# Principles of Computer Systems Validation

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# What is Computer System Validation?

The most quoted definitions of process validation come from the FDA:

***"The collection and evaluation of data, from the process design state through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product."***

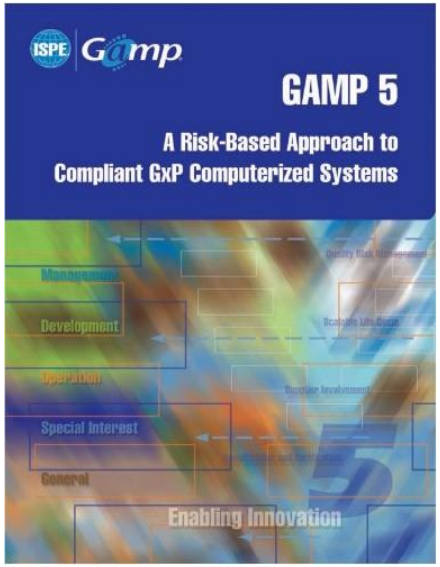
*"Guidance for Industry, Process Validation: General Principles and Practices", January 2011.*

***"Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes."***

*FDA "Guideline on general principles of process validation, May, 1987"*

***Computerized Systems Validation is the documented proof enabling to conclude with a high degree of assurance that a computerized system operates as defined in its specifications, as well as according to quality and regulatory requirements, in a constant and reproducible manner.***

***In addition, the Validation process shall provide documented evidence that the system includes the automated functionalities oriented to ensure that the GMP critical Electronic Records meet the ALCOA+ requirements.***

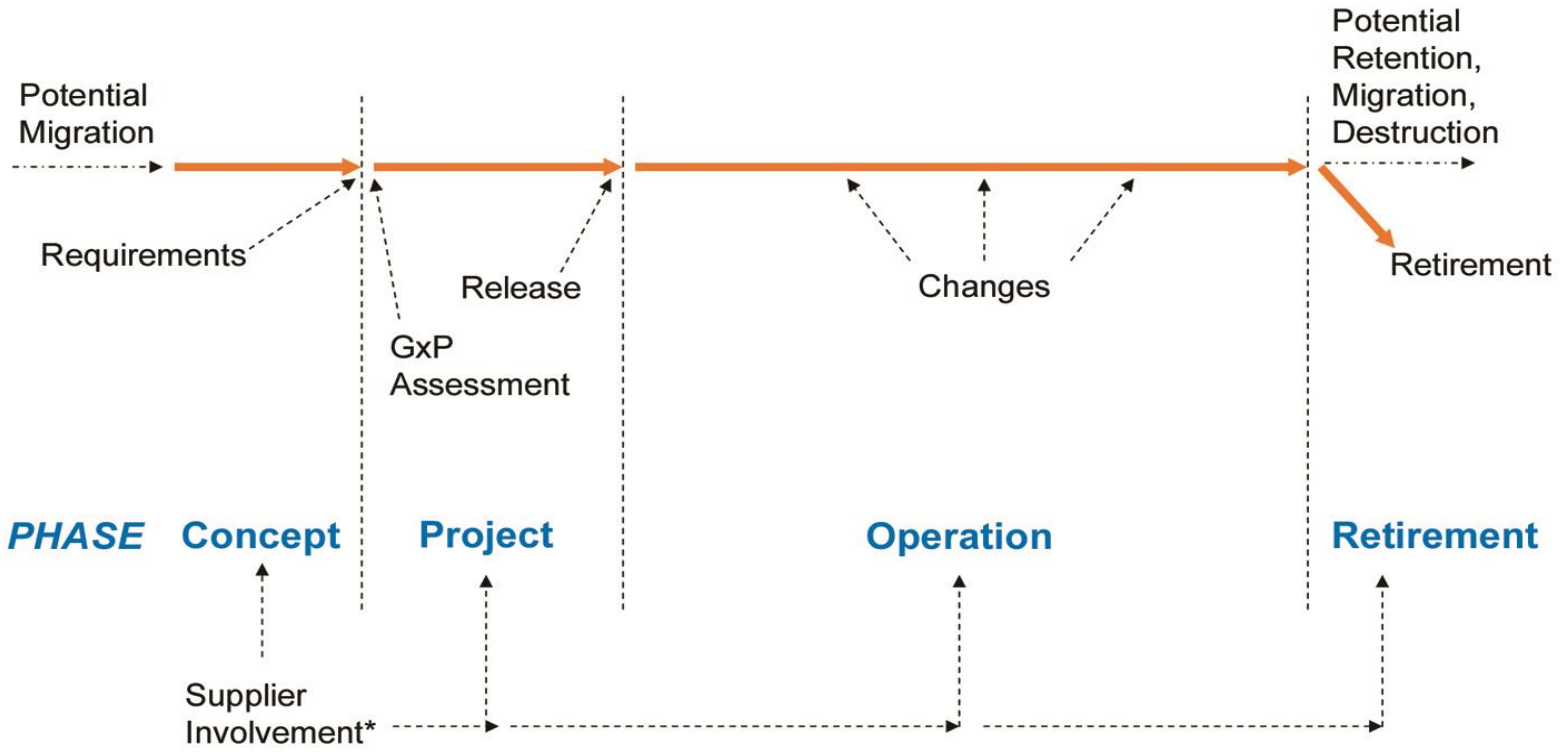



# ISPE GAMP FORUM

GAMP 5

A Risk-Based Approach to Compliant GxP Computerized Systems

# Life Cycle Phases




* - This could be a complex supply chain
- Supplier may provide knowledge, experience, documentation, and services throughout lifecycle

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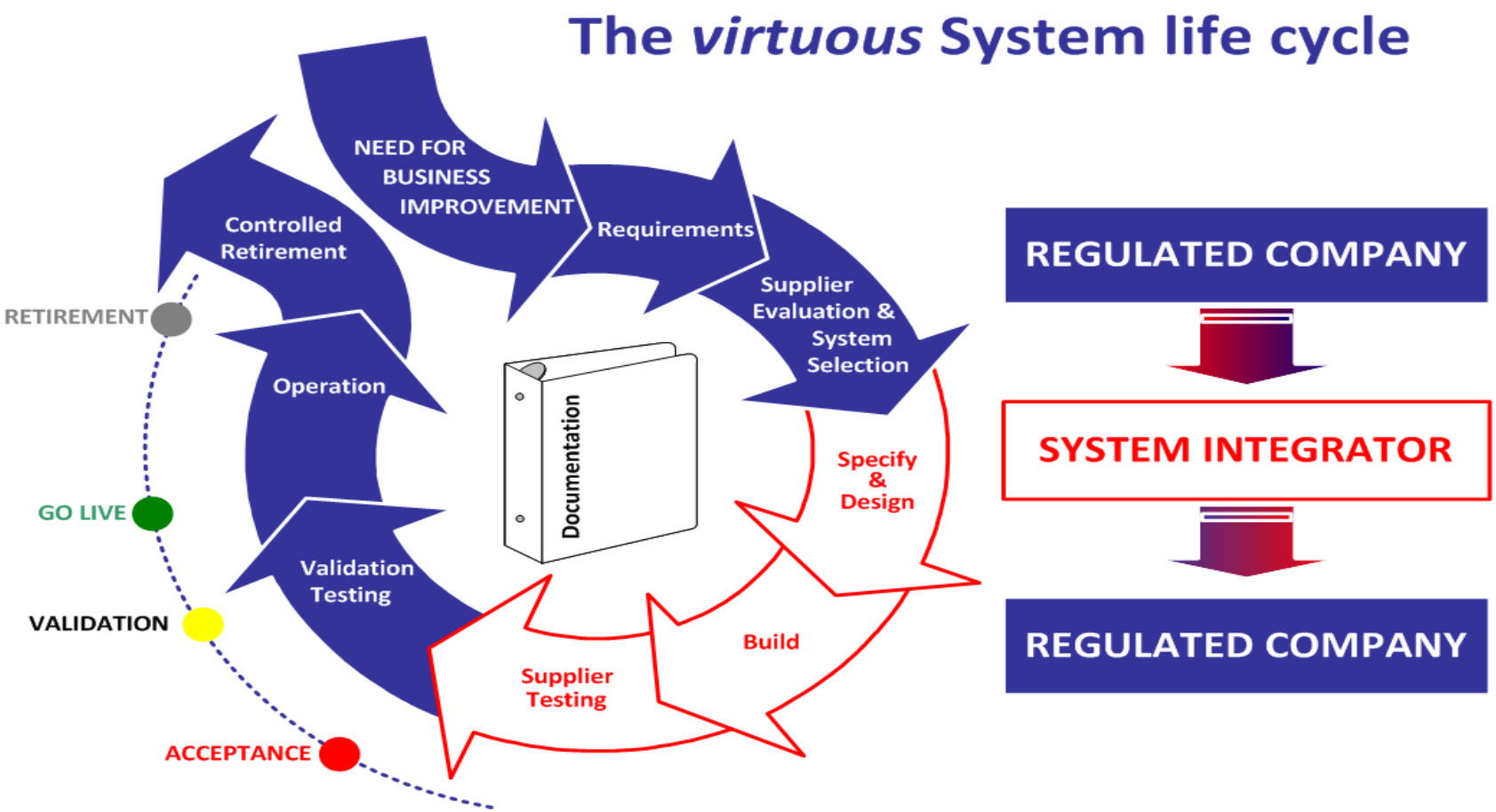
# Validation: A PROCESS NOT AN EVENT



# SW GAMP5 Categories (1/2)

## APPENDIX M4: Categories Of Software And Hardware

| SW Category | Description | Examples |
|---|---|---|
| 1 - Infrastructure Software | ⇨ Layered software (i.e., upon which applications are built)<br>⇨ Software used to manage the operating environment | ⇨ Operating Systems<br>⇨ Database Engines<br>⇨ Middleware<br>⇨ Programming languages<br>⇨ Statistical packages<br>⇨ Spreadsheet<br>⇨ Network monitoring tools<br>⇨ Scheduling tools<br>⇨ Version control tools |
| 2 - Firmware | THIS CATEGORY IS NO LONGER USED | |
| 3 - Non-Configured | Run-time parameters may be entered and stored, but the software cannot be configured to suit the business process | Firmware-based applications<br>COTS software<br>Instruments |

# SW GAMP5 Categories (2/2)

## APPENDIX M4: Categories Of Software And Hardware

| SW Category | Description | Examples |
|---|---|---|
| 4 - Configured | Software, often very complex, that can be configured by the user to meet the specific needs of the user's business process.<br>Software code is not altered | LIMS, Data Acquisition Systems, SCADA, ERP, Clinical Trial Monitoring, DCS, Building Managements Systems, CRM, Spreadsheets, Simple Human Machine Interface |
| 5 - Custom | Software custom designed and coded to suit the business process | Internally and externally developed IT applications<br>Internally and externally developed process control applications<br>Custom firmware<br>Spreadsheets (macro) |

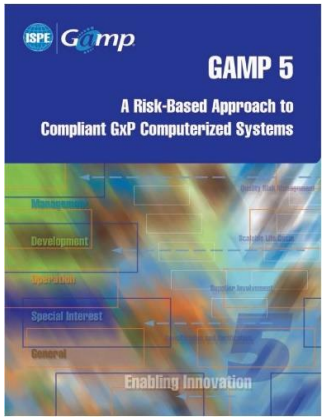
# Approach for Infrastructure Software (Cat.1)

- Documentation should be commensurate with the complexity / criticality of the system
- Documentation for any system should contain all the required elements to demonstrate that it has been validated and is in a state of Control
- How many documents is unimportant provided all required elements are present

| SW Category | Typical Approach |
|---|---|
| ⇨1 | ⇨Record version number, verify correct installation by following approved installation procedures<br>⇨See the GAMP Good Practice Guide: IT Infrastructure Control and Compliance |

# GAMP 5 Approach

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

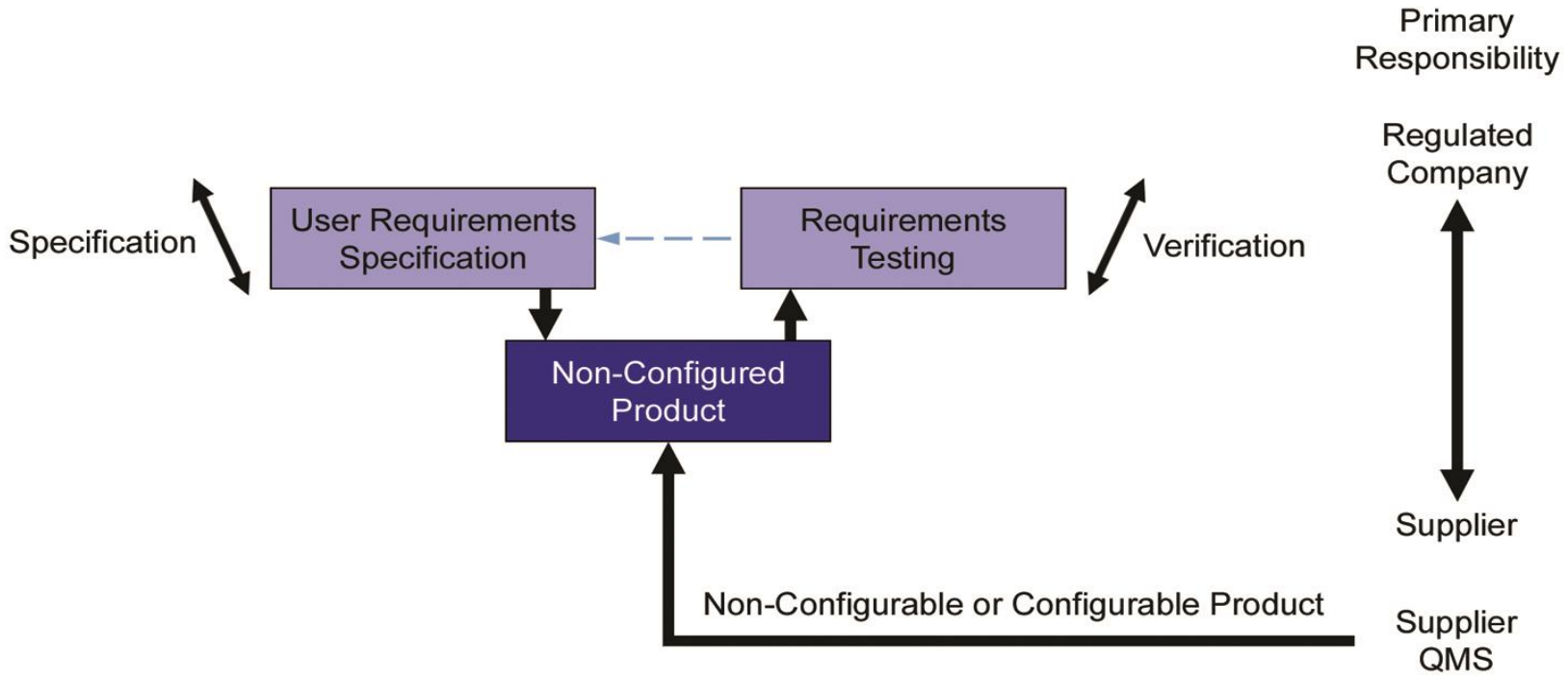



SYSTEM RISK ASSESSMENT → VALIDATION EFFORT

FUNCTIONAL RISK ANALYSIS → TESTING EFFORT

# Approach for non-configured Product

- **Non-Configured Product (Category 3)**

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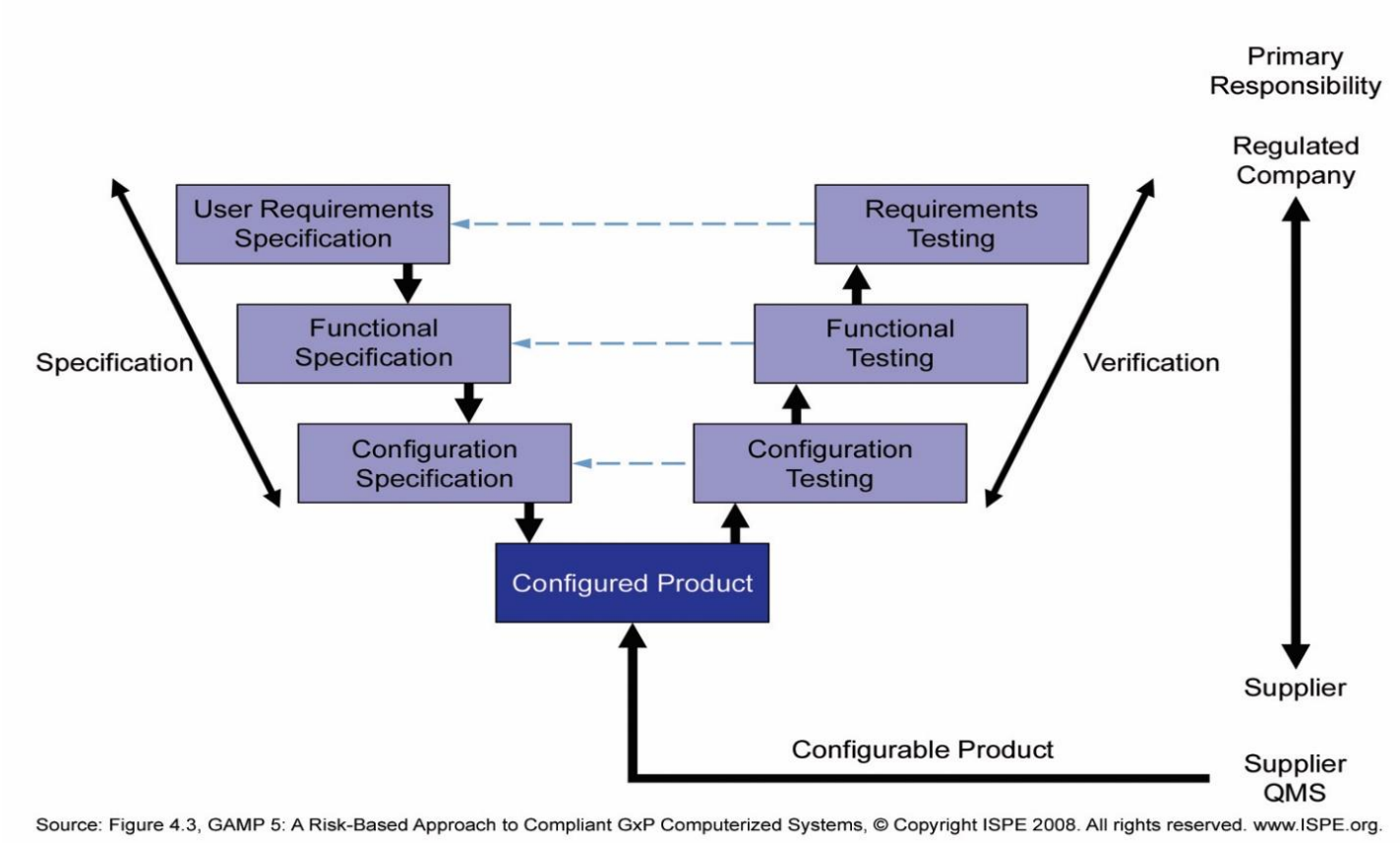
# Approach for Configured Product

- **Configured Product (category 4)**

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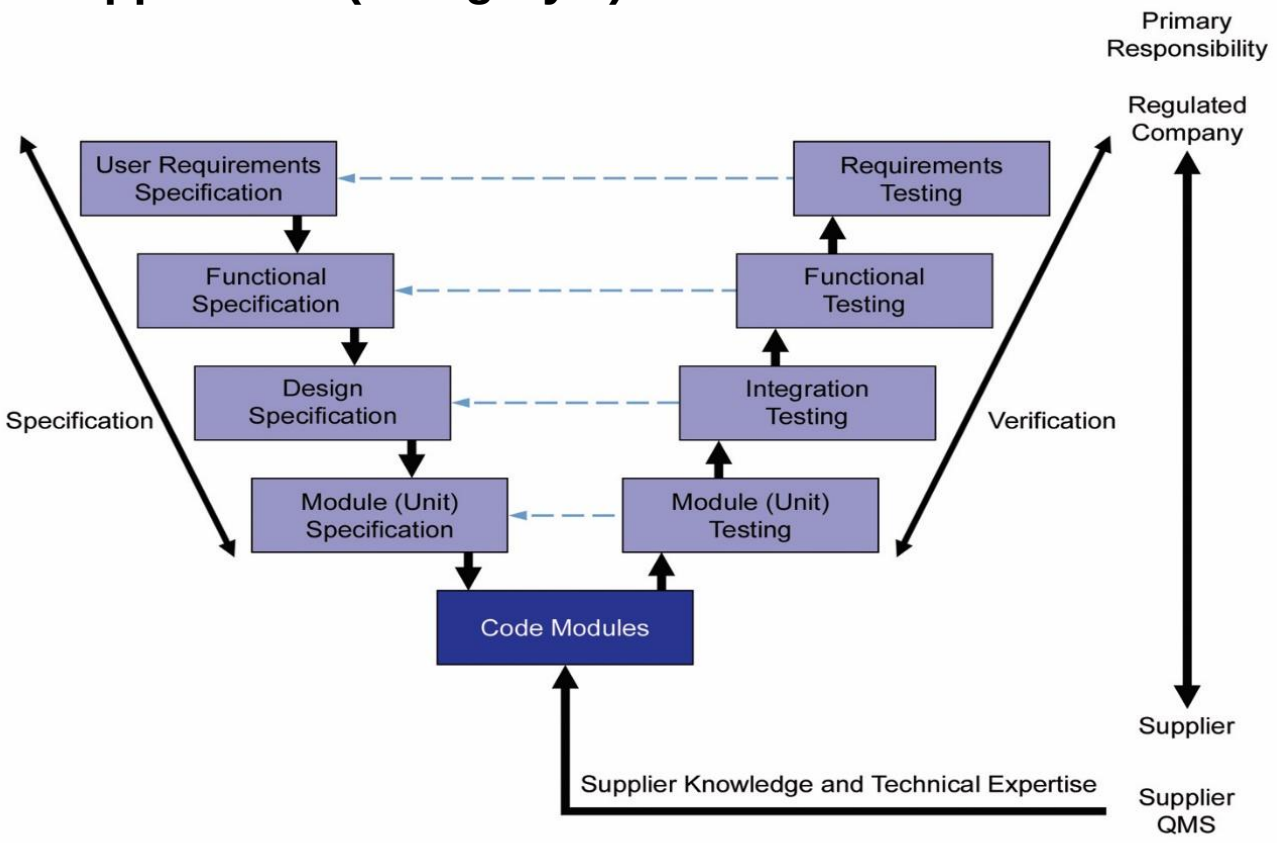
# Approach for Custom Product

- **Custom Application (Category 4)**

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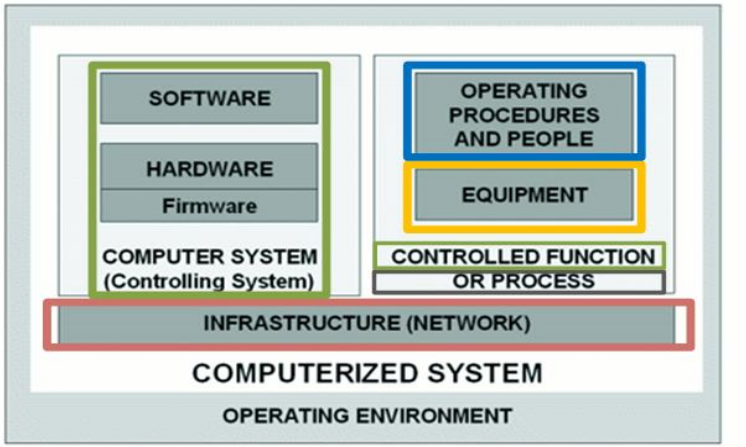
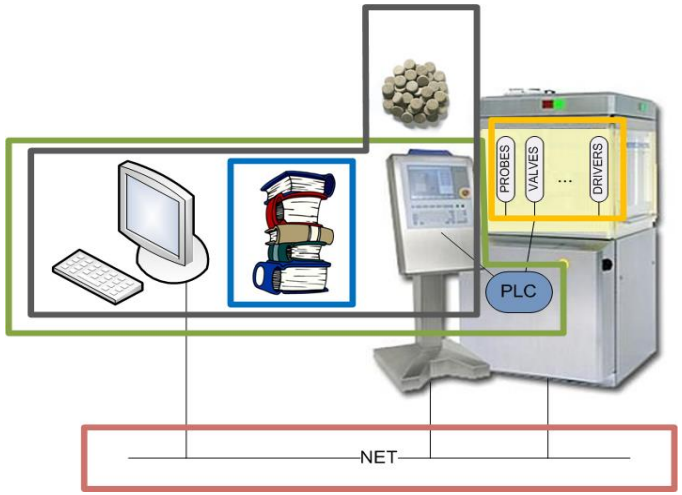
# Qualification vs. Validation




INFRASTRUCTURE QUALIFICATION

EQUIPMENT QUALIFICATION

CONTROL SYSTEM VALIDATION

QUALITY MANAGEMENT SYSTEM

PROCESS VALIDATION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# Acknowledgements

References


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