

# Table of Contents

<b>1</b>	<b>Introduction to GAMP</b> .....	<b>11</b>
1.1	How did the GAMP Initiative start? .....	11
1.2	Guidance for Suppliers .....	11
1.3	Further Revisions of the Guide .....	12
<b>2</b>	<b>Purpose</b> .....	<b>13</b>
<b>3</b>	<b>Scope</b> .....	<b>14</b>
<b>4</b>	<b>Benefits</b> .....	<b>15</b>
<b>5</b>	<b>GAMP Guidance</b> .....	<b>15</b>
5.1	Structure of the GAMP Guide .....	16
5.2	Objectives of this Revision of the GAMP Guide .....	17
<b>6</b>	<b>Validation Overview</b> .....	<b>19</b>
6.1	A Framework for Specification and Qualification .....	21
6.2	Development and Validation Activities .....	22
6.3	Terminology .....	24
6.4	Maintaining the Validated State .....	25
<b>7</b>	<b>Validation Life Cycle</b> .....	<b>26</b>
7.1	Overview of User Activities .....	26
7.2	Identify System .....	28
7.3	User Requirements Specification .....	28
7.4	Determine Validation Strategy .....	28
7.5	Validation, Quality, and Project Planning .....	29
7.6	System Specifications .....	31
7.7	System Description .....	31
7.8	Development and Review of Software .....	31
7.9	Testing .....	32
7.10	Validation Reporting .....	32
7.11	Maintaining the Validated State .....	33
<b>8</b>	<b>Management System for Suppliers of IT Systems</b> .....	<b>36</b>
8.1	Management System: Life Cycle Activities .....	37
8.2	Management System: Supporting Activities During Development .....	46
8.3	System Operation .....	47

<b>9</b>	<b>Process Control System Validation</b> .....	<b>47</b>
9.1	Introduction .....	47
9.2	Life Cycle Models .....	48
9.3	Types of Process Control Systems .....	50
9.4	Planning .....	53
9.5	Specification and Design .....	53
9.6	Development and Build .....	55
9.7	Design Review .....	56
9.8	Software Development .....	56
9.9	System Build .....	56
9.10	Software Review .....	57
9.11	Supplier Testing .....	57
9.12	Development Testing .....	57
9.13	Acceptance Testing .....	57
9.14	Instrument Inspection and Calibration .....	58
9.15	Qualification .....	58
9.16	Validation Report .....	59
9.17	Maintaining the Validated State .....	59
9.18	Retirement .....	59
<b>10</b>	<b>Benefits of Validation</b> .....	<b>60</b>
10.1	Introduction .....	60
10.2	Knowledge Benefits .....	60
10.3	Business Benefits of Validation .....	61
<b>11</b>	<b>Good Practice Definitions</b> .....	<b>61</b>
11.1	Good Documentation Practice .....	61
11.2	Good Testing Practice .....	62
11.3	Good Engineering Practice .....	63
<b>12</b>	<b>Glossary and Acronyms</b> .....	<b>65</b>
12.1	Glossary .....	65
12.2	Acronyms .....	71
<b>13</b>	<b>Source Material</b> .....	<b>72</b>
13.1	References and Reading List .....	72
13.2	ISO Models, Standards, and Guidelines .....	75
13.3	ANSI/IEEE Standards .....	76
13.4	GMA/NAMUR Guidelines .....	76
13.5	Other Standards .....	77
13.6	Sources of Information and Publications .....	77
<b>14</b>	<b>Previous Acknowledgements</b> .....	<b>78</b>
14.1	Full Acknowledgements for Version 3.0 .....	78
14.2	Acknowledgements from Version 2.0 .....	80
14.3	Acknowledgements From Previous Revisions .....	81
<b>15</b>	<b>Appendices</b> .....	<b>84</b>

# Table of Appendices

## Management Appendices

Appendix M1	Guideline for Validation Planning
Appendix M2	Guideline for Supplier Audit
Appendix M3	Guideline for Risk Assessment
Appendix M4	Guideline for Categories of Software and Hardware
Appendix M5	Guideline for Design Review and Requirements Traceability Matrix
Appendix M6	Guideline for Quality and Project Planning
Appendix M7	Guideline for Validation Reporting
Appendix M8	Guideline for Project Change Control
Appendix M9	Guideline for Configuration Management
Appendix M10	Guideline for Document Management

## Development Appendices

Appendix D1	Example Procedure for the Production of a User Requirements Specification
Appendix D2	Example Procedure for the Production of a Functional Specification
Appendix D3	Example Procedure for the Production of a Hardware Design Specification
Appendix D4	Example Procedure for the Production of Software Design Specifications and Software Module Design Specifications
Appendix D5	Guideline for the Production, Control, and Review of Software
Appendix D6	Guideline for the Testing of an Automated System

## Operation Appendices

Appendix O1	Guideline for Periodic Review
Appendix O2	Example Procedure for the Production of a Service Level Agreement
Appendix O3	Guideline for Automated System Security
Appendix O4	Guideline for Operational Change Control
Appendix O5	Guideline for Performance Monitoring
Appendix O6	Guideline for Record Retention, Archiving, and Retrieval
Appendix O7	Guideline for Backup and Recovery of Software and Data
Appendix O8	Guideline for Business Continuity Planning
Appendix O9	EU Guideline on Computerized Systems, with APV Interpretation