



Devicix

Engineering the Future of Medicine

Quality Assurance

For today's medical device firms, compliance with ISO 13485:2003 and 14971:2007 standards, international standards for quality management systems, is a critically important aspect of quality assurance. By meeting these standards, medical device manufacturers can market products, not just in the U.S., but abroad.

Devicix is ISO 13485:2003 and 14971:2007 certified, providing customers with the highest level of assurance that the products we design and develop meet all of the qualification of these standards and will fit seamlessly into client and end-user systems. It accelerates the time to market and decreases overall project cost.

Devicix's capabilities provide/address:

- Implementation of a quality control system. Such a system can speed time to market by up to 18 months.
- Assessment of gaps in a current compliance system.
- Identification of deficiencies and obstacles to ISO 13485/14971 compliance.
- Resolution of FDA 483 resolutions, in which the FDA asks a company to reexamine some part of its quality control system.
- Definition of all business processes, using flow charts to describe everything from how a company handles sales to how it prepares proposals and works with distributors.
- Written policies and procedures around every element of a company's business process, ultimately creating a written, implemented quality control manual.
- Creation of standard operating procedures that support policies and procedures, and demonstrate these procedures to a third-party ISO 13485/14971 compliance monitor.

ISO 13485 ISO 9001 EN 62
21 CFR 820 EN 45502 EN 4
ISO 14971 EN 60601 UL
ASTM History File
FDA Guid