



RECORDS AND
DATA INTEGRITY

GOOD PRACTICE GUIDE:

Data Integrity by Design



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Preface

Data Integrity by Design is the concept that data integrity must be incorporated from the initial planning of a business process through to the implementation, operation, and retirement of computerized systems supporting that business process. It promotes the application of critical thinking to identify how data flows through the business process, and to proactively assess and mitigate risks across both the system and data lifecycles. It emphasizes data integrity as foundational to protecting patient safety and product quality.

This *ISPE GAMP® RDI Good Practice Guide: Data Integrity by Design* supports organizations as they embrace and implement a holistic approach by leveraging data governance and knowledge management activities to drive continual improvement in data integrity. The Guide fosters a patient-centric mindset, focusing resources and management attention on quality best practices that inherently facilitate meeting regulatory compliance requirements.

This Guide provides a bridge between the system lifecycle approach defined in *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems*, and the data lifecycle approach in the *ISPE GAMP® Guide: Records and Data Integrity*. Data integrity can only be achieved when both lifecycle approaches are adopted, understood, and actively managed.

Part of the *ISPE GAMP® Guide: Records and Data Integrity* series, this Guide replaces and significantly expands upon the *ISPE GAMP® Good Practice Guide: Electronic Data Archiving* from 2007.

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