THE DIAGNOSTIC QUALITY REVIEW

A fixed-scope, seven-day technical analysis for scaling medical device and biotech SMBs.

When an unexpected FDA RFI letter hits, a critical CAPA stalls, or an audit is looming, you don't need a massive, open-ended consulting contract. You need an objective, rapid assessment of where you stand and a clear path forward before committing substantial capital or writing resources.

The **Diagnostic Quality Review** is a high-impact, rapid-turnaround evaluation designed to uncover documentation gaps and provide an immediate execution roadmap.

WHAT YOU GET

• **Regulatory Translation:** A plain-English breakdown of what the FDA, auditor, or reviewer is actually asking for—stripping away the bureaucratic noise so your team can focus.

• **Gap Analysis:** An objective, rigorous technical check of your troubled CAPA files, engineering deviations, or RFI deficiency letters to pinpoint exactly where your documentation falls short.

• **Action Blueprint:** A precise, step-by-step technical roadmap detailing the exact revisions, evidence, and structural changes required to get your team completely audit ready.

THE LOGISTICS

• **Delivery:** Seven business days from secure file intake.

• **Scope Boundaries:** Limited to the initial diagnostic evaluation of an active deficiency letter, stalled CAPA file, or defined quality record set.

• **Investment:** $950 flat rate.

• **Added Value:** The entire $950 fee is applied as a direct credit to your balance if you choose to retain us for full remediation writing support or an **Investigation Support Sprint™**.

Stop second-guessing your compliance documentation. Get a definitive, expert second opinion in less than a week.

Secure File Intake and Booking