

## System Engineer

### JOB DESCRIPTION

He/she is responsible for the Design and the definition of IVD Medical Devices architecture including complex electro-mechanical instruments for biological applications.

### DUTIES AND RESPONSIBILITIES

- Define the layout and the architecture of electro-mechanical systems for biological applications (system sub-assembly definition, identify the core technical specifications for each sub-assembly, evaluate the risks related to each technical solution, provide to the design team the technical specs)
- Support the design of automatic machines (integrating precision moving parts, thermal management, fluid handling, pneumatics, optical and electronic subsystems)
- Support the design of microsystems assembly (integrating microfluidic structures, circuits, sensors, plastic cartridges)
- Support the fabrication of prototypes, the debugging and the verification & validation phases, the design of endurance tests
- 2D & 3D CAD design and simulations (structural, fluidics, thermal)
- Prepare and revise design layouts, diagrams, bills of material, drawings/schematics and manufacturing documents of components and assemblies in compliance with the prescribed standards
- Support the product certifications process (UL, CE, IVD)
- Support the execution of Failure Mode and Effects Analysis (FMEA), Criticality Analysis (FMECA) and Risk Analysis
- Support the transfer to manufacture and provide technical assistance for prototype and pilot production

### BASIC QUALIFICATIONS

- Degree in engineering
- Strong technical background in electro-mechanical system design and in manufacturing process of mechanical and electronic parts or sub-assembly
- 5-plus years related experience, including 2D & 3D CAD design
- Ability to lead projects in a dynamic environments
- Capability to develop technical solutions autonomously and to manage collaborators
- Capability to manage multidisciplinary projects involving international partners
- Good English knowledge (written and spoken)

### PREFERRED QUALIFICATIONS

- SolidWorks 2D & 3D CAD
- Knowledge of ISO 13485 and USA 21 CFR 820 quality system regulation
- Knowledge of IEC/UL 61010, ISO 14971, UNI EN ISO 12100, IEC 60812 standards
- Knowledge of MEMS photolithographic processes, injection molding fabrication processes
- Experience in biological application instruments and fluid handling in microfluidic systems
- Knowledge of MS Project