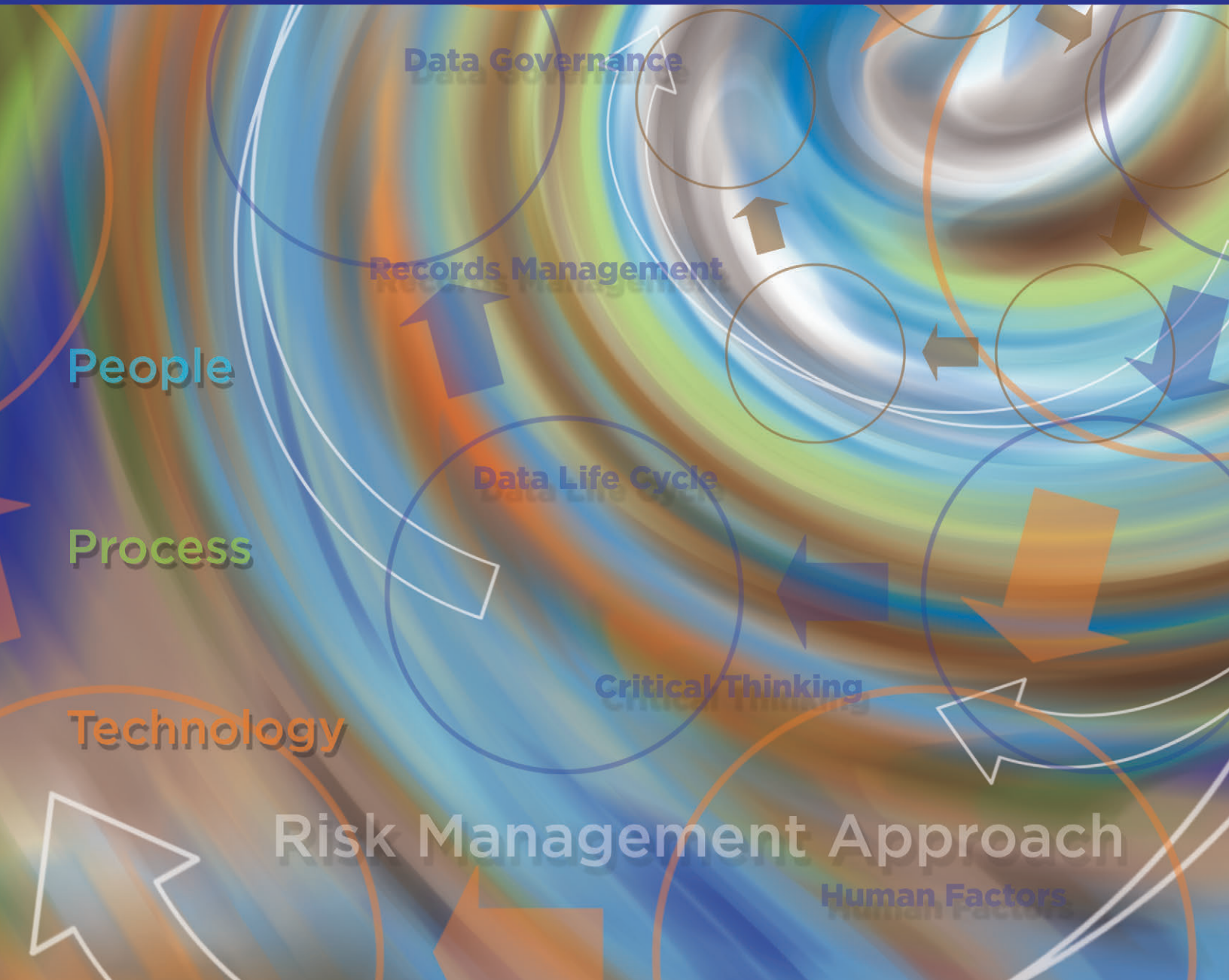


# Records and Data Integrity GUIDE







# Records and Data Integrity GUIDE

**Disclaimer:**

This Guide is intended to assist regulated companies in managing records and data throughout the data life cycle. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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# Preface

The importance of data integrity is reflected in recent 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.

Patient safety is affected by the integrity of critical records, data, and decisions, as well as those aspects concerned with physical attributes of the product. That the phrase “patient safety, product quality, and data integrity” is commonly used in regulatory and industry guidance underlines this point.

The use of information technology and computerized systems in all aspects of life sciences continues to grow and has resulted in the generation of more data to support the development and manufacture of products. Key decisions and actions are routinely being made based on this data, and the integrity of the data, whether in electronic or paper form, is of paramount importance to the industry, the regulatory agencies, and ultimately the patient.

Industry will benefit from clear guidance on ensuring that the management of records and data forms an integral part of the Quality Management System, and is compliant with GxP requirements. This Guide intends to provide such guidance and is aligned with *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems*.

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# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>9</b>
1.1	Background .....	9
1.2	Purpose .....	9
1.3	Scope .....	10
1.4	Structure of this Guide .....	10
1.5	Key Concepts .....	11
1.6	Key Terms .....	15
<b>2</b>	<b>Regulatory Focus .....</b>	<b>17</b>
2.1	Introduction .....	17
2.2	Data Integrity Requirements .....	17
<b>3</b>	<b>Data Governance Framework .....</b>	<b>21</b>
3.1	Introduction .....	21
3.2	Overview .....	21
3.3	Elements of the Data Governance Framework .....	23
3.4	Human Factors in Data Integrity .....	30
3.5	Data Integrity Maturity Model .....	31
<b>4</b>	<b>Data Life Cycle.....</b>	<b>33</b>
4.1	Introduction .....	33
4.2	Data Creation .....	34
4.3	Data Processing .....	35
4.4	Data Review Reporting and Use .....	36
4.5	Data Retention and Retrieval .....	39
4.6	Data Destruction .....	42
<b>5</b>	<b>Quality Risk Management .....</b>	<b>43</b>
5.1	Introduction .....	43
5.2	Process Risk Assessment .....	43
5.3	Quality Risk Management Approach .....	43
5.4	Product and Process Context .....	45
 <b><u>Management Appendices</u></b>		
<b>6</b>	<b>Appendix M1 - Corporate Data Integrity Program.....</b>	<b>47</b>
6.1	Introduction .....	47
6.2	Is a Corporate Data Integrity Program Required?.....	47
6.3	Indicators of Program Scope and Effort .....	48
6.4	Implementation Considerations.....	50
6.5	Keys to Success.....	52
<b>7</b>	<b>Appendix M2 - Data Integrity Maturity Model .....</b>	<b>55</b>
7.1	Maturity Model.....	55
7.2	Data Integrity Maturity Level Characterization .....	59

<b>8</b>	<b>Appendix M3 – Human Factors .....</b>	<b>67</b>
8.1	Introduction .....	67
8.2	Corporate and Local Cultures .....	67
8.3	Classification of Incidents.....	68
8.4	Human Error.....	69
8.5	Data Falsification and Fraud .....	70
8.6	Impartiality.....	71
8.7	Behavioral Controls.....	71
<b>9</b>	<b>Appendix M4 – Data Audit Trail and Audit Trail Review .....</b>	<b>75</b>
9.1	Introduction .....	75
9.2	Regulatory Background.....	76
9.3	Application and Use of Audit Trails.....	77
9.4	Audit Trail Review .....	79
9.5	Technical Aspects and System Design .....	79
<b>10</b>	<b>Appendix M5 – Data Auditing and Periodic Review.....</b>	<b>81</b>
10.1	Introduction .....	81
10.2	Auditing for Data Integrity.....	81
10.3	Periodic Review .....	82
10.4	Other Reviews.....	83
10.5	Documenting Review Processes .....	83
<b>11</b>	<b>Appendix M6 – Inspection Readiness .....</b>	<b>85</b>
11.1	General Procedures.....	85
11.2	Key Information for Regulatory Inspections .....	86
<b>12</b>	<b>Appendix M7 – Integrating Data Integrity into Existing Records Management Processes.....</b>	<b>91</b>
12.1	Introduction .....	91
12.2	Record Creation.....	92
12.3	Active Records.....	92
12.4	Semi-active Records.....	92
12.5	Inactive Records .....	92
 <b>Development Appendices</b>		
<b>13</b>	<b>Appendix D1 – User Requirements .....</b>	<b>93</b>
13.1	Introduction .....	93
13.2	Business Process.....	93
13.3	General Data Integrity Requirements.....	94
<b>14</b>	<b>Appendix D2 – Process Mapping and Interfaces.....</b>	<b>99</b>
14.1	Introduction .....	99
14.2	Process Flowcharts.....	99
14.3	Data Flow Diagrams.....	102
14.4	How Much Is Needed?.....	103

<b>15 Appendix D3 – Risk Control Measures for Records, Data, and Electronic Signatures.....</b>	<b>105</b>
15.1 Introduction .....	105
15.2 Record and Data Controls.....	105
15.3 Electronic Signature Controls.....	105
15.4 Implementation of Record and Data Controls .....	107
15.5 Rigor of Controls .....	110
<b>16 Appendix D4 – Data Integrity Concerns Related to System Architecture .....</b>	<b>111</b>
16.1 Data Resides on a Local Hard Disk .....	111
16.2 Internally Managed Central Database.....	112
16.3 Internally Managed Distributed Data.....	112
16.4 Outsourced Managed Services.....	113
<b>17 Appendix D5 – Data Integrity for End-User Applications.....</b>	<b>117</b>
17.1 Introduction .....	117
17.2 Data Integrity for Spreadsheets .....	117
17.3 Data Integrity for PC Databases .....	119
17.4 Data Integrity for Statistical Tools.....	120

### **Operation Appendices**

<b>18 Appendix O1 – Retention, Archiving, and Migration.....</b>	<b>121</b>
18.1 Introduction .....	121
18.2 Retention Options .....	121
18.3 Protection of Records.....	121
18.4 Record Aging and Risk.....	122
18.5 Archival .....	122
18.6 Hybrid Situations and Archives .....	123
18.7 Audit Trail Considerations .....	124
18.8 Alternative Systems .....	125
18.9 Converting Electronic to Alternative Format or Alternative Media Hybrids.....	126
<b>19 Appendix O2 – Paper Records and Hybrid Situations.....</b>	<b>131</b>
19.1 Paper Records .....	131
19.2 Hybrid Situations.....	133
19.3 Use of Forms to Enforce Procedures.....	135

### **General Appendices**

<b>20 Appendix G1 – References .....</b>	<b>137</b>
<b>21 Appendix G2 – Glossary .....</b>	<b>141</b>
21.1 Acronyms and Abbreviations.....	141
21.2 Definitions .....	143



# 1 Introduction

## 1.1 Background

The impact of record and data integrity issues can be significant on a regulated company. It can result in recalls of products, warning or untitled letters, import alerts, injunctions, seizures, Application Integrity Policy Invocations/legal action, and ultimately the potential for patient harm. These regulatory actions can also have a significant financial impact.

There has been increased regulatory focus on all aspects of data integrity, including publication of specific regulatory guidance on the topic, and increased number of citations in the area.

For the purposes of this Guide:

- Regulated data is information used for a regulated purpose or to support a regulated process.
- *“Metadata is data that describes the attributes of other data, and provide context and meaning. Typically, these are data that describe the structure, data elements, inter-relationships, and other characteristics of data.”* [1].
- A regulated record<sup>1</sup> is a collection of regulated data (and any metadata necessary to provide meaning and context) with a specific GxP purpose, content, and meaning, and required by GxP regulations. Records include instructions as well as data and reports.
- *“Data Integrity is defined as the extent to which all data are complete, consistent and accurate throughout the data life cycle.”* [1]
- The integrity of records depends on the integrity of underlying data, and signatures executed to electronic records should be trustworthy and reliable. See Appendix D3.

This Guide addresses paper records, electronic records, and hybrid situations, while encouraging a move away from hybrid situations, wherever practical.

## 1.2 Purpose

This *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 approach is intended to encourage innovation and technological advance while avoiding unacceptable risk to product quality, patient safety, and public health.

This Guide is intended as a stand-alone Guide. It is aligned with *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* [3]. This Guide has been designed so that it can be used in parallel with guidance provided both in *ISPE GAMP® 5* [3] and other *ISPE GAMP® Good Practice Guides* [4].

Although the scope of this document is wider, it replaces the *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures*.

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<sup>1</sup> Within the US regulatory framework regulated electronic records, and associated signatures, are subject to 21 CFR Part 11 [2]. For further information see Appendix D3.