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Staying Compliant in a Changing Regulatory World – MedTech Standards Checklist

- Are you actively tracking updates to applicable standards such as ISO 14971, IEC 60601 series, and ISO 13485, including country-specific adoptions?
- Have you assessed if recent standards impact your product risk profile?
- Is your QMS updated to reflect new or revised standards?
- Do your technical documentation and CER align with the latest guidance?
- Have you subscribed to FDA & ISO update notifications?
- Do you maintain a regulatory change log with actions taken?
- Are RA/QA staff trained on new standard requirements?
- Is your UDI, labeling, or cybersecurity compliance plan affected?
- Have you consulted with a regulatory partner on impact analysis?