

CAREER OBJECTIVE

Looking for a challenging career as an engineer in environment embedded with growth avenues, ability to learn and work with current trends.

PROFESSIONAL SUMMARY

- Hands on experience in ISO 80369 QMS documentation, verification and validation
- Hands on experience in ISO 80369 compliance testing & documentation.
- Hands on experience in documenting test results, verification and review as per ISO standards
- Design History File – improvising to current standards, Change management
- Measurement System Analysis (MSA) for test methods and protocol revision
- Quality control/ Assurance- Final Test verification, product approval documentation, CAPA creation and closing and ISO 14971
- Product design and development support & Engineering Change Management.
- Good knowledge in product development and compliance testing of medical products.

EXPERIENCE SUMMARY

Company Name	Designation	Duration
HCL Technologies, Coimbatore	Mechanical Engineer	Aug-2022 to till date

TOOLS PROFICIENCY:

Technical Tools: PTC Creo & Solid works.

ERP Tools: Master control, Team Center, PM smart, MS office.

SKILLS & ROLES

- Good knowledge in ISO 13485 process validation (IQ/OQ/PQ)
- Verification and validation- compliance testing of newly developed products as per ISO regulations.
- Validation of test protocols and creating documents for customer submission.
- Sustenance Engineering and EU MDR support for regulatory affairs.
- Test method Validation of medical products as per ISO 80369-7, ISO 80369-20
- Products design and documentation as per standards
- DHF (Design History File) documentation and change modifications
- ECO, ECN Change management in PLM.
- Monitoring the process flow for the project and completing before deadline.

PROFESSIONAL EXPERIENCE:

Key Projects Overseen		
Employer Name/ Role	Projects	Responsibilities
HCLTech, Chennai / Mechanical Engineer.	Becton and Dickinson- BD Peripheral Vascular intervention and diagnostics equipment parts	<ul style="list-style-type: none">• Verification & Validation of medical products and test reports creation• Verifying test data and documentation as per ISO 80369• Creating work flow for the testing team and managing daily activities• ISO 14971, CAPA creation and closing• DHF(Design History File) – Change management• Testing intravascular devices and diabetics care devices as per ISO 80369-7 for insulin pen, swabs.• MSA process validation of medical devices by implementing IQ/OQ/PQ for equipment.• Collaborated across all departments and levels of management to gain consensus on documentation.• Test Protocol as per ISO guidelines and leading the team for tasks completion.• Preparing Fixture Inspection report for the verified products and submitting to customer.

CERTIFICATIONS & ACHIEVEMENTS:

- **SolidWorks** for beginners in Udemy.
- Heating Ventilation and Air Conditioning (HVAC) from L&T EdTech
- Awarded for on-time delivery of engineering reports by HCLTech.

EDUCATIONAL QUALIFICATION:

Course	Institute/ University	Percentage / CGPA	Year of passing
B.E Mechanical Engineering	KPR Institute of Engg. & Technology, Coimbatore	84	2022
HSC	Amrita Vidyalayam Mat. Hr. Sec. School, Tirupur	90	2018

Regards,
Chandru G.