RESCOP

GxP COMPLIANCE SERVICES & SOLUTIONS

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

ABOUT US

WORLDWIDE SERVICES & SOLUTIONS

Regulatory System Compliance Partners

- ✓ Founded in 2005 as a response to challenges experienced within the GxP regulated industry
- ✓ Privately owned company
- ✓ Global one-stop solution provider for GxP compliance services and software
  - Compliance and Quality Management Software
  - Consultancy Services, Rescop Academy, Turnkey Projects
- ✓ Board, Corporate Management Team, Corporate QA, Global Business Development and Operations, Business Development and Operations per area
- ✓ 120 FTEs
- ✓ ISO 9001:2008 and ISO 27001:2013 certified

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GAMP 5

Introduction

For Interactivity

- Please open the following page on your Laptop / Phone:

https://pollev.com/rescop386

Agenda

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

Agenda

- **What is GAMP5?**
- Key concepts
- System Life Cycle
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- Risk management
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- Summary

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**.

What is GAMP5?

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

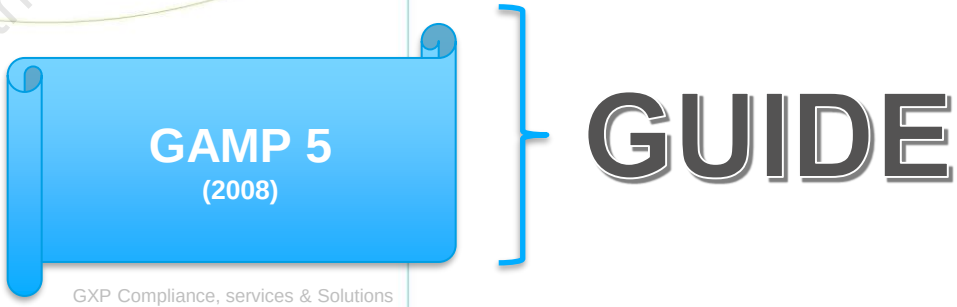
"Laboratory information management system(s)" includes the **management of data and information** contained in both computerized and non-computerized systems

What is GAMP5?

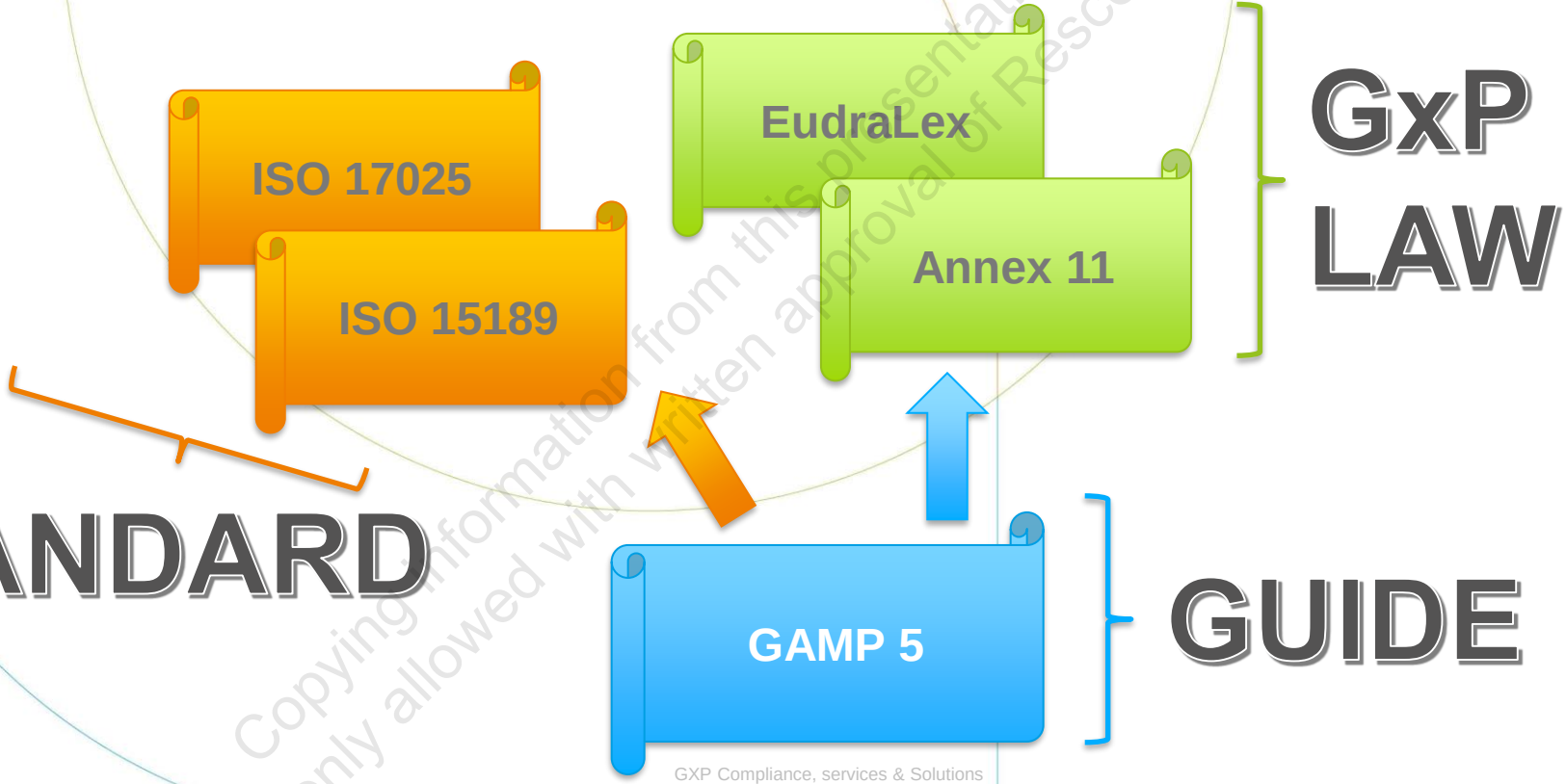
Aims to achieve **computerized systems that are fit for intended use** and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.

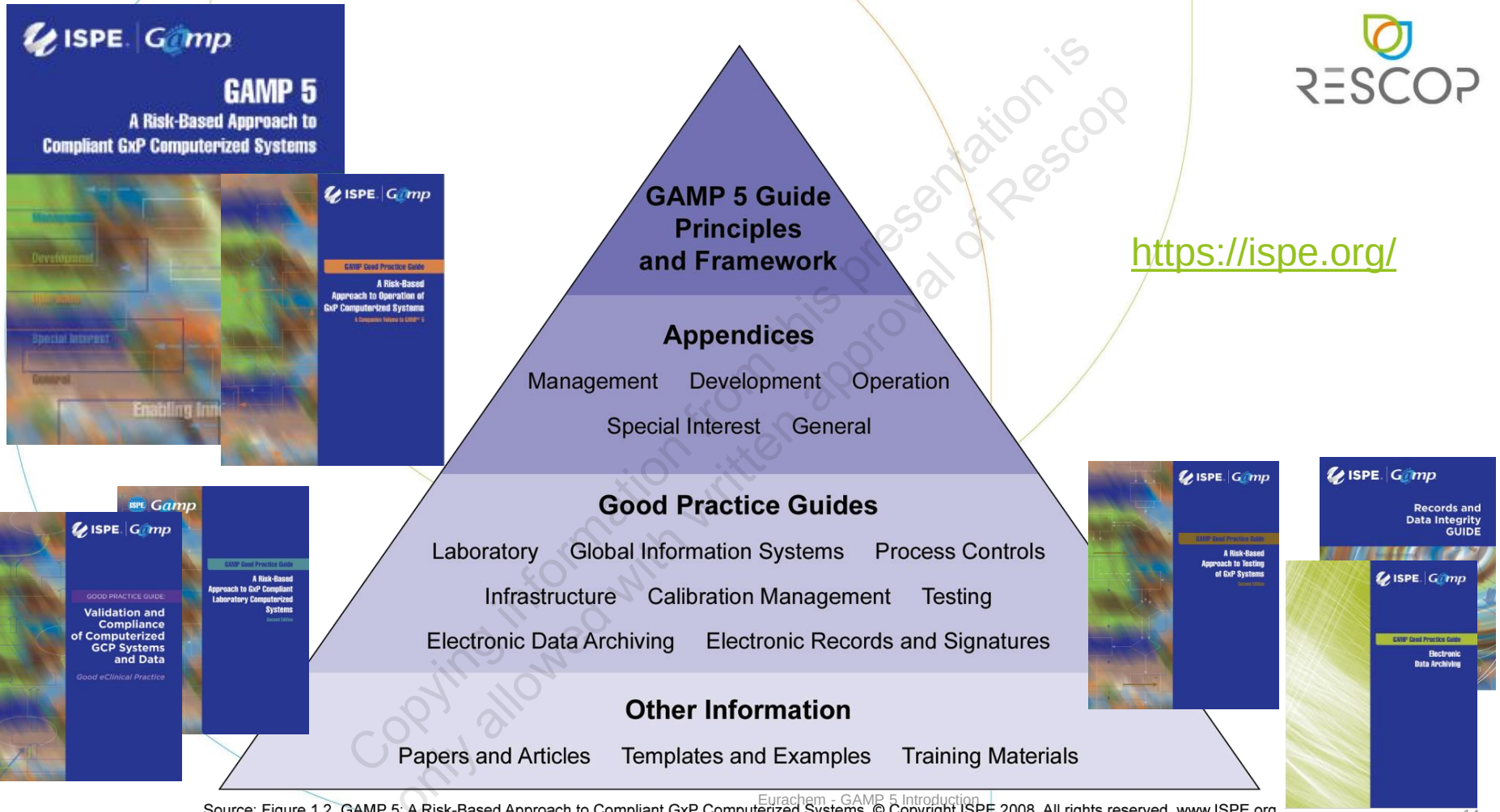
Provides practical guidance that (amongst others):

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



What is GAMP5?





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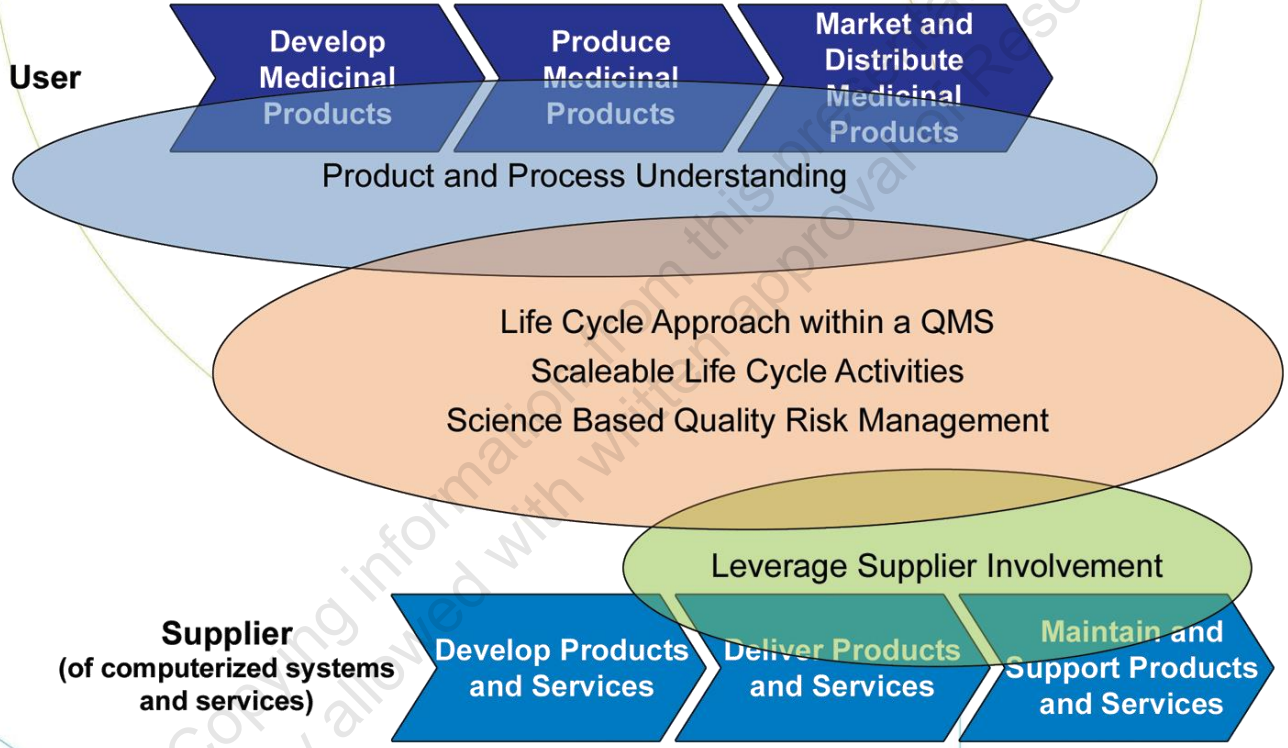
Agenda

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

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

Key concepts



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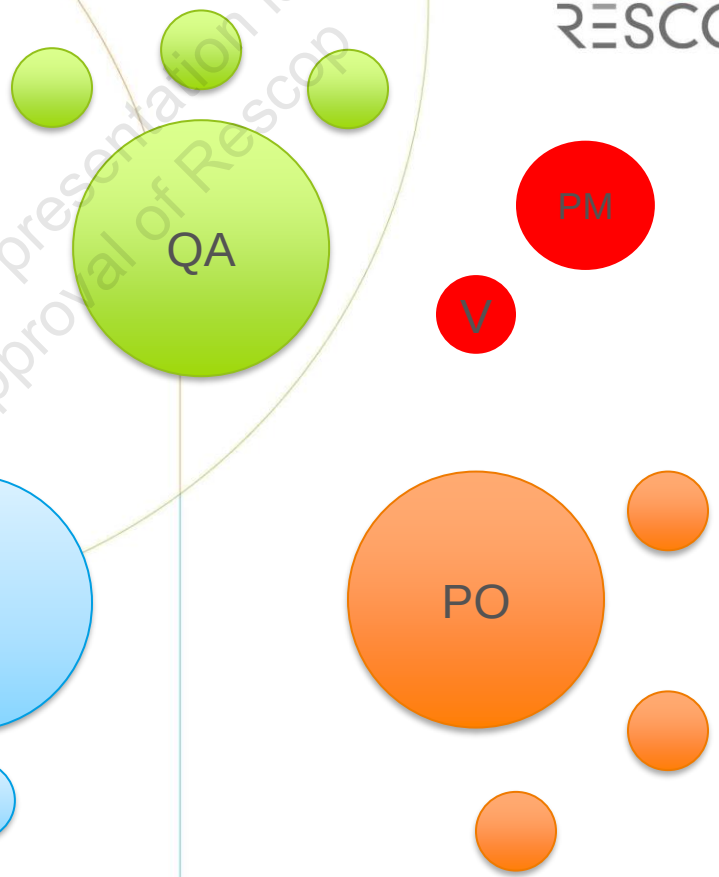
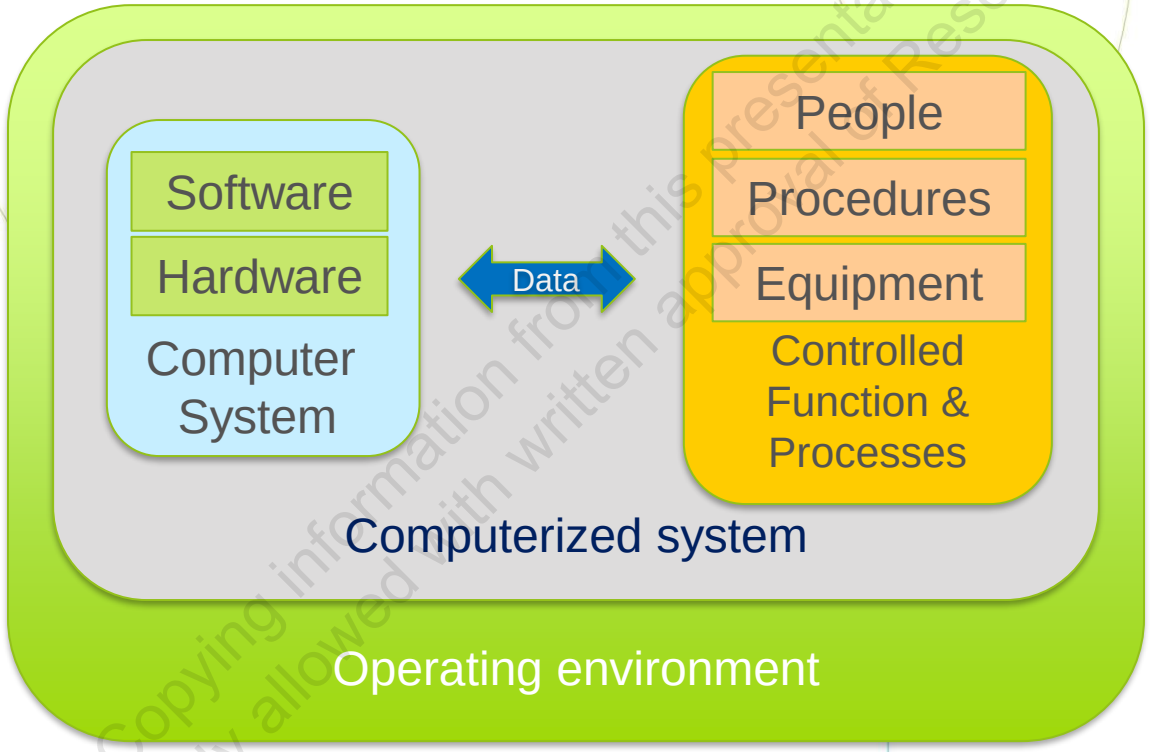
Roles and Responsibilities

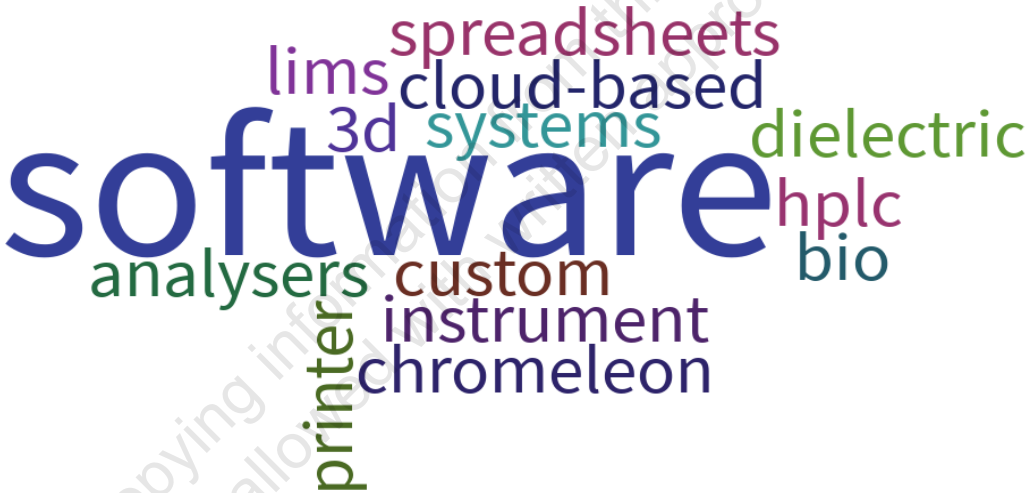
- QA – Quality Assurance
- PO – Process Owner (Business)
- SO – System Owner (IT)
- SME



Computerized system



What are examples of computerized systems?



Agenda

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

System Life Cycle

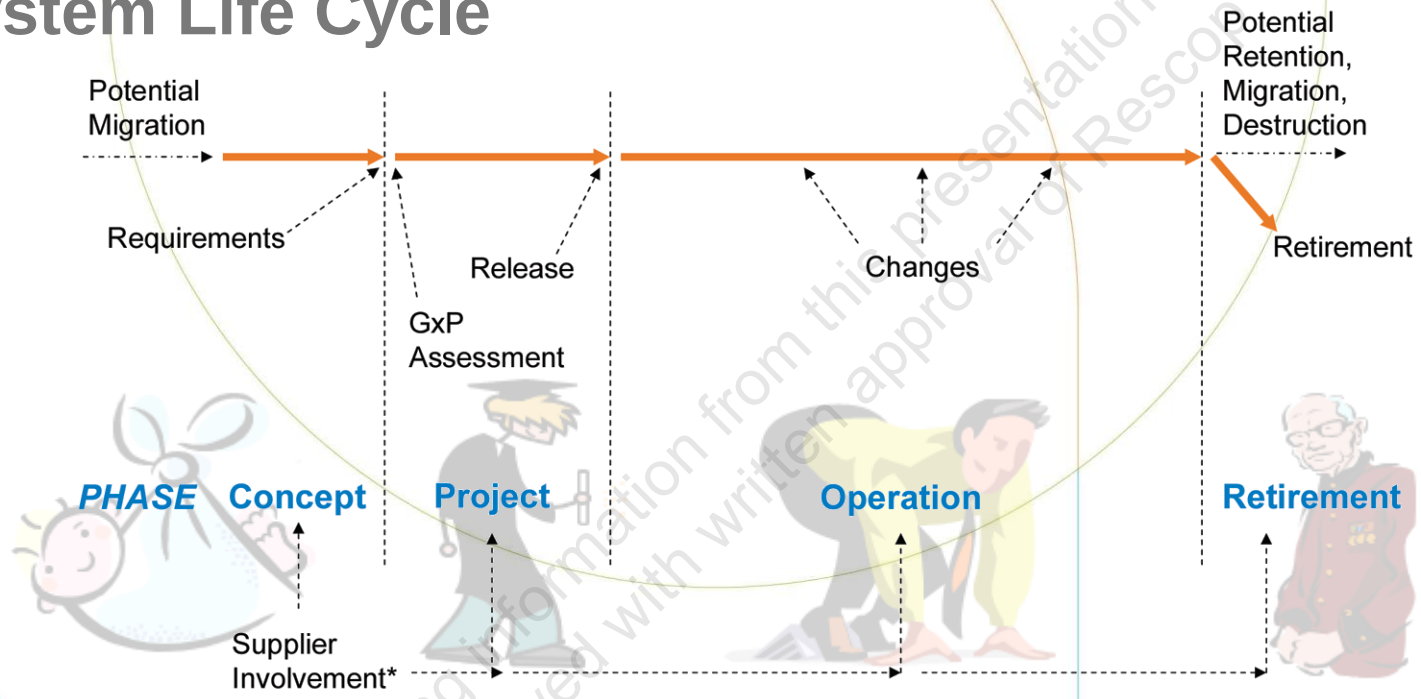
Your dream becomes reality

Development

Working life

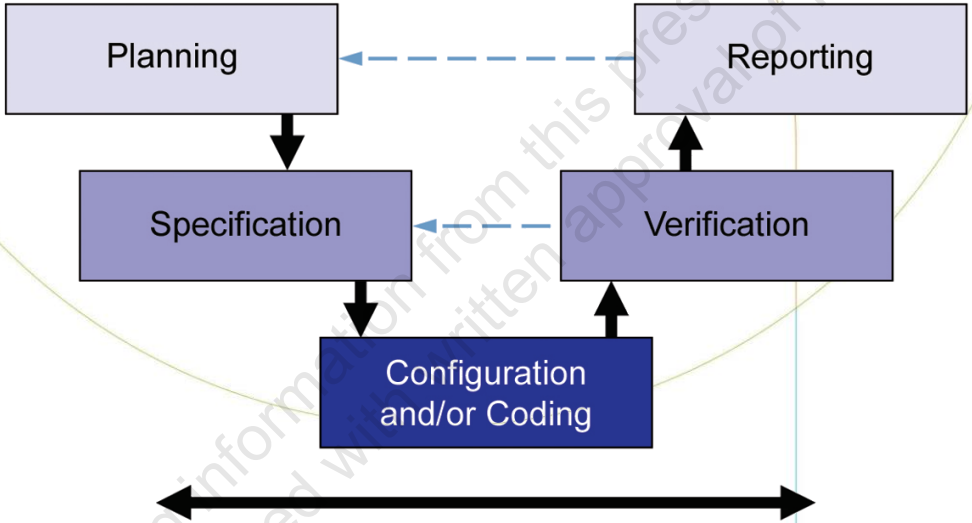
Retirement

System Life Cycle



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

V - Model



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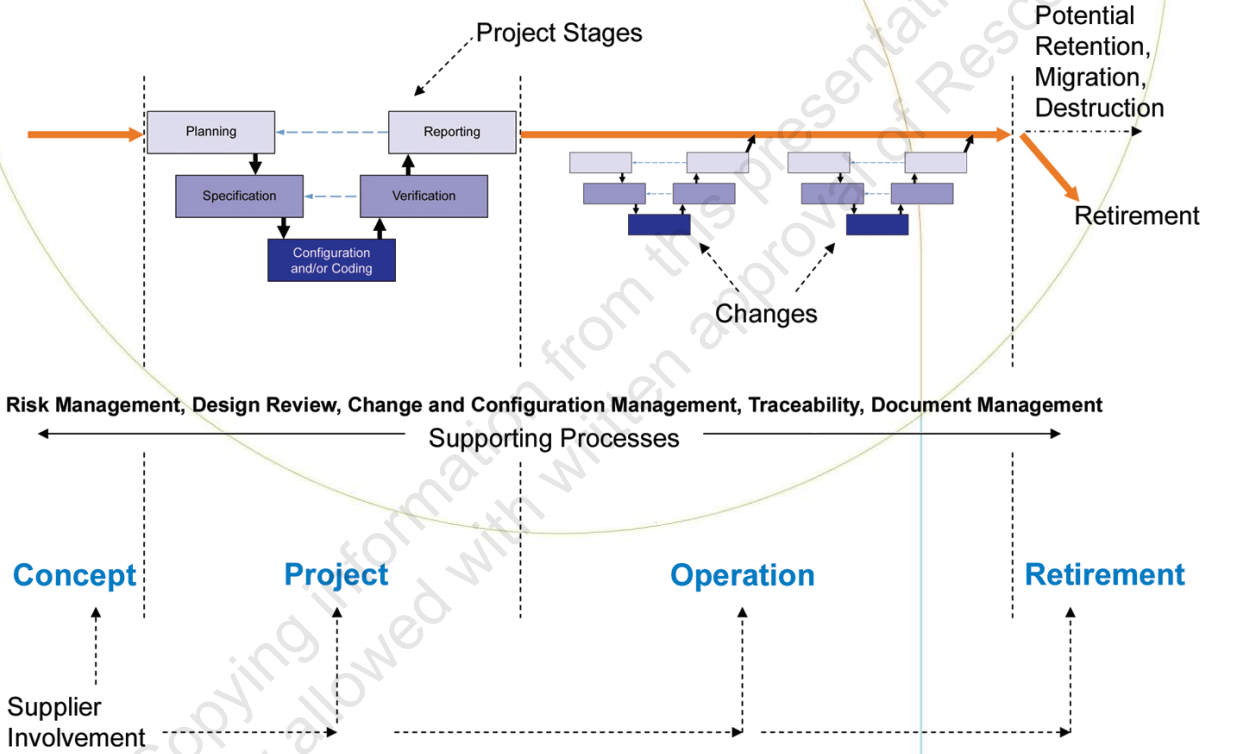
V - Model in System Life Cycle



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How we approach Validation?

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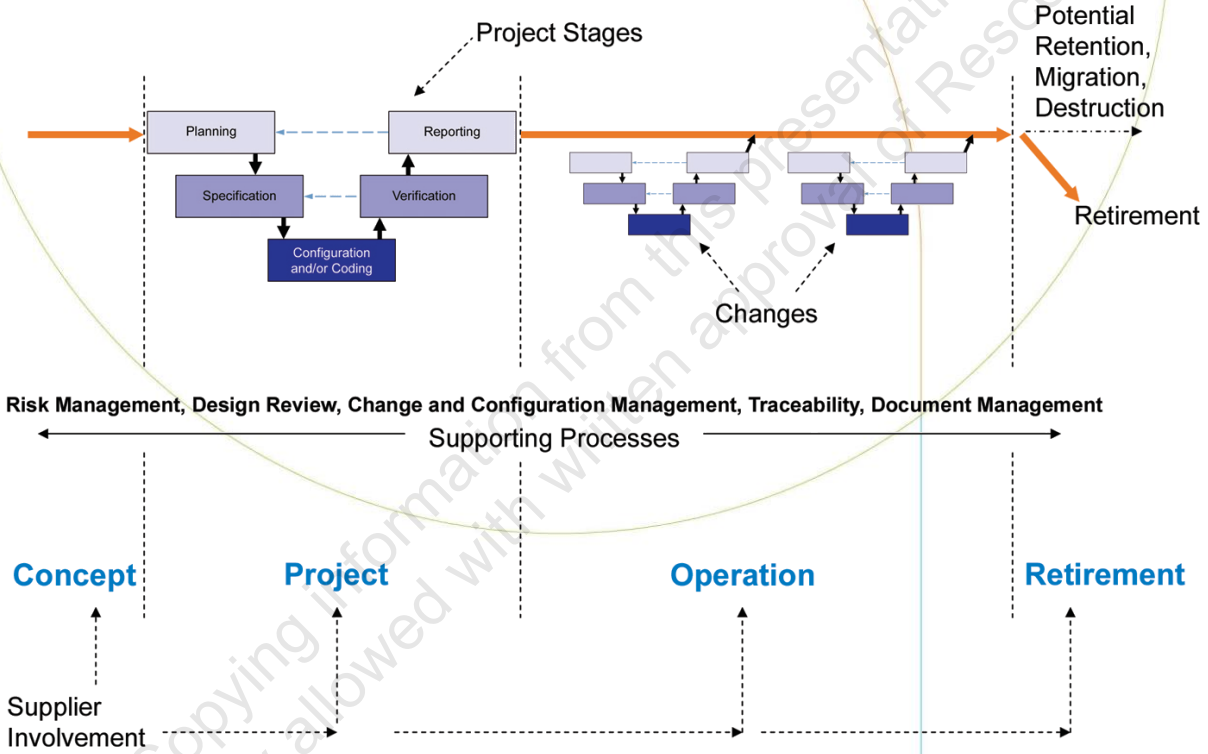
V - Model in System Life Cycle



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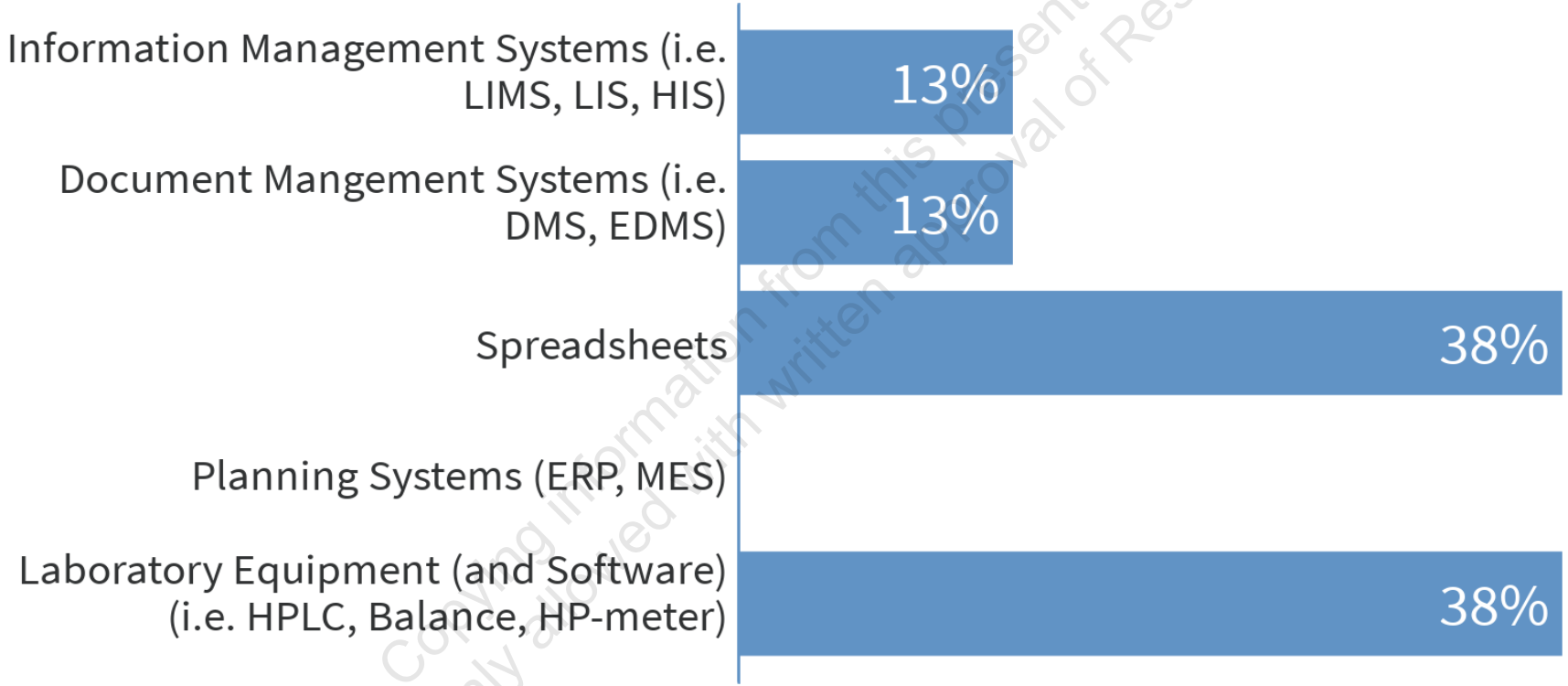
What type(s) of systems do you already validate



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

Agenda

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- System Life Cycle
- **Project Phase**
- Risk management
- Operational and Retirement phases
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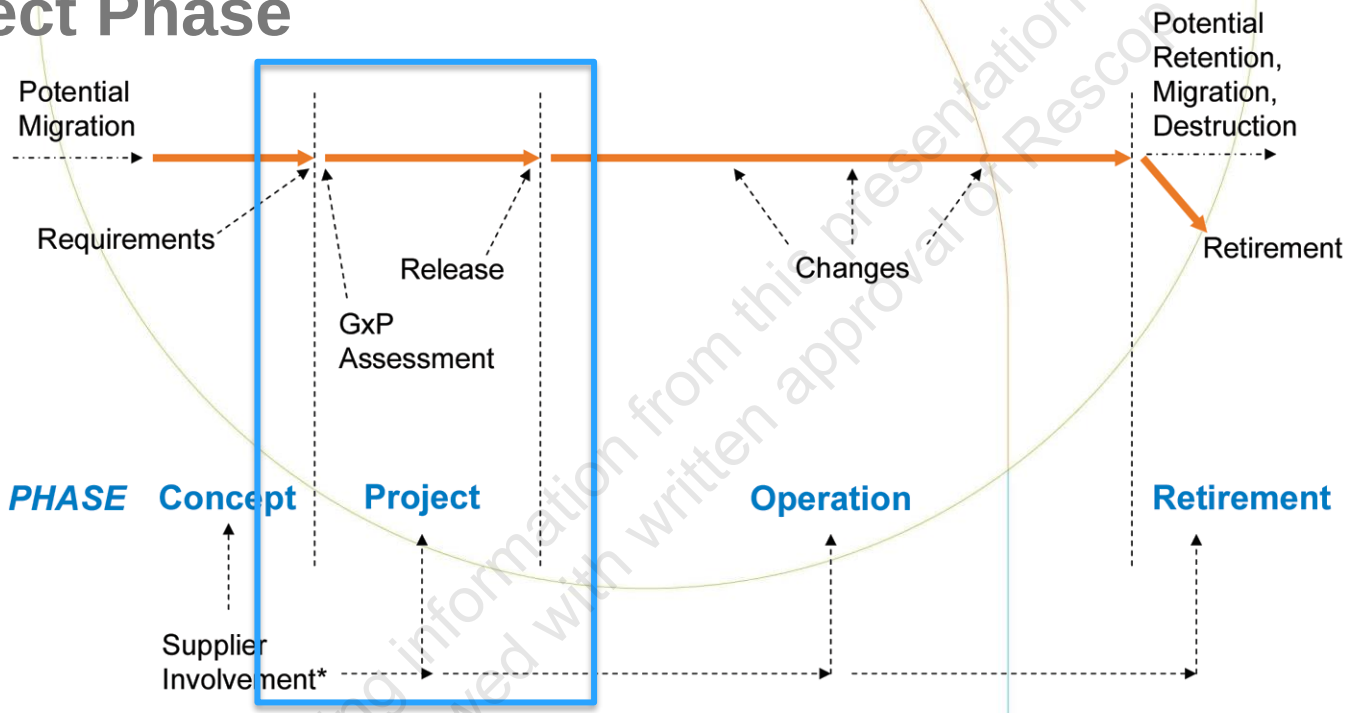
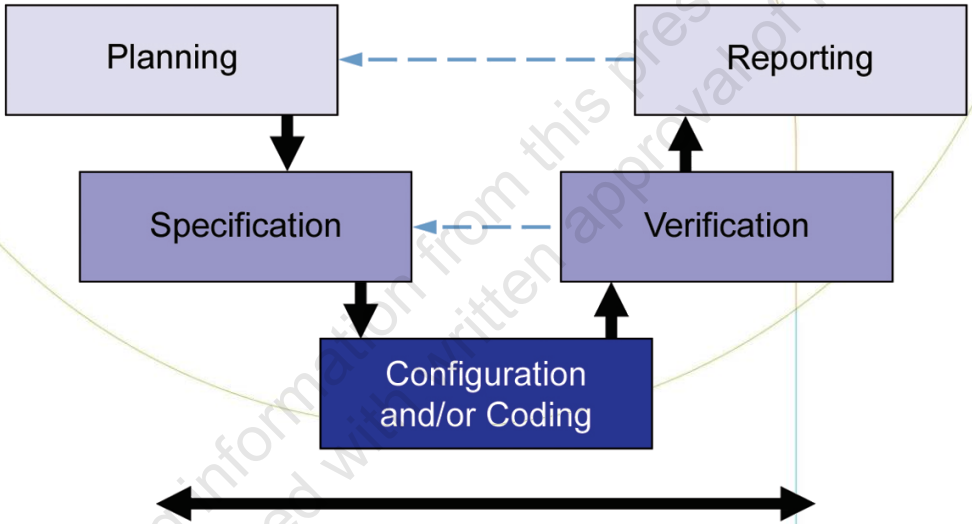
Project Phase



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

Project Phase



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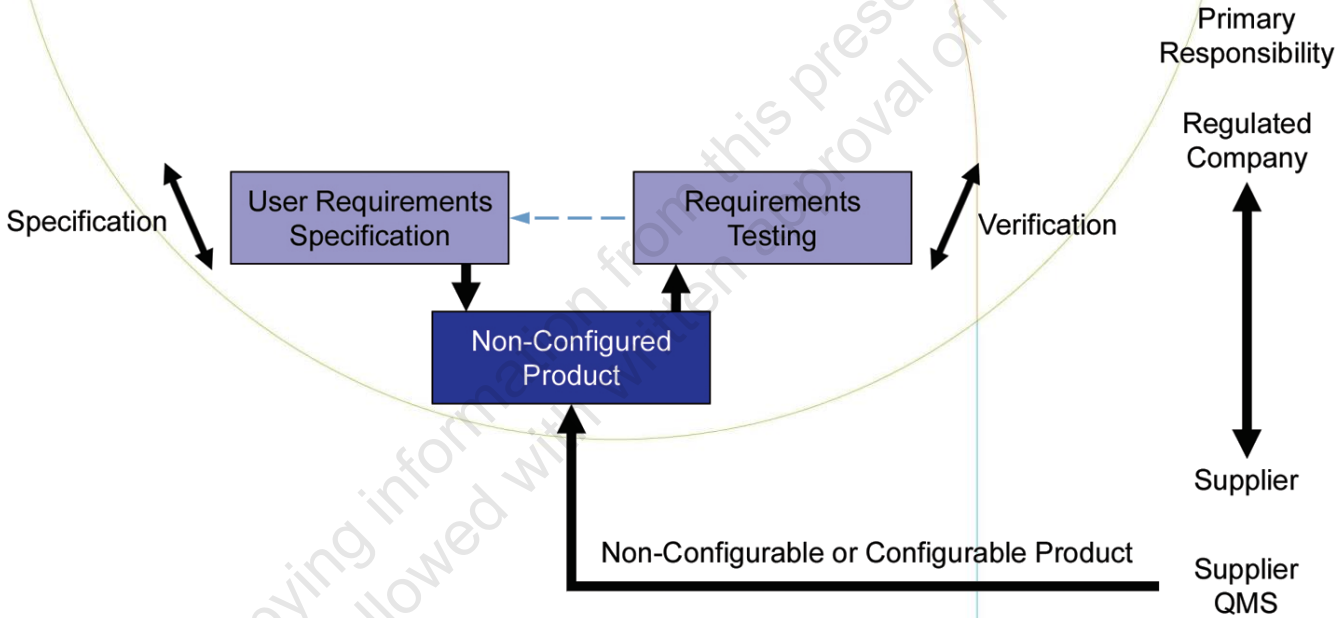
Category 3 - Non-configured Products



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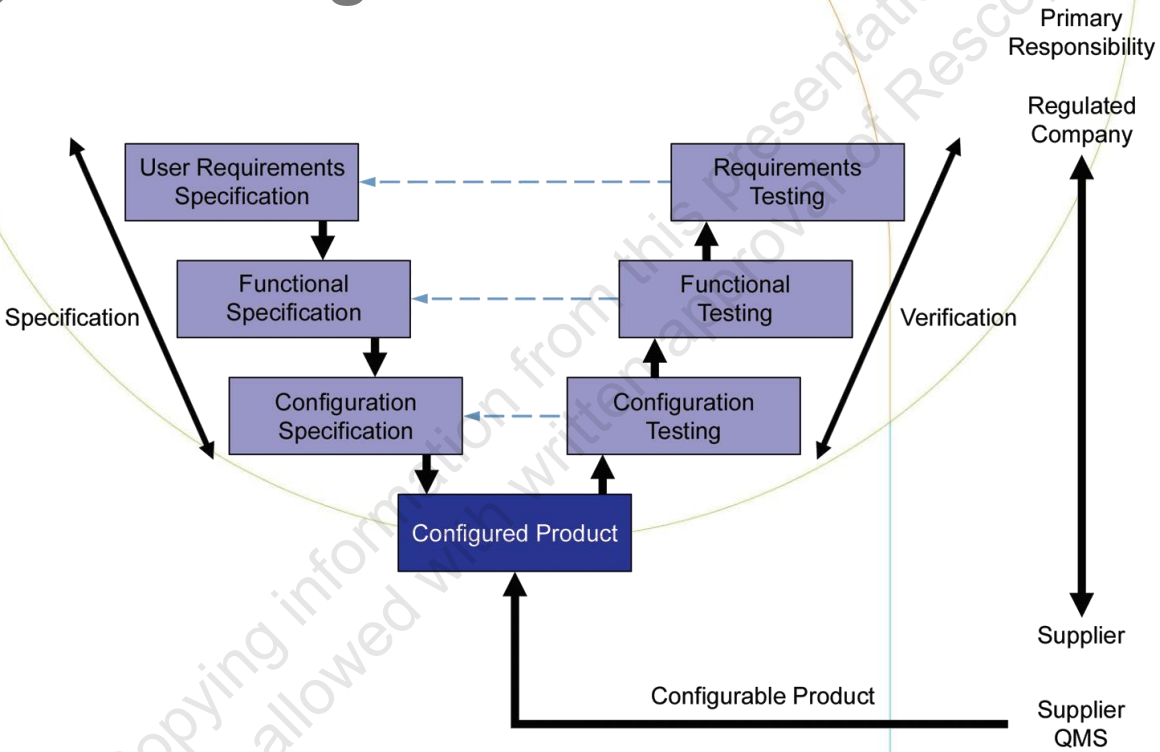
Category 4 - Configured Products



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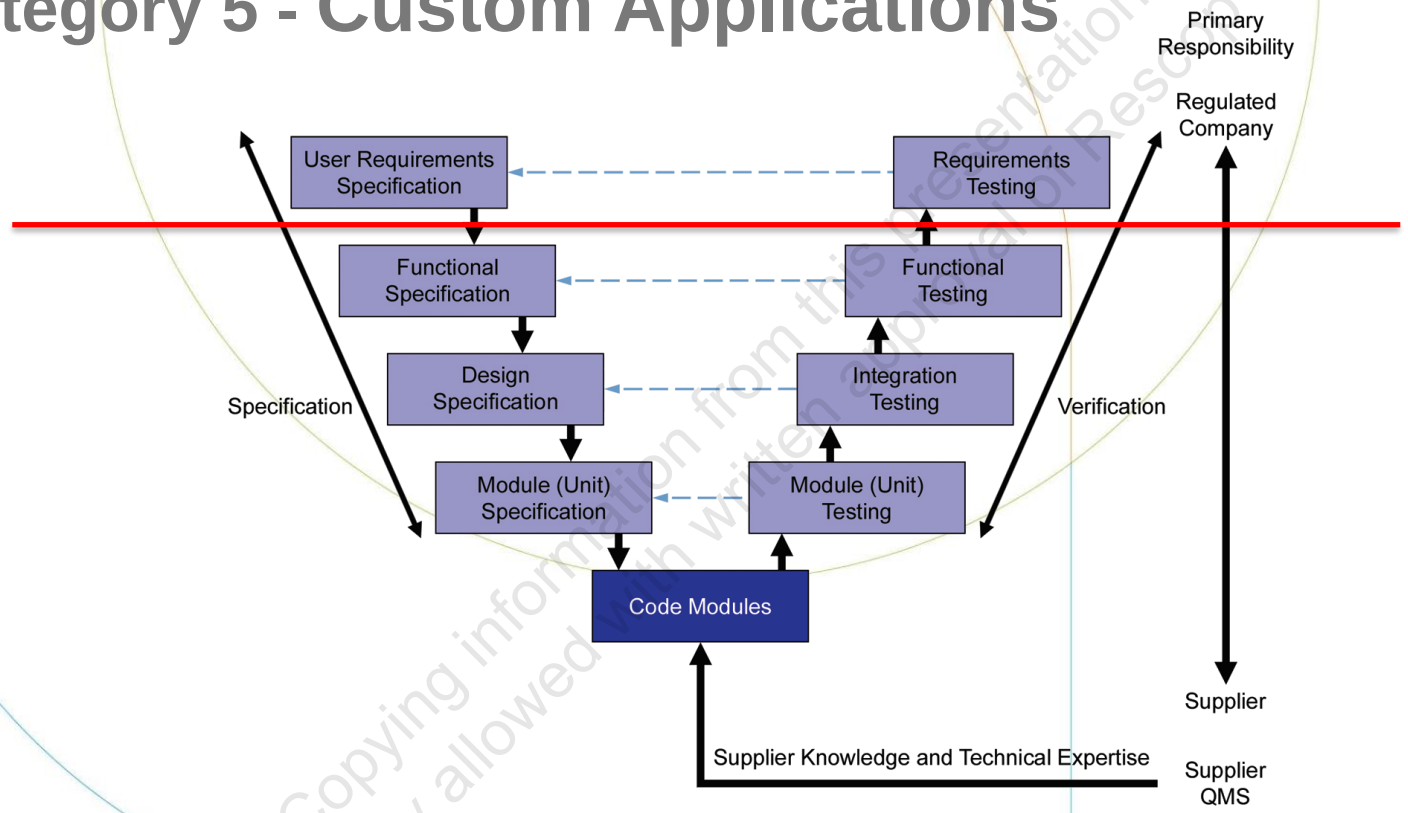
Category 5 - Custom Applications



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Agenda

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- **Risk management**
- Operational and Retirement phases
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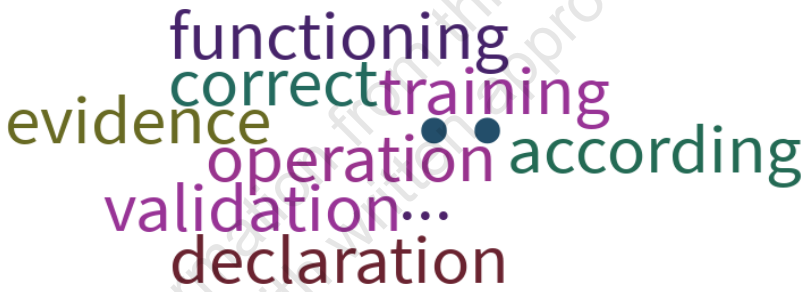
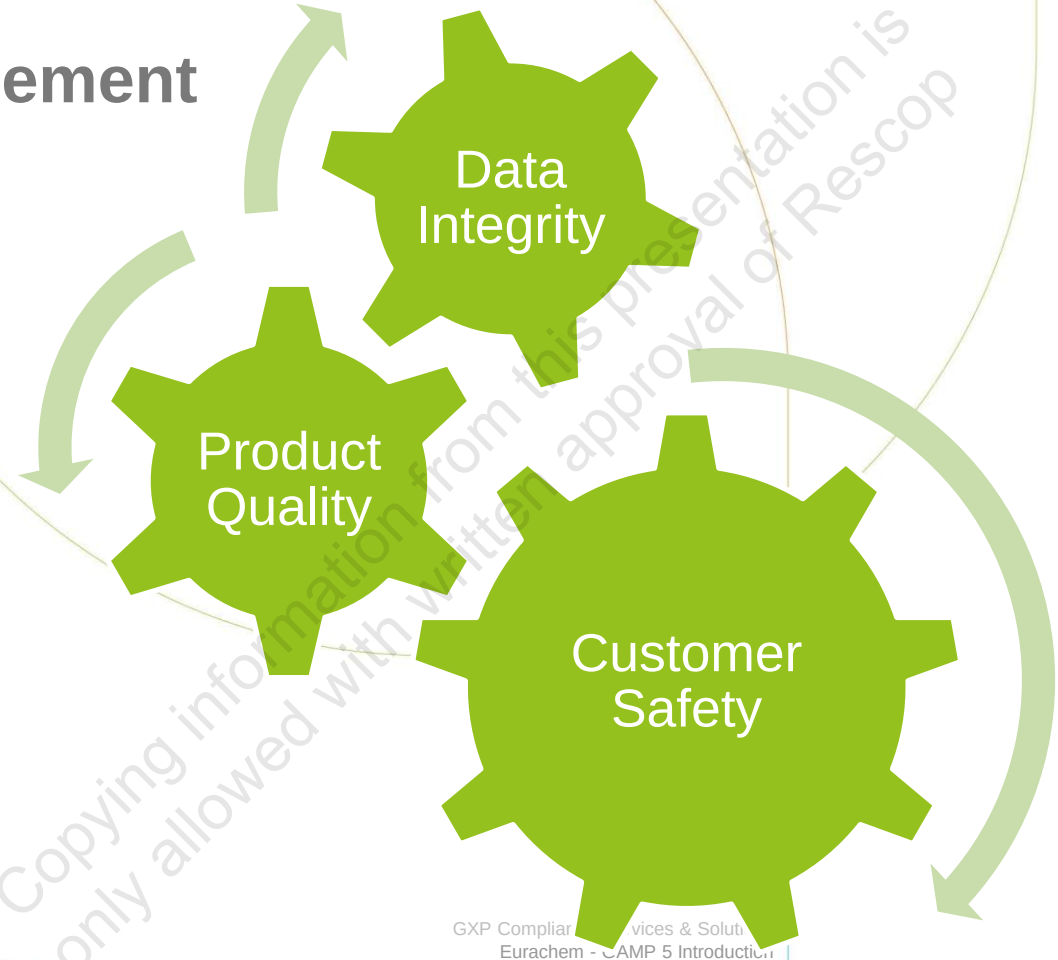
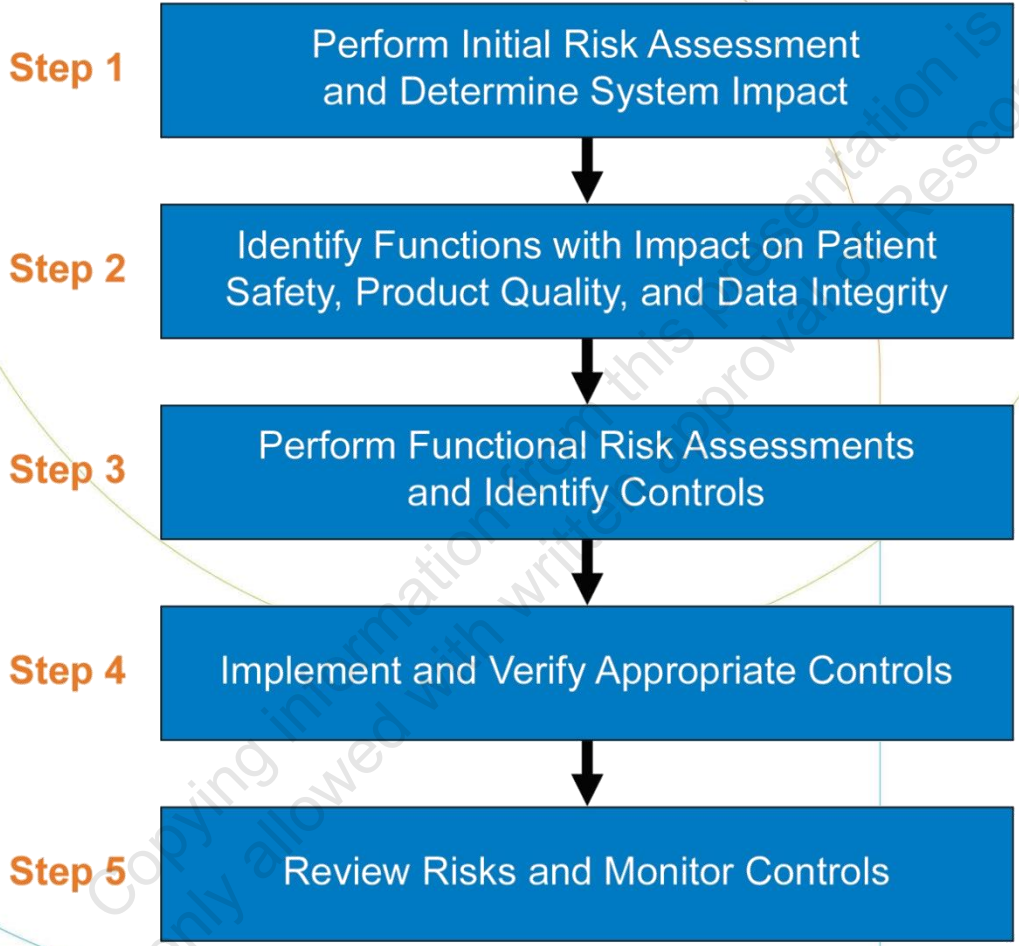
What risks do Regulators pay attention to?



Risk Management





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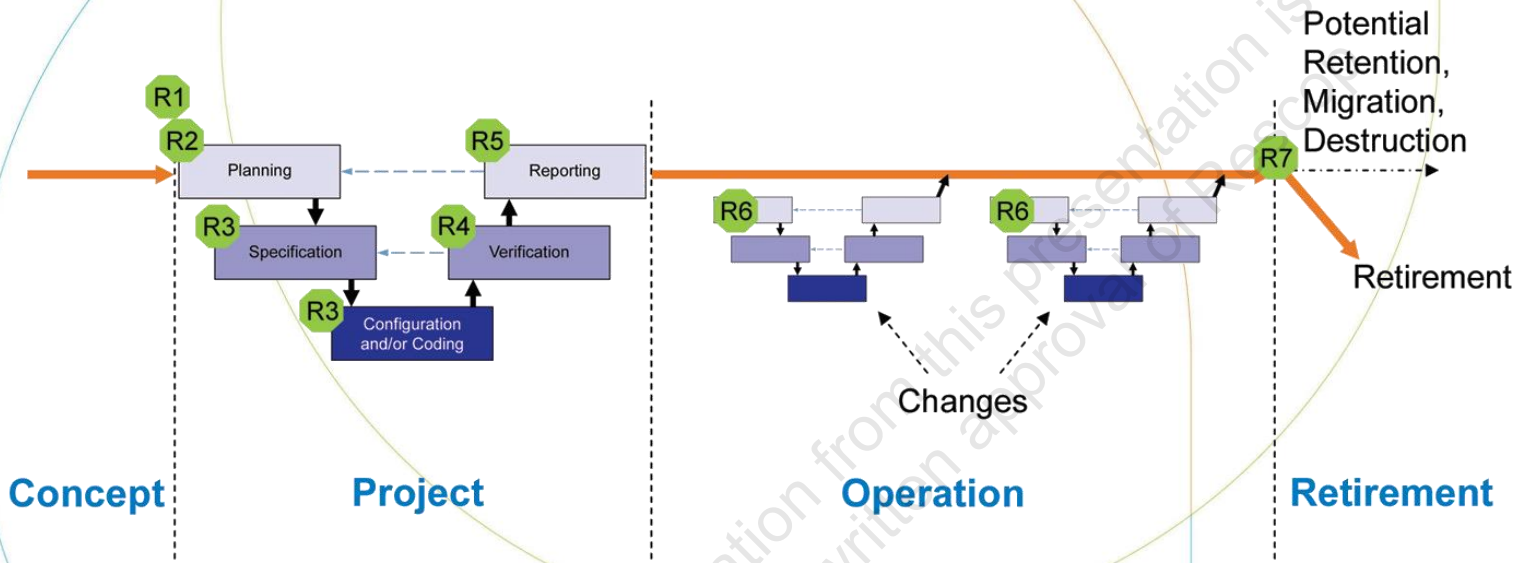

R1 Initial risk assessment

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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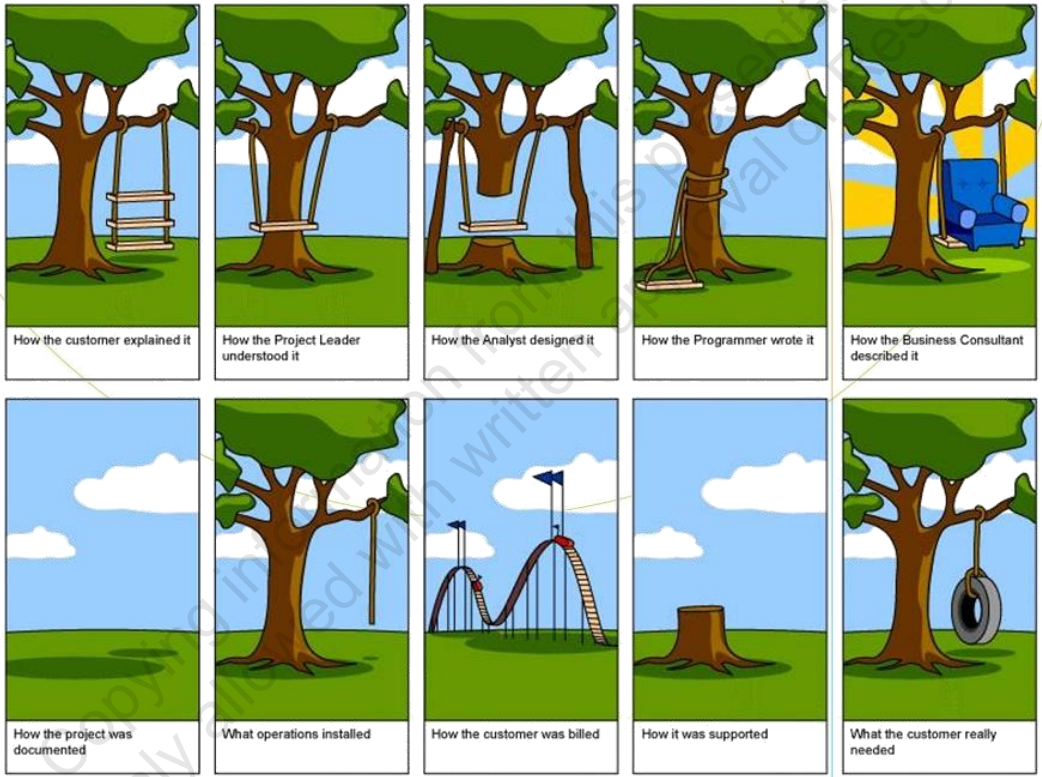
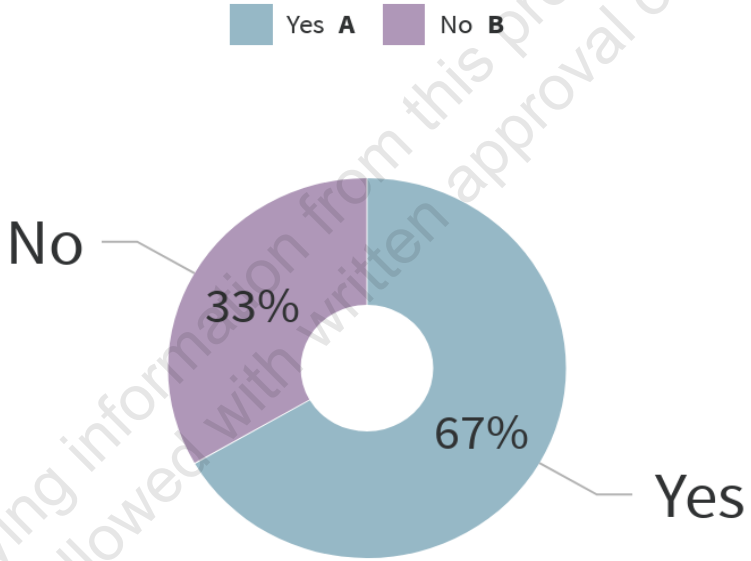
Why on earth do we need to do that?



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



Agenda

- What is GAMP5?
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- **Operational and Retirement phases**
- Summary

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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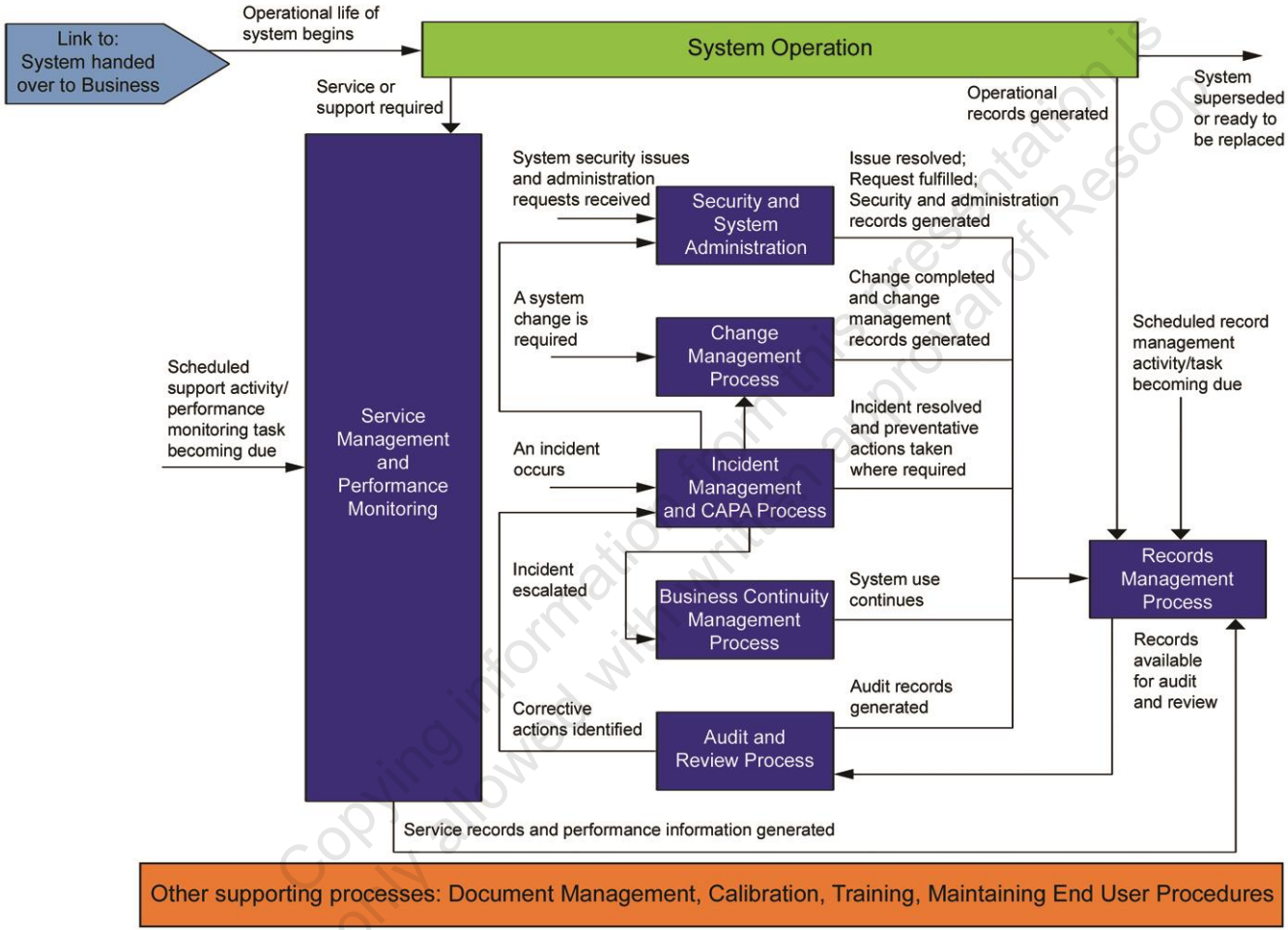
Operational and retirement phases

- Handover 7.11.5 5.10.3(b)
- Establishing and managing support services 7.11.3(d) 5.10.3(e)
- Performance monitoring
- Incident m 7.11.3(e) 5.10.3(f)
- Corrective 7.11.3(e) ti 5.10.3(f) APA)
- Operational change and configuration manageme 7.11.2 5.10.3(a)
- Repair activity
- Periodic review 8.8 4.14.5
- Backup and rest 7.11.3(b) 5.10.3(d)
- Business continuity managem 5.10.3
- Security manag 7.11.3(a) 5.10.3(c/g)
- System Adminis 7.11.3(d) 5.10.2
- Data migration 7.11.6 5.10.3(a)
- System retireme 8.4.2 4.13 decommissioning and disposal



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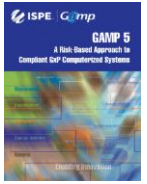
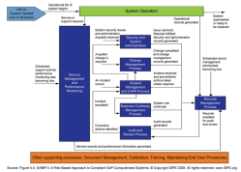
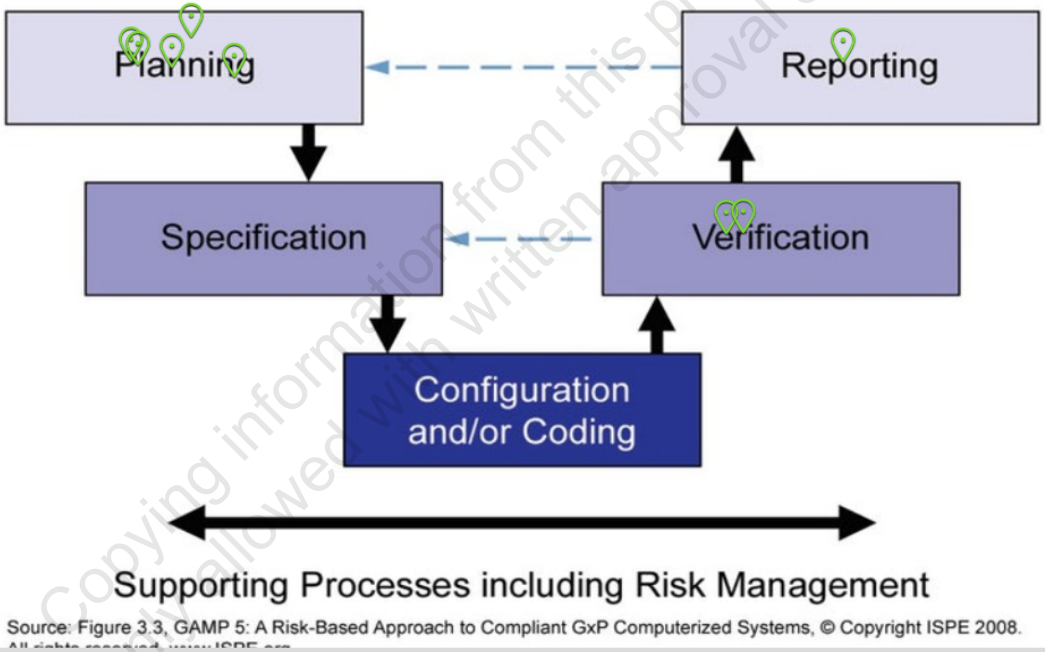
Summary

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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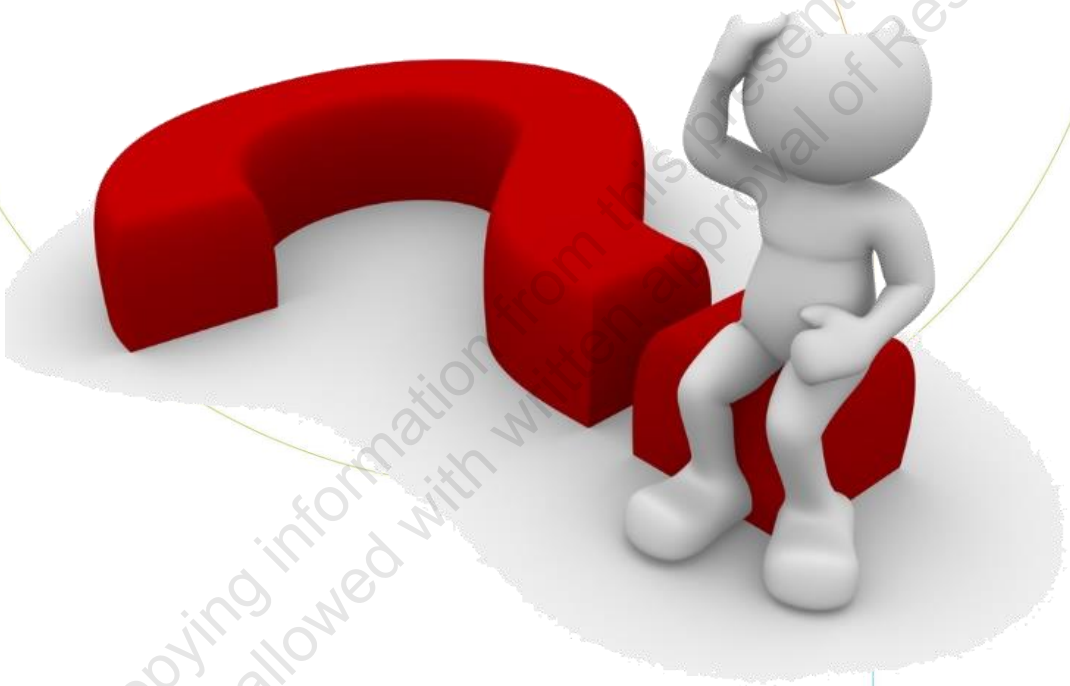
Now you are ready….

…. to start your GAMP5 adventure

with computer systems validation



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