First Consulting, Inc.

Embedded Medical Device Software Verification & Validation

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

Independent V&V Execution That Plugs Into the Team You Already Have

First Consulting, Inc. works alongside your internal QA staff to deliver FDA-grade software testing — without the ramp-up time, and without disrupting how your team already works.

20 Years	15+
in medical device software V&V	Class I products supported

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

WHY MANUFACTURERS WORK WITH US

- We integrate into your existing traceability and requirements tools from day one, not week six.
- Independent execution brings fresh eyes to test coverage — catching what internal teams may miss due to familiarity with the process and product.
- We scale up fast for submission deadlines, audit prep, or backlog clearing, and scale back down when you don't need us.
- Our engineers speak IEC 62304, ISO 14971, and 21 CFR Part 820 fluently — no translation layer, no ramp-up curve.
- Flexible engagement models: single-project scope, ongoing augmentation, or surge support around deadlines.

HOW WE WORK WITH YOUR TEAM

1. **Scope the gap —** quick call to identify where you need coverage — a project, a deadline, or ongoing bandwidth.
2. **Integrate fast —** we work inside your existing tools (Jama, Polarion, or your system of record) and your documented process.
3. **Execute —** test planning, protocol development, execution, final reporting, and traceability, delivered to your standards.
4. **Hand off clean —** submission-ready documentation and a clear record your team — and your auditors — can rely on.

PROOF STATEMENT

"First Consulting, Inc. has supported software V&V for 15+ Class I medical device products, including engagements with Ortho Clinical Diagnostics, Quaero Life Science, and Tecan Group, integrating directly into client QA teams and tools."

Tell us about your current bottleneck.

Phone: (585) 387-0302 **Email:** info@firstconsultinginc.com **Web:** www.firstconsultinginc.com

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