First Consulting, Inc.

FIRST CONSULTING CASE STUDY | TECHNICAL WRITING

Managed Technical Publications for a Global In Vitro Diagnostics Manufacturer

PART 1

The Engagement at a Glance

Executive Summary

A global in vitro diagnostics manufacturer maintains a large portfolio of laboratory analyzers, data management software, and point-of-care products used by hospital and reference laboratories around the world. Every one of those products ships with publications: operator manuals, reference guides, and other labeling that is part of the regulated product. Those publications have to change whenever the product changes, be verified and approved before release, be translated for international markets, and leave an auditable record behind them.

The client engaged First Consulting to staff and manage a publications team working inside its own technical publications group. Under a calendar-year statement of work, First Consulting provides technical writers, test engineers who verify publications against the product, and a publishing technologies documentation specialist, together with an on-site management team responsible for scheduling, training, reporting, and keeping the team fully staffed.

First Consulting has supported the group for several years, renewing the statement of work each year, and over that time the team has released multiple publications across the client's product lines.

Background and Context

The client

The client is a major in vitro diagnostics company, serving hospital, reference, and other clinical laboratories. Its instruments and software are used in regulated laboratories worldwide, and it maintains a central technical publications group responsible for the publications that ship with them.

The products

The publications work supports products that are already on the market as well as changes coming through sustaining engineering. The table below summarizes the kinds of products the team documents.

Product family	What the publications cover
Clinical laboratory analyzers	High-throughput chemistry and immunoassay systems used in hospital and reference laboratories
Specialty laboratory analyzers	Automated systems for specialized hospital laboratory testing
Laboratory software	Results management and connectivity software that links instruments to the laboratory
Point-of-care products	Readers and meters used close to the patient
Assay menu	Content supporting the tests run on the client's systems

Product families supported.

Why the publications matter

For a diagnostics manufacturer, publications are not marketing material. They are part of the labeling of a regulated medical device: they tell a laboratory how to operate the system, maintain it, and interpret what it reports. Errors or out-of-date content can lead to incorrect use, field corrections, or findings in an audit.

- **Regulated labeling:** publications fall under medical device labeling and quality system requirements in the United States, Europe, and other markets, so every change needs controlled review, approval, and records
- **Accuracy to the product:** content has to match the instrument and software exactly, which is why the team includes test engineers who verify publications against the product
- **Global markets:** publications are translated for the countries where the products are sold, so the English source has to be final and correct before translation begins

Scope of the engagement

Under the statement of work, First Consulting technical publications personnel:

- **Author:** update and create publications based on subject matter input and design specifications
- **Verify and approve:** obtain verification and approval of each publication
- **Translate:** send publications to translation as needed
- **Produce:** support print production and the delivery of publications included with the instrument
- **Document:** complete the auditable records required for each publication

Constraints

- **The client's processes and tools:** the team works within the client's established document control, review, and publishing systems, not its own

- **Schedules set by the client:** publication work follows product and project schedules that the client sets and revises during the year
- **Sustaining work:** much of the work is driven by sustaining engineering, reliability improvements, and component obsolescence, so priorities shift as product changes arrive
- **Continuity:** the client depends on the team year round, so turnover cannot be allowed to interrupt the work

How the engagement is structured

The engagement runs under an annual statement of work issued under a master services agreement. Work is billed monthly on actual hours, and milestones are reviewed with the client's management each month.

Each statement of work renews the previous year's, and the current one adds authors for specific product and assay menu teams as the work has grown.

Key Challenges

- **A large, mixed portfolio:** analyzers, software, and point-of-care products, some current and some mature, each with its own publications, terminology, and history that writers must understand well enough to change correctly
- **Change driven by sustaining engineering:** reliability improvements, software releases, and replacements for obsolete components arrive on no predictable schedule, and each change must be carried through review, approval, translation, and production
- **Accuracy has to be proven:** in a regulated environment, the team must show that each publication was verified against the product and approved by the right people, with records that stand up to an audit
- **Specialized skills:** the work needs engineers who can verify procedures on the instrument and specialists in the publishing tools, not just writers, all working to the same processes
- **Keeping a team in place:** product knowledge builds up over years and leaves with people, so the team has to stay staffed, with departures replaced quickly and new people brought up to speed

Is This Relevant to You?

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

- A regulated product portfolio whose publications must stay current with ongoing engineering change
- Publications that must be verified against the product and supported by auditable records
- Difficulty hiring and keeping writers, verification engineers, and publishing specialists
- A need for a publications team that grows or shrinks with the product schedule

To discuss a regulated publications or technical writing need, contact First Consulting.

> **Continue to Part 2 for the details.** Part 2 covers the challenges the engagement addresses, the documentation objectives, First Consulting's approach, execution and results, and why this approach matters.

PART 2

Inside the Engagement

This part goes deeper into the engagement: what makes the work difficult, what the team is set up to achieve, and how the work is staffed, managed, and carried out.

The Challenge

A diagnostics company's technical publications group has to keep a large, regulated document set accurate across many products, while the products themselves keep changing.

A large, mixed portfolio

The group supports analyzers, software, and point-of-care products, some current and some mature. Each has its own publications, terminology, and history, and the writers need to understand them well enough to change them correctly.

Change driven by sustaining engineering

Publication changes arrive with reliability improvements, software releases, and replacements for obsolete components. They do not arrive on a predictable schedule, and each one must be carried through review, approval, translation, and production.

Accuracy has to be proven

In a regulated environment it is not enough for a publication to be correct. The team has to show that it was verified against the product and approved by the right people, with records that will stand up to an audit.

Specialized skills

The work needs more than writers. It needs engineers who can verify procedures on the instrument and specialists who understand the publishing tools and output formats, all working to the same processes.

Keeping a team in place

A publications team builds up product knowledge over years. When someone leaves, the knowledge leaves too. The client needed a partner that would keep the team staffed, replace people quickly, and bring new people up to speed on its processes.

Documentation Objectives

The engagement has three goals: publications that are correct and compliant, delivered on the client's schedule, by a team that stays in place and keeps improving.

Quality and compliance objectives

- **Accurate:** every publication matches the product and its design specifications
- **Verified and approved:** each publication goes through the client's verification and approval process before release
- **Auditable:** complete records for every publication, ready for internal and external audits

Delivery objectives

- **On schedule:** publications ready in time for product and project milestones
- **Responsive:** requests from the client handled and prioritized promptly, with product support reviewed every week
- **Ready for global markets:** final source content handed to translation, and translated publications carried through to production

Team objectives

- **Stable staffing:** departing personnel replaced promptly, with open and filled positions reviewed with the client every month
- **Continuous improvement:** gaps identified, best practices shared, and lessons learned carried into each new statement of work

Approach and Methodology

First Consulting's approach is to act as an extension of the client's technical publications group: people who work in the client's systems and to its processes, supported by a First Consulting management team that takes responsibility for staffing, scheduling, training, and reporting. The client directs the work; First Consulting makes sure the team is there to do it.

Continuity of the workforce

First Consulting commits to keeping the team and its services in place for the work the client outsources. Departing personnel are replaced promptly, new roles are recruited as the client's needs grow, and all open and filled positions are reviewed with the client every month.

Continuous improvement

The statement of work builds improvement into the relationship. In the first 60 days, the client and First Consulting identify and document gaps to address in future statements of work, and both sides share best practices and lessons learned. A contingency and risk mitigation plan is developed within the first 90 days.

Execution and Results

Engagement at a glance

Measure	Status
Relationship	Multi-year, renewed annually
Current term	Calendar-year statement of work
Contract type	Time and materials, billed monthly on actual hours
Publications released	Multiple, across the client's product lines

Engagement summary.

Delivery to date

Because First Consulting had supported the group in previous years, the current engagement began with an experienced team already in place. Over the course of the relationship, the team has updated and released multiple publications across the client's product lines, each taken through verification, approval, and, where needed, translation and print production, with its records completed for audit.

Why It Matters

Medical device companies cannot treat publications as an afterthought. They are regulated labeling, they change with every product change, and they must be right in every language the product is sold in. Many companies struggle to keep a publications team staffed with the right mix of writers, verification engineers, and publishing specialists. This engagement shows a managed approach: a full team working inside the client's quality system, with First Consulting responsible for keeping it staffed, trained, and on schedule.

What this demonstrates

- **Regulated publications:** authoring, verification, approval, translation, production, and records for medical device labeling
- **A complete team:** technical writers, test engineers, and publishing specialists working together
- **Managed service:** First Consulting manages the team and is responsible for keeping it staffed
- **Continuity:** a committed, stable workforce with prompt replacement and recruiting as needs grow
- **Built-in improvement:** gap reviews and shared lessons learned feeding each new statement of work