GAMP 4 to GAMP 5 Summary

Introduction

This document provides summary information on the GAMP 5 Guide and provides a mapping to the previous version, GAMP 4. It specifically provides:

1. Summary of Need for GAMP 5
2. Overview of GAMP Documentation Structure
3. GAMP 5 Main Body Structure
4. GAMP 5 Appendices
5. New and Revised Material
6. GAMP 4 to GAMP 5 Mapping

1   Summary of Need for GAMP 5

The GAMP Guide has been significantly updated to align with the concepts and terminology of recent regulatory and industry developments.

These regulatory and industry developments focus attention on patient safety, product quality, and data integrity. This is a key driver for GAMP 5.

Coupled to this there is the need to:

- Avoid duplication of activities (e.g., by fully integrating engineering and computer system activities so that they are only performed once)
- Leverage supplier activities to the maximum possible extent, while still ensuring fitness for intended use
- Scale all life cycle activities and associated documentation according to risk, complexity, and novelty
- Recognize that most computerized systems are now based on configurable packages, many of them networked
- Acknowledge that traditional linear or waterfall development models are not the most appropriate in all cases

2 Overview of GAMP Documentation Structure

The GAMP Guide forms part of a family of documents that together provide a powerful and comprehensive body of knowledge covering all aspects of computerized systems good practice and compliance.
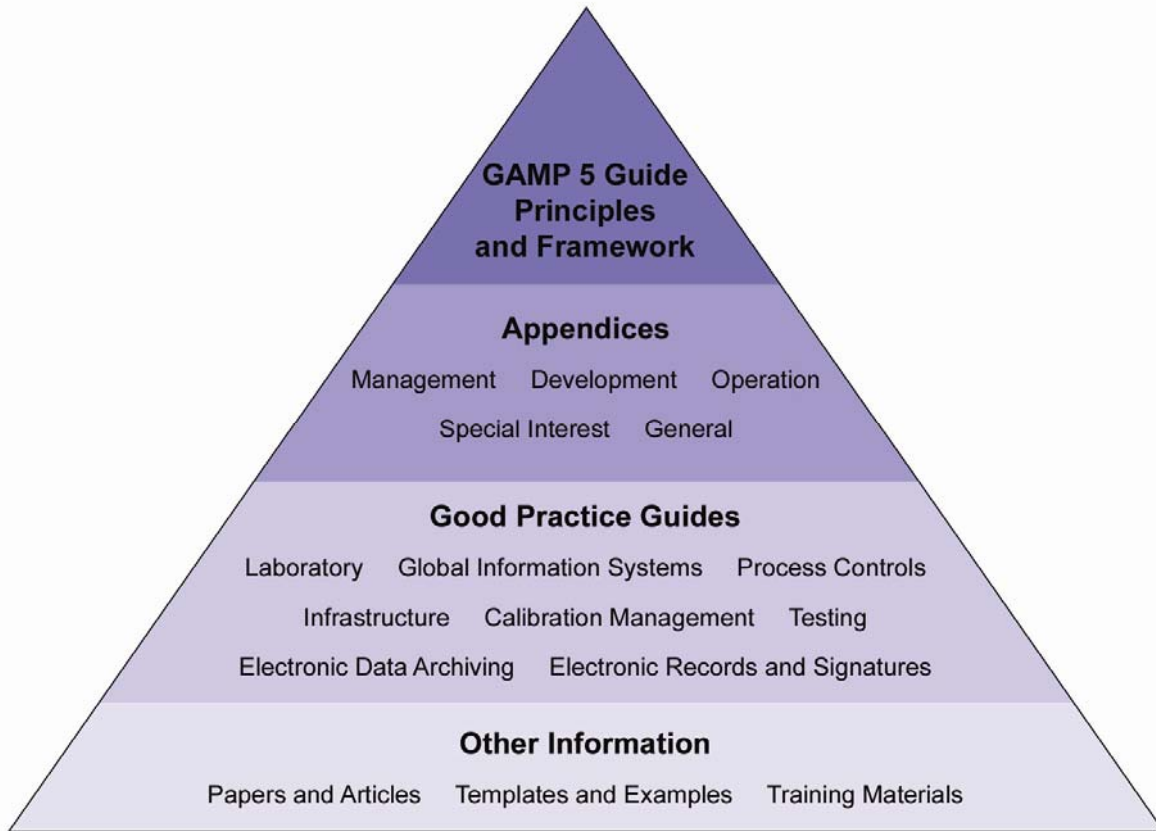
Source: Figure 1.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

This Guide comprises a **Main Body** and a set of supporting **Appendices**.

The **Main Body** provides principles and a life cycle framework applicable to all GxP regulated computerized systems.

Practical guidance on a wide range of specific topics such as planning, specification, risk management, testing, operation, and change management is provided in the supporting **Appendices**. A new set of appendices is also provided in GAMP 5 to cover topics of current interest such as outsourcing and end user applications. The full list of Appendices is found after the Table of Contents.

Separate GAMP **Good Practice Guides** (GPGs) cover the application of these general principles and framework to specific types of systems and platforms. Other GPGs provide detailed approaches to specific activities and topics.

3   GAMP 5 Main Body Structure

The Main Body introduction covers the purpose, scope, benefits, and structure of GAMP 5. Subsequent sections of the Main Body cover the following topics:

- Key Concepts
- Life Cycle Approach
- Life Cycle Phases:
    - Concept
    - Project
    - Operation
    - Retirement
- Science Based Quality Risk Management
- Regulated Company Activities:
    - Governance for Achieving Compliance
    - System Specific Activities
- Supplier Activities
- Efficiency Improvements

The **key concepts** described in Section 2.1 are the five concepts, based on current and innovative industry thinking, that underpin the rest of the document.

The computerized system **life cycle** encompasses all activities from initial concept, and understanding the requirements, through development, release, and operational use, to system retirement. Section 3 describes these activities and how they are related.

Section 4 describes the **project life cycle phase** in more detail:

- Planning
- Specification, Configuration, and Coding
- Verification
- Reporting and Release

The key supporting processes of risk management, change and configuration management, design review, traceability and document management are also introduced.

Quality risk management is a systematic approach for the assessment, control, communication, and review of risks to patient safety, product quality, and data integrity. It is an iterative process applied throughout the entire system life cycle. Section 5 describes this approach, and how the activities should be based on good science and product and process understanding.

Ensuring compliance and fitness for purpose is the responsibility of the regulated company. Effective and consistent **regulated company activities** for individual systems requires a defined organizational and **governance** framework, covering aspects such as policies, responsibilities, management, and continuous improvement. Governance and system specific regulated company activities are covered in Section 6.

While the responsibility for compliance lies with the regulated company, the supplier has a key role to play. An overview of typical **supplier activities** is given in Section 7.

This document provides a flexible framework for achieving compliant computerized systems that are fit for intended use, but the full benefits will be obtained only if the framework is applied effectively in the context of a particular organization. Section 8 covers key topics leading to **efficiency improvements**.

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4 GAMP 5 Appendices

Practical guidance on a wide range of specific topics is provided in the following appendices, which are grouped as management, development, operational, special interest, and general appendices.

Management Appendices

Appendix M1 Validation Planning
Appendix M2 Supplier Assessment
Appendix M3 Science Based Quality Risk Management
Appendix M4 Categories of Software and Hardware
Appendix M5 Design Review and Traceability
Appendix M6 Supplier Quality and Project Planning
Appendix M7 Validation Reporting
Appendix M8 Project Change and Configuration Management
Appendix M9 Document Management
Appendix M10 System Retirement *(new appendix topic in GAMP 5)*

Development Appendices

Appendix D1 User Requirements Specifications
Appendix D2 Functional Specifications
Appendix D3 Configuration and Design
Appendix D4 Management, Development, and Review of Software
Appendix D5 Testing of Computerized Systems
Appendix D6 System Descriptions *(new appendix topic in GAMP 5)*
Appendix D7 Data Migration *(new appendix topic in GAMP 5)*

Operation Appendices

Introduction to Operation Appendices
Appendix O1 Handover *(new appendix topic in GAMP 5)*
Appendix O2 Establishing and Managing Support Services
Appendix O3 Performance Monitoring
Appendix O4 Incident Management *(new appendix topic in GAMP 5)*
Appendix O5 Corrective and Preventive Action *(new appendix topic in GAMP 5)*
Appendix O6 Operational Change and Configuration Management
Appendix O7 Repair Activity *(new appendix topic in GAMP 5)*
Appendix O8 Periodic Review
Appendix O9 Backup and Restore
Appendix O10 Business Continuity Management
Appendix O11 Security Management
Appendix O12 System Administration *(new appendix topic in GAMP 5)*
Appendix O13 Archiving and Retrieval

Special Interest Topics Appendices

Appendix S1 Alignment with ASTM E2500 *(new appendix topic in GAMP 5)*
Appendix S2 Electronic Production Records (EPR) *(new appendix topic in GAMP 5)*
Appendix S3 End User Applications Including Spreadsheets *(new appendix topic in GAMP 5)*
Appendix S4 Patch Management *(new appendix topic in GAMP 5)*
Appendix S5 Managing Quality within an Outsourced IS/IT Environment *(new appendix topic in GAMP 5)*
Appendix S6 Organizational Change *(new appendix topic in GAMP 5)*

General Appendices

Appendix G1 GAMP Good Practice Guide Summary *(new appendix topic in GAMP 5)*
Appendix G2 Glossary and Acronyms
Appendix G3 References

New and Revised Material

Particular emphasis is given in GAMP 5 on providing a cost effective approach to compliance and demonstrating fitness for intended use. To support this, new and updated guidance is given on the following aspects:

- A complete system life cycle approach as part of a Quality Management System (QMS), from concept to retirement
- A scaleable approach to achieve and maintain GxP compliance driven by novelty, complexity, and risk to patient safety, product quality, and data integrity
- Clarifying the role of the Quality Unit, and introducing the roles of Process Owner, System Owner, and Subject Matter Experts
- In the GMP environment, stressing the importance of clear requirements based on a thorough understanding of the science and of the Critical Quality Attributes (CQAs) of the development and manufacturing process and drug products, to facilitate the adoption of a Quality by Design (QbD) approach
- The leveraging of supplier documentation and knowledge, wherever possible, and subject to satisfactory supplier assessment to avoid unnecessary duplication
- Improving efficiency by promoting practical and effective interpretation of GAMP guidance
- Maximizing use of documentation from activities such as development and commissioning as verification evidence
- The importance of effective governance to achieve and maintain compliance
- Identifying opportunities for process and system improvements based on periodic review, root-cause analysis, and CAPA (Corrective and Preventive Action)

New information is provided in specific appendices on the following topics of special interest to industry:

- Alignment with ASTM E2500
- Organizational change
- Outsourcing
- Electronic batch recording
- End user applications such as spreadsheets and small databases
- Patch management

The CD accompanying the Guide provides supporting materials, including key diagrams, templates, forms, example documents, and background information.

The Guide also contains a comprehensive and highly usable Index for the first time in a GAMP document.

In summary, GAMP 5 has been updated to address the changing environment while still satisfying current international GxP regulatory expectations. The document represents current industry good practice and remains compatible with the principles presented in GAMP 4. The scope has been widened to include related industries and their suppliers, including biotechnology and systems used in medical device manufacturing (excluding software embedded within the medical devices themselves).

5   GAMP 4 to GAMP 5 Mapping

5.1   GAMP 4 Main Body

GAMP 4 Section	GAMP 4 Section Name	GAMP 5 Comments
1	Introduction	Equivalent GAMP 5 Introduction, which has been aligned with standard Introduction Section template for GAMP GPGs
2	Purpose	Covered in Section 1.3 in GAMP 5
3	Scope	Covered in Section 1.4 in GAMP 5 Specific sub-section covering supplier aspects
4	Benefits	Covered in Section 1.5 in GAMP 5
5	GAMP Guidance	Covered in Section 1.6 in GAMP 5
6	Validation Overview	The focus of GAMP 5 is to: • Provide a cost effective framework of good practice to ensure that computerized systems are fit for intended use and compliant with applicable regulations • Safeguard patient safety, product quality, and data integrity, while also delivering business benefit • Provide suppliers to the life science industry with guidance on the development and maintenance of systems by following good practice Section 2 *Key Concepts* provides and overview of the approach The role of validation is covered in Section 3.3 *Computerized System Validation Framework*
7	Validation Life-cycle	The life cycle approach in GAMP 4 has been expanded to encompass the entire computerized system life cycle, with comprehensive guidance on all phases from concept through project and operation to retirement; see Sections 3 *Life Cycle Approach* and 4 *Life Cycle Phases* Practical examples are provided in Section 4.2.6 Significant new material has been provided on the Operation Phase in Section 4.3 Guidance on risk management has been significantly enhanced; see Section 5 Regulated company activities are described in a dedicated section covering both governance for achieving compliance and system specific activities; see Section 6 Opportunities for efficiency improvements are also provided; see Section 8

GAMP 4 Section	GAMP 4 Section Name	GAMP 5 Comments
8	Management System for Suppliers of IT Systems	A dedicated section has been provided in GAMP 5 covering supplier activities, including a clear set of supplier good practice activities; see Section 7 GAMP 5 does not give separate guidance only relevant to IT systems. The Guide has been written to cover all types of systems, allowing particular aspects of specific types of systems to be covered by relevant GPGs
9	Process Control System Validation	GAMP 5 does not give separate guidance only relevant to process control systems See also comments above in previous row
10	Benefits of Validation	Covered in Section 1.5 in GAMP 5
11	Good Practice Definitions	Topics covered under relevant sections, e.g., documentation, testing
12	Glossary and Acronyms	Covered in Appendix G2 in GAMP 5
13	Source Material	References provided in Appendix G3 in GAMP 5
14	Previous Acknowledgments	Provided separately in GAMP 5
15	Appendices	Covered in Table of Appendices at start of GAMP 5 Main Body

5.2   GAMP 4 Management Appendices

All management appendices have been revised and rationalized to align with the new Main Body. They assist regulated companies and their suppliers with developing and revising their own procedures based on the material presented.

GAMP 4 Appendix Number	GAMP 4 Appendix Name	GAMP 5 Comments
M1	Guideline for Validation Planning (including validation master plans and validation plans)	Remains Appendix M1 in GAMP 5
M2	Guideline for Supplier Audit	Remains Appendix M2 in GAMP 5 Has been expanded to *Supplier Assessment*, which includes supplier audit based on risk, complexity, and novelty

GAMP 4 Appendix Number	GAMP 4 Appendix Name	GAMP 5 Comments
M3	Guideline for Risk Assessment	Remains Appendix M3 in GAMP 5 Appendix now titled *Science Based Quality Risk Management* to reflect expanded scope, which includes a quality risk management process and numerous examples
M4	Guideline for Categories of Software and Hardware	Remains Appendix M4 in GAMP 5 Categories have been refined and Category 2 no longer exists – for a full description see Section 4 of Appendix M4
M5	Guideline for Design Review and Requirements Traceability Matrix	Remains Appendix M5 in GAMP 5 Appendix now titled *Design Review and Traceability* to reflect the enhanced guidance on traceability, recognizing that a Requirements Traceability Matrix is only one valid method of providing traceability
M6	Guideline for Quality and Project Planning	Remains Appendix M6 in GAMP 5 Appendix now titled *Supplier Quality and Project Planning* to reflect the new focus
M7	Guideline for Validation Reporting	Remains Appendix M7 in GAMP 5
M8	Guideline for Project Change Control	Remains M8 in GAMP 5 and has been merged with M9 from GAMP 4 Appendix M8 is therefore now titled *Project Change and Configuration Management*
M9	Guideline for Configuration Management	Configuration Management now merged with M8 in GAMP 5 (see above) M9 is now Document Management (see below)
M10	Guideline for Document Management	Is now Appendix M9 in GAMP 5

5.3   GAMP 4 Development Appendices

All development appendices are now guidelines to assist regulated companies and their suppliers with developing and revising their own procedures based on the material presented.

GAMP 4 Appendix Number	*GAMP 4 Appendix Name*	*GAMP 5 Comments*
D1	Example Procedure for the Production of a User Requirements Specification	Remains Appendix D1 in GAMP 5 Is now guidance rather than an example procedure New guidance provided on requirements capture
D2	Example Procedure for the Production of a Functional Specification	Remains Appendix D2 in GAMP 5 Is now guidance rather than an example procedure
D3	Example Procedure for the Production of a Hardware Design Specification	Appendix D3 has been expanded to cover both *Configuration and Design* Appendix D3 now covers software design and software module design that was in Appendix M4 in GAMP 4
D4	Example Procedure for the Production of Software Design Specifications and Software Module Design Specifications	Software design and software module design now covered in Appendix D3 (see above) Appendix D4 is now *Management, Development, and Review of Software* (was Appendix D5 in GAMP 4)
D5	Guideline for the Production, Control, and Review of Software	Production, control, and review of software now covered in Appendix D4 (see above) Appendix D5 is now *Testing of Computerized Systems* (was Appendix D6 in GAMP 4) New guidance is provided on test strategy, supplier test activities, automated testing, and testing applied to different categories of systems
D6	Guideline for the Testing of an Automated System	Testing now covered in Appendix D5 (see above) Appendix D6 is now *System Descriptions* (new topic in GAMP 5)

5.4   GAMP 4 Operational Appendices

Operational appendices have been significantly revised to cover all aspects of the Operation Phase. A new introductory section has been provided in GAMP 5 to describe the organization of each operational appendix and the approach adopted. Information on the key relationships between the various operational processes is also given.

As a result, the operational appendices have been reorganized, with five new appendices in GAMP 5 covering:

- Handover (Appendix O1)
- Incident Management (Appendix O4)
- Corrective and Preventive Action (Appendix O5)
- Repair Activity (Appendix O7)
- System Administration (Appendix O12)

The following table summarizes where the operational topics covered in GAMP 4 may now be found, along with relevant commentary.

GAMP 4 Appendix Number	GAMP 4 Appendix Name	GAMP 5 Comments
O1	Guideline for Periodic Review	Periodic review covered in Appendix O8 in GAMP 5
O2	Example Procedure for the Production of a Service Level Agreement	Appendix O2 has been expanded to cover *Establishing and Managing Support Services*, which includes the use of SLAs; *see* Appendix O2 for further details
O3	Guideline for Automated System Security	Automated system security covered in Appendix O11, *Security Management* in GAMP 5
O4	Guideline for Operational Change Control	Operational change control now covered in Appendix O6, which has been expanded to cover *Operational Change and Configuration Management*
O5	Guideline for Performance Monitoring	Performance monitoring covered in Appendix O3 in GAMP 5
O6	Guideline for Record Retention, Archiving, and Retrieval	Record retention, archiving, and retrieval covered in Appendix O13 in GAMP 5
O7	Guideline for Backup and Recovery of Software and Data	Backup and recovery covered in Appendix O9 in GAMP 5
O8	Guideline for Business Continuity Planning	Business continuity planning covered in Appendix O10 in GAMP 5
O9	EU Guideline on Computerized Systems, with APV Interpretation	Not in GAMP 5