

# GAMP5 Introduction

by Richard Mulders



# Richard Mulders

- Principal Consultant, Auditor & Trainer
- 10+ years experience in (GxP) Computer System Validation
  - IT Systems (Manufacturing, Reporting, Control, Monitoring)
  - Equipment (Production, Laboratory)
  - Quality Management Systems
- Subject Matter Expert on Computerized Systems for the Dutch Accreditation Board (RvA)
  - ISO17025
  - ISO15189



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## Contact Us



Luchthavenweg 81-41  
5657 EA Eindhoven

+31 (0)85 201 72 77  
info@rescop.com  
www.rescop.com



Kwakerpad 5  
4844 RP Terheijden

+31 (0)85 130 16 35  
info@qaducation.nl  
www.qaducation.nl

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# GAMP 5

## Introduction

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# Agenda

- What is GAMP5?
- Key concepts
- System Life Cycle
- Project Phase
- Risk management
- Operational and Retirement phases
- Summary

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# Agenda

- **What is GAMP5?**
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# What is GAMP5?

A computerized system is a **set of software and hardware** components which together fulfill certain functionalities.

The **application should be validated**; IT infrastructure should be qualified.

**Where a computerized system replaces a manual operation**, there should be no resultant decrease in product quality, process control or quality assurance. There should be **no increase in the overall risk of the process**.



**GxP  
LAW**

# What is GAMP5?

ISO 17025  
(2017)

ISO 15189  
(2015)

**STANDARD**

The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data **shall be validated for functionality.**

“Laboratory information management system(s)” includes the **management of data and information** contained in both computerized and non-computerized systems

# What is GAMP5?

Aims to achieve **computerized systems that are fit for intended use** and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.

Provides practical guidance that (amongst others):

- Establishes a **common language and terminology**
- Promotes a **system life cycle approach** based on good practice

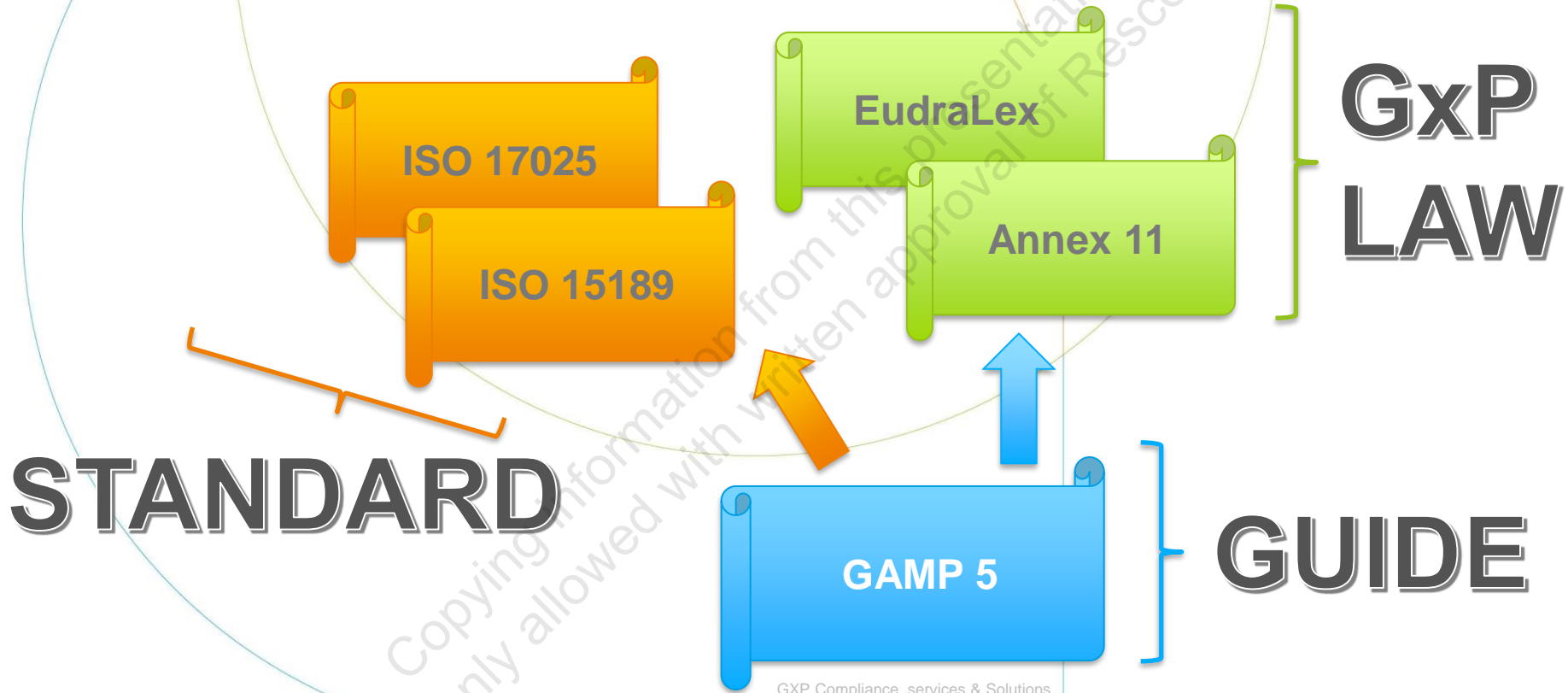
A blue graphic of a rolled-up scroll with a white border, containing the text "GAMP 5 (2008)".

**GAMP 5**  
(2008)

A large blue bracket graphic pointing to the right, grouping the scroll and the word "GUIDE".

**GUIDE**

# What is GAMP5?



# GAMP 5

A Risk-Based Approach to Compliant GxP Computerized Systems

GAMP Good Practice Guide  
A Risk-Based Approach to Operation of GxP Computerized Systems  
A Computer System to GAMP 5

<https://ispe.org/>

## GAMP 5 Guide Principles and Framework

### Appendices

Management Development Operation  
Special Interest General

### Good Practice Guides

Laboratory Global Information Systems Process Controls  
Infrastructure Calibration Management Testing  
Electronic Data Archiving Electronic Records and Signatures

### Other Information

Papers and Articles Templates and Examples Training Materials

GOOD PRACTICE GUIDE  
Validation and Compliance of Computerized GCP Systems and Data  
Good eClinical Practice

GAMP Good Practice Guide  
A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems  
Second Edition

GAMP Good Practice Guide  
A Risk-Based Approach to Testing of GxP Systems

Records and Data Integrity GUIDE

GAMP Good Practice Guide  
Electronic Data Archiving

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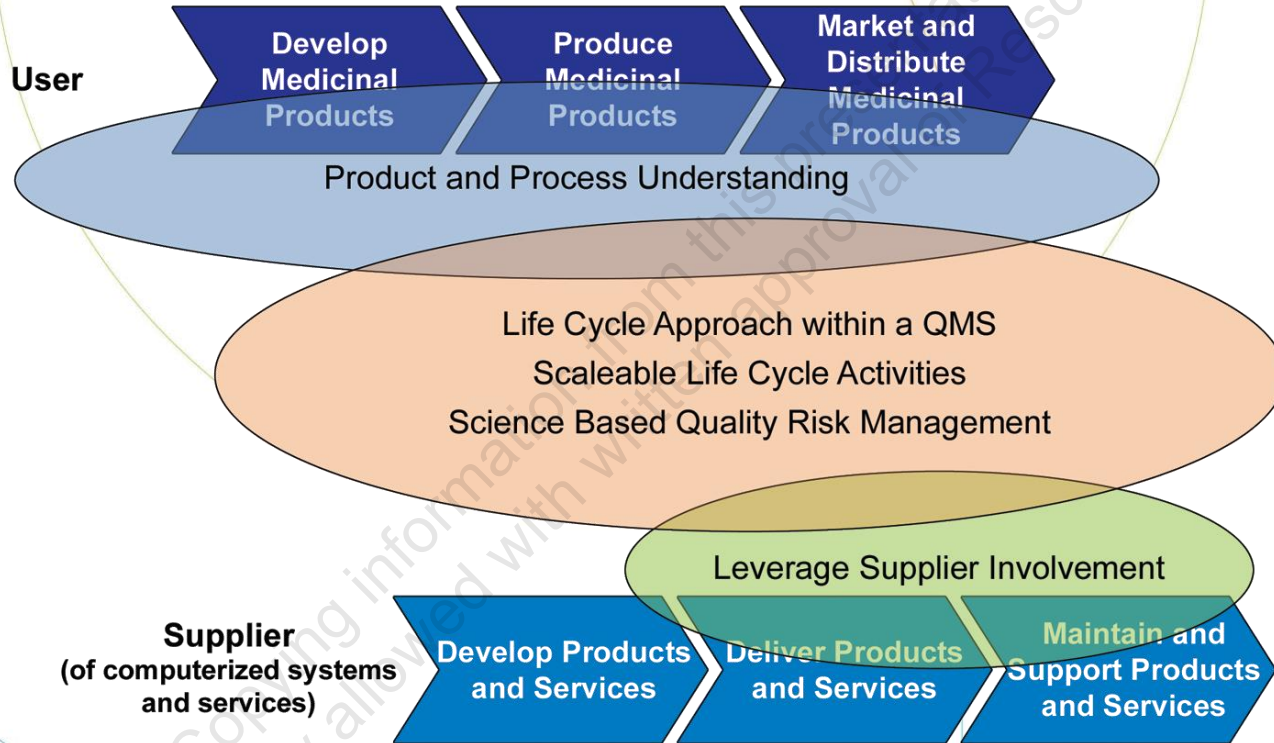
What, in your opinion, can a computerized system supplier do to support you?

A word cloud visualization of responses to the question. The words are arranged in a roughly circular pattern. The largest words are 'provide' (in red) and 'support' (in purple). Other prominent words include 'complete' (blue), 'customisation' (blue), 'yes' (red), 'implementation' (blue), 'validation' (orange), 'method' (blue), 'preserve' (teal), and 'documentation' (green).

provide  
support  
complete  
customisation  
yes  
implementation  
validation  
method  
preserve  
documentation



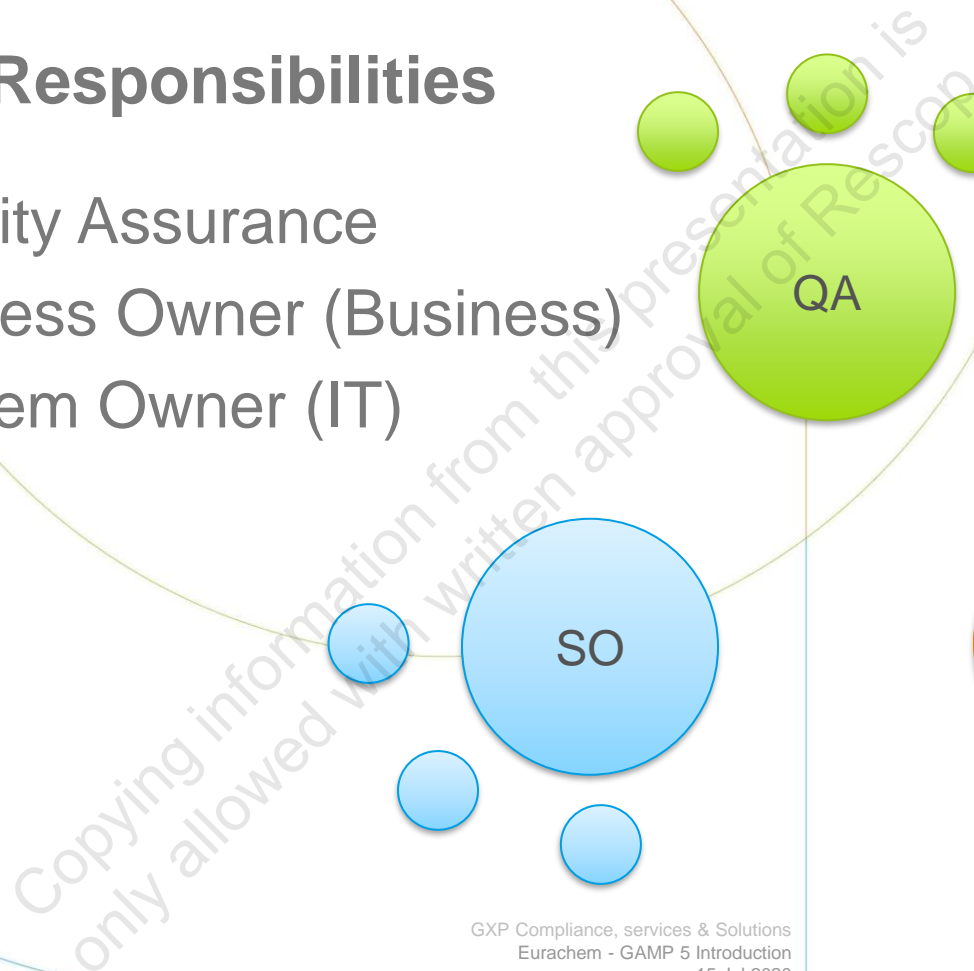
# Key concepts



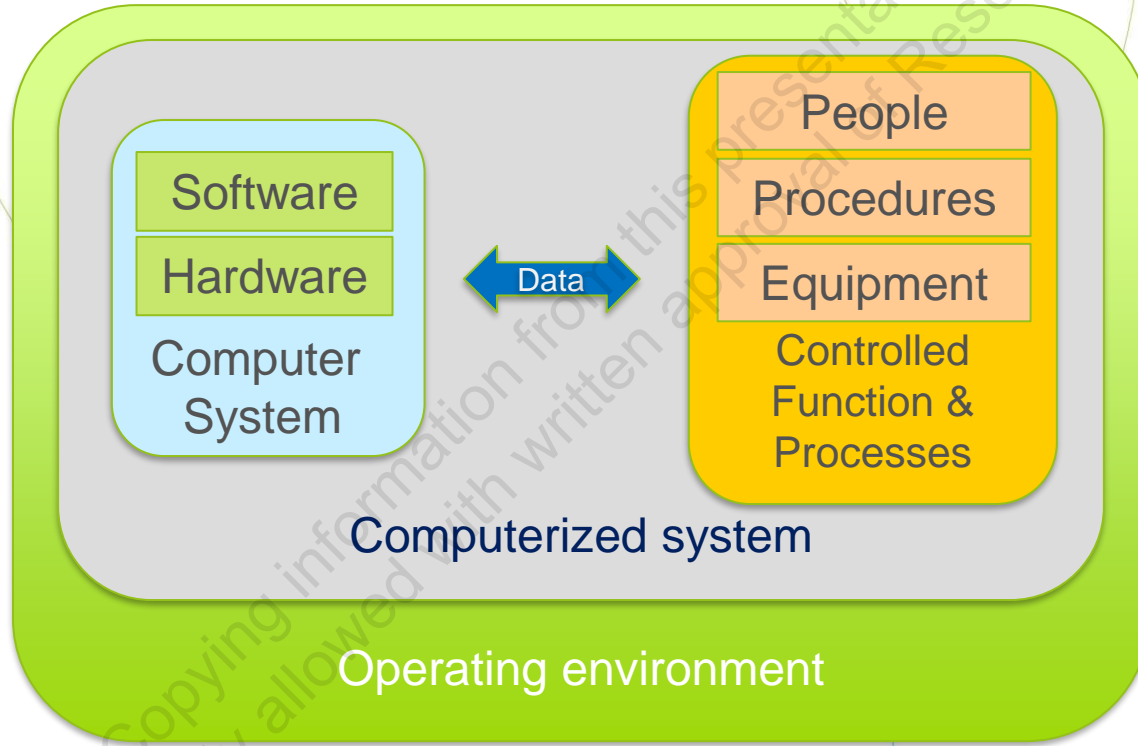
Source: Figure 2.1, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. [www.ISPE.org](http://www.ISPE.org).

# Roles and Responsibilities

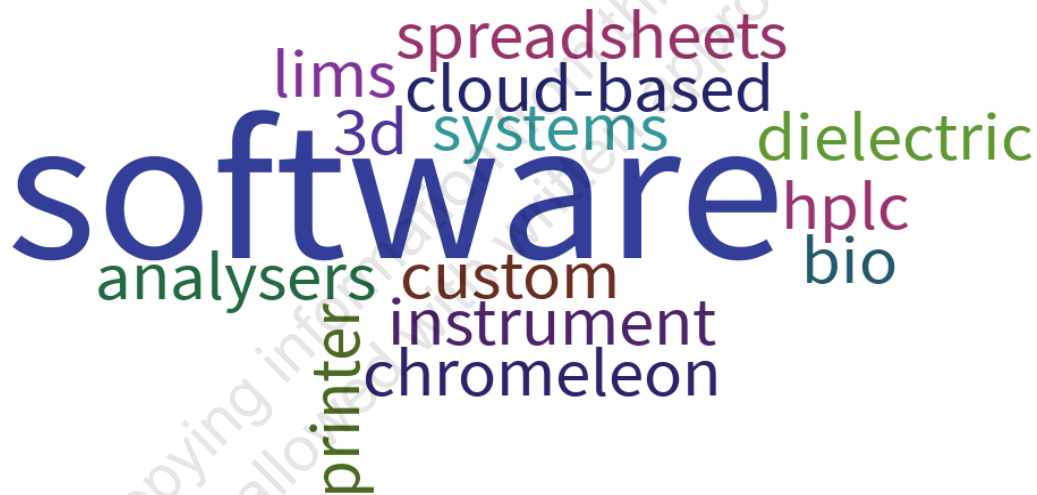
- QA – Quality Assurance
- PO – Process Owner (Business)
- SO – System Owner (IT)
- SME



# Computerized system



# What are examples of computerized systems?



A word cloud of computerized systems examples. The word 'software' is the largest and most prominent, centered in blue. Other words include 'spreadsheets' (purple), 'cloud-based' (purple), 'systems' (green), 'dielectric' (green), 'hplc' (purple), 'bio' (purple), 'instrument' (purple), 'chromeleon' (purple), 'custom' (brown), 'analysers' (green), '3d' (green), 'lms' (purple), and 'printer' (green). The words are arranged in a circular pattern around the central 'software' word.

software

spreadsheets

cloud-based

systems

dielectric

hplc

bio

instrument

chromeleon

custom

analysers

3d

lms

printer

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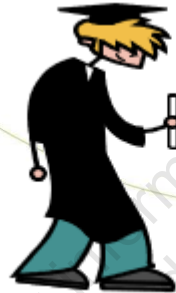
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# System Life Cycle

Your dream  
becomes reality



Development



Working life

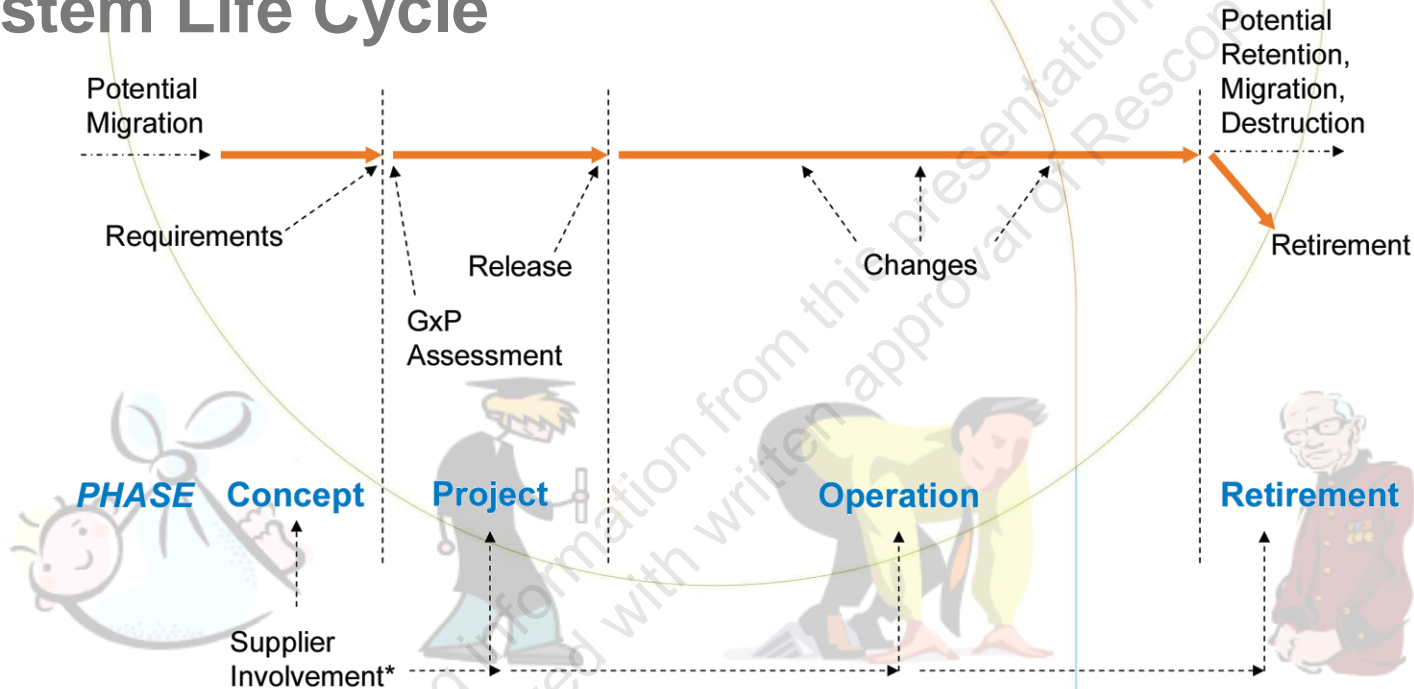


Retirement



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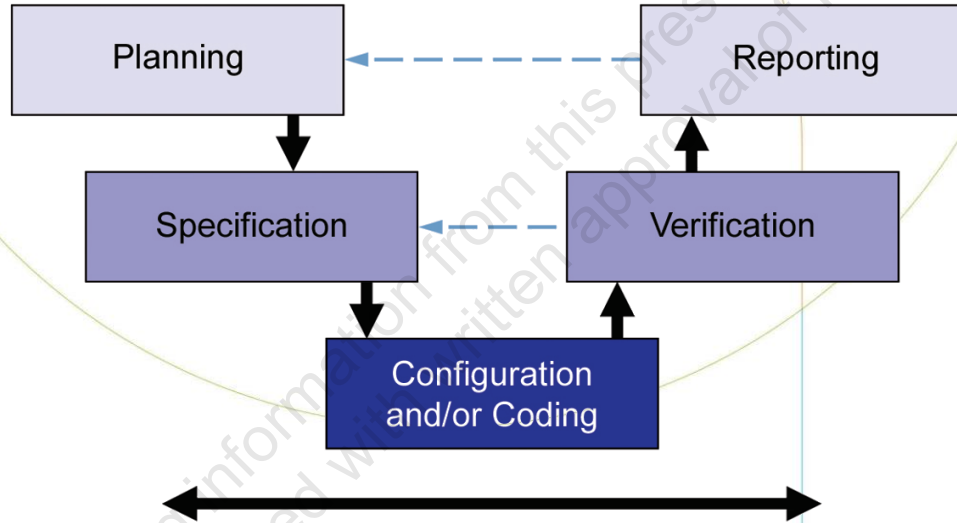
# System Life Cycle



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

Source: Figure 3.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

# V - Model

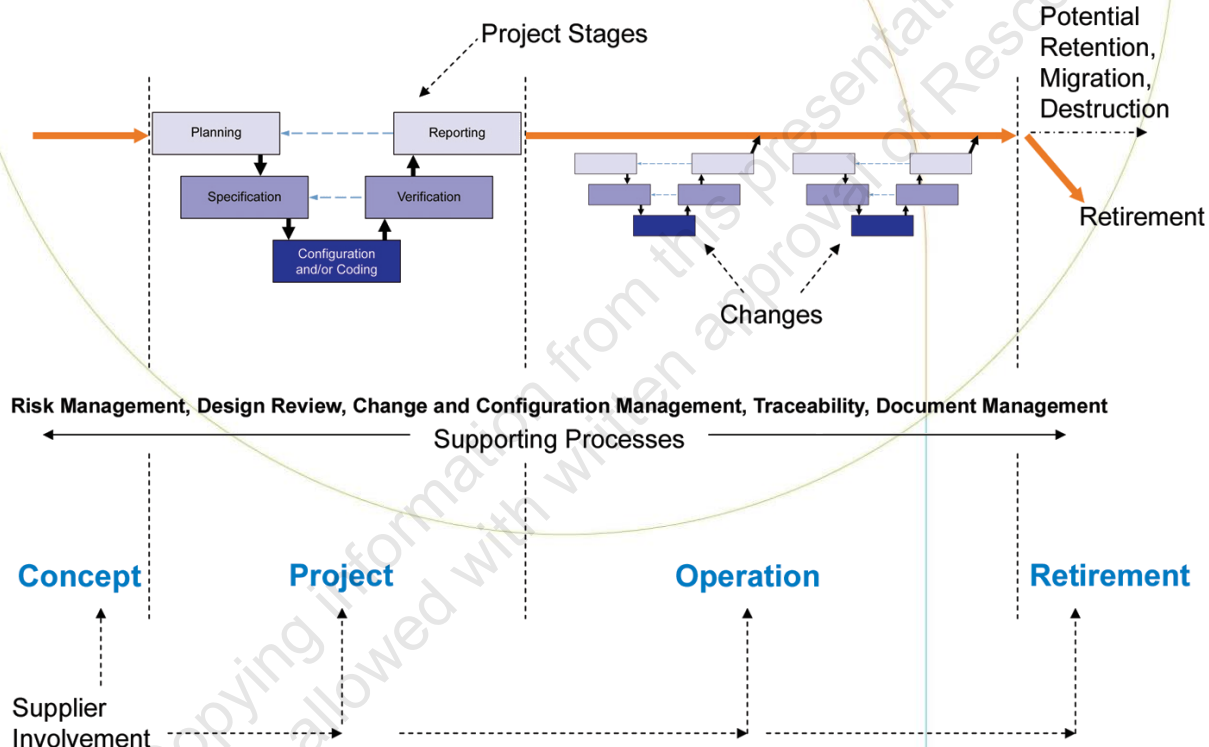


**Supporting Processes including Risk Management**

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# V - Model in System Life Cycle



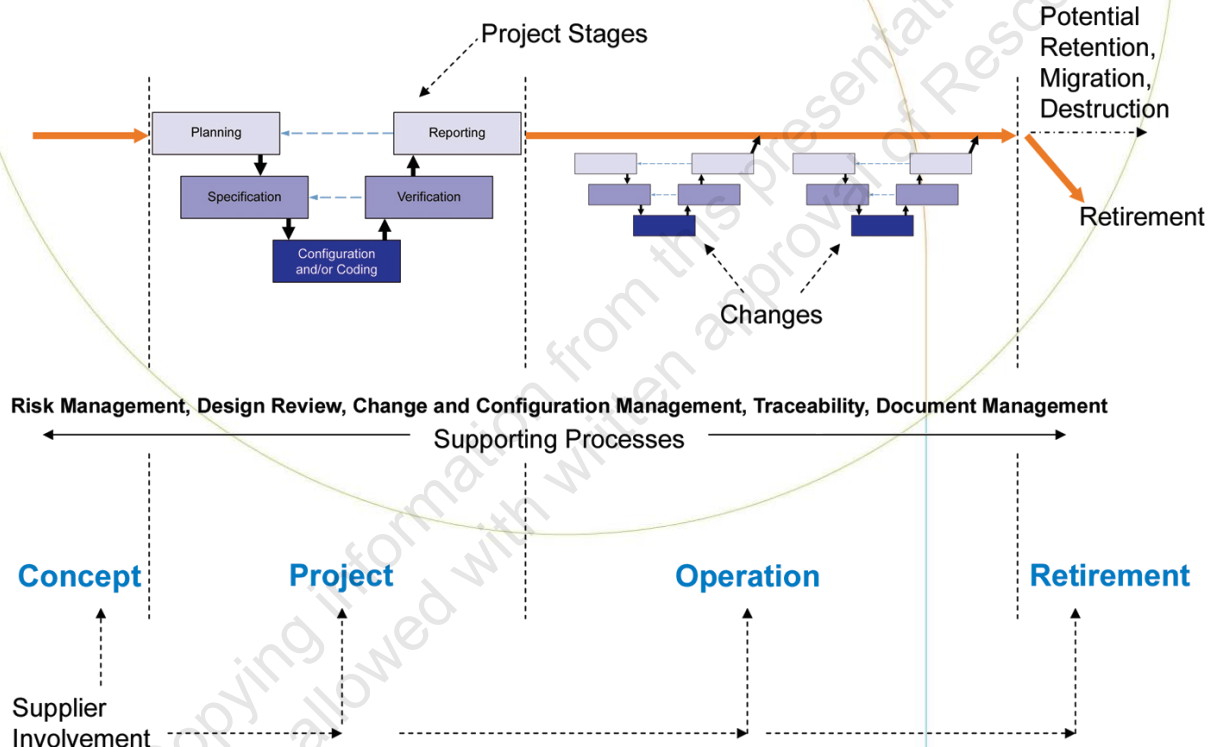
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# How we approach Validation?



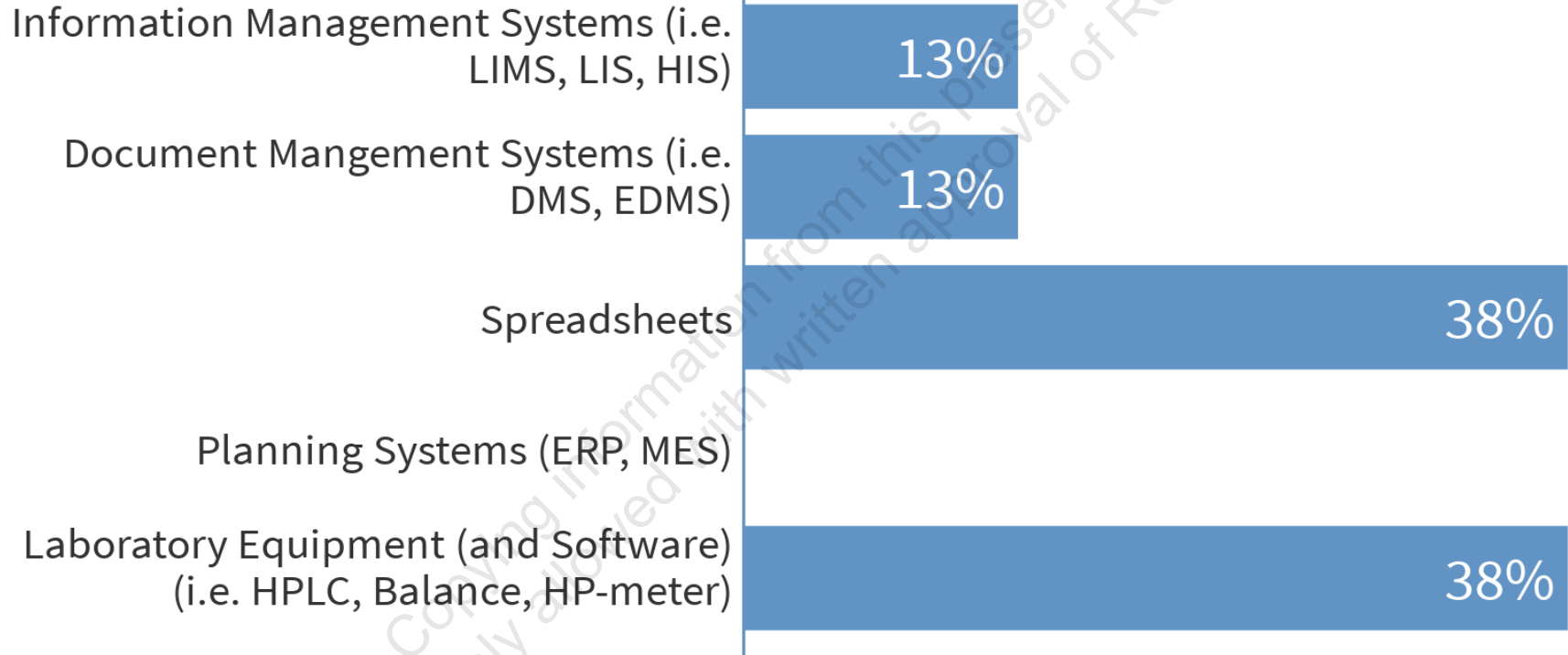
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# V - Model in System Life Cycle



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# What type(s) of systems do you already validate



# GAMP Software Categories

Category	GAMP 5	Example
1	Infrastructure software	IT Infrastructure – tools layer software – OS, DB, Middleware
2	No longer used	
3	Non-configured Products	Firmware-based applications, COTS software, Instruments
4	Configured Products	ERP, EDMS, LIMS, Spreadsheets
5	Custom Applications	Dedicated Applications, Custom Firmware, Spreadsheets (Macro)

# GAMP Software Categories

## Category 3



## Category 4



## Category 5



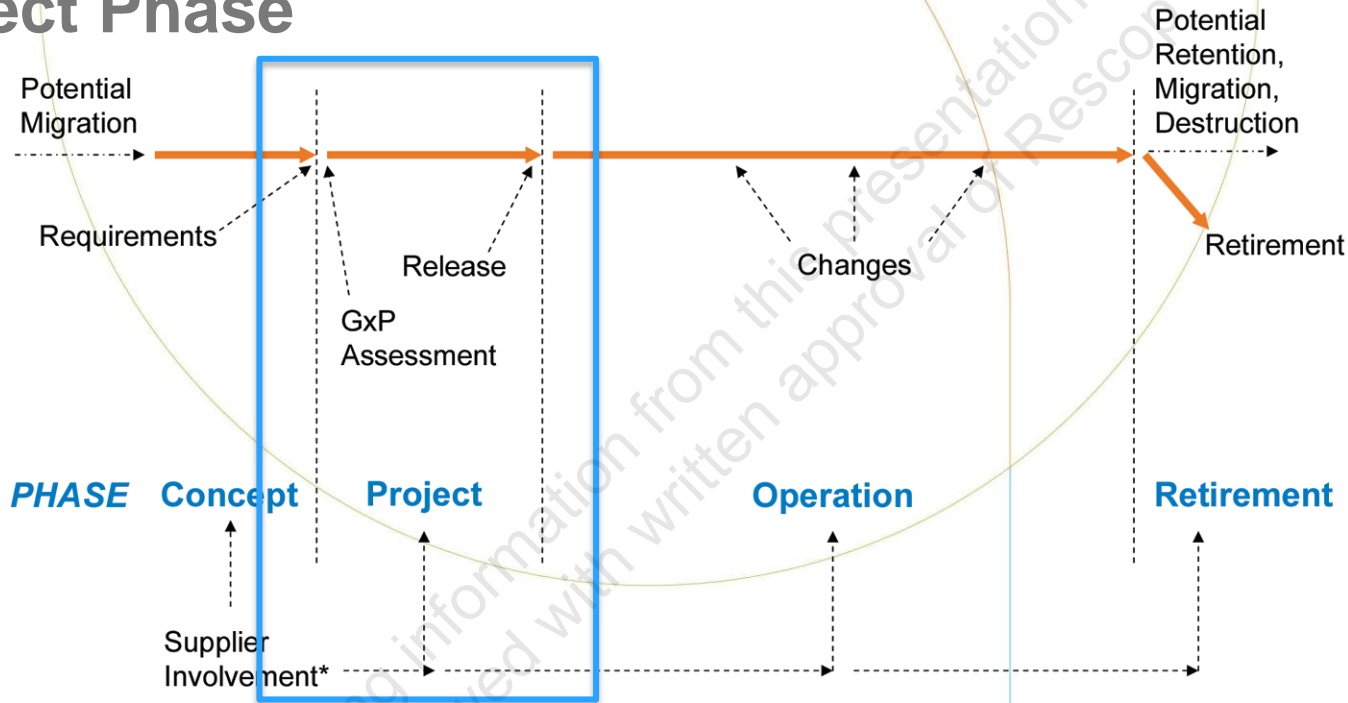
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# Project Phase

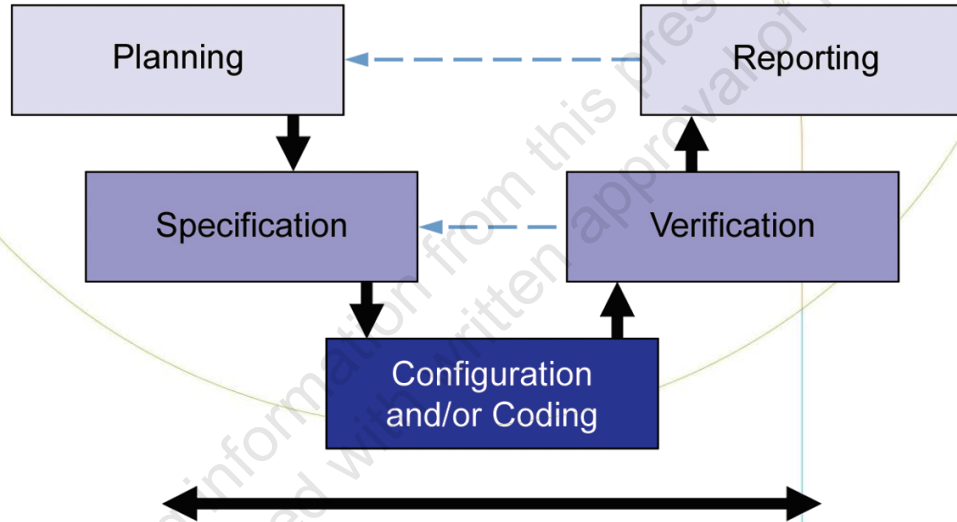


- \* - This could be a complex supply chain
- Supplier may provide knowledge, experience, documentation, and services throughout lifecycle

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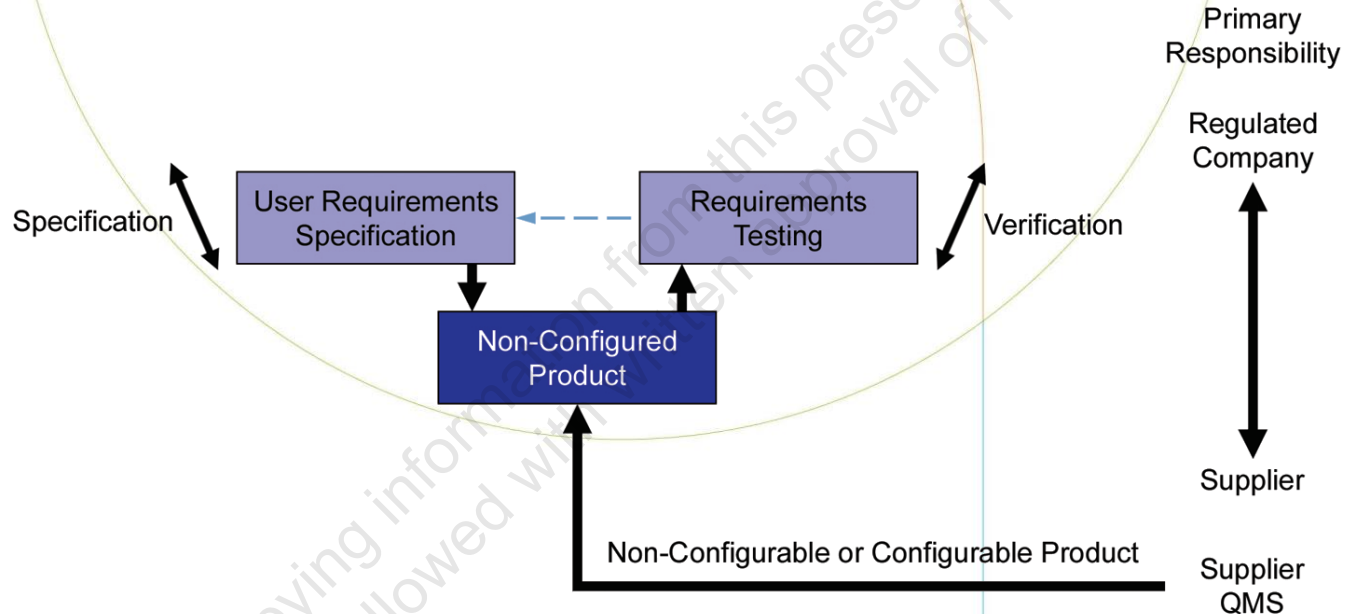
# Project Phase



Supporting Processes including Risk Management

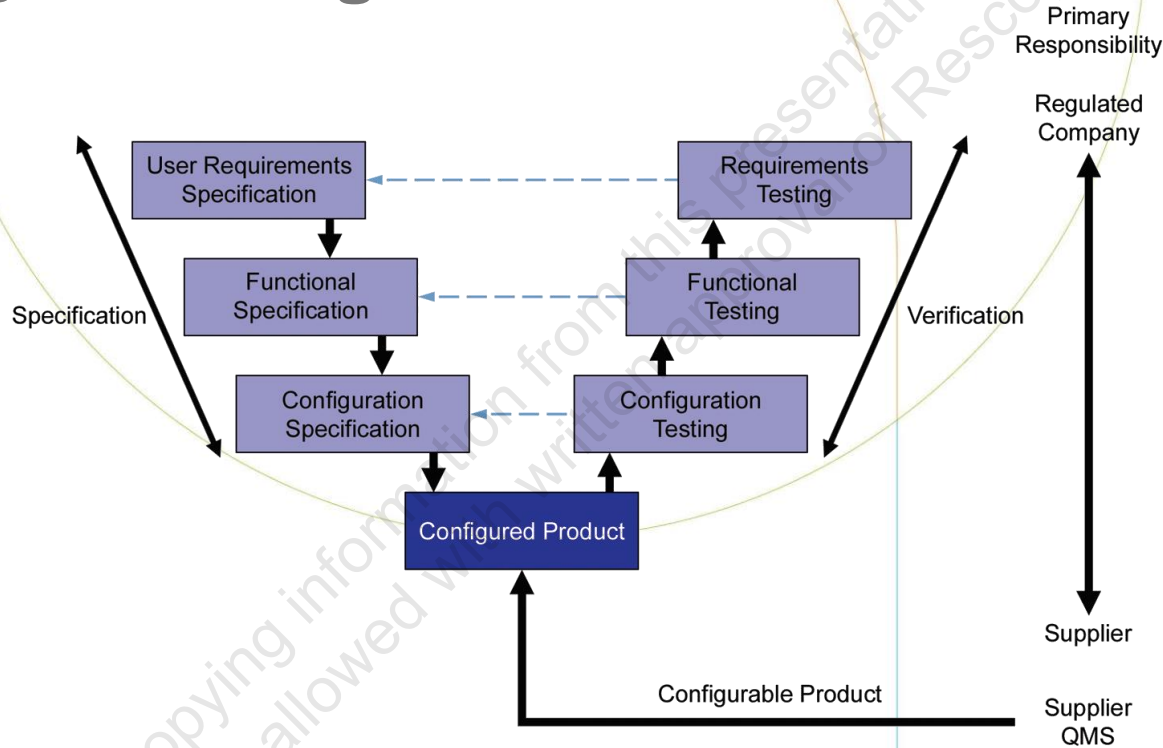
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# Category 3 - Non-configured Products



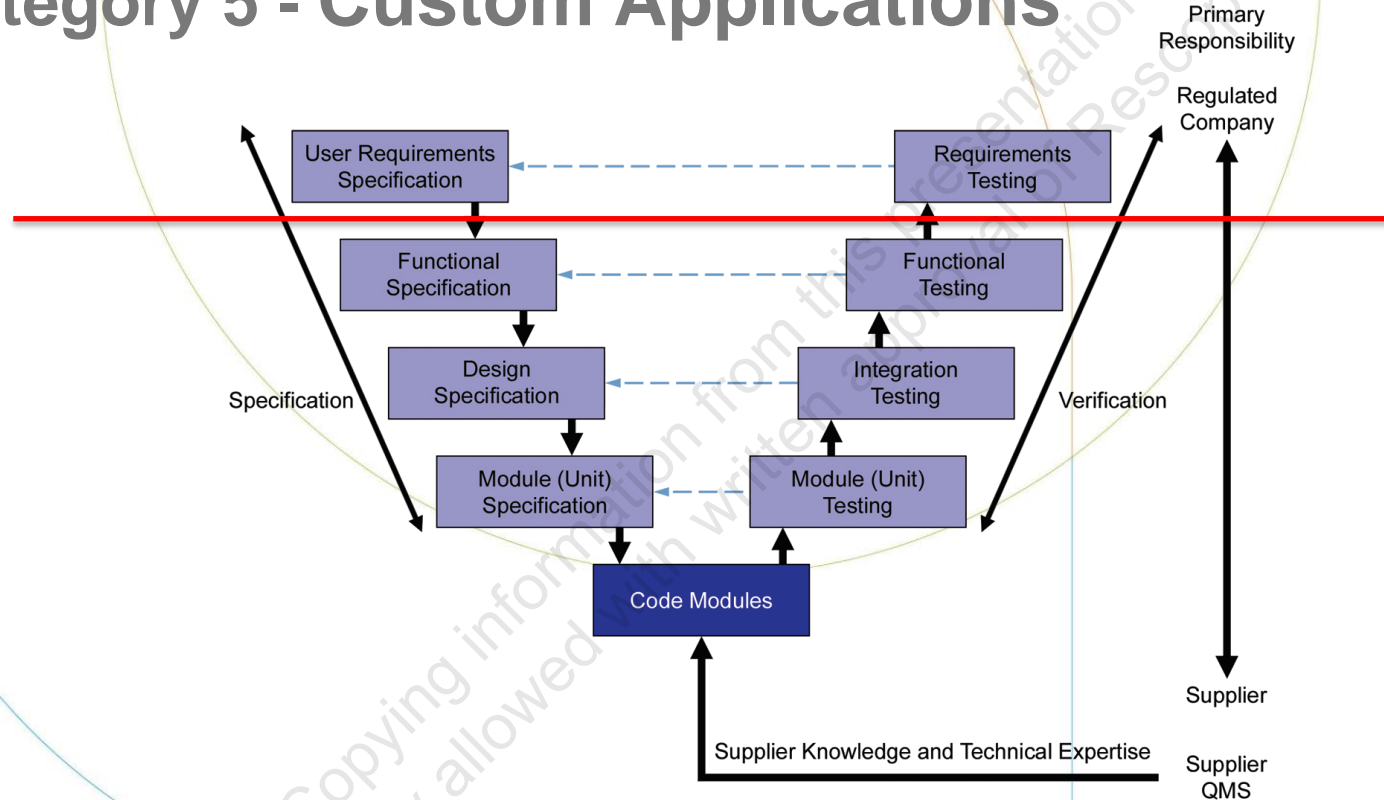
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# Category 4 - Configured Products



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# Category 5 - Custom Applications



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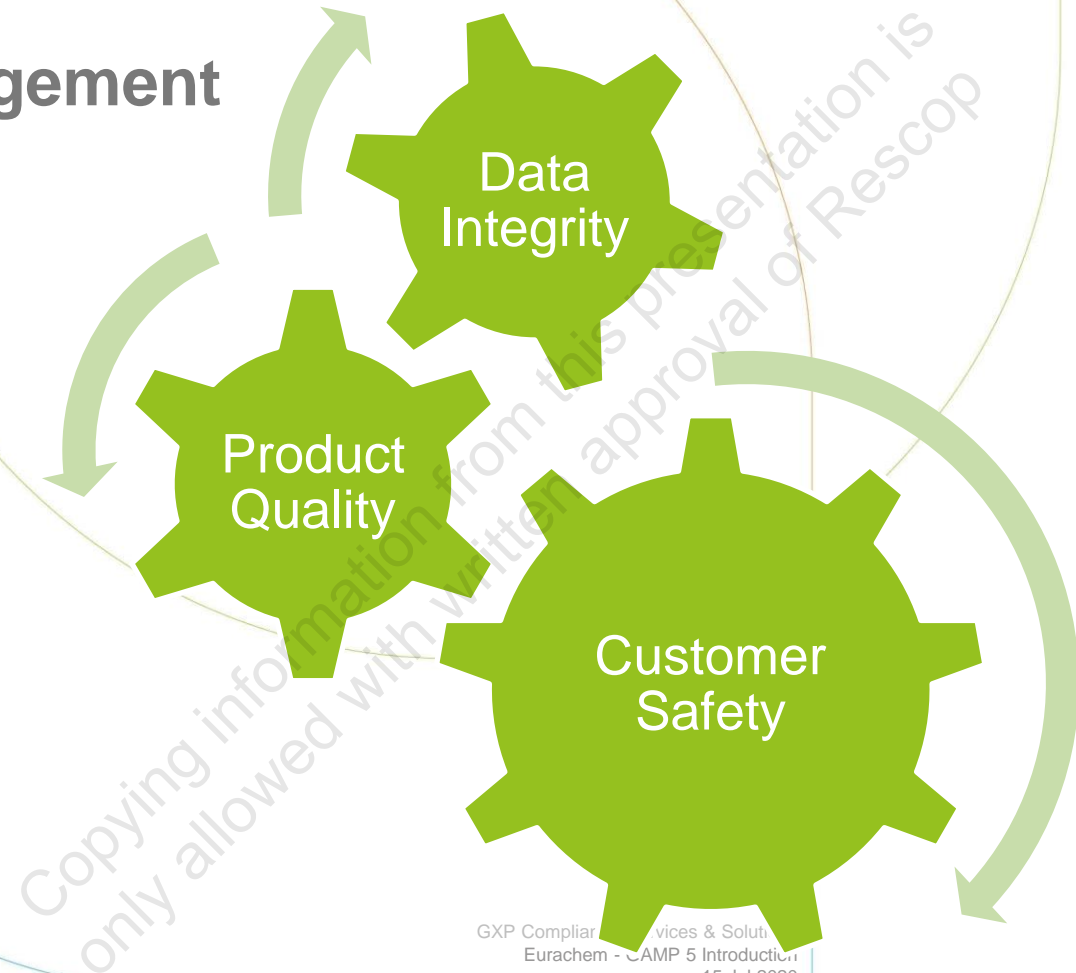
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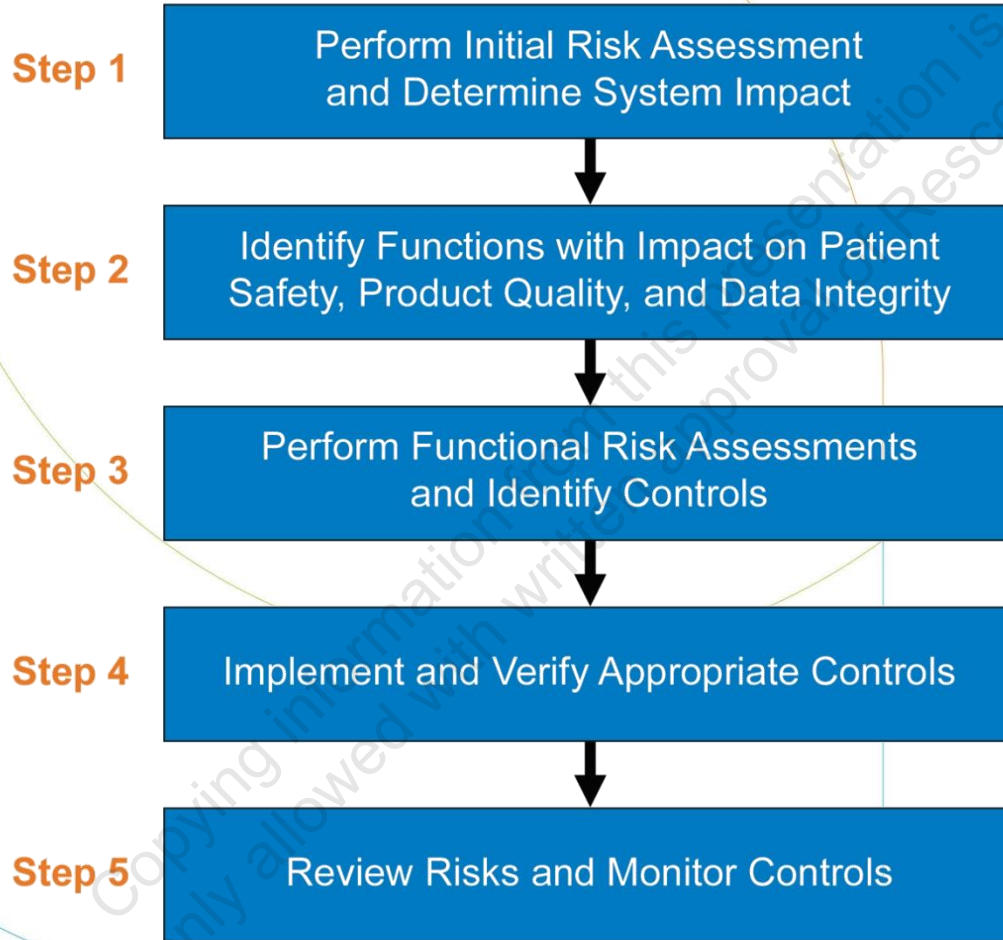
# What risks do Regulators pay attention to?

functioning  
correct training  
evidence operation according  
validation...  
declaration

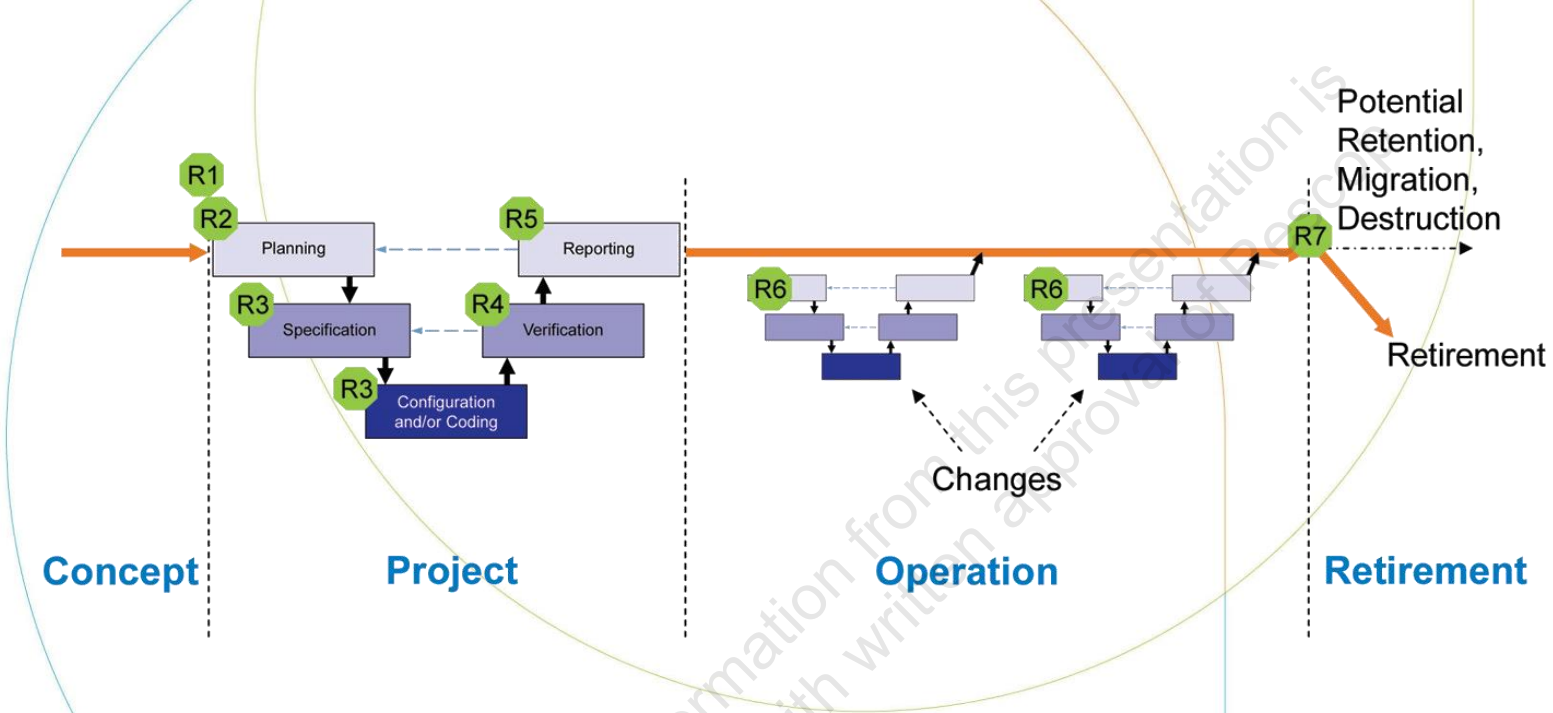
# Risk Management



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R1 Initial risk assessment

R2 Risk-based decisions during planning

R3 Functional risk assessments

R4 Risk-based decisions during test planning

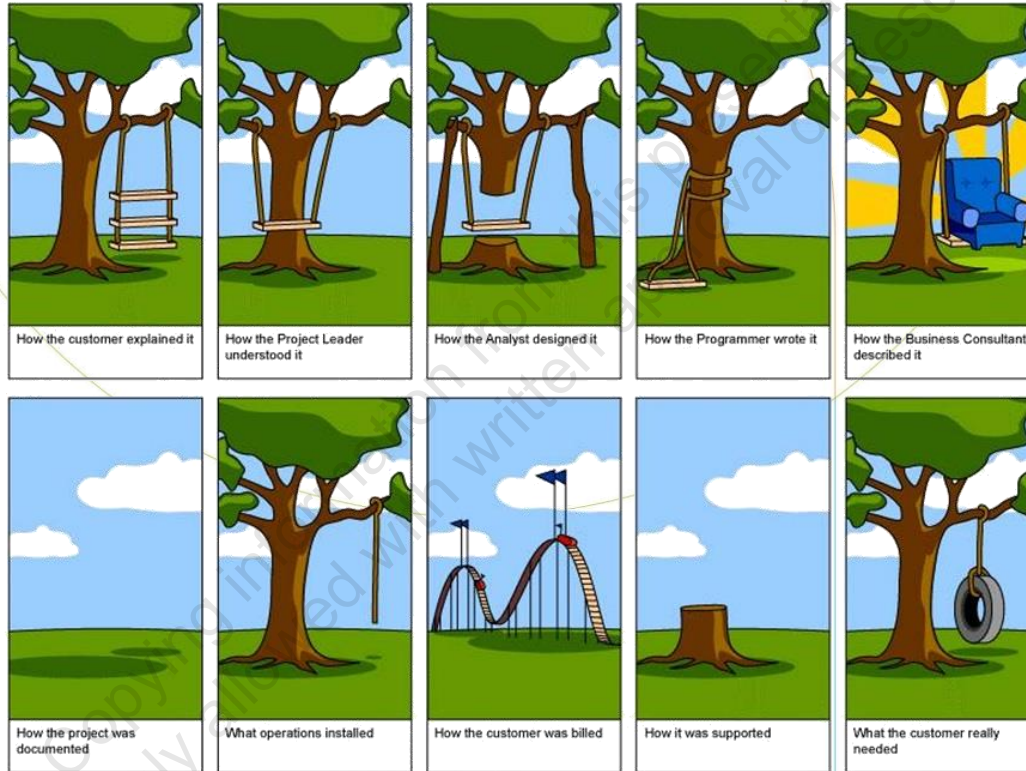
R5 Risk-based decisions during planning of operational activities

R6 Functional risk assessments in change control

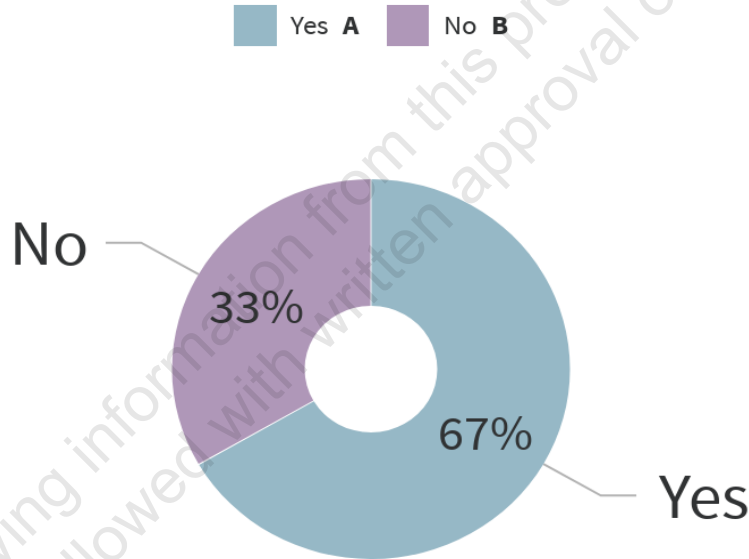
R7 Risk-based decisions when planning system retirement

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# Why on earth do we need to do that?



# Have you ever misreported a result due to a computerized system (can also be a Spreadsheet) error?



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# Operational and retirement phases

- Handover
- Establishing and managing support services
- Performance monitoring
- Incident management
- Corrective And Preventive Action (CAPA)
- Operational change and configuration management
- Repair activity
- Periodic review
- Backup and restore
- Business continuity management
- Security management
- System Administration
- Data migration
- System retirement, decommissioning and disposal

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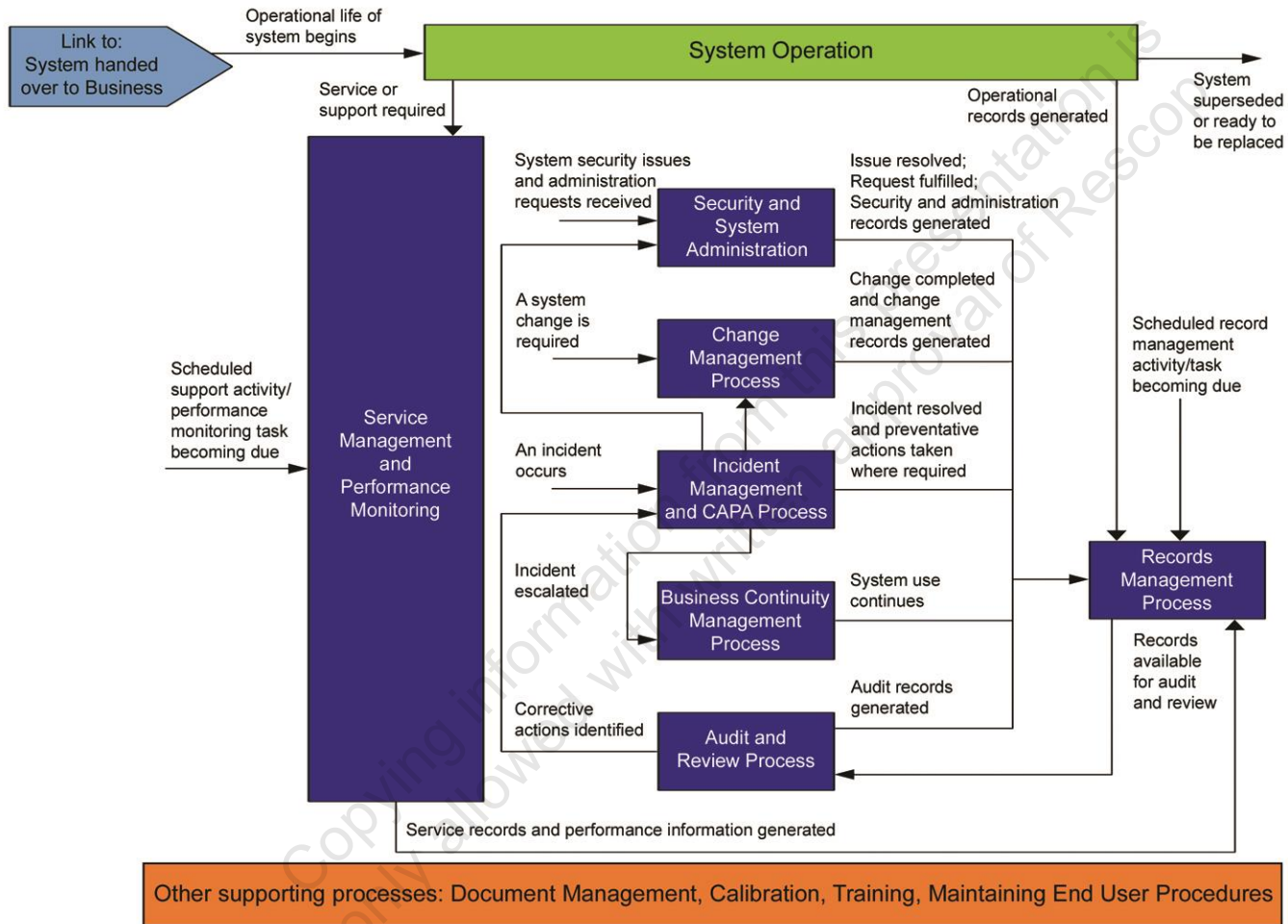
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# Operational and retirement phases

- |   |           |           |   |           |             |
|---|-----------|-----------|---|-----------|-------------|
| • Handover  | 7.11.5    | 5.10.3(b) | • Periodic review                                 | 8.8       | 4.14.5      |
| • Establishing and managing support services      | 7.11.3(d) | 5.10.3(e) | • Backup and restore                              | 7.11.3(b) | 5.10.3(d)   |
| • Performance monitoring                          |           |           | • Business continuity management                  |           | 5.10.3      |
| • Incident management                             | 7.11.3(e) | 5.10.3(f) | • Security management                             | 7.11.3(a) | 5.10.3(c/g) |
| • Corrective maintenance activities (APA)         | 7.11.3(e) | 5.10.3(f) | • System Administration                           | 7.11.3(d) | 5.10.2      |
| • Operational change and configuration management | 7.11.2    | 5.10.3(a) | • Data migration                                  | 7.11.6    | 5.10.3(a)   |
| • Repair activity                                 |           |           | • System retirement, decommissioning and disposal | 8.4.2     | 4.13        |



# Agenda

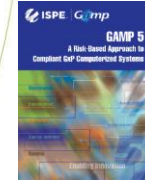
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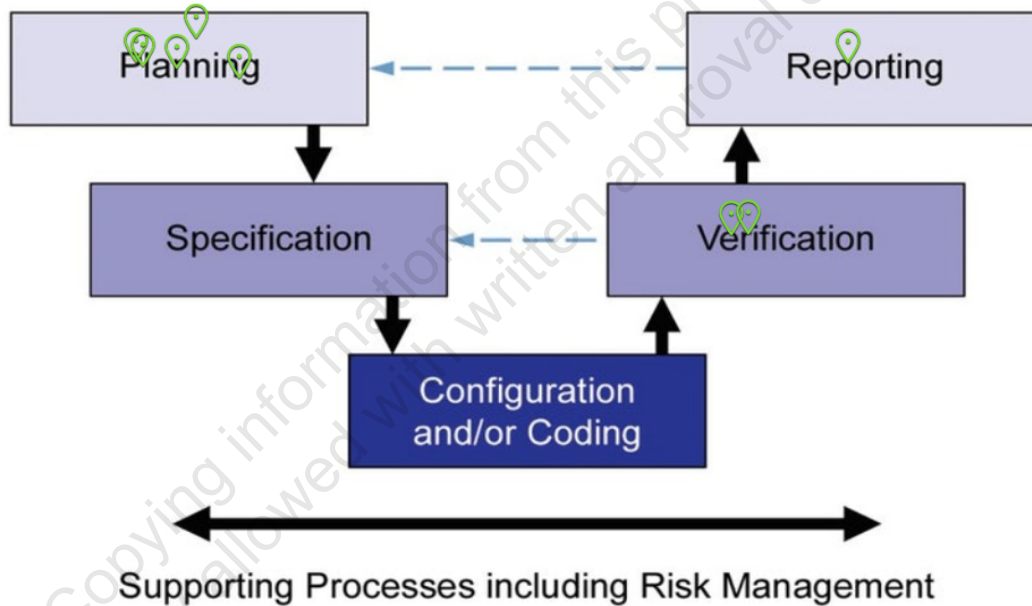


# Summary

1. GAMP is the best engineering practice Guide
2. Validation is taking pictures 
3. Focus on Risk to the Patient, Product Quality and Data Integrity
4. Perform validation, but remember to maintain controls during operational and retirement phases
5. Use GAMP5 to avoid mistakes



# Which stage in the life cycle do you think is the most important?



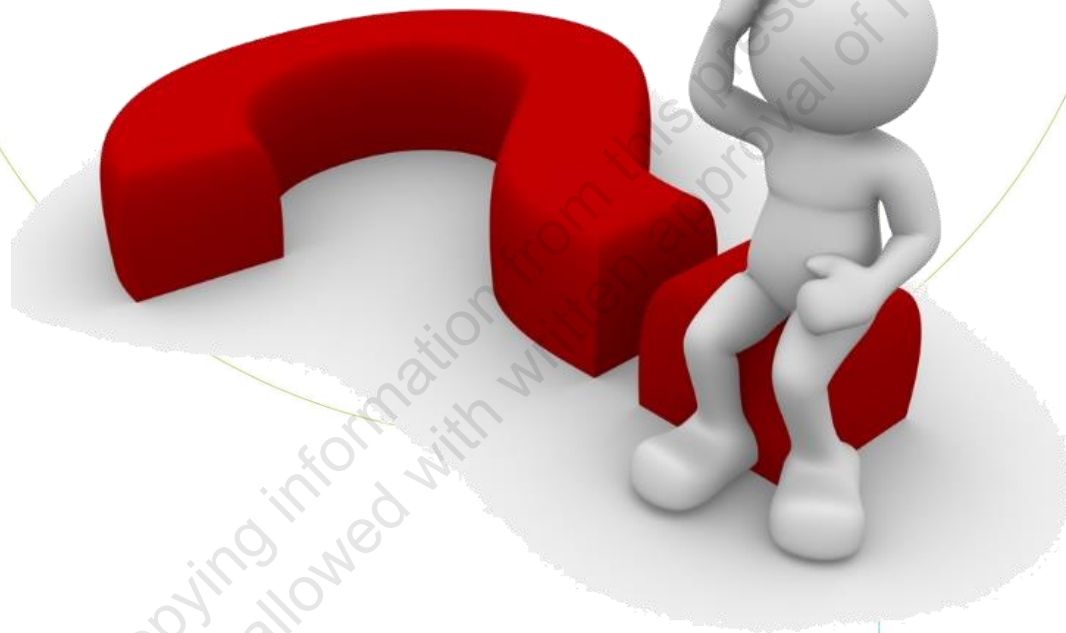
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# Now you are ready....

.... to start your GAMP5 adventure  
with computer systems validation





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## More information? Contact:

Richard Mulders  
Principal Consultant Rescop  
[r.mulders@rescop.com](mailto:r.mulders@rescop.com)  
+31 6 13138575