

## **WHAT'S NEW IN GAMP4?**

The GAMP4 Guide for Validation of Automated Systems has just been launched at the ISPE Amsterdam conference on 3<sup>d</sup> and 4<sup>th</sup> December 2001. The Guide is considerably enhanced, having undergone a major restructuring since GAMP3 with much new or revised material

## WHAT'S NEW IN GAMP4 - SCOPE

### Target Audience

The target audience has been expanded from just pharmaceuticals to the whole healthcare industry including biotechnology and medical devices. The scope has been expanded to cover automated systems within Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Distribution Practice (GDP) in addition to the original Good Manufacturing Practice (GMP) environment.

## WHAT'S NEW IN GAMP4 – STRUCTURE

In place of the separate guidelines for end users and suppliers, the new GAMP4 guide is structured around the automated system lifecycle – with responsibilities of user and supplier brought out at each lifecycle stage. The structure has also been modified to stabilise the main Guide content and allow supporting ‘good practice guides’ to be issued for various areas. The overall structure for guidance is as follows:



### GAMP Principles and Framework

The main body of the GAMP4 Guide now covers: objectives of the Guide; an overview of validation; a discussion of the stages which make up the validation lifecycle; separate sections dealing with validation of IT systems and process control systems; a discussion of the benefits of validation; good practice definitions for documentation, testing and engineering; a glossary and list of source material.

### GAMP Appendices

The GAMP appendices have been greatly streamlined and are now divided into management activities (validation planning/reporting, risk assessment, project change control, etc); development activities (specification, code production, testing); and operating activities (service level agreements, performance monitoring, archive etc).

## WHAT'S NEW IN GAMP4 – SOFTWARE AND HARDWARE CATEGORIES

GAMP4 builds on the software categories 1 to 5 established in previous versions of the guide. Changes in GAMP4 include the following:

- Emphasis identifying categories for each component within a system.
- Category 2 is now renamed 'Firmware' (was 'Standard Instruments, Micro Controllers, Smart Instrumentation')
- Category 3 now concentrates on standard packages as purchased from the supplier. Spreadsheets have been removed to a separate discussion and are classified according to complexity as '3', '4' or '5'.
- Discussion of Application Development and Diagnostic Tools has been added.
- Hardware categories have been introduced.

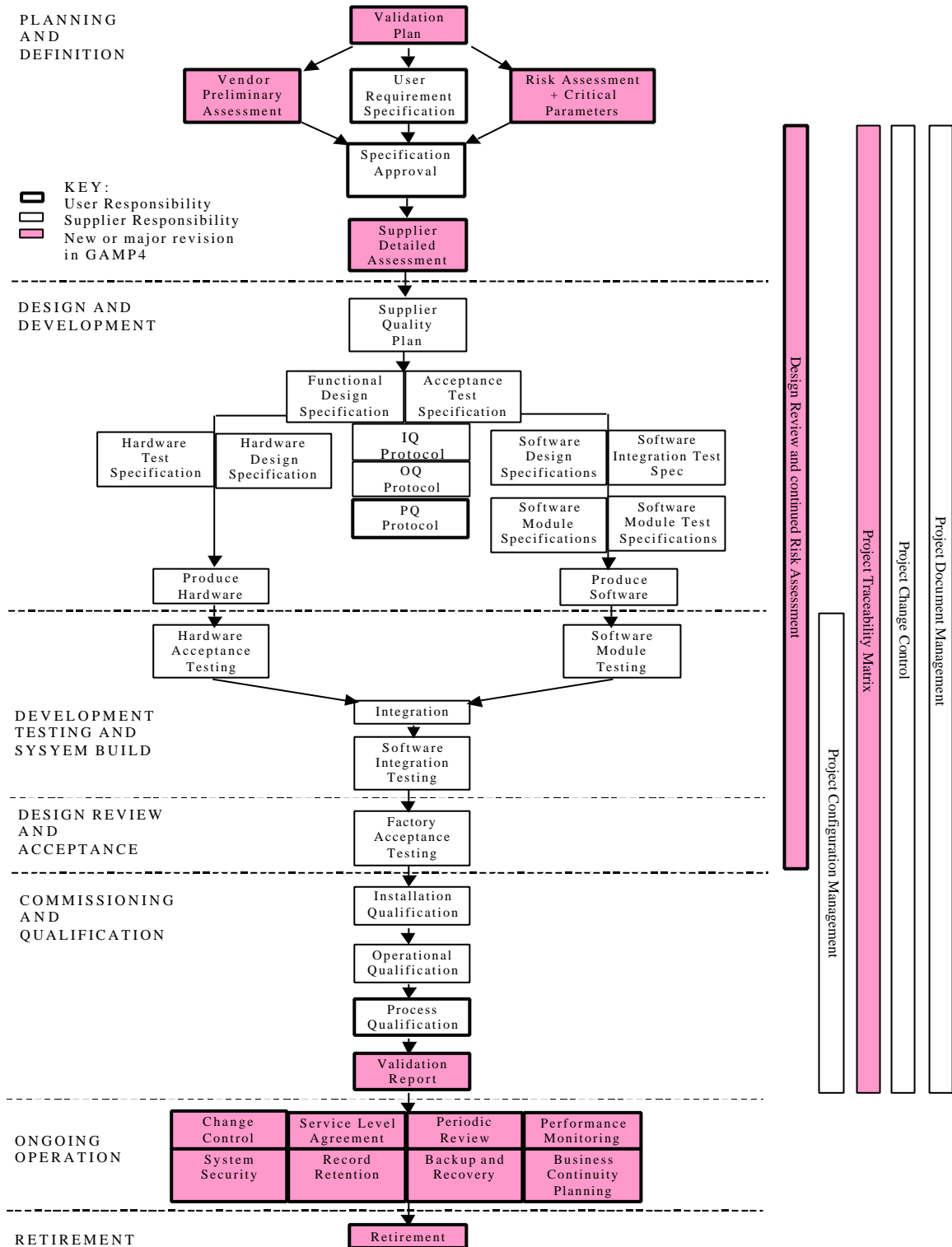
The categories are now summarized as follows:

Category	Software Type	Validation Approach
1	Operating Systems	Record version (include service pack). The Operating System will be challenged indirectly by the functional testing of the application.
2	Firmware	For non-configurable firmware record version. Calibrate instruments as necessary. Verify operation against user requirements.
		For configurable firmware record version and configuration. Calibrate instruments as necessary and verify operation against user requirements.
		Manage custom (bespoke) firmware as Category 5 software
3	Standard Software Packages	Record version (and configuration of environment) and verify operation against user requirements.
		Consider auditing the supplier for critical and complex applications.
4	Configurable Software Packages	Record version and configuration, and verify operation against user requirements.
		Normally audit the supplier for critical and complex applications.
		Manage any custom (bespoke) programming as Category 5.
5	Custom Software	Audit supplier and validate complete system

Category	Hardware Type	Validation Approach
1	Standard Hardware Components	Record model, version, serial number. Verify correct installation / connection. Apply change control.
2	Custom Built Hardware Components	As for standard components but also require a design specification and acceptance test. Supplier may be audited.

# WHAT'S NEW IN GAMP4 – LIFECYCLE ACTIVITIES

All lifecycle activities have been brought up-to-date with current best practice and regulatory requirements. The following example lifecycle model for a process control system highlights areas which are new or have undergone major revision in GAMP4.



### **Validation Planning and Reporting**

GAMP4 appendix M1 (Validation Planning) is much expanded from the GAMP3 appendix 6 although it builds on the same validation planning hierarchy through Validation Master Plans and individual system Validation Plans. The validation plan contents have been brought in line with current best practice by the inclusion of:

- GxP criticality assessment
- revised validation strategy to cover the revised lifecycle model
- formal list of validation deliverables
- formal acceptance criteria for each lifecycle phase
- formal detail of change control and document management procedures to be followed
- formal list of SOP's to be created or updated
- Actions and procedures required to maintain the validated state after handover from project to ongoing operation

GAMP4 appendix M7 (Validation Reporting) is new material detailing best practice for validation reporting for both individual lifecycle phases and the final validation report.

### **Supplier Audit**

GAMP4 appendix M2 (Supplier Audit) is new material covering both preliminary assessment and detailed supplier audit. It makes recommendations for audit planning and execution and also contains example checklists for both postal (preliminary assessment) audits and full supplier audits.

### **Risk Assessment**

GAMP4 appendix M3 (Risk Assessment) is new material covering risk assessment as part of the validation process. An initial risk assessment during URS generation is recommended in order to identify how much validation effort is required for a system and which areas are critical to GxP product quality, safety, environmental protection, or business continuity. A review of the risk assessment is then required during the design and development stage (to ensure that choice of supplier / implementation method has not introduced additional risks) and at completion of the design review prior to validation testing (to ensure that any problems identified or work-arounds implemented have not introduced additional risks). Once the system is in ongoing operation, risk assessment should form part of the ongoing change control strategy.

The appendix also describes an example risk assessment process used to identify risks, categorise according to severity and likelihood and determine appropriate mitigation strategies.

### **Design Review and Traceability**

GAMP4 appendix M5 (Design Review and Requirements Traceability Matrix) is new material covering design review planning and deliverables. Typically, a review is required at the end of each specification stage. In order for the review process to be meaningful, a formal traceability of user requirements through to design documentation and tests carried out is required. An example traceability matrix format is provided.

### Ongoing Operation (Maintaining the Validated State)

GAMP4 appendices O1 to O9 introduce new guidance on maintaining the validated state in an operating environment.

O1 – Periodic Review	Guideline for establishing whether validated state is being maintained (checking operation of O2 to O8 plus assessing changes in environment, legislation, operating procedures, personnel)
O2 – Service Level Agreements	Procedure for defining support requirements and agreeing support provisions between user and supplier (including control of fault reporting, workarounds / patches / upgrades, spares / consumables, routine calibration, support for software tools / hardware / infrastructure etc)
O3 – Automated System Security	Guideline for ensuring control, integrity, availability and confidentiality of data.
O4 – Operational Change Control	Guideline for review, risk assessment, authorization, documentation and re-test of changes. Allows exclusion of like-for-like replacement and emergency repairs (though emergency repairs must undergo the same review and control ‘after the event’).
O5 – Performance Monitoring	Guideline for parameters to be monitored (eg disk utilization, response times) and appropriate notification mechanisms.
O6 – Record Retention, Archiving and Retrieval	Guideline to address retention (security, indexing, availability during full retention period, etc) of all GxP records. Particular requirements for electronic record archival and retrieval.
O7 – Backup and Recovery	Guideline for data and software backups to guard against physical loss or accidental deletion.
O8 – Business Continuity Planning	Guideline covering broad issues of business continuity planning including risk assessment; disaster recovery procedures; contingency planning; emergency response planning; training; and rehearsal of the continuity plan.
O9 – EU Guideline on Computerized Systems	APV Specialist section interpretation of the Annex 11 ‘Computerized Systems’ points.

### Retirement

GAMP4 recommends an ‘archive report’ on decommissioning of a system including archival of documents, data and system software and detailing how access to electronic records is to be preserved.

## **GAMP Documentation**

Products and Services to assist with validation

Eurotherm is able to supply GAMP documentation for its range of recording and data acquisition products. Depending on the complexity of the project, documentation can be provided for either Software category 2 or 4.

On-site services are available to ensure that the installation and qualification stages are smoothly implemented. These services cover, IQ support, training, calibration and service contracts. All personnel and equipment used exceed the required standards for training and certification.

- **Documentation for Firmware (Software Category 2)**  
For simple applications of the 5000 series, it may be possible to use Category 2 (Firmware) documentation. This provides a simpler and more cost-effective route in the validation process. Provided that the configuration of the recorder is limited to paramatising only, Quality Managers may find this a useful approach. Category 2 documentation from Eurotherm comprises of a standard Functional Specification, a standard Installation Qualification, configuration of recorder to written specification and un-witnessed internal testing.
- **Documentation for Configurable Software Packages (Software Category 4)**  
All Eurotherm recording and data acquisition products can be provided with Category 4 (Configurable Software Packages) documentation. All configurations for these products can be covered by Category 4. The documentation service includes: Customer vendor audit, Functional Specification, Hardware Test Specification, Configuration Test Specification, IQ Specification, Configuration Management, Witnessed in-house testing.
- **Calibration Certification**  
Calibration certificates are available to either NPL or UKAS standards. This can be provided delivered with the product or on site. Routine calibration contracts can be arranged as required by the GAMP standard. This contract can include routine maintenance and spares support.
- **Installation Qualification**  
Eurotherm Service Support Engineers are available for on-site installation qualification. The Engineers are fully trained in GAMP procedures. Configuration control and documentation changes are all part of Eurotherms IQ service.
- **Training**  
Certificated training courses are available for all Eurotherm products. This can be on-site as part of the Installation Qualification or at Eurotherms headquarters. Courses can be tailored to individual needs and provide a simple method for complying with the GAMP training requirements.
- **Vendor Audits**  
Eurotherm welcomes audits by Customer Quality departments and regulatory bodies. We provide access to all necessary areas of the company including design, production and training records.

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