THE PCCP ARCHITECTURE BLUEPRINT

A fixed-scope, targeted technical writing service for dynamic MedTech and Software teams.

When your product roadmap requires continuous iteration, software updates, or hardware optimizations, you don't want to freeze your development pipeline or drown in endless 510(k) supplements. You need an upfront, FDA-authorized framework that allows your team to ship validated updates without asking permission twice.

The PCCP Architecture Blueprint delivers a precise, boundary-enforcing protocol built strictly to withstand modern FDA adjudication trends.

WHAT YOU GET

- **Modification Boundary Map:** A granular, legally tight Description of Modifications that defines exactly what future software or hardware updates are covered—and what safely triggers automated deployment.
- **Validation Protocol Structure:** A rigorous, step-by-step technical protocol outlining the precise testing, data sources, and acceptance criteria required to validate modifications post-clearance.
- **Impact Analysis Matrix:** A comprehensive Cumulative Impact Assessment that links your modifications back to core device safety, ensuring your engineering team never accidentally steps outside your cleared intended use.

THE LOGISTICS

• **Delivery:** Ten business days from complete technical intake.

• **Scope Boundaries:** • Limited to the development of one complete Predetermined Change Control Plan (PCCP) for a specified device family or software application.

• **Investment:** $1,850 flat rate.

• **Added Value:** Includes one post-draft alignment session with your lead engineering or product management team to ensure total harmony with your commercial roadmap.

Stop filing static submissions for dynamic technology. Build an authorized framework to innovate at speed.

Secure Technical Intake and Booking