

## Navigating FDA's Updated Quality System Regulation (QSR) and ISO 13485 Consulting: What You Need to Know



Introduction: The Food and Drug Administration (FDA) recently announced significant updates to its Quality System Regulation (QSR), specifically focusing on aligning with international standards, particularly ISO 13485. These changes signal a major shift in the regulatory landscape for medical device manufacturers, necessitating a thorough understanding of the new requirements and their implications.

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