First Consulting, Inc.

FIRST CONSULTING CASE STUDY | SOFTWARE VERIFICATION & VALIDATION

Remediating Software Verification for a Clinical Laboratory Platform

PART 1

The Engagement at a Glance

Executive Summary

A global in vitro diagnostics manufacturer engaged First Consulting to remediate the verification of its core clinical laboratory platform software. Over a two-year program, a dedicated team of more than ten V&V engineers, most at senior level, is updating and authoring test protocols, executing testing against more than 4,400 software requirements, and producing a complete verification traceability matrix and final verification report, all within the client's FDA- and ISO 13485-governed quality system.

To meet an aggressive, milestone-driven schedule, First Consulting fielded a senior-heavy team, sequenced requirements by complexity so new engineers could deliver during ramp-up, and built quality reviews into the cycle rather than leaving them to the end. A continuously maintained traceability matrix keeps coverage of every requirement visible throughout the program, not just at its close.

Background and Context

The client

The client is a global manufacturer of in vitro diagnostic instruments and assays, operating as a regulated medical device company. Its clinical laboratory platform is built on a core software layer that carries a large and evolving set of software requirements. As a medical device manufacturer, the client must be able to demonstrate, with objective evidence, that every one of those requirements has been verified.

Why remediation was needed

As the platform's requirements evolved, the existing body of verification documentation needed to be brought back into alignment with the current requirements set. That meant assessing every requirement to determine which existing test cases could be reused, which needed to be updated, and where new test cases had to be written, then executing the full set and re-establishing complete traceability from requirement to objective evidence.

The regulatory driver

The work falls under medical device design controls, so it has to conform to the client's quality management system and to FDA's Quality Management System Regulation (21 CFR Part 820), which incorporates ISO 13485 by reference. The acceptance bar is explicit: deliverables are accepted only when test documentation passes the client's technical review, execution evidence is complete with all defects logged and resolved, and the traceability matrix demonstrates coverage of 100% of identified requirements.

Scope of the engagement

- **Test documentation:** updating existing and authoring new test plans, procedures, and test cases, with traceability and front matter
- **Execution and review:** manual test execution, technical reviews, defect reporting, test data analysis, and compliance checks
- **Reporting:** data notebooks, test reports, a Verification Traceability Matrix, and a Final Verification Report
- **Coverage:** 4,409 software requirements

Constraints

- **Schedule:** a 23-month term, with test documentation and execution delivered against staged percentage milestones rather than a single end date
- **Staffing:** a minimum of ten dedicated resources, at least eight of them senior-level testers, working fully on-site at the client's facility
- **Client systems:** all work performed with the client's own processes, software tools, and test equipment, with every resource trained on those systems before performing work
- **Throughput:** test execution organized across staggered, multi-shift schedules to maximize use of shared test equipment
- **Performance commitments:** contractual service levels including onboarding within ten business days, less than 3% rework, at least 95% on-time milestone completion, and 24-hour communication response

How the engagement was awarded

The work was competitively sourced through a formal request for proposal. First Consulting brought a long-standing track record of delivering verification work in the client's environment, an advantage when onboarding a team of this size.

The Challenge

On paper, the assignment was straightforward: verify every requirement and prove it. In practice, the size of the requirements set, the shape of the schedule, and the strictness of the acceptance criteria combined to make this a demanding program to staff, plan, and run.

Scale, with scope still to be confirmed

With 4,409 software requirements in scope, every one had to be individually assessed: was there an existing test case that still held, one that needed to be revised, or a gap that called for a new test case? The engagement terms gave both parties the first 60 days to finalize their shared understanding of scope and effort, which meant planning and early execution had to begin before the full picture was known.

Two parallel tracks on a staged schedule

Test documentation and test execution were not sequential phases. Each had its own cumulative milestones, and execution was due to start delivering results only a month after the first documentation milestone. The team had to author and revise protocols while executing those already approved, keeping both tracks moving without one starving the other.

Program month	Test documentation (cumulative)	Test execution (cumulative)
Month 6	25% complete	—
Month 7	—	20% complete
Month 12	60% complete	—
Month 13	—	55% complete
Month 18	95% complete	—
Month 21	100% complete	—
Month 23	—	100% complete
End of term	Final Verification Report and Traceability Matrix	All 4,409 requirements covered

Contractual milestone profile, shown relative to the program start.

Ramping a large team quickly

The program called for at least ten dedicated testers, eight of them senior, onboarded within ten business days. Every resource had to be trained on the client's processes, tools, and equipment before performing any work, so the time needed for training competed directly with the time needed to hit the first milestones.

Shared equipment and limited test windows

All testing ran on the client's own instruments and test environments. Getting enough throughput from a finite set of equipment meant organizing the team across multiple shifts with staggered start times, and depended on reliable, uninterrupted access to those environments.

A quality bar with little room for rework

The service levels set a rework ceiling below 3%, required 100% compliance with the client's quality system on all documentation, and made 100% requirements traceability a condition of acceptance. Because the client could take up to 90 days to review a deliverable, a quality issue could surface months after the work was done, when correcting it would compete with current milestones.

Holding the team together for two years

On a program of nearly two years, losing experienced testers partway through means losing hard-won knowledge of the system and its test history.

What was at stake

For the client, the verification record is the evidence that the platform's software does what its requirements say it does. Missed milestones would ripple into the wider program schedule, excessive rework would consume review capacity, and any gap in traceability would leave the client unable to demonstrate full verification coverage.

Is This Relevant to You?

First Consulting's approach fits organizations facing any of the following:

- A backlog of requirements whose verification documentation has drifted out of date
- A remediation effort ahead of a submission, audit, or product release
- A need for experienced, on-site testers who can work within existing processes from day one
- A program with contractual milestones and service levels that leave little room for slippage

To discuss a verification or remediation program, contact First Consulting.

> **Continue to Part 2 for the details.** Part 2 covers the V&V objectives and acceptance criteria, the team structure and phased methodology behind the program, and why this approach matters.

PART 2

Inside the Engagement

This part goes deeper into how the program is structured and delivered: what the team set out to verify, how the work is staffed and sequenced, and how performance is being measured.

V&V Objectives

This program is primarily a verification effort: demonstrating, with objective evidence, that the platform software meets each of its specified requirements. Validation activities are supported where the client needs them, but the core commitment is complete, documented, traceable verification.

Verification objectives

- **Complete coverage:** every one of the 4,409 software requirements traced to approved, executed test cases, with no gaps in the traceability matrix
- **Current test documentation:** each test case confirmed against the current requirement, then reused, revised, or newly authored, and approved through the client's technical review before execution
- **Objective evidence:** results recorded in data notebooks, anomalies investigated, and every defect logged and resolved or formally dispositioned
- **Compliant records:** all documentation produced within the client's quality system and consistent with FDA design-control and ISO 13485 expectations

Validation support

Where requested, the team supports validation activities such as user needs confirmation, laboratory evaluations, and final product readiness assessments, and provides documentation and subject-matter support for reviews and inspections.

Program objectives

Alongside the technical goals, the engagement carries contractual performance targets that define what successful delivery looks like:

Objective	Measure	Target
Requirements coverage	Requirements traced to executed tests	100%
Documentation quality	Compliance with client quality system	100%
Deliverable quality	Rework rate	Below 3%
Schedule	Milestones completed on time	95% or better

Objective	Measure	Target
Ramp-up	Time to onboard resources	10 business days or less
Responsiveness	Response to client communications	Within 24 hours
Reporting	Accuracy of status reporting	100%

Acceptance criteria and service levels for the engagement.

Approach and Methodology

First Consulting's approach combines a structured, phase-based V&V methodology with practical decisions about how to staff, sequence, and review the work so the team could ramp quickly without compromising quality.

Team structure

The team was built senior-heavy by design, with a mix of backgrounds chosen to match the breadth of the platform's requirements. All are full-time employees rather than subcontractors.

Role	Count	Focus
Test Lead / Project Manager	1	Day-to-day direction, scheduling, client coordination, and reporting; prior experience leading test teams in the client's environment
Senior V&V Engineer	8	Protocol authoring and revision, execution of complex requirements; backgrounds spanning embedded and firmware testing, test automation and performance, API and database validation, and regulated medical, military, and commercial systems
V&V Engineer II	2	Test execution, defect analysis, and documentation, working alongside senior engineers
Notebook review and training support	2	Senior consultants with deep experience in the client's systems who review test notebooks and coach the team

Team composition.

A phased methodology

The work follows six core phases. On a program of this size they overlap rather than running once end to end: documentation for later groups of requirements continues while earlier groups are in execution.

Phase	Typical duration	Key activities
1. Planning and strategy	1–3 weeks	V&V plan, test approach, resources, environments, acceptance criteria; assessment of which test cases to reuse, revise, or create
2. Requirements analysis and traceability setup	2–4 weeks	Review of all requirements; build or refine the requirements traceability matrix; detailed

Phase	Typical duration	Key activities
		milestone schedule
3. Test case and procedure development	3–6 weeks	Protocols, test data, acceptance criteria, and steps; internal review, then client approval
4. Execution and data collection	4–10 weeks	Execution to approved protocols; objective evidence; anomaly investigation; defect resolution with engineering
5. Analysis, reporting, and closure	Ongoing	Results analysis, traceability updates, deviation disposition, and the Final Verification Report
6. Validation support and readiness	As required	User needs confirmation, lab evaluation, and support for reviews and inspections

Typical phase durations per cycle; the program runs multiple cycles across the requirements set.

Sequencing work by complexity

Rather than tackling requirements in document order, the team grades them by complexity during planning. Testing starts with the least complex requirements, giving newly onboarded engineers a controlled way to learn the client's tools, processes, and environment while still producing deliverable work. The most complex requirements are assigned to the most experienced testers. This lets the team deliver early milestones during ramp-up instead of waiting for everyone to be fully up to speed.

Traceability as the backbone

The requirements traceability matrix is set up early and maintained continuously, linking each requirement to its risk controls, test procedures, and execution results. Because 100% coverage is the acceptance condition, the matrix doubles as the team's progress tracker: gaps are visible as they arise, not discovered at the end. Once the requirements analysis is complete, the team uses the matrix to produce a detailed, milestone-driven schedule.

Structured onboarding

Onboarding runs in three steps. All consultants first complete an orientation covering project objectives, client processes and tools, and regulatory requirements, aligned with the client's own training schedule. They then enter a shadow phase, working alongside experienced staff and taking on responsibilities progressively under supervision. Guides, checklists, mentoring, and regular readiness checkpoints confirm each person is ready before they are assigned work independently.

Quality built in, not inspected in

With a rework ceiling below 3% and a client review window of up to 90 days, catching problems late is expensive. A dedicated two-person team reviews test notebooks throughout the cycle rather than at the

end, and all protocols go through internal review before they are submitted for client approval. The same reviewers provide ongoing coaching, so recurring issues are corrected at the source.

Maximizing test throughput

- **Extended test window:** execution runs across an extended daily window with staggered start times, getting more use from shared test equipment
- **Representative configurations:** requirements common to several configurations are verified on a single representative configuration unless the approved test plan specifies otherwise
- **Single point of contact:** a designated client contact coordinates clarification questions and hardware needs so testers are not blocked waiting for answers

Continuity of staffing

To protect the knowledge the team builds over two years, each area of work has a primary and a secondary consultant who are both briefed on its scope, backed by cross-trained personnel. A full-time recruiting team is available to scale or backfill quickly, with the client involved in interviews for any new hires.

Governance and communication

The management team is in place within the first ten days of the engagement. The test lead manages day-to-day work and schedules, and reports directly to First Consulting's executive leadership, who stay involved throughout the program. The client receives weekly delivery status reports and a monthly review of staffing and positions.

Why It Matters

Large verification programs in regulated industries tend to fail in predictable ways: teams take too long to become productive, quality problems surface late in review, and experienced people leave partway through. First Consulting designed this engagement to avoid all three.

What this demonstrates

- **Scale:** standing up a senior-heavy team of more than ten V&V engineers and verifying thousands of requirements to a fixed, staged schedule
- **Fast integration:** working inside a client's own quality system, tools, and test equipment, with a structured onboarding path that produces deliverable work during ramp-up
- **Regulatory rigor:** test documentation and evidence built for FDA design controls and ISO 13485, with 100% traceability as the standard rather than the goal
- **Continuity:** a full-time team with backups and cross-training designed to stay intact for a multi-year program