SOFTWARE ENGINEERING SERVICES

Development & Testing for the Medical Device Industry

CAPABILITIES

Software Development

- Requirements development and analysis
- Retrofitting tools into legacy systems
- Project coordination
- Updating software to be agency compatible
- Reverse engineering software to existing hardware
- Documentation

Hardware Engineering

- Electronics development
- Mechanical development
- Systems integration services
- Production services

Independent Verification & Validation

- Requirements development and analysis
- Tool validation/ qualification
- Test planning and execution
  - System testing
  - Regression testing
  - Integration testing (HSIT, SSIT)
  - Unit/module testing for safety-critical embedded systems
  - Code review
- Project coordination
- Discrepancy reporting & resolution
- Results reporting

IV&V, AUTOMATED

GenIViVe™, our proprietary suite of unit testing software, predetermines many of the necessary conditions to meet the requirements of certain constructs. Additionally, it automates test cases, reducing manual steps and letting our testers do what they do best—build and execute test cases.

GenIViVe saves time and money, standardizes quality by reducing user error, and ensures 100% independent coverage to the requirements—every time.

GenIViVe interfaces with tools such as VectorCAST, LDRA, and TRACE32 to create clear, concise documentation that gives auditors a transparent picture of what is being tested.

While the FAA and other certifying bodies do not define reporting standards, our processes and results are consistently praised for reporting format, traceability, and maintaining compliance.

Developed—and proven—to work in aviation and other certified environments, **GenIViVe** continues to evolve, giving us (to quote an FDA consultant we work with) a "20-year head start" when it comes to unit testing in support of medical device compliance.

GENERAL DIGITAL™

HISTORY

Safety-critical software development and testing has been one of our core competencies since our founding in 1973.

In the nearly 50 years that we've provided safety-critical software engineering services, we've never once validated a project that failed a submission.

In 2016, we began working on medical devices, as new FDA guidelines began to require more thorough documentation and testing to ensure Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) being used in the market is safe.

We act as an extension of your engineering department, able to provide as much (or as little) assistance as required.

We've completed projects ranging from a few hours of testing to a full software and hardware redesign in support of a successful 510(k) Pre-market Notification.

Don't wait until after you've gotten a 483 warning letter to ensure your product development processes are in compliance.

CODES & ID NUMBERS

CAGE 1JA77

DUNS 06-551-9563

EUID DWMEGPGHBGY5

DDTC Registered

PSC 7010, 7021, 7025

SAM/CCR Registered

NAICS 541511, 541512, 541519

MEDICAL COMPLIANCE

ISO

- 9001:2015 QMS Certified
- 13485:2016
- 14971:2019 (Risk)
- 31000 (Risk)
- 13482:2014 (Robotics)
- 16142 (Safety)
- 81001-1:2021 (Security)

HIPAA

CE/MDR

IEC

- 60601/80601 (Electrical)
- 62304 (SDLC)
- 80001-1:2001 (Risk)
- 62366 (UX)

FDA 510(k) Premarket Notifications

CFR 820.30

999-0901-012r13

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ISO 9001:2015 QUALITY MANAGEMENT SYSTEM CERTIFIED