THE STRATEGIC URRA FRAMEWORK

A high-authority human factors documentation sprint for regulatory acceleration.

Under the FDA's newly finalized guidance and strict PDUFA VII milestones, your Use-Related Risk Analysis (URRA) is the absolute gatekeeper of your submission timeline. A disorganized risk table using outdated terminology will trigger an immediate 60-day review stall or force your company into months of unnecessary, expensive clinical usability testing.

The **Strategic URRA Framework** modernizes your usability documentation, completely aligning it with updated QMSR expectations and ISO 14971 standards.

WHAT YOU GET

- **QMSR Alignment Audit:** A rigorous vocabulary and structure sweep to completely eliminate retired design control terms, replacing them with updated developer and risk control framework language.
- **Critical Task Matrix:** A highly logical, defensible mapping of user interface tasks, use errors, and explicit risk control measures tailored to withstand automated FDA screening tools.
- **Justification Architecture:** The technical construction of an objective, data-backed rationale within your URRA tables designed to legally minimize or completely bypass clinical human factors validation testing where safely applicable.

THE LOGISTICS

• **Delivery:** Seven business days from initial hazard and user interface intake.

• **Scope Boundaries:** Limited to the structural overhaul, tabular optimization, and compliance logic generation for a single device user interface or instruction set.

• **Investment:** $1,450 flat rate.

• **Added Value:** The entire fee serves as an immediate credit toward full-scale human factors protocol drafting or remediation writing support if required.

Don't let legacy terminology stall your market access. Master the gatekeeper document.

Secure Technical Intake and Booking