



Medical Device Development Capabilities



Devicix is a multidisciplinary engineering firm that delivers innovative design solutions and comprehensive product development services to the medical device industry. Devicix has a complete staff of electrical, mechanical, biomedical and software engineers to support product development programs. We have created Class I, II and III medical devices for numerous medical specialties. Typical development work involves point-of-care diagnostic instruments, therapeutic devices, manual and powered delivery systems, implantable devices, and monitoring equipment. Support is also provided for quality assurance, regulatory approval, intellectual property, process development and manufacturing.

Software Design

- Software risk management
- IEC 62304
- Embedded and real-time software
- User interface development (GUI)
- Desktop applications

Electrical Design

- EN/IEC 60601-1 CSA, JIS, MIC equivalent
- MPU to MCU embedded design
- Design of open and closed systems
- Field programmable gate arrays
- Digital signaling processing
- Wireless design
- Sensor design
- Protocol & communication development

Mechanical Design

- Design Inputs, VOC, Req's and Specs
- Electromechanical packaging and design
- Catheter design
- FEA & CFD
- Rapid prototyping
- Device & GUI human factors
- Biocompatibility

Process Development and Manufacturing

- Supply chain development
- Materials procurement & BOM management
- Work instructions
- Electromechanical assembly
- Manufacturing work instructions/records
- Process development and validation

Quality Assurance

- 21 CFR 820 Quality System compliance
- ISO 13485:2003 Quality System compliance
- ISO 14971:2007 Risk Management compliance
- Regulatory compliance GAP assessment
- Quality system development and implementation
- Regulatory strategy and guidance (501(k), PMA)
- Clinical trial management
- Verification and validation

Risk Management

- Total product life cycle
- Risk management planning
- Clinical effects analysis (CEA)
- Fault tree analysis (FTA)
- Design failure mode effects analysis (DFMEA)
- Process failure mode effects analysis (PFMEA)

Engineering the Future of Medicine

Government Contract-related Information

- Limited Liability Corporation, MN, 2004, privately held
- Over 20 technical personnel
- 15,000 sq ft, including offices, conference rooms, laboratory, workshop, manufacturing space
- DUNS Number: 187664292, CAGE Code: 48X83
- Small business
- CCR registered, ORCA registered
- Certified in ISO 13485:2003 (quality systems for medical devices) and 14971:2007 (risk management for medical devices)
- Registered with FDA for quality system regulation (21 CFR 820) and as medical device manufacturer (21 CFR 808, 812 and 820)
- NAICS codes: 541330 (primary), 541712, 541511, 541340, 541380, 541420, 541711, 541990, 541690
- Product service codes: AN10, AN40, AN60, AN70, AN90, AD20, AE20, AJ50, R414, R425
- Federal supply codes: 6515

For More Information

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Performance Record

Our clients range from individual physicians and entrepreneurs, to established medical device companies. Example testimonials:

Executive VP and COO, startup company: "A partnership with Devicix means speed-to-market and effective use of capital, backed by proven new technology development success."

Director of Global R&D, multinational orthopedic OEM: "Devicix was a great source of flexible engineering resources for a recent Class III medical device development project."

Differentiators

Focused medical device development company:

- Concept through commercialization of advanced technologies
- Fully staffed engineering team, with average of 15 years experience
- Multidisciplinary approach to problem solving
- Risk management experts
- Manufacturing services
- ISO 13485 and 14971 certified
- Dedicated account manager and project manager for each account/project
- Located in Minneapolis-St. Paul metro area, with access to a talented, educated workforce in biotechnology