Validation responsibilities and role of suppliers

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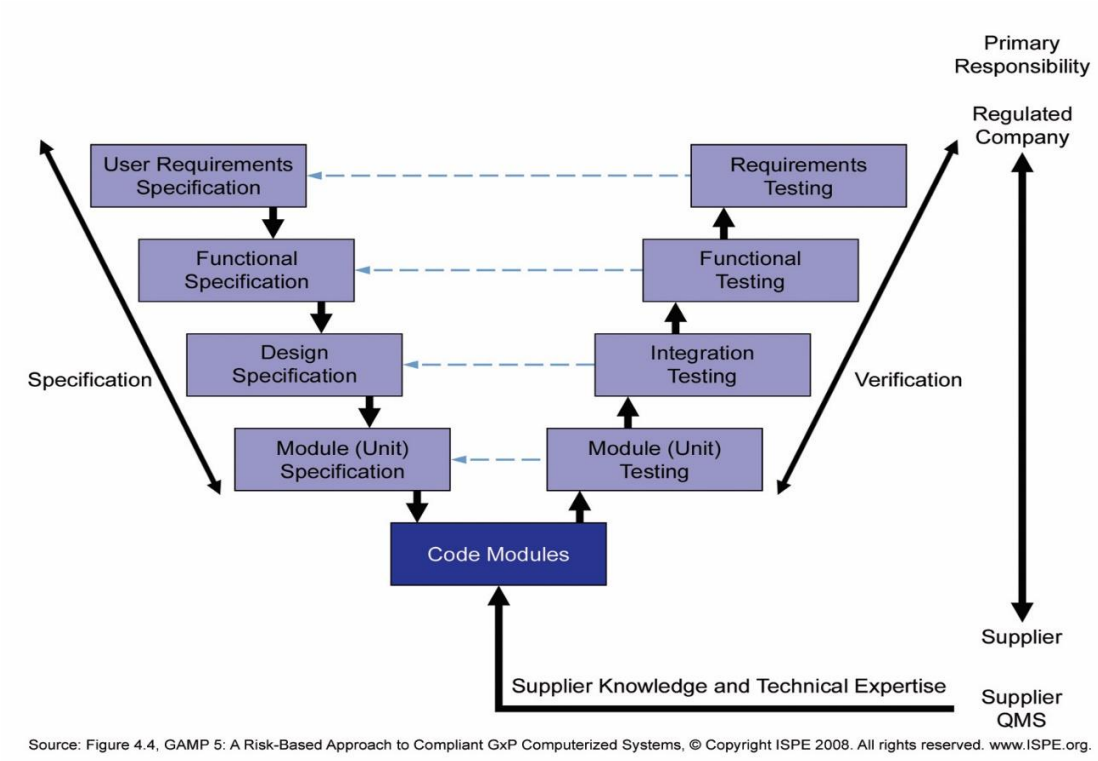
Validation Responsibility – Regulated Company vs Supplier

Regulated Companies are ultimately responsible for the Validation of Computerized System



Source: Figure 4.4, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

Supplier vs Regulated company

- GAMP guidelinestates clearly that Validation documentation shall leverage the documentation created by the System Supplier according to its own Quality System
- However, the MHRA recent position document has explicitly clarified that

  - the Computerized systems should comply with the requirements of EU GMP Annex 11 and be validated for their intended purpose. This requires an understanding of the computerized system's function within a process. For this reason, the acceptance of vendor-supplied validation data in isolation of system configuration and intended use is not acceptable.

  - In isolation from the intended process or end user IT infrastructure, vendor testing is likely to be limited to functional verification only, and may not fulfil the requirements for performance qualification.

  - 'Validation for intended use' would include testing during PQ to confirm that the required data is correctly extracted by the custom report, and presented in a manner which is aligned with the data review process described in the SOP.

  ➔ VALIDATION CANNOT BE EXECUTED ONLY BY THE VENDOR

Part 11 / Annex11 Compliance

- Supplier Declarations/White Papers and “standard” Testing are not enough to demonstrate System Compliance to Part 11/Annex 11
- Computerized Systems must be properly configured and used to ensure compliance to Part 11/Annex 11 provisions
- Compliance must be documented during the initial Validation through a full set of Specifications and Testing documents and maintained throughout the whole Life-Cycle of the System through the application of necessary SOPs
- GAMP documents are guides and not standards. It is inappropriate for suppliers to claim their “GAMP certification”

Validation Players

REGULATORY AGENCIES

INSPECTOR

PHARMACEUTICAL FIRM

SYSTEM OWNER

- QA
- IT
- End User

SW SUPPLIERS

SUPPLIER PM

- Analyst
- Developer

Validation responsibility: Process Owner

The **Process Owner** (PO) is a member of the business function that sponsors development and receives the most benefit from the system. Usually, he/she is the head of the department having in charge the system or a delegated person.

This individual shall ensure compliance with all quality and regulatory requirements, including system validation and applicable requirements

The Process Owner is responsible for the integrity, administration, operation, maintenance, and decommissioning of the system throughout the system's lifecycle. A third party may be designated to perform tasks associated with these activities.

The Process Owner can make decisions based on Subject Matter Expert (SME) input.

Validation responsibility: Quality Assurance (1/2)

The Quality Assurance (QA) approves all the Validation documents and assures their compliance with the company Policies and SOPs and with the applicable rules. QA coordinates and supervise the execution of the Validation activities and the issue of the related deliverables, in order to ensure their compliance to the reference standards and regulations

Validation responsibility: Quality Assurance (2/2)

The **Quality Assurance** covers also the following tasks:

- Identify the need for vendor assessment and to participate in the process of evaluation of the Supplier
- Assure that the Validation activities has been concluded before the system becomes operative
- Approve the Validation Standard Operative Procedures of the computerized systems and to verify their application
- Assure that the “Change Control” procedure is properly applied
- Organize periodical audits, in order to verify the maintenance of the Validation status of the Computerized Systems
- Review and to approve the training Plans
- Release the system

Validation responsibility: System Administrator

The **System Owner (System Administrator)** has the following tasks:

- Responsible for system configuration
- Manage system and assure its maintenance during and after system implementation
- Responsible for ensuring that the hardware meets the minimum requirements indicated by the Vendor
- Responsible for ensuring that the platform is installed and qualified as per standard IT procedures
- Responsible hardware is capable of supporting the application SW
- Responsible for the hardware and OS level software installation
- Responsible for reviewing and approving all the installation qualification documentation
- Support system operators' workstations maintenance activities
- Ensure Help desk support during the life cycle of the system

Validation responsibility: System key User

The **System Key User** (KU) is the person, group or department who use the system. He/she can eventually prepare the testing document and participate in validation activities

The Key User is required to:

- Support the validation process
- Attend required training
- Properly apply in the operative procedures defined concerning the “operation” step of the system
- Inform timely the System Owner of any relevant anomalies

Validation responsibility: IT

The **Information Management** provides additional technical expertise during the execution of the project or the normal functioning of the system.

Validation responsibility: SW Supplier

The **SW Supplier** has the following tasks:

- Primary responsible for indicating minimum hardware and OS level software requirements to support the application
- Primary responsible for writing application configuration and installation documentation
- Primary responsible for application SW/DB installation
- Primary responsible for providing training
- Primary Responsible for system configuration, customization and testing
- Support on validation activities

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Acknowledgements

References

- ISPE GAMP Forum - GAMP 5 - A Risk-Based Approach to Compliant GxP Computerized Systems