FDA RFI HOLD RESCUE

A structured, fixed-fee response framework to unlock your submission and freeze your market runway loss.

When the FDA issues a Substantive Hold, an Additional Information (AI) request, or a Refusal to Accept (RTA), your market runway freezes. Internal teams frequently lose critical time making two mistakes: writing defensive, overly academic answers, or providing fragmented technical data without addressing the core quality framework.

The **FDA RFI Hold Rescue** is an intensive, milestone-driven execution process that translates complex technical data into clean, logically defensible, and audit-ready response packages on a predictable, fixed-fee basis.

WHAT YOU GET

• **The T-Minus 15-Day Blueprint:** A structured, four-phase execution timeline encompassing Technical Data Review, Blast Radius Architecture, Low-Ambiguity Narrative Authoring, and Pre-Submission Schema Review.

• **Root-Cause and QMS Alignment:** We tie your technical failures or data anomalies directly to your QMS, building out the formal Risk Assessments and systemic CAPA frameworks for reviewers.

• **Cross-Industry Technical Resolution:** Specialized handling of medical device validation gaps, pharmaceutical/biologic 483 deviations (ALCOA+), and advanced AI/ML diagnostic algorithmic drift or dataset bias anomalies.

• **The Jargon-Free Guarantee:** Complex engineering and software metrics are translated into highly structured text, replacing vague assertions with ironclad, objective evidence that a reviewer can quickly approve.

THE LOGISTICS

• **Delivery:** Executed on a strict, guaranteed timeline tailored to your submission window, including a hard milestone built-in for final review days before deadline.

• **Scope Boundaries:** Scaled objectively to your specific deficiency letter. Single-point clarifications are handled efficiently, while complex, multi-disciplinary holds are scoped by total deficiency count.

• **Investment:** Fixed project fee starting at a $3,500 baseline.

• **The Writing for Results Commitment:** Absolutely zero hourly billing. If your timeline constraints are impossible to meet safely, we will tell you upfront before a single dollar changes hands.

Stop letting a ticking FDA clock stall your commercial launch. Let us handle the structural writing and regulatory alignment so your team can stay focused on product.

Secure Deficiency Letter Upload and Priority Scoping