

# Ispe Gamp Good Practice Guide Electronic Records And Data

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GAMP Good Practice Guide  
A Risk-based Approach to Operation of GxP Computerized Systems  
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this gamp good practice guide a risk based approach to gxp process control systems is a revision of the gamp good practice guide validation of process control systems it provides guidance and examples on the application of the principles and framework of gamp 5 a risk based approach to compliant gxp computerized systems to a wide range of systems from basic instruments to large complex distributed control systems this guide aims to achieve process control systems that are fit for intended use and compliant with applicable regulations providing recommended good practice based on a life cycle approach for the development maintenance and management of process control systems the guide applies science based quality risk management as described in ich q9 and gamp 5 it describes the system life cycle from concept to retirement

providing a high level overview of the approach together with guidance on how activities might be scaled based on risk to product quality system novelty and complexity as well as other project specific factors

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