



Principal Systems Engineer - Illinois and Massachusetts Offices

10+ years of strong and direct experience in developing product development of medical devices:

- Experience with requirements elicitation (user needs, VOC)
- Requirements analysis and experience in requirement allocation and decomposition (allocation of system requirements to the software or hardware)
- Risk analysis experience and experience working on FMEA's, software Hazard Analysis experience, thorough understanding of ISO14971.
- Understand the software lifecycle and familiar with IEC62304
- Understand of configuration management, tools for configuration management, particularly with software systems.
- Experience writing or using use cases to drive requirements.
- Development document writing for regulated design controls.
- Experience in writing V&V plans and test design methods.
- Written formal development Project plan
- Understand of FDA design controls
- Experience with regulatory standards

In addition to strong development experience and Systems Engineering skills, successful candidates will have the following attributes and pluses:

- Experience with forms of systems architectures (includes software and software embedded) and understands the risks and benefits of the architecture decisions
- Ability to act as a technical lead on larger projects, and as project manager on smaller projects.
- Ability to discuss and review with client the engineering processes required by the project.
- Ability to manage a positive relationship with client and demonstrate a mastery of technical area to client.
- Ability to evaluate defect trends and process flaws.
- Ability to analyze customer requirements and select approach and tools required.
- Ability to identify new project tasks and estimate durations for completion for overall software projects.
- Evaluate and identify trends and suggest directions to expand Intertech's abilities.
- Ability to assist in proposal discussions, and preparation.
- Ability to motivate and encourage subordinates and peers.
- Ability to work on and manage resources on several projects.
- Experience in Agile development projects

Further pluses to have

- Lead a team performing risk analysis and/or software Hazards analysis
- Testing and V&V experience
- DOORS or Seapine tool experience
- Use case development
- SysML or UML design tool experience
- Embedded software device experience
- Electronics experience
- Mobile Development experience
- Experience with Usability testing.