

We eliminate the challenges, you capture the market.

Design Space: 12,000 sq. ft.

Industry Focus: Medical & Biotechnology

Overview:

Sparton's Rochester, NY software engineering operation is uniquely qualified for the Medical and Biotechnology device OEMs. From concept through design, hazard analysis, code construction, verification, documentation, and transition to manufacturing, we can be your partner throughout the product development lifecycle. We have spent the last 35+ years in the medical device industry, working with customers to fulfill their requirements in the Life Science, IVD or Medical Technology Markets. We work with startups to large OEMs where we produce inspirational designs, improve the time-to-market, reduce risk & cost, and improve compliance.

Key Capabilities:

- Software engineering (waterfall and agile models)
- Requirements definition
- Firmware & embedded software design
- Machine control (motion, thermal, fluidic)
- Web app & cloud services
- Smartphone app development
- Architecture evaluation & design consulting
- Extend life of existing products
- Verification & validation
- DHF creation
- Connectivity – Wi-Fi/bluetooth
- Database design
- User interface design – touchscreen/tablet/smartphone
- Remote device management
- Quality management system creation

Services:

- New product development
- Quality assurance & testing
- Sustaining engineering
- Regulatory compliance

Certifications/Regulations/Standards:

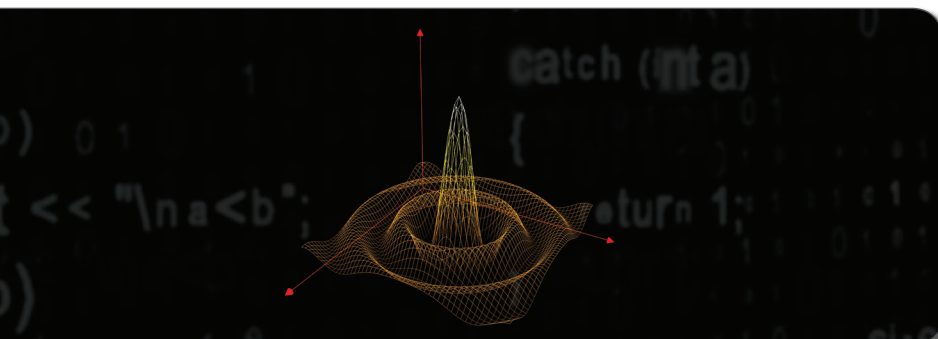
- ISO 9001
- ISO 13485
- ISO 14971
- IEC 62304
- 21 CFR part 820, 21 CFR part 11
- HIPAA
- IEC 60601, IEC 61010
- HL7, DICOM, IEEE 11073
- Microsoft Partner

Technological Expertise:

- Project management
- Software development (embedded device to cloud services)
- Automated testing
- Multi-system communication
- Regulatory gap analysis/remediation

Application Experience:

- Body-fluid analyzers (ClinChem, immunoassay, hematology, PCR)
- Infusion pump (including ambulatory & PCA)
- Cognitive function assessment
- Patient monitoring
- Point-Of-Care (POC) testing
- Medical imaging
- Urinary incontinence detection
- Cancer biopsy & treatment
- Lipoprotein analysis via NMR
- LIS and LAS communication
- Electronic Medical Records (EMR)
- Hemodialysis
- Sterilization systems
- Patient temperature management system
- Concussion & TBI detection
- Home medication dispenser
- Cosmetic injector



Microsoft
Partner



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