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Practice Guide: Data Integrity by Design  
 The ISPE GAMP® RDI Good Practice Guide: Data Integrity - Key Concepts provides detailed practical guidance to support data integrity within a regulated organization. In recent years significant problems with data integrity have been found in the pharmaceutical, biotechnology, and medical device industries worldwide.  
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The enormous strength of the ISPE GAMP® Data Integrity for Manufacturing Records guide is that it takes the reader through a logical pathway to define all of the data flows through the manufacturing process,

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The importance of data integrity is reflected in guidance, citations, and public comments of Regulators and Health Agencies. A number of companies have suffered serious regulatory and financial consequences as a result of unacceptable data integrity practices. [GAMP Guide: Records & Data Integrity](#)

(German Translation)

The ISPE GAMP® Guide: Records and Data Integrity provides principles and practical guidance on meeting current expectations for the management of GxP regulated records and data, ensuring that they are complete, consistent, secure, accurate, and available throughout their life cycle. This Guide is intended as a stand-alone ISPE GAMP® Guide aligned with the ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems.

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Title: GAMP Guide: Records & Data Integrity (German Translation) Author(s): Clark, Chris; Jones, Colin; Margetts, Tony; Newton, Mark; Perez, Arthur "Randy"; Price ...

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