First Consulting, Inc.

Embedded Medical Device Software Verification & Validation

IEC 62304 · ISO 14971 · IEC 60601-1 · 21 CFR Part 820

The FDA-Grade V&V Team You Don't Have to Hire

First Consulting, Inc. brings the same rigor we use to support established medical device manufacturers to companies building their software V&V function from scratch — so you get enterprise-grade compliance without building an internal team first.

20 Years	15+
of the same rigor, now available to startups	Class I products supported

TRUSTED BY: Ortho Clinical Diagnostics · Quaero Life Science · Tecan Group

WHY STARTUPS CHOOSE US

- The same team and process we use to support QA departments at established manufacturers is the process we bring to you as your full V&V function.
- We translate FDA and IEC 62304 requirements into a clear, concrete plan — no jargon, no guessing what "compliant" actually means for your product.
- End-to-end ownership: test planning, execution, traceability, and documentation, built to be submission-ready.
- Enterprise-grade rigor without the cost or risk of building that function internally before you're ready to.
- Start small: we can own V&V for a single subsystem or release cycle end-to-end, so you can see how we work before scaling up.

HOW WE BUILD YOUR V&V FUNCTION

1. **Readiness assessment —** a free scoping call to map what's needed for your device class and submission path.
2. **Build the plan —** test strategy, protocol development, and a traceability structure sized to your product.
3. **Execute —** full-scope test execution, documentation, and defect resolution — owned start to finish.
4. **Submission-ready hand-off —** a documentation package built to hold up under FDA review, not just internal sign-off.

PROOF STATEMENT

"Our engineers have led full-scope test strategy, execution, and traceability for 15+ Class I medical device products, including work with Ortho Clinical Diagnostics, Quaero Life Science, and Tecan Group. We bring that same capability directly to companies building their V&V function from the ground up."

Get a free V&V readiness assessment.

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