

Frestedt incorporated



SALES PLAYBOOK

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I. USING THE SALES PLAYBOOK

Packed with proven strategies, valuable insights, and actionable tips, this playbook is designed to equip sales representatives with the tools they need to thrive in their daily interactions with prospects and customers.

From handling objections with finesse to tailoring pitches to specific buyer personas, this comprehensive resource will empower the reps to build strong relationships, drive results, and achieve sales greatness. Let them embark on this exciting journey and elevate their sales performance to new heights!

Sales playbooks lay the foundation for repeatable, scalable sales

Standardized Approach: Sales reps can refer to the playbook to ensure consistency in their interactions with prospects and customers. They follow the guidelines to deliver a unified message and align their sales strategy with the company's vision. For example, when introducing a new product or service, the playbook provides a script with key talking points to convey the value proposition accurately.

Sales Process Guidance: In their daily workflow, sales reps can rely on the playbook to navigate different stages of the sales process. From initial outreach to closing the deal, the playbook outlines the best practices for each stage. For example, during the discovery phase, the playbook offers a set of well-crafted questions to better understand the prospect's needs and pain points.

Buyer Persona and Industry Insights: Sales reps can leverage the playbook's buyer personas and industry overviews to tailor their sales approach to specific customers. Armed with this knowledge, they can have more meaningful conversations that resonate with prospects' unique challenges and goals.

Competitor Analysis: The playbook may include competitive intelligence, helping sales reps understand the strengths and weaknesses of competitors. By referencing this information, reps can position the company's offerings more effectively, highlighting key differentiators.

II. FRESTEDT INCORPORATED HISTORY

Founded on February 26, 2008, Frestedt Incorporated established itself as a highly specialized consulting firm providing clinical, regulatory, quality, and engineering services to pharmaceutical, biotechnology, medical device, in-vitro diagnostic, and food industry clients.

Over its lifetime, Frestedt has served both major global companies and smaller organizations—including academic centers and contract research organizations—distinguishing itself through a lean, expert-driven model.

From its inception, the firm framed its mission around acting as an “integrated extension” of its clients—bringing high-level, practical, and ethical support across the product life-cycle: from early clinical development to regulatory negotiation, from quality systems to engineering documentation.

Milestones

- 2008: Frestedt Incorporated is founded
- 2011: Dr. Frestedt awarded Top 25 “Industry Leaders” (Minneapolis/St. Paul Business Journal)
- 2014: Alimentix is founded
- 2016: Dr. Frestedt published first book: “Warning Letters: 2016 Reference Guide”
- 2016–2021: Recognized for excellence, including “Best for Biotechnology Clinical Research” and “CRO Company of the Year” awards
- 2017: Dr. Frestedt published second book, “FDA Warning Letters About Food Products”
- 2020-2025: Frestedt Inc. named Best of Minneapolis (Research Institute) by Minneapolis Award Program
- 2024: Dr. Frestedt published third book “Planning, Writing and Reviewing Medical Device Clinical and Performance Evaluation Reports (CERs/PERs): A Practical Guide for the European Union and Other Countries”
- 2026: Frestedt Incorporated re-organized to fully remote expert network

Business Model & Differentiation

Frestedt Incorporated stands apart through a unique combination of agility, expertise, and credibility. The company operates on a virtual-consultant network model, allowing it to deploy specialized talent precisely aligned with each client's project requirements. This structure provides exceptional flexibility and responsiveness while maintaining the depth and rigor typically associated with much larger contract research organizations. Frestedt Inc.'s cross-disciplinary expertise spans clinical affairs, regulatory strategy, quality management, and biomedical engineering, enabling the firm to bridge communication gaps that often exist between these specialized domains. Its service model is intentionally designed to support both large global enterprises and emerging innovators, offering the scalability of a major CRO with the personalized service of a boutique consultancy. The company's excellence has been further recognized through certifications such as Women-Owned Small Business status and multiple regional awards celebrating its contributions to the life sciences industry.

Scope of Services

Frestedt Incorporated offers an integrated suite of services covering every stage of the product lifecycle. Its clinical affairs practice includes protocol design, feasibility assessments, site initiation, study monitoring, and the preparation of comprehensive final reports. The regulatory affairs team develops and executes submission strategies for drugs, biologics, and medical devices, managing complex negotiations with regulatory authorities in the United States and internationally. In the quality domain, Frestedt provides full Quality Management System (QMS) development, internal and external audits, standard operating procedures (SOPs), and ongoing compliance support aligned with ISO and FDA requirements. The firm's biomedical engineering capabilities further strengthen its offering, encompassing technical file development, method validation, unique device identification (UDI) implementation, labeling reviews, and change management processes. Together, these disciplines reflect Frestedt Inc.'s commitment to providing end-to-end, science-driven support across the highly regulated landscape of medical and health-related product development.

Current Position

Today, Frestedt Incorporated operates as a dynamic, expert-driven consulting firm supporting clients globally across drugs, biologics, devices, and food/dietary supplement markets. With a deep bench of subject matter experts and recognized leadership, the company continues to tailor its services to meet increasingly complex regulatory and scientific demands.

III. FRESTEDT INCORPORATED LEADERSHIP

Dr. Joy L. Frestedt, PhD, CPI, RAC, FRAPS, FACRP serves as President & Chief Executive Officer of Frestedt Incorporated. She bringing over four decades of experience spanning regulatory affairs, clinical research, quality systems, and biomedical engineering across pharmaceutical, biologics, medical device, and food industries.

Industry Leadership

Dr. Frestedt's experience includes senior leadership roles at major companies:

- Manager of Clinical Affairs, Ortho Biotech/Johnson & Johnson
- Vice President of Scientific/Clinical Affairs, Humanetics
- Vice President of Clinical Affairs, BridgePoint Medical

In 2008, she founded Frestedt Incorporated and has served as its CEO since.

Expertise & Thought Leadership

Dr. Frestedt is known for combining scientific rigor with regulatory and operational strategy. Her expertise includes running and overseeing clinical trials, regulatory submissions for complex products, developing QMS systems, and leading engineering support for medical devices. She is a frequent industry educator and has been recognized among the "100 Most Inspiring People in the Life Sciences Industry."

Alimentix: Expanding into Food, Ingredient & Supplement Research

In 2012, Frestedt Incorporated launched Alimentix as a dedicated subsidiary and research site serving the needs of foods, food ingredients, dietary supplements, natural products, and low-risk devices. Alimentix was created to deliver scientifically rigorous yet cost-effective human studies designed for lower-risk products.

The subsidiary designs, conducts, and manages human studies, including protocol development, customized diets, recruitment, monitoring, data

analysis, and report publication. Clients turn to Alimentix for safety and efficacy validation of food and supplement claims, supported by regulatory-ready documentation.

The Frestedt Learning Center: Building Capability & Empowering Clients

Frestedt Incorporated established the Frestedt Learning Center to provide structured education for clients seeking to strengthen their in-house clinical, regulatory, quality, and engineering expertise. The Learning Center offers customized training programs—both virtual and in-person—covering topics such as SOP and QMS development, regulatory submissions, clinical protocol design, and quality audits.

The Learning Center's approach ensures knowledge transfer is built into every engagement, promoting client autonomy and readiness for regulatory scrutiny. This commitment to education positions Frestedt not only as a consulting leader but also as a thought partner and educator within the global life sciences community.

Together, the Learning Center and Alimentix extend Frestedt's reach beyond consulting into research operations and professional education—further strengthening the company's standing as a comprehensive life sciences partner.

IV. INDUSTRY OVERVIEW

Frestedt Incorporated provides integrated expertise across four core disciplines that drive success for life sciences companies — Clinical, Regulatory, Quality, and Engineering Affairs. Together, these areas help clients bring products to market faster, more safely, and in full compliance with global standards.

Clinical Affairs

Overview

Frestedt's clinical team designs and manages clinical evidence needed for product approval and market credibility. This includes feasibility assessments, protocol development, site management, data collection, risk-based monitoring, and comprehensive clinical data analysis. The company supports projects ranging from drug and device trials through Frestedt Inc. to dietary supplement and food studies through its Alimentix division.

Industry Context

In today's regulatory climate, clinical evidence is not just a requirement — it's a differentiator. Life sciences companies face increasing scrutiny to demonstrate safety and efficacy before and after launch. Many lack internal expertise or bandwidth to run compliant trials, making outsourcing both strategic and essential.

Sales Positioning

Salespeople should position Frestedt's clinical group as a full-service solution for organizations that need:

- Strategy for creating and managing clinical evidence.
- End-to-end clinical study execution without building an in-house team.
- Independent oversight to satisfy Institutional Review Boards (IRBs) and regulatory authorities.
- Rapid remediation of stalled or noncompliant trials.

The team's risk-based monitoring approach saves clients both time and audit exposure, while the ability to author study reports and peer-reviewed publications adds scientific credibility. For prospects in food and supplement industries, emphasize Alimentix's expertise in substantiating marketing claims through scientifically rigorous, low-risk studies.

Key Talking Points

- "We deliver clinical evidence that drives both regulatory approval and marketing advantage."
 - "Our team can rescue a struggling study, fix compliance issues, or design a new one from scratch."
 - "Clients value how we integrate seamlessly with their team, managing clinical evidence from concept through publication."
-

Regulatory Affairs

Overview

Frestedt's regulatory group provides strategic and tactical guidance to bring drugs, devices, and biologics to market in the U.S., EU, and beyond. Services include regulatory pathway assessment, submission development (e.g., PMA, 510(k), De Novo, IDE, NDA, 505(b)(2), IND application), labeling support, and ongoing regulatory correspondence.

Industry Context

Global regulatory requirements evolve constantly. Companies must navigate complex approval pathways, shifting standards, and varying documentation needs. For many organizations — particularly start-ups and mid-sized firms — a misstep in regulatory strategy can delay launches or trigger costly rework.

Sales Positioning

Salespeople should emphasize Frestedt's ability to simplify the regulatory maze. Unlike traditional Contract Research Organizations (CROs) that focus narrowly on clinical trial execution, Frestedt delivers strategic insight and hands-on negotiation with agencies worldwide. This combination of expertise

and responsiveness helps clients achieve approvals faster and more efficiently.

When discussing regulatory services:

- Highlight success stories (e.g., securing FDA clearance “without questions” for special 510(k)s or leading early combination drug/device approvals).
- Underscore that Frestedt’s team doesn’t just prepare submissions — they strategize pathways, train client teams, and advise on labeling and risk.
- Reinforce the company’s reputation as a trusted extension of a client’s internal regulatory department.

Key Talking Points

- “We know the agencies, their expectations, and how to move your product through faster.”
 - “Our team crafts regulatory strategies that save you time, testing, and money.”
 - “Frestedt is where technical expertise meets real-world negotiation.”
-

Quality Systems

Overview

Frestedt designs, implements, and audits Quality Management Systems (QMS) to ensure compliance with ISO, FDA, and global standards. Services include SOP development, training, risk management, vendor audits, Corrective and Preventive Action (CAPA) programs, and remediation support.

Industry Context

A company’s quality system is the backbone of its compliance and reputation. Yet maintaining QMS compliance — particularly after rapid growth, recalls, or acquisitions — can overwhelm internal resources. Increasingly, regulators expect robust risk management systems integrated throughout the product lifecycle.

Sales Positioning

Position Frestedt's quality team as the partner that transforms compliance from a burden into a business advantage. Frestedt's flexible, hybrid model (virtual and on-site) allows for scalable engagement — from a single SOP review to full system rebuilds.

When speaking with prospects:

- Stress the company's track record of delivering complete QMS rebuilds in short timeframes (e.g., quality manual, 20 SOPs, and 30+ templates in six months).
- Emphasize risk management integration: Frestedt not only audits — it teaches clients how to sustain compliance.
- Mention ongoing relationships: many companies rehire Frestedt post-audit to maintain continuous improvement.

Key Talking Points

- "We help clients turn audit risk into audit readiness."
 - "Our QMS projects don't just meet standards — they strengthen operations."
 - "Clients stay with us because we teach their teams, not just fix their paperwork."
-

Engineering Affairs

Overview

Frestedt's engineering group bridges the technical and regulatory worlds, supporting documentation, validation, and labeling for complex medical devices and combination products. Services include design history files (DHF), technical file preparation, process and test method validation, labeling compliance, Unique Device Identification (UDI) implementation, and project management.

Industry Context

Manufacturers today face a constant balancing act: accelerating innovation while maintaining tight regulatory compliance. Engineering teams must produce precise technical documentation for audits, submissions, and post-market updates — often with lean staff and shifting requirements.

Sales Positioning

Present Engineering Affairs as the hands-on technical partner that ensures no compliance detail is overlooked. The team has supported global device leaders and start-ups alike, managing everything from DHF creation to labeling overhauls. They also play a crucial role in remediation projects, such as UDI compliance.

For sales conversations:

- Emphasize cross-functional coordination: engineering, quality, and regulatory must align — and Frestedt does that better than anyone.
- Point out that Frestedt’s engineering support can prevent rework, reduce inspection findings, and speed up FDA submissions.
- Use testimonials and case studies (e.g., “There’s no way on earth we could have done this DHF without you”) to build credibility.

Key Talking Points

- “We make sure your documentation stands up to any audit.”
- “Our engineers speak clinical, technical, and regulatory languages.”
- “Frestedt provides the bridge between design intent and market approval.”

Summary for Salespeople

When discussing Frestedt’s specialties, always tie conversations back to client pain points:

- **Speed** – helping clients reach the market faster.
- **Confidence** – ensuring compliance under evolving regulations.
- **Integration** – combining CRQE expertise for seamless solutions.

Frestedt isn't just a consulting company — it's a strategic partner that gives life sciences innovators the structure, insight, and documentation they need to bring products to life.

V. BUYER PERSONAS (CLINICAL, REGULATORY, QUALITY, ENGINEERING)

Frestedt's buyers span four highly specialized disciplines. While their goals differ, they are united by **regulatory pressure, compliance risk, short timelines, and the need for credible documentation**. These personas help sales teams tailor conversations to the urgency, constraints, and expectations each buyer brings to an engagement.

Each persona includes:

- Who they are
- What they are responsible for
- What they fear (risk drivers)
- What triggers them to buy
- What they value from Frestedt
- How to best communicate with them

Persona 1: — VP of Clinical Affairs (Strategic Clinical Leader)

Who They Are

Senior executive in drug, device or food company responsible for overseeing clinical strategy, evidence generation, timelines, budgets, and organizational risk. They also work across departmental silos which aligns with Frestedt's cross-disciplinary approach.

Responsibilities

- Align clinical evidence with regulatory and commercial goals
- Oversee entire clinical portfolio
- Approve budgets for studies and clinical vendors
- Report clinical research activities and risks to executive leadership
- Ensure clinical evidence supports intended claims

Pressures & Pain Points

- High visibility to CEO, Board, investors and customers
- Timelines can slip across multiple studies
- Rising cost of clinical operations
- A large clinical research project depends on clinical (and regulatory and quality) readiness
- Clinical trials are significantly behind schedule

Buying Triggers

- An identified need to bring in external support to fit team and project needs
- An identified lack of internal resources or knowledge to complete trial
- Executive leadership applies pressure to accelerate clinical evidence development
- Cross-study inconsistencies surface
- Clinical Research Organization (CRO) performance issues
- Lack of senior oversight

What They Value

- Senior clinical expertise, not junior staff
- Understanding across clinical, regulatory and quality needs
- Timeline predictability
- Risk mitigation for high-profile clinical data collections
- A partner who can “own” clinical components end-to-end

How to Sell to Them

- Speak about **outcomes** (clinical research readiness, operational risk reduction)
- Tie clinical evidence directly to **business goals**
- Emphasize Frestedt’s ability to **stabilize** timelines and costs
- Show expertise in clinical research scenarios including rescue

Persona 2 — Director of Clinical Affairs (Operational Clinical Lead)

Who They Are

Hands-on manager in drug, device or food company responsible for trial execution, documentation, monitoring, and day-to-day study management.

Responsibilities

- Designing or reviewing clinical research protocols
- Ensuring FDA, ICH, and ISO 14155 compliance
- Overseeing site selection, monitoring, data integrity
- Moving studies through IRB approval
- Reporting safety events
- Producing clinical study reports for regulatory review
- Creating clinical research publications and meeting materials

Pressures & Pain Points

- Study falls behind schedule
- Missing or incomplete documentation discovered
- Gaps identified during sponsor/site readiness meetings
- Need for independent monitoring or auditing
- Preparing for publication or claim substantiation (especially in food/supplements)

Buying Triggers

- Limited internal staff or knowledge to run or rescue trials
- Tight development timelines
- Rising scrutiny around data quality and risk-based monitoring
- Fear that a stalled or non-compliant trial will derail regulatory submission

What They Value

- Fast deployment of specialized clinical resources
- Risk-based monitoring that reduces audit findings
- Independent oversight to satisfy regulators
- Ability to turn raw data into credible reports and publications

How to Sell to Them

- Emphasize clinical rescue experience capability
- Show case studies of cleaned-up studies and successful audits
- Stress Frestedt's ability to integrate with team immediately

- Focus on quality and regulatory defensibility
-

Persona 3 — VP of Regulatory Affairs (Strategic Regulatory Architect)

Who They Are

Executive-level regulatory strategy owner in drug, device or food company, responsible for pathway selection, submission timing, and agency readiness. They also work across departmental silos.

Responsibilities

- Driving regulatory submission and negotiation strategy
 - Drug: Investigational New Drug Application (IND), New Drug Application (NDA), 505(b)(2) paper NDA
 - Investigational Device Exemption (IDE), Premarket Notification (510(k)), De Novo (DEN), Premarket Approval (PMA)
 - New Dietary Ingredient (NDI), Generally Recognized as Safe (GRAS)
- Preparing and reviewing regulatory documentation
- Communicating with US FDA, EU Notified Bodies, and global agencies
- Ensuring labeling meets requirements
- Guiding cross-functional teams toward approval

Pressures & Pain Points

- Gaps identified in upcoming submission documents
- Agency feedback requiring immediate remediation
- Need for specialized documentation
 - Risk benefit analyses
 - Clinical Evaluation Plans (CEPs), Clinical Evaluation Reports (CERs), Post Market Clinical Follow-Up plans (PMCFPs), Post Market Clinical Follow-Up Evaluation Reports (PMCFER), Summary of Safety and Clinical Performances (SSCP)
 - Claim substantiation reports
- Launch delays due to incomplete or inconsistent data packages

Buying Triggers

- Lack of in-house expertise for complex or combination products
- Frequent changes in regulatory expectations
- High cost of mistakes during submission
- Intense internal pressure to hit approval timelines
- Fear of “refuse to accept” or long cycles of agency questions

What They Value

- Bulletproof documentation
- Clear submission strategy that minimizes risk
- Hands-on experts who can negotiate with regulators
- Ability to translate complex science into regulatory language

How to Sell to Them

- Lead with examples of approvals “without questions”
- Highlight Frestedt’s success with drug safety reports, device clinical data evaluations, combination product reports
- Stress cross-disciplinary expertise and ease of integration
- Be concise — they buy competence and clarity

Persona 4: — Director of Regulatory Affairs (Regulatory Documentation Owner)

Who They Are

The hands-on leader in drug, device or food company managing day-to-day regulatory documentation, submission assembly, cross-functional coordination, and agency interactions.

Responsibilities

- Write and compile submission components
- Manage clinical data reports, labeling, and other regulated documents
- Coordinate inputs from clinical, engineering, and quality teams
- Address agency questions and pre-submissions
- Track submission timelines and deliverables

Pressures & Pain Points

- Endless documentation cycles
- Gaps in supporting evidence documents
- Misalignment between functions
- Incomplete clinical, regulatory, quality or engineering inputs
- Tight deadlines with limited resources

Buying Triggers

- Document review backlog
- Submission delays
- Last-minute document inconsistencies
- A need for trained regulatory writers
- Regulatory transitions and staffing changes

What They Value

- Hands-on help in a timely fashion
- Clean, accurate, consistent documentation
- Predictable turnaround time
- Reduced pressure leading up to submission

How to Sell to Them

- Lead with documentation development, alignment and ease of integration
- Offer examples of **rescued documents** and technical documentation cleanup

Persona 5: — VP of Quality/Compliance (Organizational Risk Owner)

Who They Are

Executive responsible for Quality Management System (QMS) health, compliance posture, audit readiness, and company-wide quality governance in drug, device or food company. They also work across departmental silos and bring in VPs of other areas.

Responsibilities

- Oversee QMS structure and performance
- Ensure audit readiness for FDA, ISO, MDSAP, notified bodies, global regulatory authorities
- Drive Corrective and Preventive Action (CAPA) effectiveness
- Support risk management
- Monitor compliance across departments
- Report quality metrics to leadership

Pressures & Pain Points

- Fear of FDA findings or inspectional observations (FDA Form 483)
- Cross-department misalignment
- Poor CAPA closure rates
- Legacy documentation that doesn't meet standards
- Lack of predictable, high-quality audit preparation

Buying Triggers

- Upcoming inspection or ISO audit
- Major nonconformances
- CAPA backlog
- QMS rebuild needs
- Merger/integration of quality systems

What They Value

- A partner that reduces **organizational** risk
- Mature QMS processes and templates
- Senior auditors and quality experts
- Fast, reliable remediation capability

How to Sell to Them

- Focus on audit outcomes, risk reduction, and operational readiness
 - Offer quality system development examples and case studies
-

Persona 6 — Director of Quality Systems (“QMS Execution Lead”)

Who They Are

Operational leader in drug, device or food company responsible for maintaining documentation accuracy, Standard Operating Procedures (SOPs), quality remediation workflows, and day-to-day compliance activities.

Responsibilities

- Designing, maintaining and auditing QMS systems and risk files
- Developing quality manual
- Managing SOPs, CAPAs, Work Instructions (WI)
- Preparing for FDA inspections or ISO audits
- Ensuring remediation effectiveness
- Training cross-functional teams on compliance

Pressures & Pain Points

- Limited staff or knowledge to sustain high-quality QMS processes
- Fear of audit findings or 483 observations
- Outdated or incomplete QMS documentation
- Inconsistent or absent quality processes across departments
- Post-market complaints or recalls increasing scrutiny

Buying Triggers

- Preparing for an ISO/FDA audit
- Recent audit findings requiring corrective action
- Regulatory submission review reveals quality documentation gaps
- Merger/acquisition requiring QMS integration

What They Value

- Clear, actionable guidance
- Rebuilds that work in real operations, not theoretical models
- Templates, training, and scalable documentation
- A partner who can “teach while doing”

How to Sell to Them

- Show examples of complete QMS rebuilds delivered in months
 - Emphasize Frestedt's ongoing client retention after audits
 - Focus on risk management integration
 - Stress accuracy, standards alignment, and practicality
-

Persona 7: — VP of Engineering / Product Development (Technical Strategy & Compliance Leader)

Who They Are

Executive in drug, device or food company responsible for guiding product development strategy, engineering compliance and alignment with regulatory requirements. They can also work across department silos.

Responsibilities

- Oversee product design lifecycle
- Ensure engineering documentation supports submissions
- Enforce risk reduction throughout engineering operations
- Approve verification and validation strategies
- Manage labeling/Unique Device Indicator (UDI) compliance
- Coordinate engineering implications of regulatory changes

Pressures & Pain Points

- Increasing clinical, regulatory and quality expectations
- Engineering teams focused on innovation, not documentation
- Technical file inconsistencies
- Impact of design changes on submission timelines
- Pressure to support clinical, regulatory and quality needs simultaneously

Buying Triggers

- Submission delays due to documentation gaps: Technical File (TF)
Design History File (DHF)
- UDI or labeling remediation needs
- Engineering documentation audit findings
- Major design changes requiring updated files

What They Value

- Senior engineers fluent in regulatory language
- Clean, audit-ready documentation
- Clarity on technical requirements
- Prevention of downstream product issues

How to Sell to Them

- Speak to **strategic alignment**, risk, and compliance
 - Highlight Frestedt's ability to translate engineering into clinical, regulatory and quality defensibility
-

Persona 8: — Director of Engineering / Technical Manager (Documentation & Validation Owner)

Who They Are

Operational leader responsible for creating, maintaining, and validating technical documentation that supports product submissions and audits in drug, device or food company.

Responsibilities

- Managing engineering documents within CMC, DHF, DMR, technical files
- Performing or documenting receiving inspections, product quality compliance throughout in process and finished product development
- Performing or documenting test method and process validations
- Ensuring labeling requirements are met
- Supporting regulatory submissions with engineering documentation
- Cross-walking engineering, clinical, regulatory, and quality requirements

Buying Triggers

- Heavy documentation burdens
- Conflicting priorities between innovation and compliance
- Lack of internal resources for validation or technical file updates

- Audit findings tied to incomplete or disorganized engineering files
- Post-market changes requiring updates

Pressures & Pain Points

- Need for documentation creation or cleanup
- Urgent labeling remediation
- New design iteration requiring validation
- Regulatory submission requiring clear engineering documentation

What They Value

- Extremely accurate, audit-ready documentation
- Ability to translate engineering language to clinical, regulatory and quality formats
- Reduced rework and fewer inspection findings
- A team that understands how technical decisions affect submissions

How to Sell to Them

- Lead with remediation successes (new product design, labeling)
- Emphasize technical and regulatory fluency
- Show bridge between engineering intent and market approval
- Highlight prior work with major device manufacturers

Cross-Persona Buying Themes (For Sales Use)

- 1. Bandwidth Constraints:** All eight personas may have insufficient internal resources for the volume of work required.
- 2. Incomplete Knowledge:** All eight personas may have internal employees that limit the efficacy and quality of the work.
- 3. High Value on Integration:** They prefer Frestedt because it covers **CRQE end-to-end**, reducing friction between functions.
- 4. Trust and Credibility Matter:** They want experts who can “step in now,” not be trained from scratch.
- 5. Documentation Quality:** Buyers escalate when documentation is incomplete, outdated, or challenged by regulations.

VI. DISCOVERY QUESTIONS

A strong discovery process uncovers where a prospect is in their **clinical, regulatory, quality, or engineering submission cycle** and identifies the urgency, gaps, and risks driving their buying decisions. These questions help sales teams quickly surface:

- critical documentation gaps
 - compliance risks
 - resource shortages
 - audit or submission deadlines
 - decision-making authority and budget
-

Discovery Framework (Use in Every Conversation)

These five core questions apply to every CRQE buyer and should open the discussion:

1. "Where are you right now in your process?"
 - Follow-ups:
 - "What milestones have you met so far?"
 - "Which deliverables are still outstanding?"
2. "What are the key dates or deadlines you must hit?"
 - Follow-ups:
 - "What happens if those timelines slip?"
 - "How is leadership tracking these milestones?"
3. "What internal resources are available to complete the work?"
 - Follow-ups:
 - "Where do you feel bandwidth is tight?"
 - "Which tasks are most at risk of delay?"
4. "Where are you seeing gaps, slowdowns or concerns?"
 - Follow-ups:
 - "Have regulators or auditors commented on these areas before?"
 - "What's the biggest risk if this isn't addressed?"
5. "If you could solve one problem immediately, what would it be?"
 - Follow-ups:
 - "Why that one?"

- “How long has it been a priority?”
-

Clinical Affairs Discovery Questions

For Clinical Directors, Clinical Trial Managers, Study Sponsors

1. “What evidence do you need to support marketing claims?”
 - Follow-ups:
 - “Are your endpoints aligned with your claims?”
 - “Have you completed comparable studies before?”
 2. “What stage is your study at — protocol development, site activation, enrollment, monitoring, or reporting?”
 - Follow-ups:
 - “Where are you ahead or behind plan?”
 - “What needs immediate cleanup?”
 3. “Do you have the required documentation ready for IRB or regulatory review?”
 - Follow-ups:
 - “Have any documents been rejected or flagged?”
 - “Are you confident in your risk-based monitoring plan?”
 4. “How is your enrollment progressing compared to projections?”
 - Follow-ups:
 - “What’s driving any delays?”
 - “Do you have backup sites identified?”
 5. “Do you have the clinical data cleaning, statistical analyses and reporting resources you need?”
 - Follow-ups:
 - “Do you anticipate needing rescue support?”
 - “How quickly do you need a final study report?”
-

Regulatory Affairs Discovery Questions

For VPs/Directors of Regulatory Affairs

1. “Which submission pathway are you targeting (510(k), PMA, IDE, NDA, IND, MDR, etc.)?”

- Follow-ups:
 - “Is this your preferred route or required?”
 - “Has the FDA or a Notified Body provided feedback yet?”
 - 2. “What documentation is fully complete, and what’s still in progress?”
 - Follow-ups:
 - “Do you have a current gap analysis?”
 - “What do you need most urgently?”
 - 3. “Have you had prior interactions with the agency on this product?”
 - Follow-ups:
 - “Any requests for additional information?”
 - “Any unresolved questions?”
 - 4. “Do you have the cross-functional alignment needed for a clean submission?”
 - Follow-ups:
 - “Are clinical, quality, and engineering inputs consistent?”
 - “Any missing test data or inconsistencies?”
 - 5. “What is the biggest regulatory risk you’re managing right now?”
 - Follow-ups:
 - “Has leadership been briefed?”
 - “What’s the consequence if it isn’t resolved before submission?”
-

Submission-Cycle Alignment Questions (specific to regulatory submission deadlines, as required in the SOW)

1. “What is the anticipated submission date?”
 2. “Which deliverables must be completed before you can submit?”
 3. “What will the agency expect that you’re not yet confident about?”
 4. “What internal review or signoff steps could delay submission?”
 5. “What could jeopardize your submission if not addressed now?”
-

Quality Systems Discovery Questions

For QA/RA Managers, Quality Directors, QA Leads

1. “When is your next FDA inspection or ISO audit scheduled?”

- Follow-ups:
 - “How prepared do you feel?”
 - “Have mock audits been performed?”
 - 2. “Which parts of your QMS need the most attention?”
 - Follow-ups:
 - “SOPs? CAPA? Risk management? Templates?”
 - “Are departments aligned or operating in silos?”
 - 3. “Are there any recent audit findings, complaints, or CAPAs still open?”
 - Follow-ups:
 - “What triggered them?”
 - “What help do you need to close them quickly?”
 - 4. “Do you have enough resources to maintain compliance during growth or change?”
 - Follow-ups:
 - “Have new hires been trained?”
 - “Are procedures consistently followed?”
 - 5. “If you could fix one quality bottleneck tomorrow, what would it be?”
 - Follow-ups:
 - “What slows it down today?”
 - “Who else is affected?”
-

Engineering Affairs Discovery Questions

For Engineering Managers, Directors of Product Development, Technical Leads

1. “What’s the current state of your DHF, DMR, or technical file?”
- Follow-ups:
- “Where is documentation incomplete?”
- “Has an auditor or regulator flagged any gaps?”
2. “Do you have validated test methods and processes?”
- Follow-ups:
- “Which ones are missing or outdated?”
- “Any validation protocols still needed?”
3. “How confident are you in your labeling and UDI compliance?”
- Follow-ups:
- “Have there been complaints or mislabeling issues?”

- “Are updates needed before launch?”
- 4. “How are engineering, regulatory, and quality coordinating on this project?”
 - Follow-ups:
 - “Where are handoffs breaking down?”
 - “Any conflicting documentation versions?”
 - 5. “What technical challenges could impact your timeline?”
 - Follow-ups:
 - “Are design changes expected?”
 - “Do you have the bandwidth to update documentation quickly?”

VII. VALUE PROPOSITION

Frestedt Incorporated delivers an integrated blend of Clinical, Regulatory, Quality, and Engineering (CRQE) expertise that helps life sciences companies accelerate development, strengthen compliance, and achieve audit-ready documentation across the entire product lifecycle. With a nimble operating model and more than 100 specialized experts, Frestedt becomes a true extension of the client's team—providing fast, credible, and scientifically rigorous support exactly when it's needed most.

Core Value Proposition (Client-Required Statement)

“Frestedt Incorporated is a nimble, integrated part of your team—bringing 100+ cross-disciplinary experts together to deliver the clinical, regulatory, quality, and engineering support you need to move products forward with speed, confidence, and compliance.”

This statement summarizes what Frestedt does, who they serve, and why clients choose them instead of larger CROs or single-discipline consultancies.

How Frestedt Creates Value for Clients

1. Integrated Expertise Across CRQE

Most firms specialize in one area—clinical OR regulatory OR quality OR engineering.

Frestedt delivers all four together, allowing clients to:

- Prevent gaps between functions that often cause submission delays
- Reduce rework and conflicting documentation
- Ensure alignment across clinical evidence, regulatory strategy, engineering files, and QMS documentation

Outcome: Fewer surprises during submissions and audits.

2. Nimble, Responsive, High-Touch Support

Frestedt operates with a **lean, virtual-plus-onsite model** that adapts to client timelines. Unlike traditional CROs or large consultancies, Frestedt can:

- Deploy experts quickly
- Scale up or down based on project needs
- Integrate directly into the client's workflows

Outcome: Faster progress with less overhead and fewer bottlenecks.

3. Deep Submission-Driven Experience

Because Frestedt supports CRQE work end-to-end, they understand how each piece affects:

- 510(k), De Novo, PMA, and MDR submissions
- IND/NDA/505(b)(2) pathways
- QMS audit readiness
- DHF/DMR technical documentation
- IRB approvals and clinical study success

Outcome: Better submission outcomes with fewer agency questions or delays.

4. Independent Scientific and Regulatory Credibility

Frestedt provides unbiased assessment, documentation, and corrective work, giving clients:

- Independent monitoring
- Cleaned-up documentation backed by professional experts
- Stronger positioning during agency interactions
- Support that stands up to audits and scrutiny

Outcome: Clients gain confidence that their submissions and files are accurate, defensible, and complete.

5. Applied Expertise From 100+ Specialists

The firm's extended network provides access to:

- Clinical research managers
- Regulatory strategists
- Quality system auditors
- Biomedical engineers
- Food/supplement science specialists (via Alimentix)
- Technical writers and documentation experts

Outcome: Clients get the *exact* expertise they need without hiring or expanding internal teams.

Why Clients Choose Frestedt Instead of Alternatives

Clients consistently choose Frestedt because they:

- Need a fast, credible solution
- Want a firm that integrates as part of their internal team
- Prefer experts who understand both scientific rigor AND practical operations
- Value documentation that withstands audit and regulatory scrutiny
- Need to accelerate timelines without sacrificing quality

This makes Frestedt a strong alternative to large CROs, overstretched internal teams, or narrow single-discipline consultancies.

Sales Message Version (Client-Ready)

(Useful for calls, email, and elevator pitch alignment)

“We help life sciences companies move faster and stay compliant by acting as an integrated extension of their team. With 100+ experts across clinical, regulatory, quality, and engineering, we fill expertise gaps, clean up documentation, and help you get to submission or audit with confidence.”

VIII. COMPETITION

Frestedt operates in a complex competitive landscape that includes CROs, regulatory consultancies, quality-system specialists, engineering documentation firms, and freelance experts. Most competitors specialize in **one** domain; very few can support **all four CRQE disciplines** together.

Understanding competitor types and their gaps helps sales teams position Frestedt's unique strengths.

Competitive Landscape Overview

Frestedt faces **three main categories** of competitors:

1. Large CROs
2. Single-Discipline Consultancies
3. Freelancers / Fractional Experts

Each category carries limitations that Frestedt can strategically position against.

1. Large Contract Research Organizations

Examples: (See Appendixes)

How They Position Themselves

- Global scale and large teams
- Full-service clinical trial outsourcing
- Infrastructure-heavy processes
- Familiarity with big pharma/device programs

Where They Commonly Fail

- Slow response times due to organizational size
- High overhead costs that price out small/mid-size clients
- Limited flexibility for projects outside large trials
- Siloed teams — clinical separate from regulatory, quality, engineering

- Rigid documentation formats not tailored for emerging innovators

How Frestedt Wins

- Faster deployment of experts
- Services optimized for smaller, mid-size, and resource-constrained teams
- Integrated CRQE model prevents cross-functional gaps
- Lower cost than large CRO structures
- Ability to “rescue” CRO-delivered documentation that fails regulatory review

2. Single Discipline Consultancies

Examples: (See Appendixes)

- **Clinical-only firms** focus on clinical trial design and execution, including protocol development, site selection, monitoring, and reporting. They typically do not address regulatory strategy, quality system requirements, or downstream submission needs.
- **Regulatory-only firms** specialize in regulatory strategy and preparation of regulatory submissions such as Premarket Notifications (510(k)) and Premarket Approval submissions (PMA). They often depend on others for clinical execution, quality systems, and technical documentation.
- **Quality-only firms** concentrate on Quality Management System (QMS) development, audit preparation, and Corrective and Preventive Action (CAPA) remediation. Their work is compliance-driven and usually disconnected from clinical strategy and product engineering.
- **Engineering-only firms** support design controls, technical documentation, and verification and validation activities. They typically do not provide clinical evidence planning, regulatory strategy, or quality system integration.

How They Position Themselves

- Deep specialization in a single domain
- Lower cost than CROs
- Niche technical expertise

Where They Commonly Fail

- Lack cross-functional alignment: (e.g., regulatory advice doesn't reflect engineering constraints)
- Documentation disconnects
 - CER may not match QMS
 - Clinical report may not align with engineering testing
- Limited capacity
- Cannot support full lifecycle from clinical trial → submission → QMS → engineering files
- No ability to absorb urgent bandwidth needs

How Frestedt Wins

- CRQE integration means no documentation gaps
- 70+ experts allow faster scaling
- End-to-end capability supports submissions holistically
- Ability to bridge engineering, clinical, and regulatory data
- Strong track record in MDR CER, PMCF, SSCP, and U.S. submissions

3. Freelancers / Fractional Experts

Examples: Independent consultants in:

- Clinical operations
- Regulatory writing
- Quality system documentation
- Engineering validation
- CER writers

How They Position Themselves

- Low-cost
- Flexible engagement
- Specialized individual expertise

Where They Commonly Fail

- Cannot manage integrated CRQE complexity
- Bandwidth risks — one person cannot absorb urgent workload
- Limited documentation rigor for MDR or FDA submissions
- Lack of internal review / QA processes

- Cannot support multi-month programs consistently
- High risk of variable quality

How Frestedt Wins

- Team-based model ensures quality review
- Redundancy ensures no stoppage if individuals become unavailable
- Integrated CRQE expertise prevents downstream errors
- QMS-backed processes ensure consistent quality
- Stronger defensibility during audits and agency review

Competitive Comparison Summary (Sales Ready)

Use these talking points when discussing competitors:

Large CROs

- **Weakness:** slow, expensive, siloed
- **Frestedt Advantage:** fast, integrated, cost-effective

Single Discipline consultancies

- **Weakness:** single-discipline, limited scope
- **Frestedt Advantage:** fully scalable CRQE lifecycle support

Freelancers/Fractionals

- **Weakness:** inconsistent quality, bandwidth limits
- **Frestedt Advantage:** team-based execution + QMS rigor

How to Talk About Competitors (Messaging Guidance)

Salespeople should follow these rules:

- Never disparage competitors
- Focus on differences and outcomes
- Emphasize integration, speed, and quality
- Ask questions that naturally highlight competitor gaps

Example: “How confident are you that your regulatory, quality, and engineering documentation all align cleanly for submission?”

This question exposes competitor limitations without attacking them.

Positioning Frestedt’s Defensible Advantages

When asked “Why choose Frestedt?”, focus on these defensible strengths:

1. Integrated CRQE Expertise

No competitor delivers clinical, regulatory, quality, and engineering with equal depth.

2. Nimble, Embedded Operating Model

Frestedt becomes **part of the client’s team** — not an arms-length vendor.

3. 100+ Specialists for On-Demand Bandwidth

Competitors struggle with urgency; Frestedt thrives in it.

4. Submission-Ready Documentation

Competitors often deliver drafts; Frestedt delivers documentation that passes regulatory scrutiny.

5. Proven Track Record in MDR and FDA Submissions

Few boutique firms can execute MDR CER/PMCF **and** U.S. drug/device pathways with equal strength.

6. Strong Reputation for “Rescue Work”

Many clients come to Frestedt after another firm or internal team has failed.

Note: While larger competitors such as CROs and local or single-disciplined consultants often compete directly with Frestedt, they can also serve as valuable allies and potential clients. These organizations sometimes face capacity constraints or encounter projects that fall outside their core expertise. In such cases, they may need to farm out work to specialized firms like Frestedt, which can provide the necessary expertise and resources to

handle these tasks efficiently. By collaborating with these larger entities, Frestedt can not only expand its client base but also build strategic partnerships that enhance its reputation and reach within the industry. This symbiotic relationship allows both parties to leverage each other's strengths, ensuring that projects are completed successfully and to the highest standards.

IX. POINTS OF DIFFERENTIATION & COMPETITIVE ADVANTAGES

Frestedt's differentiators come from its integrated service model, experienced team, and ability to execute across the entire clinical, regulatory, quality, and engineering (CRQE) lifecycle. These strengths give clients the expertise they need to move products forward with confidence, even under time pressure or regulatory scrutiny.

Below are the strongest, most defensible differentiators for sales use.

1. Integrated CRQE Expertise (Clinical + Regulatory + Quality + Engineering)

Most competitors specialize in **one** area. Frestedt is one of the only firms that integrates:

- Clinical trial design, execution, and reporting
- Regulatory strategy and submissions
- Quality system creation, remediation, and audit readiness
- Engineering documentation, validation and labeling

Why it matters:

- Prevents gaps between functions that commonly delay submissions
- Drives consistency across all documentation types
- Ensures engineering, quality, regulatory and clinical inputs align

Client impact:

- Practical, predictable evidence creation with fewer agency questions
 - Smoother audits
 - Faster progress toward submission or approval
-

2. Nimble, High-Touch Operating Model

Frestedt's team integrates directly with client operations. Unlike large CROs or rigid consultancies, Frestedt offers:

- Rapid deployment of domain experts
- Flexible resource allocation (virtual + onsite)
- Fast turnaround times
- Hands-on collaboration across siloed departments

Why it matters: Clients facing time pressure need **immediate, practical help**, not slow onboarding or layered approvals.

Client impact:

- Projects can move faster
 - Fewer bottlenecks
 - Real-time support for decisions and documentation
-

3. 100+ Experts in One Place (Immediate Access to Specialized Talent)

Frestedt maintains an extensive network of proven subject matter experts in:

- Clinical research
- Regulatory affairs
- Quality systems
- Engineering and validation
- Food/supplement science (via Alimentix)

This depth is not available through freelancers or small boutique firms.

Why it matters: Most projects require multiple types of expertise. Frestedt delivers them **all at once**, aligned under one system proven effective time after time.

Client impact:

- No need to manage multiple consultants

- Faster access to the right expertise
 - Stronger, more defensible documentation
-

4. Proven Success with Complex & High-Risk Documentation

Frestedt excels where documentation is dense, multi-disciplinary, or heavily scrutinized:

- Clinical Research including Clinical Trial Development for Drugs, Devices and Foods as well as compliant reports (e.g., European Union Medical Device Regulation (EU MDR)–compliant Clinical Evaluation Reports (CERs), Post-Market Clinical Follow-Up (PMCF) and Summary of Safety and Clinical Performance (SSCP) Reports)
- Regulatory Submissions for Drugs (Investigational New Drug (IND), New Drug Application (NDA), Devices (Investigational Device Exemption (IDE), 505(b)(2), Premarket Authorization (PMA), Premarket Notification (510(k)), De Novo Classification Request (DEN)) and Foods (New Dietary Ingredients (NDI), Generally Recognized as Safe (GRAS) Panels and Reports)
- Quality Management System (QMS) rebuilds, including Standard Operating Procedures (SOPs), Work Instructions (WIs), Corrective and Preventive Actions (CAPA), and risk management
- Design History File (DHF), Device Master Record (DMR), and technical file development.

Why it matters: These deliverables are difficult to get right — and costly when done poorly.

Client impact:

- Documentation stands up to regulatory and audit review
 - Stronger submissions with fewer back-and-forth cycles
 - Reduced risk of refusal, delays, or findings
-

5. Recognized Ability to “Rescue” Struggling Projects

Clients often call Frestedt after:

- Current operations need additional support

- A CRO has missed key milestones
- A consultant has delivered substandard documentation
- An audit reveals major gaps
- A study stalls due to poor design or execution

Frestedt is known for stepping into difficult situations and restoring order.

Why it matters: Few competitors can repair or reconstruct documentation quickly and correctly.

Client impact:

- Projects get back on track
- Risk is reduced
- Timelines become achievable

6. Strong Reputation for Training & Knowledge Transfer

Frestedt not only delivers the work — it builds internal client capability through:

- The Frestedt Learning Center
- Custom CRQE training
- Hands-on “teach while doing” support
- Documentation coaching and process alignment

Why it matters: Clients prefer partners who improve their long-term readiness, not just short-term output.

Client impact:

- Increased self-sufficiency
 - Stronger audits
 - More consistent cross-functional processes
-

7. Quality-Driven Processes Supported by Real Governance

Frestedt's work is backed by:

- ISO 9001:2015 certification
- Women-Owned small business
- A mature internal QMS
- Documented processes for the full CRQE lifecycle

Why it matters: Competitors—especially freelancers—lack rigorous quality systems.

Client impact:

- Higher documentation accuracy
 - Improved traceability and auditability
 - More confidence in the submission package
-

8. Unique Ability to Bridge Technical Detail and Regulatory Requirements

Frestedt works across silos to ensure technical and regulatory requirements are met. Frestedt translates needs because:

- Engineering and regulatory rarely speak the same language.
- Test methods require regulatory justification
- Engineering changes must connect to risk management impacts
- Labeling/UDI are requirements within technical documentation
- Clinical evidence and engineering documentation must be aligned

Why it matters: This bridging capability is rare and essential during submission preparation.

Client impact:

- Fewer inconsistencies across documents
- Smoother technical file reviews
- Reduced regulatory pushback

9. Direct Access to Senior Experts

Clients work with seasoned professionals, not junior coordinators. This leads to:

- Faster problem solving
- Higher quality outputs
- More credible documentation
- Confident regulatory interactions

Why it matters: CROs often assign junior staff unless clients pay premium rates.

Client impact:

- Better outcomes
 - Faster decisions
 - Greater trust
-

Sales-Ready Summary: What Makes Frestedt Different

Use this summary for calls, presentations, and proposals:

“Frestedt is the only partner that integrates clinical, regulatory, quality, and engineering expertise under one roof, with 100+ senior specialists ready to step in. We deliver fast, defensible, audit-ready documentation — and we work as an extension of your team, not as an outside vendor.”

X. PROSPECTING STRATEGY

Frestedt's best prospects respond to expertise, credibility, and practical solutions—not mass marketing, generic cold calls, or broad CRO-style outreach. The most effective prospecting strategy highlights Frestedt's greatest strengths:

- ability to de-risk clinical, regulatory, quality, and engineering projects
- 100+ expert bench
- hands-on, integrated model

Frestedt wins opportunities by showing value early, demonstrating understanding of submission pressures, and positioning the team as a trusted partner rather than a vendor.

Use this summary section as a training aid:

“Prospecting at Frestedt means leading with expertise, solving submission problems early, and drawing prospects into educational conversations. We don't push services — we surface risks, offer insight, and show how our integrated CRQE team prevents delays and compliance failures.”

Below are the most effective prospecting approaches.

Expertise-Led Prospecting

Frestedt's clients respond strongly to **expert insight**, not sales announcements.

How to prospect with expertise

- Share short, direct insights about clinical, regulatory, quality, or engineering issues.
- Reference current regulatory changes (MDR updates, FDA guidance shifts).
- Offer to review a specific deliverable (DHF, CER, monitoring plan, SOP).
- Invite prospects to discuss a challenge with a specialist (not a salesperson).

Why it works

Prospects in life sciences are more receptive when they believe the outreach is coming from someone who **understands their regulatory pressure and documentation needs.**

Thought Leadership Prospecting (Learning Center + Webinars)

“Prospecting tied to thought leadership (Learning Center, webinars, education).”

Frestedt has a natural advantage here: buyers want to hear from experts who can teach, explain, and clarify complex requirements.

Key assets to leverage

- Frestedt Learning Center
- Educational content (protocol design, CER writing, risk management, labeling, UDI)
- Webinars hosted by subject matter experts
- Guest speaking at conferences or virtual events
- Short “explainer” posts or videos

Prospecting plays

- Invite prospects to free or low-cost webinars
- Offer a 20-minute “Ask Me Anything” session with a CRQE expert
- Provide training previews or sample modules
- Promote case-based sessions (e.g., “How clients navigated MDR changes”)

Why it works

Educational content attracts buyers **before** they start a vendor search.

Problem-Driven Prospecting (Submission Pressure)

The strongest theme across all buyer personas is **submission urgency**.

Questions to open prospecting conversations

- “Do you have any submissions coming up in the next 3–9 months?”
- “Have regulators asked for any changes or clarifications recently?”
- “Do you feel confident in your documentation for the next audit?”

Signals of need

- Gaps in documentation
- Slow clinical enrollment
- Stalled CERs
- Audit findings
- Internal bandwidth shortages

Why it works

- Submission-related problems force decisions.
- Frestedt solves those problems better than competitors.

Portfolio-Based Prospecting (CRQE Quadrant)

Align prospecting with the four CRQE domains:

Domain	Best Prospecting Hooks
Clinical	Stalled studies, missing monitoring, enrollment challenges, reporting needs, protocol cleanup
Regulatory	Upcoming submission deadlines, CER/PMCF gaps, MDR transitions, agency questions

Quality	QMS rebuilds, audit readiness, CAPA overload, risk management inconsistencies
Engineering	DHF cleanup, validation needs, labeling/UDI updates, technical file gaps

Why it works

Prospects respond when you speak directly to their specific domain stresses.

Use Case Prospecting (Vertical-Specific)

Frestedt supports several verticals:

- pharmaceuticals & biologics
- medical devices
- food, supplements, functional ingredients (via **Alimentix**)

Use case lead-ins

- “Are you preparing evidence for a marketing claim?”
- “Are you updating CERs/SSCPs for EU MDR?”
- “Are you preparing validation documentation for a device change?”

Why it works

Prospects see that Frestedt understands their exact type of work.

Warm Prospecting Through Existing Clients & Partners

Because Frestedt excels at **rescue work**, this creates natural referral flows.

Plays that work well

- Ask project champions for introductions (“Who else is struggling with timelines?”)

- Create referral chains inside client organizations
- Follow up with warm contacts from training sessions

Why it works

Frestedt's value is most evident to people who have **already experienced** the work.

LinkedIn-Led Prospecting (Part of Social Selling)

This overlaps with Chapter 10 but is included here because LinkedIn is a **prospecting engine** for Frestedt:

LinkedIn actions that generate conversations

- Posting bite-sized insights
- Sharing lessons from CER writing, QMS rebuilds, DHF cleanup
- Commenting on regulatory updates with actionable advice
- Connecting after webinars or Learning Center sessions
- Sharing case-study wins (without disclosing confidential details)

Why it works

Regulatory and engineering buyers are highly active on LinkedIn and respond to credible expertise.

Sequence-Based Prospecting (Email + LinkedIn + Expertise)

A multi-touch sequence works better than single outreach:

- **Day 1:** Email (problem + value)
- **Day 3:** LinkedIn connect
- **Day 4:** Send “useful resource” (checklist, SOP tip, CER insight)
- **Day 7:** Follow-up with a question (“Any submission deadlines coming up?”)
- **Day 10:** Invite to a webinar or AMA session

Why it works

Prospects need multiple touches to trust expertise in regulated environments.

Prospect Qualification Criteria (High Fit vs. Low Fit)

The top fit indicators to pursue aggressively:

High-Fit Prospects

- Submission deadlines within 3–12 months
- Gaps in documentation or QMS
- Bandwidth issues
- Stalled clinical work
- MDR obligations (CER/PMCF/SSCP updates)
- Device engineering documentation needs
- Cross-functional misalignment causing delays

Lower-Fit Prospects

- Pure R&D without regulatory intent
- Early-stage companies with no funding
- Organizations wanting the cheapest vendor
- Firms with established CRO contracts and large internal teams

Sales teams should prioritize high-fit accounts for best conversion and velocity.

Sales Messaging for Prospecting (Short Scripts)

Clinical Lead-In

“Many teams come to us when studies fall behind or IRB issues slow things down. Are you facing anything like that right now?”

Regulatory Lead-In

“With MDR updates and FDA guidance shifts, we’re seeing a lot of teams needing gap analysis help. Want to compare notes on your upcoming submission?”

Quality Lead-In

“We’ve helped several companies prepare for FDA/ISO audits by rebuilding their QMS quickly. Any audits coming up that you’re preparing for?”

Engineering Lead-In

“A lot of device teams struggle with DHF cleanup and labeling/UDI updates. How confident do you feel about your engineering documentation?”

Buying indicators are signals that a prospect has a *real, pressing, and budgeted* need for Frestedt’s CRQE expertise. These indicators help salespeople quickly identify which prospects to pursue — and which to deprioritize.

Across clinical, regulatory, quality, and engineering teams, the strongest buying signals fall into four categories:

1. Submission pressure
2. Documentation gaps
3. Bandwidth constraints
4. Audit or compliance risk

Prospects who show even *one* of these indicators often require fast, credible CRQE support — exactly what Frestedt provides best.

Top 10 Buying Indicators (Universal CRQE)

1. **Acknowledged Gaps in Documentation:** Examples: incomplete CERs, missing DHF sections, outdated SOPs, unvalidated test methods.
2. **Internal Bandwidth Shortages:** Teams admit they “don’t have enough people” or “don’t have time” to complete required tasks.

3. **A Desire for Independent Validation / Outside Review:** Prospects asking for a gap analysis, audit, or “fresh set of eyes” are high-fit.
4. **Cross-Functional Misalignment:** Clinical, regulatory, quality, and engineering documentation do not agree.
5. **Leadership Escalation:** When directors/VPs start attending meetings or asking for timelines, urgency is real.
6. **Stalled or Struggling Projects:** Studies aren’t enrolling, CERs are behind schedule, QMS rebuilds are half-finished, etc.
7. **Upcoming Submission Deadlines (3–12 Months Out):** Any timeline that requires rapid CRQE alignment is a strong buying signal.
8. **Recent Auditor or Regulator Feedback:** FDA, ISO, or Notified Body comments indicating deficiencies or required corrections.
9. **Organizational Change:** M&A, leadership turnover, rapid growth, or downsizing that disrupts CRQE operations.
10. **New Product Development or Design Changes:** New iterations trigger new documentation requirements (validation, labelling, risk, DHF).

Buying Indicators by Persona (CRQE-Specific)

Below are domain-specific buying indicators tied to the buyer personas in Chapter 3.

Clinical Affairs Buying Indicators

Strong Signals

- Study behind schedule or at risk of missing milestones
- Enrollment issues or site management problems
- Protocol needing redesign or cleanup
- Monitoring backlog or data queries piling up
- Need for experienced CRAs or oversight
- Final clinical study report required quickly for submission

Why It Matters

Clinical delays create downstream delays in **regulatory, quality, and engineering** work. Frestedt can step in immediately.

Regulatory Affairs Buying Indicators

Strong Signals

- CER/CEP/PMCF documents behind schedule
- Unanswered FDA or Notified Body questions
- Submission pathway unclear or recently changed
- Internal teams disagree on required documentation
- Need for labeling or claims review
- Early MDR compliance concerns

Why It Matters

Regulatory urgency is a potentially fastest path to a closed deal — these buyers need immediate help.

Quality Systems Buying Indicators

Strong Signals

- Upcoming FDA/ISO/MDSAP audit
- CAPAs overdue or frequently reopened
- Outdated, inconsistent, or incomplete SOPs
- Complaints or nonconformances increasing
- Quality documentation spread across multiple systems
- Need for risk management integration

Why It Matters

Quality issues create organizational risk; buyers move fast to protect compliance.

Engineering Affairs Buying Indicators

Strong Signals

- Disorganized or incomplete DHF/DMR
- Required test method or process validations outstanding
- Labeling/UDI compliance not up to date
- Engineering and regulatory documents not aligned

- Design changes requiring updated documentation
- Device file reviews delayed due to gaps

Why It Matters

Engineering gaps are often found late in preparation — and Frestedt excels in rapid remediation.

Buying Indicators for High-Priority Deals (Fastest to Close)

These are the *strongest* signals a prospect is ready to buy soon:

1. **Stalled or “rescued” projects:** If another vendor has failed, Frestedt is the ideal rescue partner.
 2. **VP-level involvement:** When senior leadership escalates, budgets get approved faster.
 3. **Submission due in less than 6 months:** This is the single strongest buying indicator.
 4. **Recent audit findings:** Any FDA 483, ISO nonconformance, or internal compliance issue triggers immediate action.
 5. “We need help now” language: Phrases such as:
 - “We’re behind schedule.”
 - “We don’t have bandwidth.”
 - “We’re not confident in this documentation.”
 - “We need outside help.”
-

Negative Buying Indicators (Low Fit)

1. **No budget or no urgency:** Exploratory conversations without timelines rarely convert.
 2. **Companies seeking the lowest-cost vendor:** Frestedt is a high-value, expertise-driven partner.
 3. Teams already locked into CRO contracts with fixed scopes: Unless the CRO is failing, the opportunity is low.
-

How to Use Buying Indicators in Sales Calls

1. Identify bandwidth gaps:
 - a. “What internal resources do you have dedicated to this?”
 - b. “Do you have enrollment issues or site management problems?”
 - c. “Could your protocol use some updating or clean-up?”
 - d. “Are there any delayed device file reviews due to gaps?”
 2. Surface documentation risks:
 - a. When was the last time you updated your SOPs”?
 - b. “How confident are you that your documentation is submission-ready?”
 3. Start with timeline questions:
 - a. “Do you have any regulatory or audit deadlines in the next 6–12 months?”
 4. Confirm urgency:
 - a. “What happens if these slips?”
 - b. “How are you feeling about the impending deadlines you’re facing?”
 5. Qualify budget:
 - a. “Do you already have budget allocated for this submission or compliance work?”
 - b. What are the costs associated with delay?”
-

Sales-Ready Summary: Buying Indicators

Use this summary when prospecting or qualifying:

“Frestedt’s strongest opportunities come from teams facing submission deadlines, documentation gaps, audit pressure, or bandwidth shortages. When prospects acknowledge these issues, they are almost always high-fit and ready to move quickly.”

XI. SOCIAL SELLING

Frestedt's clients respond best to **expert guidance, practical insights, verified experience, and thought leadership.**

Traditional promotional marketing is less effective; buyers want to learn, not be sold to.

Social selling for Frestedt centers on sharing knowledge, demonstrating credibility, and opening conversations through educational value.

The Frestedt Social Selling Philosophy

1. **Teach First — Sell Second:** Social selling should position Frestedt as the *teacher*, not the vendor.
 2. **Share Insights, Not Ads:** Buyers engage with content that helps them solve a problem.
 3. **Build Trust Through Consistency:** Small, regular contributions carry more weight than infrequent big posts.
 4. **Elevate Frestedt Experts:** The company's biggest advantage is its **people** — their knowledge, experience, and credibility.
 5. **Use Social Selling to Start Conversations, Not Close Deals:** The goal: spark dialogue → establish expertise → book a meeting.
-

The Three Pillars of Frestedt Social Selling

1. Content: Share Expertise That Solves Real Problems

Buyers care about insights related to:

Clinical

- Data analysis focused on safety and efficacy
- Risk-based monitoring
- Common protocol design challenges
- How to avoid data inconsistencies before submission

Regulatory

- Submissions and Negotiations with agencies regarding vigilance for pharma, device and foods
- FDA trends in submission questions
- Labeling and claims pitfalls

Quality

- Mistakes companies keep making
- How to prepare for FDA/ISO audits
- Risk management alignment across departments
- Specification development

Engineering

- Technical file best practices
- Validation documentation made simple
- Compliance essentials

Food/Supplements (Alimentix)

- Evidence needed for marketing claims
- Study designs that hold up to scrutiny

Content should give buyers something they can use immediately, increasing trust and positioning Frestedt as the go-to expert.

2. Conversation: Engage Directly & Authentically

Effective social sellers:

- **Respond to Comments Thoughtfully:** Offer clarifications, examples, or recommendations.
- **Join Discussions in Relevant Groups/Hashtags:** e.g.,
 - #RegulatoryAffairs
 - #MedicalDevices
 - #ClinicalTrials
 - #QualityManagement
 - #FDA
 - #MDR
- **Add Value to Other Posts:** Salespeople should comment like experts, not advertisers.

Example: “We’ve seen similar issues in MDR CER updates — especially around benefit-risk alignment.”

- **Use DMs (sparingly) to Invite Conversations:** DMs should follow a real interaction, not be the first touch.
-

3. Credibility: Highlight Frestedt’s Strengths

Salespeople should emphasize:

- Frestedt’s 100+ experts
- 17+ years of experience
- ISO-certified QMS
- Success with regulatory submissions
- The Frestedt Learning Center
- Case studies demonstrating rescue work

This builds social proof and differentiates Frestedt from freelancers and single-specialty consultants.

Social Selling Playbook: What to Post

Here are **ready-to-use categories** that fit Frestedt’s expertise-driven brand.

1. “Lessons Learned” Posts (High-Engagement)

Example topics:

- “Missing IQPSS details in CMC Specifications”
- “Three mistakes companies make in CER writing”
- “Why DHF gaps cause downstream regulatory delays”
- “How early QMS alignment reduces audit risk”
- “Top requirements for expert panels in GRAS/GRASE reporting”

These posts show expertise without selling.

2. Mini Case Studies (No client names)

Example:

“A client came to us with a stalled CER. In three weeks, we completed a compliant CER, aligned risk documentation, and prepared for NB submission.”

Examples from site

These build credibility without revealing confidential details.

3. Quick Tips & Checklists

Short, actionable items like:

- “Top three things to know about pharma safety”
 - “Five must-have sections for a clean DHF”
 - “How to prepare for an FDA inspection”
 - “Regulatory updates every RA professional should know”
-

4. Updates on Regulatory Changes

Regulatory content performs extremely well on LinkedIn.

Examples:

- New slide decks around current topics on our website
- FDA draft guidance summaries
- MDR transition deadlines
- EU expectations for PMCF

Keeping prospects informed positions Frestedt as a source of truth.

5. Behind-the-Scenes Learning Center Content

Showcase Frestedt’s educational DNA.

Examples:

- “This week we trained a team on risk management alignment.”
 - “New module: How to write audit-proof SOPs.”
 - “How technical writing training can help companies succeed”
-

6. Expert Q&A Snippet

Showcase individual experts on the team.

Examples:

- “How do I train my staff to triage and manage safety signals?”
 - “Ask an expert: What triggers an NB follow-up question?”
 - “What’s the biggest gap in technical files today?”
 - “Where’s the boundary for scientific substantiation of claims?”
-

Social Selling Scripts (For LinkedIn)

Connection Request

“Hi [Name], I enjoyed your post about [topic]. We work closely with teams managing similar challenges in clinical/regulatory/quality/engineering work. Happy to connect and share insights.”

Post-Connection Message

“Thanks for connecting. Curious — do you have any submissions or audits coming up this year? We’re seeing a lot of teams preparing early due to MDR/FDA updates.”

Webinar/Event Invite

“We’re hosting a short session on MDR documentation best practices. Thought it might be useful to you or your team — want me to send the link?”

Soft Offer

“If you ever want a second set of eyes on a CER, DHF, or QMS gap, happy to take a look.”

Behavioral Guidelines for Social Selling

DO

- Teach and share expertise
- Engage with industry content
- Highlight the expert bench
- Be generous with insights
- Stay professional and evidence-based

DON'T

- Push services in comments
- Request meetings too early
- Debate publicly
- Disclose client details
- Criticize competitors or regulators

KPIs for Social Selling (Simple & Effective)

- 3–5 posts per month per salesperson
- 10–15 meaningful comments per week
- 50+ new relevant connections per month
- 1–2 webinar or Learning Center invites per week
- 4–6 new conversations per month from social selling
- 1–2 booked meetings per month

These are realistic numbers that build influence over time.

Sales-Ready Summary: Social Selling

“Social selling at Frestedt means demonstrating expertise, using educational content to attract buyers, and creating conversations rooted in credibility. This approach strengthens brand trust and opens doors to high-quality opportunities.”

XII. KEY MESSAGING, ELEVATOR PITCH & SHORT SCRIPTS

Frestedt’s messaging must consistently reinforce the company’s strengths:

- CRQE integration
- Nimble, high-touch support
- 100+ experts on demand
- Submission-driven urgency
- Audit-ready documentation
- Ability to “rescue” struggling projects

This chapter provides the essential messaging toolkit every salesperson should use.

Core Message Pillars

These are the **core truths** every piece of messaging must communicate:

1. **Frestedt provides integrated CRQE expertise:** Clinical, regulatory, quality, and engineering support under one roof.
 2. **Frestedt is nimble and fast:** Clients choose Frestedt because projects need to move now.
 3. **Frestedt becomes part of the client’s team:** High-touch, embedded execution — not an arms-length vendor.
 4. **Frestedt prevents submission and audit delays:** Documentation is clean, aligned, and defensible.
 5. **Frestedt has a deep, senior expert bench:** 100+ subject matter experts across all disciplines.
-

Primary Value Message (Sales-Ready)

“We help life sciences companies move faster and stay compliant by providing integrated clinical, regulatory, quality, and engineering expertise.

With 100+ specialists and a hands-on operating model, we deliver the documentation, strategy, and execution you need with confidence.”

Use this message at the start of calls, emails, and presentations.

Elevator Pitches (3 Versions)

1. Business Outcome Version (Executive-Focused)

“Frestedt provides fast, integrated support across clinical, regulatory, quality, and engineering. We help teams close documentation gaps, stay on track for submissions, and avoid delays caused by bandwidth constraints or inconsistent files. With 100+ experts, we become part of your team and accelerate your processes.”

CTA: “Would a 20-minute call this week be helpful to explore your upcoming milestones?”

2. Technical/Operational Version (CRQE Leads)

“Most submission problems come from misalignment between clinical, regulatory, quality, and engineering documentation. Frestedt solves this by bringing all four disciplines together under one team.”

CTA: “Would reviewing your current documentation together be useful?”

3. Rescue/Urgency Version (Time-Sensitive Projects)

“Many of our clients come to us when CMS or toxicology need documentation or review, a study is stalled, a CER is overdue, or an audit finding needs fast remediation. We deploy specialists quickly, fix gaps, and get projects back on track and stay on schedule. Our team works side-by-side with yours to reduce risk and keep momentum.”

CTA: “Do you have any deadlines approaching where outside support would help?”

XIII. SHORT SCRIPTS (FOR EVERYDAY SALES USE)

1. Opening Call Script (Universal CRQE)

Goal: Immediately anchor on urgency + expertise.

Option 1

Rep: “Thanks for your time. We work with teams that need fast, credible support on clinical, regulatory, quality, and engineering projects — especially when deadlines or documentation requirements are approaching. Before we dive in, where are you right now in your submission or audit timeline?”

Option 2

Rep: “Hi [Client Name], this is [YOUR Name] from Frestedt Inc. Do you have 30 seconds, or did I catch you in the middle of something?” [If they are busy ask for a better time to call back].

“We provide life sciences companies with fast, and credible clinical, regulatory, quality, and engineering support. So, when deadlines for audits or documentation pile up, you can integrate our over 100 experts directly into your team. If any of this sounds relevant, I’d be happy to connect you with my VP of Sales for a short conversation on how we can help?”

Stop Talking

2. Voicemail Script

Option 1: “Hi [Client Name], this is [YOUR Name] with Frestedt Inc. I see from your LinkedIn profile that you serve as the (Title) of (Company). Frestedt provides life sciences companies with fast, and credible clinical, regulatory, quality, and engineering support. So, when deadlines for audits or documentation pile up, you can integrate our over 100 experts directly into your team. If any of this sounds relevant, I’ll send a short email with more context. Thanks, have a good one.”

Option 2: “Hello, this message is for [Client Full Name]. This Is [YOUR Name] with Frestedt Incorporated calling regarding ____ [clinical, regulatory, quality, engineering] support. No action needed – I’ll follow up directly. Thank you.”

3. Email Intro Script

Subject: Quick question about your upcoming projects

Body:

Hi [Name],

We help life science teams close gaps in clinical, regulatory, quality, and engineering documentation — especially when submissions, audits, or regulatory updates are coming up.

If you’re managing timelines around clinical trials, regulatory submissions, quality system development, we can usually add value quickly.

Open to a brief conversation?

— [Rep Name]

Simple. Direct. Outcome-focused.

4. LinkedIn DM Script (After Connecting)

Hi [Name],

I appreciated your recent post on [topic]. Many teams we work with are navigating similar challenges.

If you ever want a quick outside perspective on a [topic] timeline, happy to help.

— [Rep Name]

Low pressure. High value.

5. Clinical Persona Script (“Clinical Director”)

“A lot of teams reach out when studies fall behind schedule or when monitoring, reporting, or protocol cleanup becomes overwhelming. We can step in quickly to design, monitor, or rescue a study — and prepare the final reports regulators expect. What does your current timeline look like?”

6. Regulatory Persona Script (“Regulatory VP”)

“We’re supporting many teams through quality systems updates, compliance to new standards, labeling reviews, and regulatory submissions. If you have any documentation gaps or anticipate agency questions, we can help tighten your documentation quickly. What’s your most pressing regulatory concern?”

7. Quality Persona Script (“Quality VP”)

“If you need training support, have an audit coming up or CAPAs that need closing, our quality team can help rebuild or clean up SOPs, risk files, and QMS documentation fast. Any inspections or internal audits planned in the next few months?”

8. Engineering Persona Script (“Engineering VP” Device or Pharma)

“Many pharma teams call us with CMC, third-party audit, scientific substantiation concerns and device teams call us when DHFs, validations, or labeling/UDI updates are behind schedule. We can help organize, validate, or complete technical documentation fast. What engineering deliverables are currently at risk for your next submission?”

9. Script for Stalled or “Rescue” Projects

“We’re often asked to step in when documentation is late, inconsistent, or causing delays in clinical, regulatory, or quality work. Happy to share how we

typically get projects back on track quickly. What's the biggest bottleneck you're facing now?"

10. Closing Script (Soft CTA)

"If it would be helpful, we can do a quick review of your documentation or project timeline and give you a sense of where Frestedt could support. Want to schedule something this week or next?"

XIV. HANDLING OBJECTIONS

In regulated industries, objections are almost never about price—they are about **risk, trust, timelines, internal bandwidth, and documentation quality.**

Prospects want to ensure the partner they choose can *protect* them:

- from process delays
- from audit findings
- from incomplete documentation
- from engineering inconsistencies
- from clinical misalignment

This chapter gives salespeople the tools to respond to objections with clarity, expertise, and confidence, using real CRQE evidence.

Top Objections and How to Address Them

These objections reflect comments heard across Clinical, Regulatory, Quality, and Engineering leads.

OBJECTION 1. “We’re already working with a CRO/consultant.”

What it really means:

- They’re unsure whether switching (or adding help) will create more work.
- They may be frustrated but don’t want to admit it yet.
- Their existing partner may be siloed (clinical-only, regulatory-only).

Core Response (Sales-Ready):

“Many clients come to us while working with another CRO or consultant. We don’t replace your team — we fill the CRQE gaps and leverage addition skills that they can’t cover. Our 100+ specialists coordinate clinical, regulatory, quality, and engineering so documentation stays aligned and deadlines stay intact.”

Proof-based Follow-Up:

- “Are there any deliverables your current partner isn’t covering?”
- Do you need additional support for a clinical trial?”
- “Is your CER aligned with engineering and QMS documentation?”
- “Do you feel confident your submission is fully integrated across CRQE?”

Most competitors can’t back up “integration.” Frestedt can.

OBJECTION 2. “We’re concerned about cost.”

What it really means:

- They’ve been quoted high CRO pricing.
- They don’t understand how Frestedt reduces downstream costs.
- They assume expertise = expensive.

Core Response:

“Our model is far more efficient than CRO pricing because you only pay for the specific experts you need. Most clients save money because our integrated CRQE work prevents rework, submission delays, and extensive agency questions.”

Evidence-Based Additions:

- “We’ve managed hundreds of clinical trials to support start-up, execution, data analysis and reporting.”
- “A clean submission package avoids costly back-and-forth cycles.”
- “Aligned CRQE documentation eliminates rework between functions.”
- “Rescue projects cost far more than doing it right the first time.”

Follow-Up Question:

- “How much would a 3–6 month delay cost your team?”

Reframing cost around **risk avoidance** closes this objection quickly.

OBJECTION 3. “We think we can handle this internally.”

What it really means:

- They're bandwidth-limited but don't want to admit it.
- Leadership may not understand the true workload.
- They fear losing control of the project.

Core Response:

"We work best when we partner with internal teams. Most clients can handle some of the work — but timelines slip when clinical, regulatory, quality, and engineering documents all need alignment. We handle the heavy lift so your team stays focused on core responsibilities."

Supportive Messaging:

- "We integrate with your internal systems."
- "You maintain control — we accelerate the work."
- "Your team stays the decision-maker."

Good Follow-Up:

- "Which parts of the submission feel fully resourced internally?"
- "Where is your team already stretched thin?"

This gently surfaces the bandwidth gap without confrontation.

OBJECTION 4. "We're not ready yet."

What it really means:

- They aren't clear on scope or requirements.
- Early clinical, regulatory, quality, or engineering gaps exist.
- They fear committing before understanding complexity.

Core Response:

"Most clients who say they're not ready, soon discover there are key CRQE elements that must begin early. Detailed processes, CER planning, risk management, protocol design, labeling and other regulatory submission work all take significant amounts of time to plan and execute. We can start with a gap analysis to show exactly what's needed and when."

Evidence-Based Reinforcement:

- “We’ve rescued hundreds of clinical trials needing better planning and support.”
- “Regulators expect early alignment across documentation.”
- “Engineering and regulatory work can’t wait until the end.”
- “QMS gaps become much more expensive later.”

Follow-Up Question:

- “Have you mapped your timeline with all required CRQE deliverables?”
- “Do you have a publication plan for your marketing team?”

This reveals risks they hadn’t considered.

OBJECTION 5. “We’ve had bad experiences with consultants before.”

What it really means:

- They received poor-quality work.
- A consultant delivered generic documentation.
- A vendor missed deadlines or abandoned a project.
- CRO replaced the project leader with someone less experienced.

Core Response:

“We hear this often. Many clients come to us for rescue projects after another consultant or CRO has delivered incomplete work. Our quality system, senior experts, and integrated CRQE process prevent the gaps that cause delays or findings.”

Add Credibility Using Factual Differentiators:

- ISO-certified QMS
- 100+ senior-level experts
- Experience cleaning up and completing stalled projects
- Strong track record with rebuilding and supporting new documentation

Follow-Up Question:

- “Which part of the previous experience was most frustrating?”
This opens a clear path to show how Frestedt is different.
-

OBJECTION 6. “We need to see more technical detail before moving forward.”

What it really means:

- They want to ensure Frestedt understands their product.
- They fear paying for learning curves.

Core Response:

“Absolutely — we can review your clinical trial, QMS, or risk documentation to provide initial insight. Our experts have worked across hundreds of products, so we adapt quickly and reduce your workload.”

Follow-Up Questions:

- “Which document would you like us to review first?”
- “Where do you feel technical detail is most critical?”

This moves the conversation toward a paid engagement or gap analysis.

OBJECTION 7. “We’re trying to keep costs down.”

What it really means:

- Don’t realize the true risk or eventual costs of sufficiently resourced help.
- They don’t realize the risks of siloed work.
- They’ve never experienced integrated CRQE documentation.

Core Response:

“Freelancers can be helpful for isolated tasks, but submissions require aligned clinical, regulatory, quality, and engineering documentation. We catch issues freelancers can’t see because we review everything holistically under a quality system.”

Evidence to Support:

- “Freelancers rarely coordinate with each other.”
- “Submissions fail due to cross-document inconsistencies.”
- “Audit findings often trace back to partial or inconsistent work.”

Follow-Up Question:

- “How are you ensuring engineering, regulatory, and quality documents align?”

This usually exposes the flaw in their plan.

OBJECTION 8. “We don’t need help unless something goes wrong.”

What it really means:

- They’re underestimating risk.
- They assume work can be fixed later.

Core Response:

“Most submission problems come from issues that develop early in the process. Starting late makes projects much more expensive and harder to fix. Our clients bring us in early to prevent delays and reduce audit risk.”

Optional Reinforcements:

- “A small issue in a clinical protocol becomes a major issue during analysis and reporting.”
- “Incomplete documentation can jeopardize an entire project.”
- “Unaligned risk files create regulatory rejection points.”

Follow-Up Question:

- “What’s your plan if the agency asks for additional documentation?”

Creates awareness of future vulnerability.

OBJECTION 9. “Your team is not local.”

What it really means:

- They’re used to onsite consulting.
- They don’t understand the virtual model.

Core Response:

“We operate with a hybrid model — virtual for efficiency, onsite when needed. Most documentation work benefits from virtual collaboration, and we can be onsite for audits, testing, or critical milestones.”

Evidence-Based Additions:

- “Our virtual model is why we can move quickly.”
- “Clients appreciate access to 100+ experts without travel delays.”

Follow-Up Question:

- “Which parts of the project might benefit from virtual experts and support?”

This helps tailor the engagement.

OBJECTION 10. “It feels like a lot of work to switch vendors.”

What it really means:

- Fear of rework
- Fear of disruption
- Lack of visibility into transition process

Core Response:

“Our transition process is designed to be seamless. We review current documentation, identify gaps, and pick up exactly where things left off. We handle the heavy lift — your team stays focused.”

Follow-Up Question:

- “Which part of transitioning concerns you most?”

This allows targeted reassurance.

Sales-Ready Summary: Handling Objections

Use this summary in training and coaching:

“Objections in regulated industries are about risk, not price. Respond by showing how Frestedt reduces clinical trial burden, submission delays, cleans up documentation, aligns CRQE deliverables, and provides a deep bench of experts who solve problems other firms can't.”

XV. FRESTEDT SALES PROCESS & STAGES

Built for multi-discipline consulting across Clinical, Regulatory, Quality & Engineering (CRQE) services

Selling Frestedt's CRQE services requires a process that reflects how life-sciences buyers make decisions:

- urgency around regulatory and audit timelines
- documentation gaps
- clinical delays
- engineering and quality misalignment
- cross-functional risk
- need for immediate expertise

This sales process aligns closely to the **client buying journey**, enabling sales teams to diagnose urgency, mitigate risk, and accelerate contracting.

Sales Cycle Stages

Stage 1. Lead Engagement & Trigger Identification

Stage 2. Discovery Meeting

Stage 3. Solution Framing & Internal Alignment

Stage 4. Bid Development & Review

Stage 5. Proposal Presentation & Objection Handling

Stage 6. Final Bid Alignment

Stage 7. Contracting & Kickoff Preparation

Stage 9. Kickoff Meeting

Stage 10. Growth, Renewal & Expansion

These 10 stages reflect how Frestedt prospects buy, not just how salespeople sell.

Stage 1. Lead Engagement & Trigger Identification (New Business Outbound Initiative)

- Goal
 - Identify whether prospect has a real, time-bound CRQE need
- Buyer Triggers
 - Lacks internal bandwidth
 - Has a stalled clinical study or research problem
 - Worries about upcoming regulatory submission deadline
 - Needs help with an upcoming audit
- Sales Actions
 - Determine whether the lead operates in medical device, biotech, diagnostics, pharma, or adjacent space
 - Initiate conversation (email, LinkedIn, referral)
 - Identify current challenges: clinical evidence, regulatory pathway, quality systems, engineering gaps, or “not sure”
- Seller Prompts
 - Use “trigger questions” from Chapter IV
 - Determine if a Non-Disclosure Agreement is needed to discuss project details
 - Confirm authority: Who signs consulting agreements?
 - Identify timeline: Is there an active project or future planning?
- Seller Materials
 - Sales Playbook (this document)
 - Outreach Lead List
 - Non-Disclosure Agreement
- Sales Outputs
 - Prospect demonstrates at least one **Buying Indicator** from Chapter IX
 - Document timeline, urgency, and documentation context
 - Prospect agrees to a qualification call
 - Secure “fully executed” Non-Disclosure Agreement, if required
 - Move to *Discovery* if qualified

Stage 2. Discovery Meeting (High-Impact Diagnosis)

- Goal

- Surface the underlying problem, not just the stated one. This is where sellers differentiate Frestedt through questions, not pitches.
 - Buyer Triggers
 - Needs specific support for clinical research (e.g., protocol writing, monitoring, data analysis, manuscript development, etc.)
 - Requires specific regulatory support (e.g., pre-IND/IDE meeting with FDA, 510(k) submission or CMC document development, etc.)
 - Seeks training or quality system documentation development (e.g., to prepare for Notified Body audit against ISO standards)
 - Explores engineering gaps (e.g., technical file development, etc.)
 - Sales Actions
 - Understand their product (class, stage, risk category)
 - Map the project lifecycle: where are they stuck?
 - Uncover whether their challenge touches multiple silos (e.g., clinical design affects regulatory, or engineering change requires updated documentation)
 - Ask about previous failures with consultants, CROs or service providers
 - Evaluate risk (technical, regulatory, bandwidth, timeline)
 - Evaluate need for gap analysis
 - Establish success criteria.
 - Seller Prompts
 - “What is the risk if this problem isn’t solved?”
 - “Has this issue surfaced in clinical, regulatory, quality, or engineering before?”
 - Seller Materials
 - Multi-discipline Opportunity Map (which service lines might apply)
 - Needs (Risk) Assessment Summary
 - Sales Outputs
 - Identify whether the prospect has a real, time-bound CRQE need and whether Frestedt can meaningfully accelerate progress
 - Budget or budget pathway exists
 - Prospect requests scoping or wants next steps
 - Move to Solution Framing
-

Stage 3. Solution Framing & Internal Alignment

- Goal
 - Translate issues into a clear, cross-functional consulting approach
- Buyer Triggers
 - Interested in Frestedt Inc. and has needs aligned with our skills
 - Has time bound needs and budget to hire Frestedt Inc.
- Sales Actions
 - Decide whether the prospect needs:
 - ✓ Single-discipline support
 - ✓ **Bundled support** (clinical + quality; regulatory + engineering)
 - ✓ End-to-end lifecycle support
 - Establish estimated hours, recommended resources, and level of effort
 - Facilitate a “deep-dive” call (30-60 minutes)
 - Gather documents when possible (even samples)
 - Identify scope boundaries
 - Surface risks that competitors might miss
- Seller Prompts
 - “When is your deadline?”
 - “What happens if timelines slip?”
 - “What internal resources are available?”
 - “What internal resources are missing or overloaded?”
 - “What documentation is missing or inconsistent?”
- Seller Materials
 - Solution Overview Template
 - Level of Effort Estimation Template
- Sales Outputs
 - Prospect signals readiness for solution design
 - Draft Solution Overview (ensure sufficient details are included)
 - Draft Level of Effort Estimation (ensure realistic proposal)
 - Move to Bid Development

Stage 4. Bid Development & Review

- Goal
 - Draft Bid in writing with clarity, structure, and optionality.

- Buyer Triggers
 - Bid addresses needs and preferences discussed
 - Price point aligns with details discussed
 - Timeframe is consistent with time available as discussed
 - Preferred differentiation from our competitors (expertise, quality, cost, timeliness)
 - Sales Actions
 - Draft Bid language to reflect Frestedt's high-compliance, FDA-fluent positioning including:
 - ✓ Brief executive summary
 - ✓ Defined problem(s)
 - ✓ Recommended solution approach
 - ✓ Clear statement of work with deliverables, timelines and costs
 - ✓ Assumptions
 - ✓ Optional add-on services (e.g., phased development, gap analyses, CRQE functions as applicable)
 - Review Bid with internal experts to ensure team roles, assumptions and next steps are accurate
 - Ensure pricing model is appropriate (i.e., retained service, fixed-fee/project-based or time-and-materials)
 - Ensure Bid has internal written approval prior to any external discussion
 - Schedule a live review session AFTER Bid is approved (never send blind)
 - Seller Prompts
 - How soon do you need our bid for this work?
 - Do you have any special needs we have not already discussed?
 - Do you have any paperwork you need from Frestedt to become a vendor for your company?
 - Seller Materials
 - Bid Template including Statement of Work language
 - Written Bid approval
 - Sales Outputs
 - Prospect verbally confirms scope and readiness to proceed
 - Final, approved Bid Proposal ready to present
 - Move to Proposal Presentation
-

Stage 5. Proposal Presentation & Objection Handling

- Goal
 - Secure Verbal Buy-In by walking the prospect through the Bid proposal and removing friction
- Buyer Triggers
 - Bid preparation is more-timely than competitors
 - Conversation is easy and mutually respectful
 - Bid revisions are welcomed and immediately addressed
 - All needs and preferences are addressed
- Sales Actions
 - Ensure any needed “Vendor Management” paperwork is completed and sent to prospect as needed
 - Present the proposal live (not by email alone)
 - Reconnect their business risk to each recommended step
 - Review pricing transparently and tie it to value—not hours
 - Handle objections such as:
 - “This is more expensive than we expected”
 - “We need to prioritize internally”
 - “We’re comparing vendors”
 - Reframe budget as risk mitigation, not cost
 - Show how Frestedt’s integrated approach with their team members benefits them
 - Highlight how Frestedt’s CRQE expertise accelerates their work
 - Anchor back to risks: FDA timelines, compliance risk, product delays, or revenue loss
- Seller Prompts
 - “Do you have any questions about the deliverables, timelines or costs?”
 - “Is this aligned with your needs?”
 - “Did I miss anything you may need?”
 - “How soon can we discuss next steps to get this signed off and the work started?”
- Seller Materials
 - W9
 - Banking Information (ACH)
 - Bid Proposal (as approved by Frestedt management)
- Sales Outputs

- All revisions are incorporated in Revised Bid (as needed)
 - Final, approved Revised Bid is ready to present
 - Move to Verbal Buy-In
-

Stage 6. Final Bid Alignment

- Goals
 - Move efficiently from Bid proposal to signed contract without losing momentum
 - Ensure mutual agreement is documented completely in writing
 - Buyer Triggers
 - Bid matches prospect needs
 - Bid revisions are complete and accurate
 - All concerns have been addressed
 - Sales Actions
 - Present final, approved Revised Bid live (not by email alone)
 - Confirm scope, deliverables, and pricing verbally
 - Identify contract signer and procurement requirements
 - Verify timelines and resource expectations.
 - Re-summarize value and expected client outcomes.
 - Seller Prompts
 - “What else do you need internally to get this approved?”
 - “Can we align on a start date so the team is ready?”
 - Seller Materials
 - Revised Bid Proposal/Contract (as approved by Frestedt management)
 - Kick Off Meeting Agenda Template
 - Sales Outputs
 - Revised Bid Proposal/Contract (as approved by Frestedt management)
 - Prospect is ready to finalize contract and start project
 - Move to Contracting & Kickoff Prep
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Stage 7. Contracting & Kickoff Preparation

- Goal

- Secure Contract signatures and ensure the Frestedt team is prepared
 - Buyer Triggers
 - Contracting questions are answered immediately
 - Frestedt team is ready to start immediately after contract is signed
 - Sales Actions
 - Send contract and answer administrative questions immediately
 - Track contract status daily
 - Reconfirm urgency and business impact
 - Coordinate legal review or procurement workflows
 - Begin internal resource planning for Kick Off Meeting
 - Gather client onboarding documents for Kick Off Meeting (SOPs, prior submissions, protocols, reports, etc.)
 - Seller Prompts
 - “Do you have any concerns about the contracting process?”
 - “Can I do anything to help keep the contract moving forward?”
 - “Do you have any additional questions or concerns?”
 - Seller Materials
 - Approved Contract (as approved by Frestedt management)
 - Final Kick Off Meeting Agenda
 - Sales Outputs
 - Signed Contract
 - Scheduled Kickoff Meeting
-

Stage 8. Kickoff Meeting

- Goal
 - Align expectations and launch the project successfully.
- Buyer Triggers
 - seamless handoff to the Frestedt team during Kickoff Meeting
- Sales Actions
 - Conduct internal handoff with CRQE experts
 - ✓ Transfer notes, documents, timelines, risks
 - ✓ Discuss project scope, risks or dependencies
 - Stay engaged for early-stage alignment (monitor from a distance)

- ✓ Team confirms scope, goals, deliverables, project timelines, communication cadence
 - ✓ Introduce Frestedt team and roles (project manager, CRQE experts) to the client
 - ✓ Establish shared workspace and document channels
 - Exit AFTER delivery team is fully onboarded and client confirms project alignment
 - Be responsive if client calls with problems
 - Seller Prompts
 - “Do you have enough information about the Frestedt team members providing our services?”
 - “How was the initial experience and can I do anything more to help ease the transition to getting this work done?”
 - “Do you have any further needs?”
 - “Are you willing to refer us to others who may need our services?”
 - Seller Materials
 - Kickoff Meeting Materials
 - Project Plan Template
 - Sales Outputs
 - Kickoff Meeting Minutes
 - Project Plan
 - Client confirms project alignment
 - Move to Active Client
-

Stage 9. Active Project (Client Management)

- Goal
 - Ensure Frestedt delivers on promises and discovers additional new opportunities and referrals.
- Buyer Triggers
 - Smooth transition and immediate start of service activities
 - Timelines are being met and deliverables are as expected
- Sales Actions
 - Monthly (or milestone-based) check-ins
 - Ask whether new needs have emerged
 - ✓ Clinical

- ✓ Regulatory
 - ✓ Quality
 - ✓ Engineering
 - Reinforce value delivered to date
 - Seller Prompts
 - “How was your Frestedt experience so far?”
 - “Can I do anything more to ensure all your company needs are met?”
 - “Do you have any new or different needs?”
 - “Are you willing to refer us to others who many need our services?”
 - Seller Materials
 - Marketing Brochures
 - Networking Meeting Schedule
 - Sales Outputs
 - Sales closes loop and monitors for expansion opportunities
 - Move to Growth, Renewal & Expansion
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Stage 10. Growth, Renewal & Expansion

- Goal
 - Turn one project into two... then five.
- Buyer Triggers
 - GREAT experience with Frestedt in the past, I want to do this again!
- Sales Actions
 - Review results and impact
 - Present new opportunities based on gaps surfaced
 - Renew retainers whenever applicable
 - Keep asking for referrals or testimonials (simple, low-pressure) at every interaction with client
- Seller Prompts
 - “What’s the next milestone where we can support you?”
 - “Would you be open to us helping with [reg/qual/clinical/eng] next?”
- Sales Outputs
 - New project to bid with this client

- New prospect from referral by this client
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Sales Pipeline Path (Summary Version)

1. Lead Engaged (Triggers Identified)
2. Discovery Meeting Completed (Impacts Diagnosed)
3. Solution Framed (Internal Team Aligned)
4. Bid Developed (Internal Review Approved)
5. Bid Presented (Objections Resolved)
6. Final Bid Aligned (Verbal Buy-In Established)
7. Contracting and Kickoff (Contract Signed)
8. Kickoff Meeting (Kickoff Meeting Completed)
9. Active Project (Clients Managed)
10. Growth, Renewal & Expansion (New Lead Engaged)

