WRITING FOR RESULTS • REGULATORY & QUALITY TECHNICAL WRITING

CROSS-BORDER REGULATORY FILE ALIGNMENT

A 7-day diagnostic and translation sprint for international-to-U.S. FDA readiness.

Achieving compliance under international frameworks—such as EU MDR, IEC 62366-1, or regional GxP standards—requires rigorous engineering, yet those formats rarely map one-to-one onto U.S. FDA expectations. When global manufacturers submit international technical files directly through eSTAR without restructuring risk matrices and narrative logic, reviews stall over granularity and justification gaps.

Cross-Border Regulatory File Alignment bridges global technical mastery and U.S. regulatory expectations, transforming existing international files into linear, FDA-ready documentation aligned with QMSR, ISO 14971, and ICH Q9.

WHAT YOU GET

- **Usability & Risk Matrix Translation:** Converting broad IEC 62366-1 usability files and ISO 14971 tables into granular, step-by-step FDA Use-Related Risk Analysis (URRA) matrices.
- **QMSR & GxP Logic Alignment:** Mapping existing international quality procedures, CAPAs, and OOS records to current FDA reviewer and investigator expectations.
- **Clinical & Regulatory Narrative Localization:** Refining technical descriptions and traceability tables so clinical harm pathways and device controls read in unambiguous FDA review logic.

THE LOGISTICS

- **Delivery:** Seven business days from initial technical file, risk table, and target pathway intake.
- **Scope Boundaries:** Limited to structural alignment, terminology localization, and risk-matrix restructuring for a single device or drug-delivery technical file.
- **Investment:** $1,450 flat rate.
- **Added Value:** The entire fee serves as an immediate credit toward full submission narrative drafting or FDA Deficiency Letter (RFI) response support if required.

Your engineers already mastered the technology. We translate that expertise into clear, defensible FDA logic.

Supporting global manufacturers and U.S. licensing partners across MedTech, Pharma, and Biologics.

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