



We eliminate the challenges, you capture the market

Manufacturing Space: 12,000 sq. ft.

Industry Focus: Medical & Biotechnology

Overview:

Sparton's Pittsford, 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 30 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 help improve the time-to-market, reduce risk & cost, and improve compliance.

Key Capabilities:

- Software engineering (waterfall and agile models)
- Extended life of existing products
- Verification & validation
- DHR, DMF creation
- Software quality assurance
- Connectivity – Wi-Fi/cloud/bluetooth/smartphone/database design
- User interface design – touchscreen/table/smartphone
- Remote device management
- Gap analysis & remediation
- MDR investigation & issues resolution
- Quality management system creation

Services:

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

Regulations/Standards:

- ISO 9001:2008
- ISO 13485:2003
- ISO 14971:2007
- IEC 62304
- 21 CFR 820, 21 CFR part 11
- HIPAA
- RoHS and reach, IEC 60601-1, CE

Technological Expertise:

- Project management
- Software development (embedded device to cloud services)
- Automated testing

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
- Prostate cancer treatment
- Regulatory evaluation & remediation
- Lipoprotein analysis via NMR
- Lens measurement using wavefront technology
- LIS and LAS communication
- Electronic Medical Records (EMR)

