

Upsizing Compliance in a Downsizing Environment: Strategies for Ensuring GXP Compliance in the Face of Cost Reductions

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The healthcare industry is currently in a period of seemingly opposing objectives—cost cutting during a period of increasing US Food and Drug Administration enforcement of compliance deficiencies. This discussion addresses the identification of areas in which we cannot minimize compliance focus while providing thoughts and approaches that might represent opportunities. Principles of quality risk management may be applied to identify compliance improvement opportunities. A seven-step approach is proposed. Industry cannot take risks with “black or white” GXP elements. Opportunities...

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