt, this including oral complaints.
* Evaluating information to determine if the feedback constitutes a complaint.
* Complaints are evaluated to determine whether they represent an event that must be reported to the applicable regulatory bodies such as FDA under Medical Device Reporting (MDR).
* Complaints are reviewed and evaluated to determine whether an investigation is necessary handling of complaint-related product.
* Determining the need to initiate corrections or corrective actions.

**Significant Projects: 2016-2017**

**Company: NOVA GLOBAL TECHNOSOFT Pvt. Ltd**

**Project Title:** FE Modelling work for BIW components.

**Designation:** CAE Engineer

**Description and Role:**

* As a team member involved in surface oriented meshing of BIW assemblies like underbody and upper body as per client requirements.
* Checking of CAD geometry and fixing the errors like cracks, free edges and duplicate geometry.
* Meshing the mid-surface with respect to guidelines parameters.
* Checking the flow, quality and criteria of the mesh.
* Assigning thickness and material properties.
* Review and finalize the mesh with all quality checks.

**Educational Qualification**

* **Master of technology, Production Engineering and Systems Technology 2015**

U.B.D.T College of engineering, Davanagere, 72.6%

* **Bachelor of Engineering, Industrial and Production Engineering 2013**

U.B.D.T College of engineering, Davanagere, 66.4%.

* **Diploma in Mechanical Engineering 2009**

D.R.R Government Polytechnic, Davangere, 61%

**Skills:**

**Software Skills:** MS office, Microsoft works, PowerPoint, Microsoft Excel, Outlook

**Preprocessor:** HYPERMESH

**CAD Tools:** Creo, NX CAD, AutoCAD

**Regulatory skills:** ISO 13485, ISO 14971, trackwise tool, good manufacturing practice, CAPA, complaint handling, EUMDR requirement, post market surveillance (PMS), Regulatory documentation.

**Contact Details:**

**Address:** Beside Shri Kalikamba wood industries

Dr. Rajkumar Extension, S.H. Road, Malebennuru-577530,

Harihara (Tq), Davanagere (DT), Karnataka.

**Marital status:** Single

**Language:** English, Hindi, & Kannada

**Hobbies:** Travelling, Reading