THE ROOT CAUSE ENGINEERING SPRINT™

A fixed-scope, volume-priced technical writing service for manufacturing deviations and stalled CAPA files.

The single most frequent citation during an FDA audit is a failure to thoroughly investigate deviations or execute objective, data-backed root cause analyses. When internal engineering teams are too close to a product or operating under tight shipping deadlines, their investigations frequently lean on subjective assumptions—leaving your quality system highly vulnerable.

The **Root Cause Engineering Sprint™** injects objective, contract-tight investigative logic and defensible technical evidence into your troubled quality records.

WHAT YOU GET

- **Technical Hazard Isolation:** A meticulous data sweep of your engineering deviations or system anomalies to isolate the true physical mechanism of failure.
- **Rigorous Investigation Matrices:** The technical construction of definitive 5-Why and Fishbone architectures that completely avoid the regulatory trap of citing "human error" as a root cause.
- **Audit-Ready Justification:** Clear, robust technical rationales that link your root cause directly to effective, measurable Corrective and Preventive Actions (CAPA).

THE LOGISTICS

- **Delivery:** Seven business days from technical file intake per individual investigation slot.
- **Scope Boundaries:** Limited to the root-cause generation, technical analysis, and tabular investigation file-drafting for defined quality records.
- **Predictable Volume Investment:**
    - *Single Emergency Sprint:* $1,250 flat rate
    - *High-Volume Block (3-Pack):* $3,300 flat rate
    - *Enterprise Backlog Clearance (5-Pack):* $5,000 flat rate

Stop carrying a backlog of open deviations. Inject mathematical logic into your quality files.

Secure Technical Intake and Booking