**DESIGN ENGINEER (DE)**

***Trice Medical was founded to fundamentally improve orthopedic diagnostics for the patient, physician, and payer by providing instant, eyes-on, answers. Trice has pioneered fully integrated camera-enabled needle technologies that provide a clinical solution that is optimized for the physician’s office. Trice’s mission is to provide more immediate and definitive patient care, eliminating the false reads associated with current indirect modalities and significantly reduce the overall cost to the healthcare system. For more information, please visit www.TriceMedical.com.***

The Design Engineer (DE) is responsible for leading efforts to create medical devices and their accessories through Feasibility & Planning, Design & Development, Verification & Validation and Transfer to Manufacturing. This position will work closely with other engineering team members, marketing, sales and physicians. Duties and responsibilities include, but are not limited to:

* Lead product development efforts (project specific) through all phases of design (e.g. feasibility through transfer to manufacturing).
* Create and manage solid models, assemblies and drawings using SolidWorks and SolidWorks Vault.
* Manage and report on project timeline/completion of tasks to ensure timely completion as projected.
* Establish and implement validation requirements for products, test methods and manufacturing processes
* Write design and process validation protocols and reports.
* Write Hazard/Risk Analysis (per ISO14971) and FMEAs (Design and Use)
* Create Item Masters and Bills of Materials. Support their entry into Sage ERP system
* Lead project document control efforts in the entering of documents into the Visual Vault and maintaining solid models not resident in the Visual Vault (e.g. SolidWorks Vault).
* Create and maintain FDA compliant Design History Files (DHF).
* Support and lead manufacturing process improvements as well sustaining engineering activities
* Cross-functional project teams including R&D, Quality Assurance, Supplier Quality, Planning, Purchasing, Regulatory, and Manufacturing

***Job Requirements***

* + 4-6 years’ experience in design and development of complex, single-use, sterile medical devices.
	+ Must have a minimum B.S. Biomedical or Mechanical Engineering Degree
	+ Strong proficiency with developing complex devices in SolidWorks
	+ Ability to convert drawings and solid models from PTC Creo to SolidWorks
	+ Ability to use hand tools to create prototype/proof of concept devices
	+ High degree of initiative and self-motivation with a strong sense of accountability
	+ Ability to work effectively in a team environment and build strong working relationships
	+ Ability to effectively problem-solve through critical thinking and root-cause analysis with minimal direction and make decisions with confidence
	+ Excellent organizational skills and attention to detail
	+ Strong communication skills, both oral and written
	+ Ability to prioritize, multi-task and adapt to change
	+ Working knowledge of quality systems regulations i.e., FDA QSR, ISO 13485, is required
	+ Candidates who have prior experience with manufacturing processes (e.g. CNC machining, injection molding, rapid prototyping) will be given higher considerations.
	+ Candidates who have prior experience with electro-optical medical devices and working in a fast-paced start-up medical device company will be given higher considerations.
	+ This position requires up to 15% travel.