Good Automated Manufacturing Practices (GAMP)

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ISPE/GAMP Americas Steering Committee

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Presentation Overview

I. GAMP - Organization and Objectives

II. GAMP4 Guide for Validation of Automated Systems
Part 1

GAMP Organization and Objectives
# Pivotal Inspection

## Before

<table>
<thead>
<tr>
<th>Validation Plan</th>
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<tbody>
<tr>
<td>IQ</td>
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<tr>
<td>OQ</td>
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<tr>
<td>PQ</td>
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<td>Validation Report</td>
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## After

**Additionally:**

- Specification
- Design Review (DQ)
- Source Code Review
- Supplier Audit

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10/7/2004

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GAMP Objectives

Achieve Compliance by building upon existing industry good practices in an effective and efficient manner
GAMP Forum

Industry Board

GAMP Council

European Steering Committee

Americas Steering Committee

Special Interest Groups (SIGs)

Local ISPE
GAMP Council
Technical Sub-Committee of ISPE

- Set Directions
- Influence Industry and Regulators on the Interpretation of Regulations pertaining to:
  - Information Systems
  - Control Systems
  - Laboratory Systems
GAMP Organizations

GAMP Japan

GAMP Americas

GAMP Europe

GAMP DACH

JETT

Supplier Forum
Special Interest Groups (SIGs)

- Laboratory Systems
- IT Infrastructure Qualification
- Manufacturing Execution Systems
- Electronic Data Archiving
- Global Information Systems
- Research and Development Systems
Special Interest Groups (SIGs)

- Building Management Systems
- Testing of GxP Critical Systems
- JETT Consortium
Organizational Links

- APV (Germany)
- GMA/NAMUR (Germany)
- JETT
- ISPE
Links to Regulatory Agencies

- FDA
- MCA
- European Union
Influence

- Established reference in UK/Europe
- Cited by regulators as baseline practice by regulators (inc. FDA and MCA)
- Training of FDA Inspectors
GAMP Good Practices Guides

- GAMP4 Validation of Automated Systems
- Calibration Management
- Validation of Process Control Systems
- Validation of Legacy Systems
GAMP Good Practices Guides

In Preparation

- Validation of Laboratory Systems
- IT Infrastructure Qualification
- Validation of Manufacturing Control Systems (MES)
- Validation of Global Information Systems
GAMP Good Practices Guides

In Preparation

- Validation of R&D Systems
- Validation of Building Management Systems
- Testing of GxP Critical Systems
- Risk based Qualification of Equipment
Questions ?
Part II

GAMP4 Guide for Validation of Automated Systems
GAMP4 Principles

- Create simple, well understood rules
- Scale validation for size, criticality, and complexity
- Benefit from supplier capabilities
- Benefit from configurable SW packages
- Maintain validated state of the system in the operational environment
GAMP4 Principles

- Harmonize GAMP terminology with international quality concepts and industry initiatives
- Collaborate with other industry groups
- Achieve greater awareness of GAMP internationally
Structure of GAMP4 Guidance

- GAMP4 Guide is main body
- Good Practices Guides are supplements to GAMP4 Guide
- Guidance follows validation life cycle
- GxP Compliance Solutions for System Users and Suppliers
GAMP4 Themes

- System Development Life Cycle
- Validation Planning
- Risk and Impact Assessment
- Supplier Quality Management
- Specifications
- Design Review
- Formal Testing/Verification
Automated System

Environment: Legal, Organizational, Physical, Technical

Documentation

Equipment, Instruments

Computer Hardware

System Software

Data

Application SW

Used together ... for a given task
GAMP4 Software Categories

- 1 - Operating Systems
- 2 - Firmware
- 3 - Standard Software Packages
- 4 - Configurable Software Package
- 5 - Custom Software
GAMP4 Life Cycle

- User Requirements Specifications
- Functional Specifications
  - Design Specifications
    - System Build
  - Operational Qualification
  - Installation Qualification
- Performance Qualification

related to

System Build
System Verification & Validation

System User Requirements

Sys. Req.  Supplier  Hardware  Software  Data  QMS

0101 0110 1010 1011 0101 1101 0101 0110


Validation Summary Report
Management of the Validation

- Validation Planning
- Supplier Audit
- Risk Assessment
- Categories of Software and Hardware
- Design Review and Traceability Matrix
- Quality and Project Planning
- Document Management
- Project Change Control
- Validation Reporting
Validation Planning

- Strategy
- Deliverables
- Responsibilities
- Standards and Procedures

- Formally approved Plan
System Categorization

- Many systems contain software components of more than one category:
  - Operating System
  - Configurable application
  - Firmware
  - Custom modules
Supplier Assessment

- Guidance and tools on:
  - Assessment of capabilities and product
  - Audits
  - Management
User – Supplier Relationship

Primary Responsible for Specification

- User Requirements Specification
- Functional Specification
- Hardware Design Specification
- Software Design Specification
- Software Module Specification
- Code Modules

Primary Responsible for Testing

- Testing of the URS
- Testing of the Functional Specification
- Testing of the Hardware Specification
- Software Integration Testing
- Software Module Testing
- Review and Test Modules

System Acceptance Testing (Operational Qualification of Computer/PLC)

Hardware Acceptance Testing (Installation Qualification of Computer/PLC)

Performance Qualification

User and Supplier

User Requirements Specification

Functional Specification

Hardware Design Specification

Software Design Specification

Software Module Specification

Code Modules

Software Integration Testing

Software Module Testing

Review and Test Modules
Validation Strategy

Based on:

- Risk Assessment
- Assessment and Categorization of System Components
- Supplier Assessment
Risk and Impact Assessment

- Identify Processes
- Analyze:
  - Risk scenarios
  - Effects for each event
  - Likelihood of events
  - Severity of Impact
  - Likelihood of Detection
- Plan for Risk Management
Validation Activities

Planning
- Prepare written Validation Plan.

Specification
- Specify and agree what is required.
- Perform Design Reviews

Test Planning
- Prepare document to describe how the equipment or system is to be tested.

Testing
- Perform tests and collect results.

Review
- Review results to show that the system performs as specified, report conclusions plus any reservations.
Validation Approach

Category 1: Operating System

- Record version (incl. Service pack)
- Challenge OS indirectly by the functional
Validation Approach

Category 2: Firmware (Off-the-Shelf)

- **IQ**: Verify name, version, configuration, and calibration
- **OQ**: Test functionality
- **Change Control** for firmware and configuration parameters
- **Supplier Audit** for complex or critical applications
Validation Approach

Category 3: Standard Software Packages

- Configuration limited to the environment and parameters
- IQ verifies name and version
- OQ tests user requirements
- Supplier Audit for critical applications
Validation Approach

Category 4: Configurable Software Packages

Treat like Category 5 if platform and package not mature and well-known
Validation Approach

Category 5: Custom Software
- Execute complete Validation Life Cycle
Qualification Approach

Category 1: Standard Hardware Component

- Record Model, Version, Serial number of pre-assembled hardware
- Verify installation and Connections
- Use hardware data sheet or other specifications for information on sealed units
- Apply change control and configuration management
Qualification Approach

- Category 2: Custom Built Hardware

- Same as Category 1, plus:
  - Design Specifications with configuration
  - Acceptance Testing
  - Supplier Audit of development process
  - Verification of Compatibility for components from different Sources
  - Verification at IQ
System Development
Build System and Achieve Validated State

- User Requirement Specification
- Functional Specification
- Hardware Design Specification
- Software Design Specification
- Production, Control, and Review of Software
- Testing of Automated System
System Specifications

- Define the System
- Allow further Specifications to be developed
- Allow the System to be developed
- Allow Maintenance of the System
Design Review (1)

- Evaluate Deliverables against Standards and requirements
- Identify problems and propose corrective actions
Design Review (2)

- Are all Requirements addressed?
- Is functionality appropriate and consistent?
- Will the system meet predefined standards?
- Is system appropriately tested?
Requirements Traceability

Forward and backward traceability:

System Requirements → Design → Test

←  ←
## Traceability Matrix

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<thead>
<tr>
<th>URS Ref</th>
<th>Description</th>
<th>GxP?</th>
<th>Other?</th>
<th>FS Ref</th>
<th>DS Ref</th>
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Software Control

- Module Traceability and Identification
- Design and Documentation Principles
- Good Programming Practice
- Source Code Review
Testing of Systems

- Test Planning, Specification, Execution, Documentation
- Scope of Testing
- Test Specifications
- Test Deliverables
- Good Practices for Testing
System Operation
Maintain Validated State

- Periodic Review
- Service Level Agreement
- Automated System Security
- Operational Change Control
- Performance Monitoring
- Record Retention, Archive, and Retrieval
- Backup and Recovery of Software and Data
- Business Continuity Planning
GAMP4 Recap

- GxP Computer Compliance Solutions
- Integration of Quality Standards (*ISO9000*) and Industry Standards (*IEEE*)
- Consensus of Regulators, Life Science Industry, and Consultants
Acknowledgments

- Dr. David Selby, Selby Hope International
- Sion Wyn, Conformity
- Arthur Perez, PhD, Novartis
Questions ?
Thank You
for your Interest in GAMP