



Devicix

Engineering the Future of Medicine

Software Engineering

Devicix's ISO 13485:2003 quality system and its associated risk standard, ISO 14971:2007, led the company to also adopt the IEC 62304 standard for developing medical device software. Together, these allow Devicix to comply with the most rigorous safety and risk management procedures in the industry.

Our team, comprising professionals with advanced degrees and decades of medical device experience, contributes to all client project that involve embedded software applications. Emphasizing safety and reliability, our software engineers provide comprehensive design services, troubleshooting, verification, and maintenance.

Devicix's capabilities provide/address:

- A software development process certified by ISO 13485:2003 and 14971:2007. Development procedures established to comply with ISO 62304:2006 standard for developing medical device software.
- Rigorous software testing and safety risk analysis.
- A team that excels, not only in software design, but also in its knowledge of electrical engineering. This combination allows Devicix to create smooth interfaces between software and electrical equipment.
- Collaborative engineering that exploits electrical and hardware mitigation design elements for safety measures.
- Full team access and input, even on a project requiring just one or two engineers.
- Design from the ground up, incorporating all client requirements.
- Troubleshooting and software enhancement services that build on software elements that already work, thereby saving client's money.
- Development and regulatory submission documents created, as required by FDA and ISO 13485.

