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GAMP 5.0 and the Cloud

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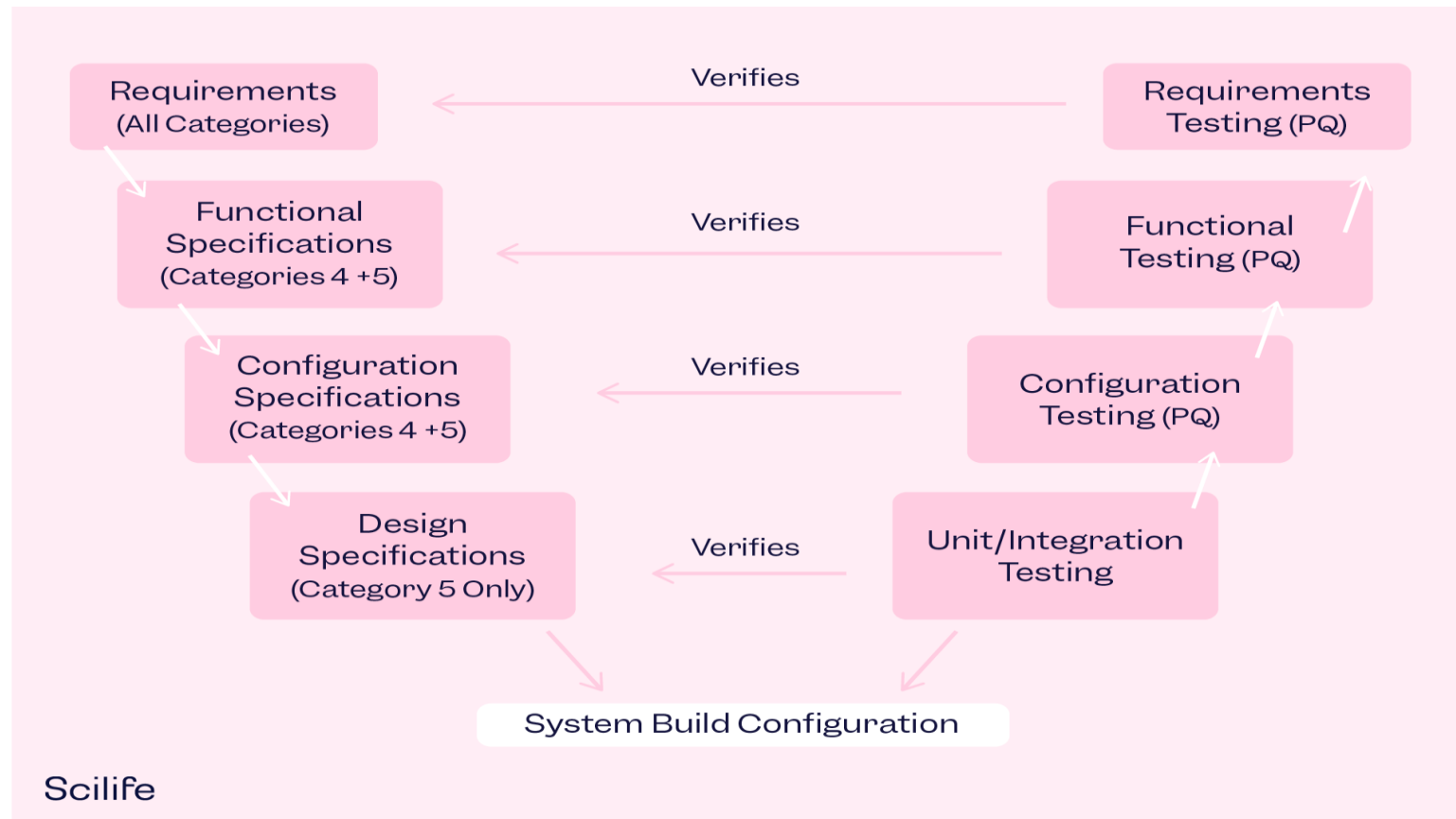


GAMP 5.0 and the Cloud

- Current Industry Computer Software Validation Approach
- Computer Software Assurance (CSA Approach)
- Introduction to Cloud Based Systems
- FDA Expectations for Cloud Based Systems
- The Supplier Role in Compliance

The “Traditional” Approach to Computer Software Validation

The “Traditional V” Model



Current “Computer System Validation” Approach

- A deterrent to pursuing process automation. Time and cost of documentation generation is **LARGE**.
- Perceived regulatory burden (e.g., Data integrity) becomes an excuse for resisting progress; other industries have moved forward and adopted frameworks for modern testing.
- All software is being validated as if it is product software.
- Burdensome and complex Risk Assessments.
- Focused on gathering evidence for auditors.
- Duplication of vendor efforts at client site.
- 80% of deviations due to tester or test script errors.
- **Numerous post-go-live issues.**

The Computer Software Assurance Approach (CSA)

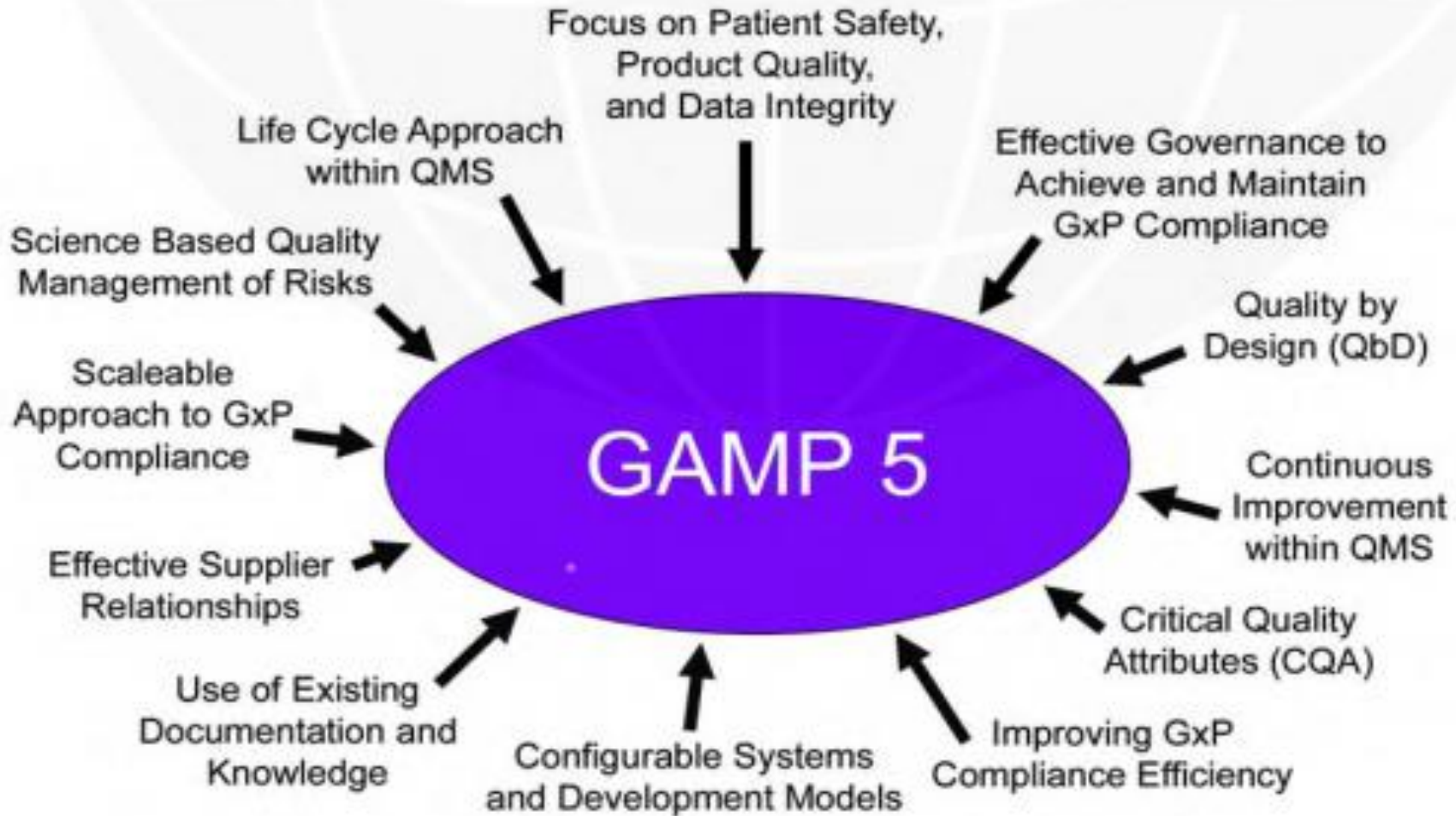


CSA Approach to Software Assurance

Computer Software Assurance for Production and Quality System Software – Draft Guidance Sept 2022

GAMP 5.0: A risk-based Approach to Compliant GxP Computerized System, Second Edition – July 2022

GAMP 5.0

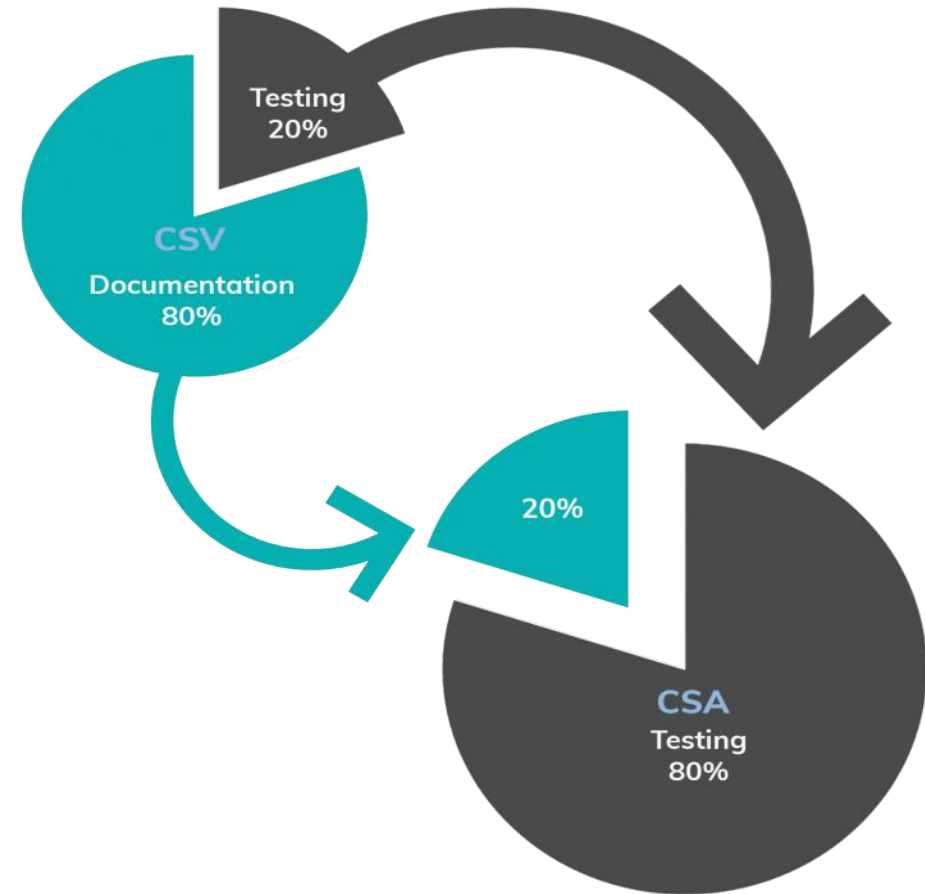


Computer Software Assurance

- **Risk Based** approach to Software Verification.
- **Critical Thinking** employed. The entire business process considered, not just the computer system when assigning risks.
- A Focus on testing for higher confidence in system performance.
- Risk based “Assurance”, applying the right level of rigor for a given level of risk to patient safety and/or product quality.
- “Take credit” for prior assurance activity and upstream/downstream risk controls.
- Focus on testing, not scripting. Use unscripted testing for low / medium risk components.

CSA - Producing the “Right” Level of Documentation

- “If it’s not documented, it didn’t happen.”
- “Unscripted Testing \neq No Documentation”
- “Traceability is still required”



Benefits of a CSA style Approach

- A reduction in test creation, review and approval time.
- A system can be broken into features, and only the High-Risk features will require scripted testing.
- Reduction in test script execution time.
- Lower number of detected defects, particularly test script related defects.
- A reduction in the number of generated documents.
- Testing focused on ensuring Software Quality.
- Better use of Supplier Qualification efforts.
- Maximized use of CSV and Project Resources expertise (e.g., SMEs)

CSA Takeaways

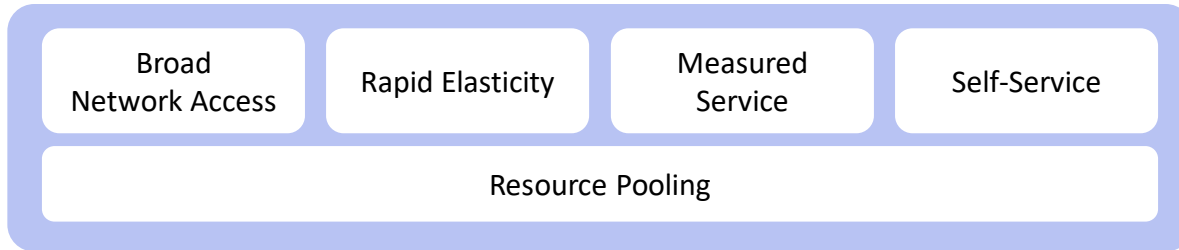
- Risk is based on the impact to patient safety and product quality measured against requirement complexity.
- It calls for a less burdensome approach to documentation.
- It can reduce paperwork by 80 % by leveraging the approved vendor's testing / quality program.
- It can result in fewer operational issues because less time is spent dry running test scripts, and more time actually testing / verifying the system.
- CSA does not involve creating of new regulations rather it is about level setting the FDA's expectations.
- CSA is supported both the FDA and the ISPE.

Introduction to Cloud Based Systems

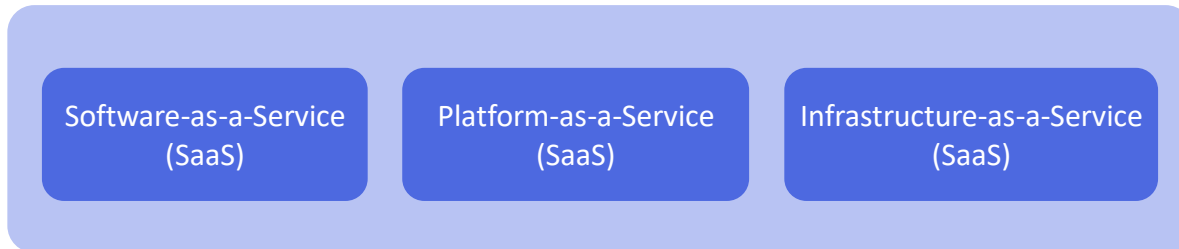


What is the Cloud

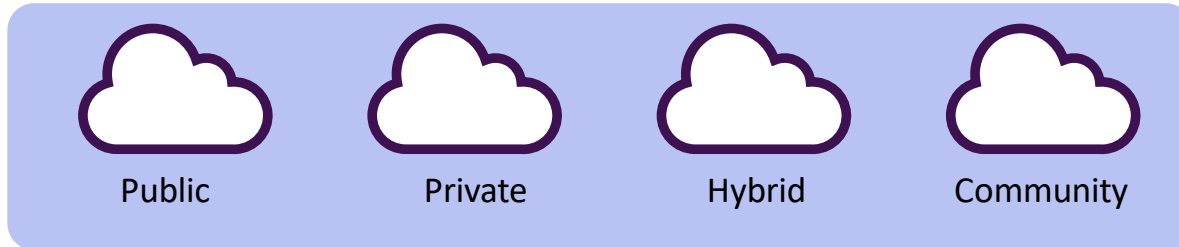
Essential Characteristics



Service Models



Deployment Models



Source: ISPE GAMP Community of Practice -UK

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Benefits of the Cloud

- Lower Costs - CAPEX vs. OPEX
- Agility/Speed to Market
- Instant Elasticity - Instantly react to increase in demand - Support for nearly infinite horizontal scaling
- Availability (24/7)
- Real-time Collaboration and Mobility

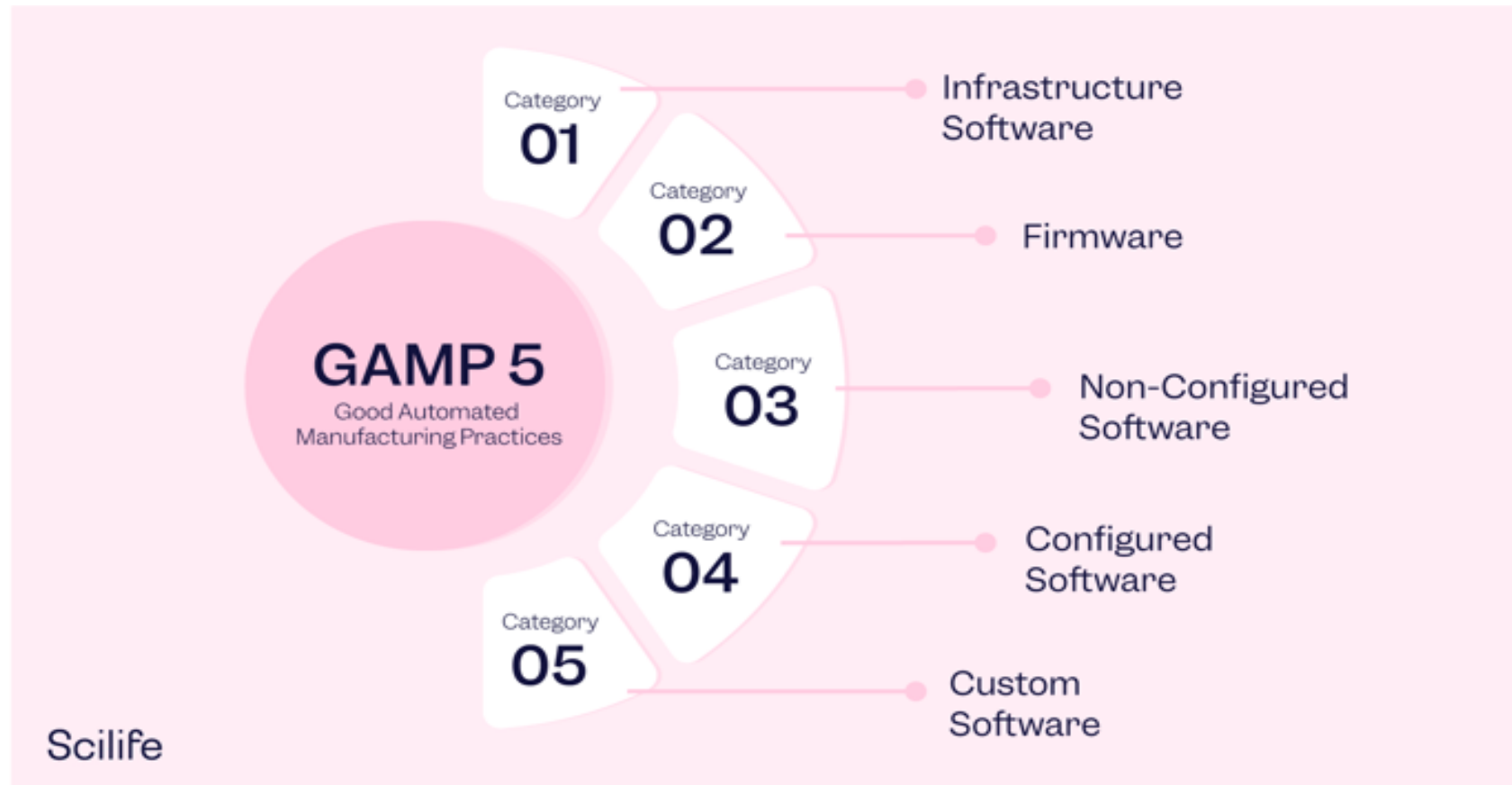
Resilience of the Cloud

- **Availability Zones**
 - Isolated systems within a Data Center
- **Multiple Regions**
 - Globally Distributed Data Centers
- **Geo-Replication**
 - Replication between Data Centers

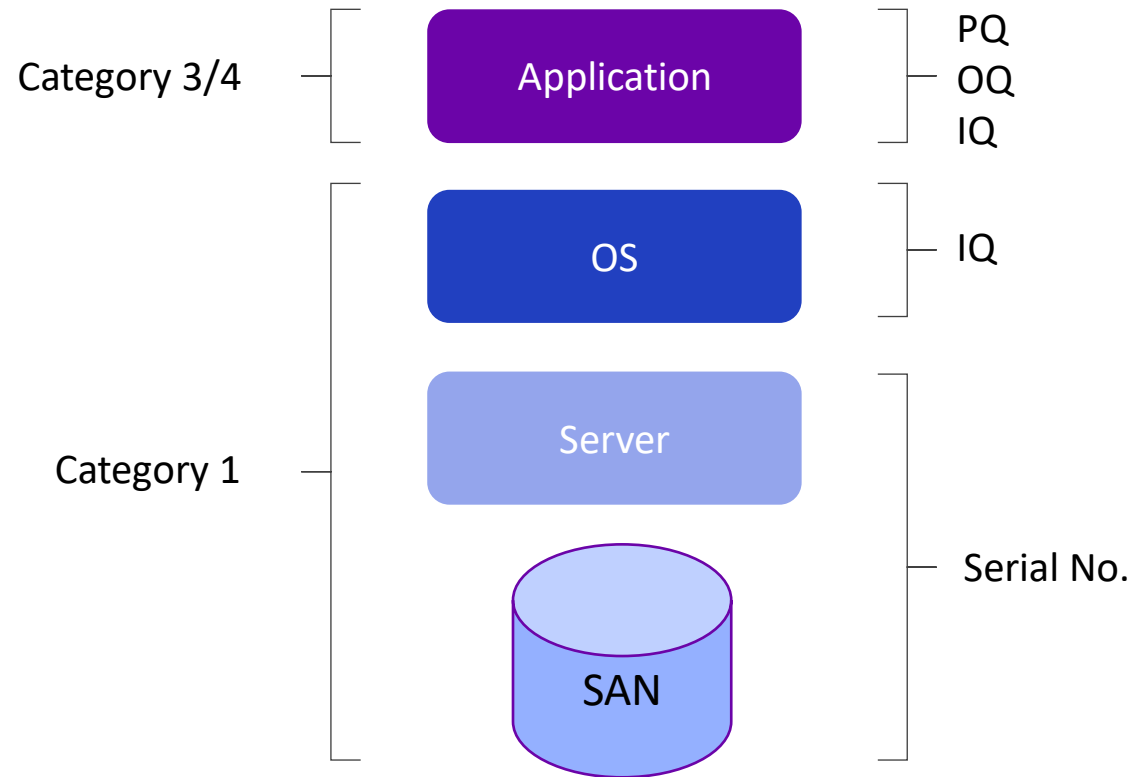
Potential Obstacles to the Cloud

- Security/Accountability
- Availability
- Quality Department Resistance
- Regulatory Needs
- Lack of Understanding of Public Cloud
- Existing IT Structures/Infrastructures

GAMP 5.0 Categories



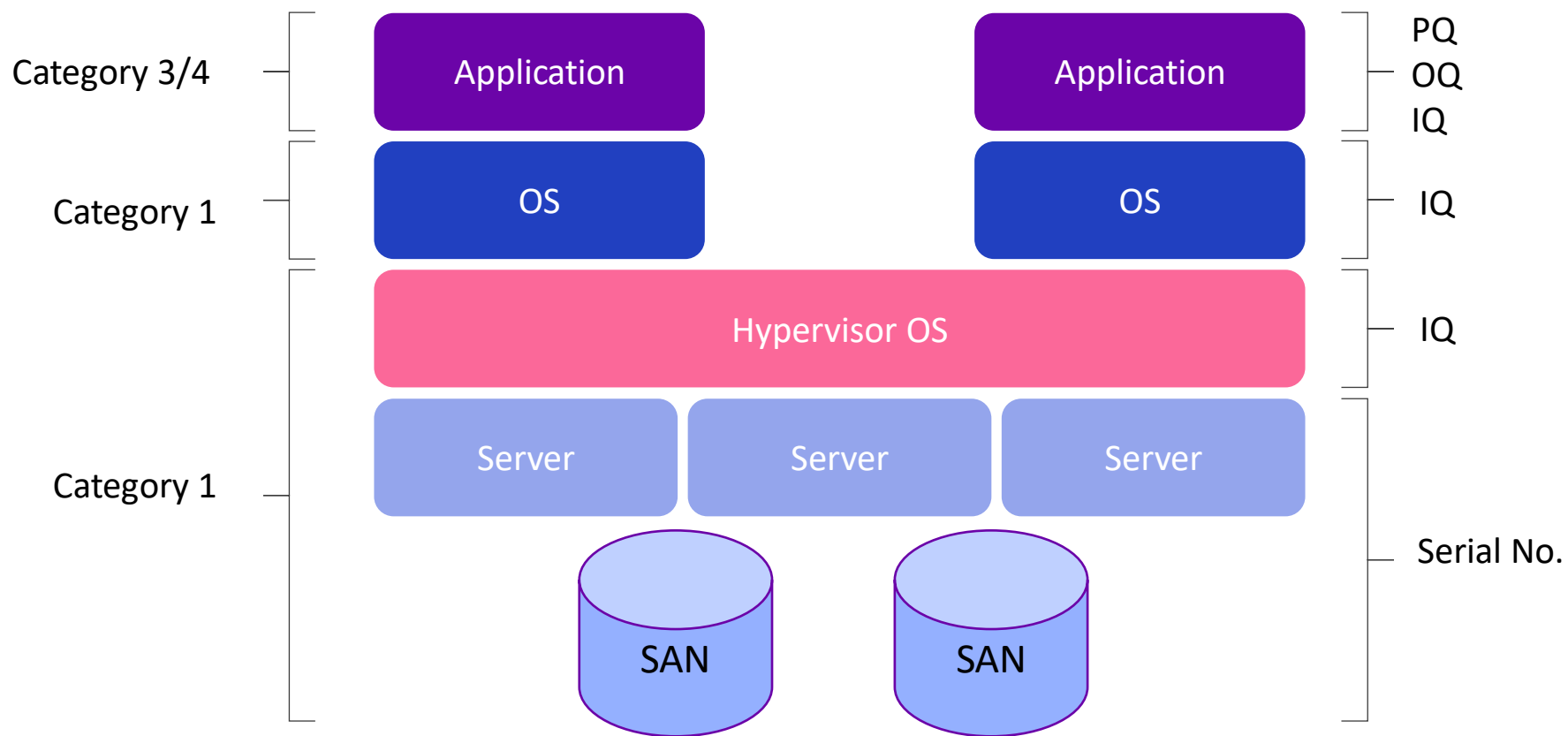
Traditional On-Premise Deployment



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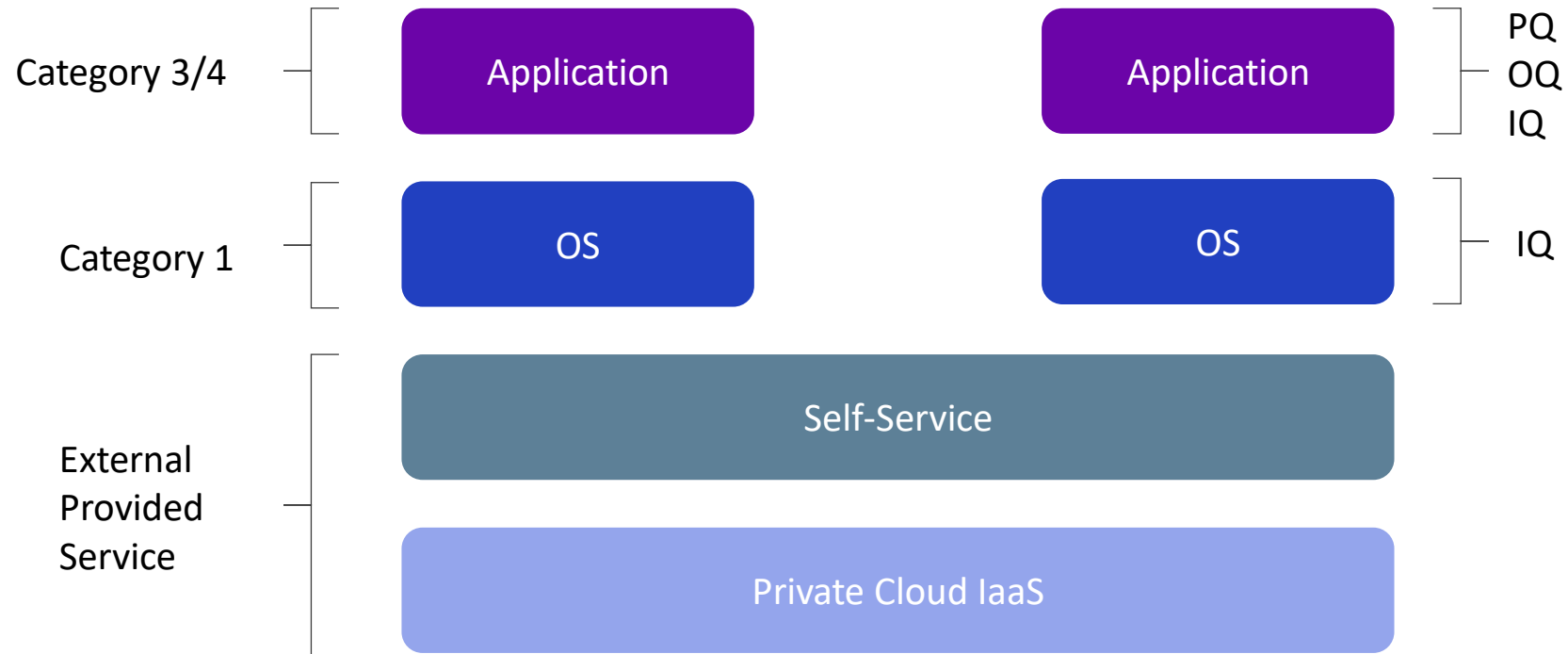
Current On-Premise Virtual Deployments



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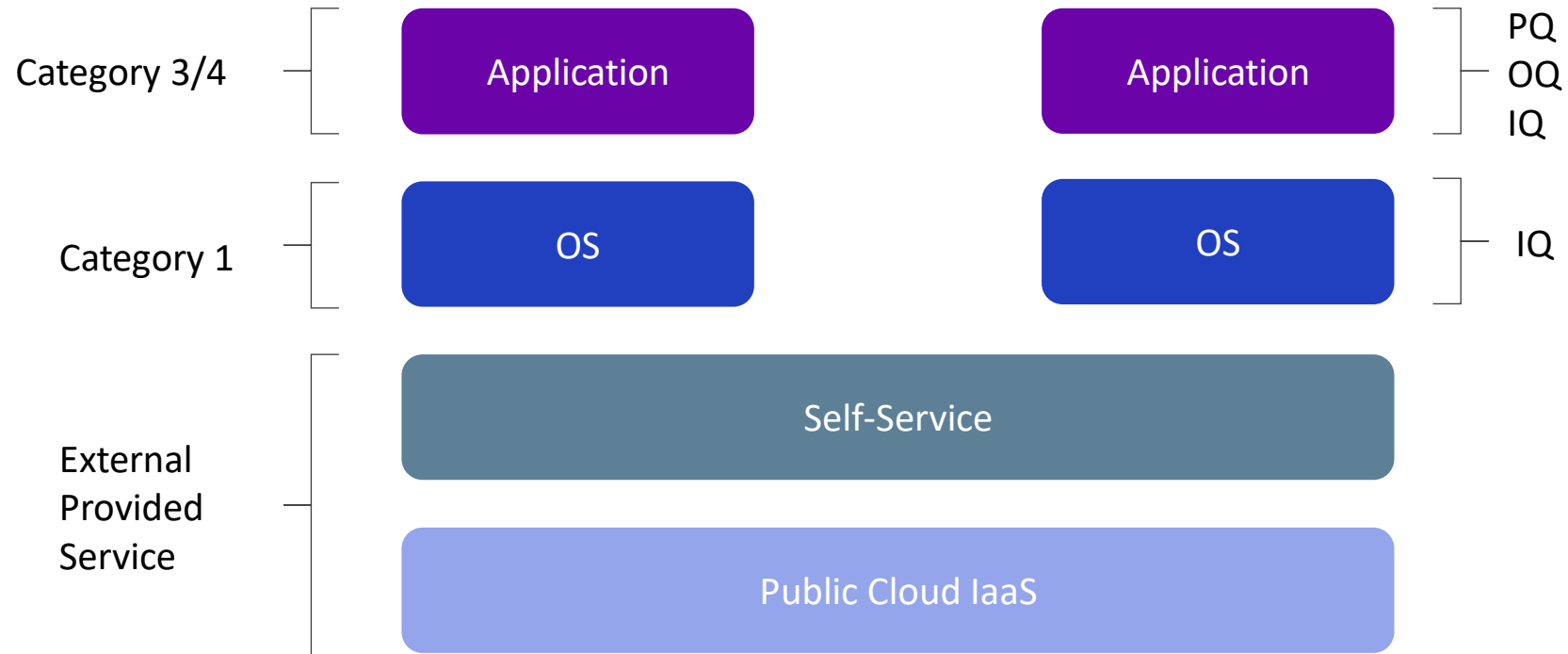
Private Cloud



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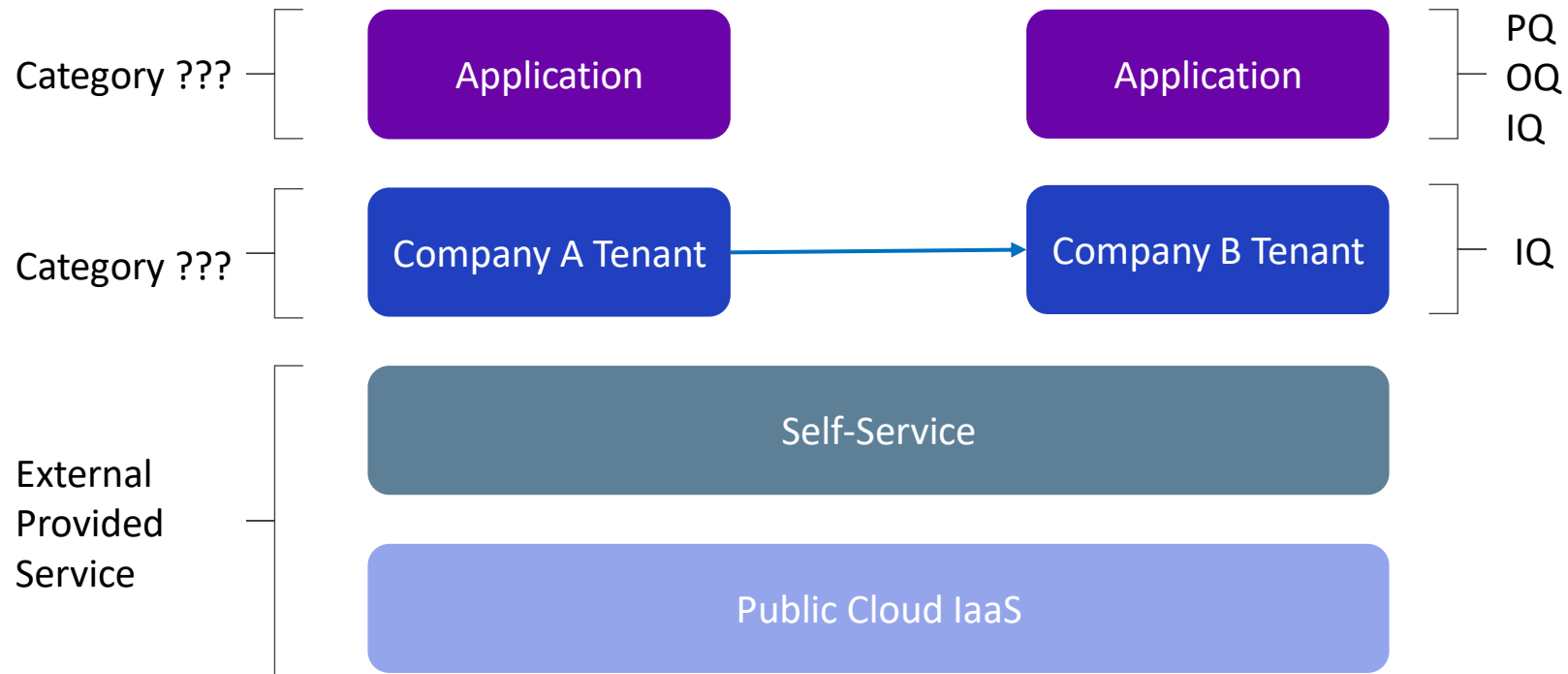
Public Cloud



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Public Cloud Multi Tenant AVEVA Connect / Data Hub



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FDA Expectations

FDA Viewpoint

- What are regulators interested in when they discover IT is outsourced?
 - Risks clearly identified & mitigated
 - Integrity of the Data is assured
 - Data Backup/Recovery
 - Cybersecurity for Networked Systems
 - Client/Provider Contracts
 - Provider Quality Systems
 - SOP's, validation, change control, training
 - Audits of Providers by FDA/Clients

Performing Due Diligence

- Risk-based Approach
- Third Party Audits
- Certifications obtain from other bodies (such ISO 27001, SOC 1 etc.)
- Completed Cloud Security Alliance (CSA) Consensus Assessment Initiative Questionnaire
- Assessment of their ability to deliver

The Supplier Role in Computer Software Assurance

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Expectations of a Cloud Provider

Step	Practice	Description
1.	Establish QMS	The supplier QMS should: <ol style="list-style-type: none">1. Provide a documented set of procedures and standards2. Ensure activities are performed by suitably competent and trained staff3. Provide evidence of conformance with the defined procedures and standards4. Enable and promote continual improvement, including adoption of current software methods, good practices, and appropriate tools and automation
2.	Establish Requirements	The supplier should ensure that clear requirements are defined or provided by the regulated company.
3.	Quality Planning	The supplier should define how their QMS will be implemented for a particular product, application, or service.
4.	Assessments of Sub-Suppliers	Suppliers should formally assess their sub-suppliers as part of the process of selection and quality planning.
5.	Produce Specifications	The supplier should specify the system to meet the defined requirements.
6.	Perform Design Review	The design of the system should be formally reviewed against requirements, standards, and identified risks to ensure that the system will meet its intended purpose and that adequate controls are established to manage the risks.
7.	Software Production/ Configuration	Software should be developed in accordance with defined standards, including the use of code review processes. Configuration should follow any defined rules or recommendations and should be documented.

Expectations of a Cloud Provider (Cont'd)

Step	Practice	Description
8.	Perform Testing	The supplier should test the system in accordance with approved test plans and test specifications.
9.	Commercial Release of the System	System release to customers should be performed in accordance with a formal process. Note: This is not release into GxP environment, which is a regulated company activity.
10.	Provide User Documentation and Training	The supplier should provide adequate system management documentation, operational documentation, and training in accordance with agreed contracts.
11.	Support and Maintain the System in Operation	The supplier should support and maintain the system in accordance with agreed contracts. The process for managing and documenting system changes should be fully described.
12.	System Replacement and Retirement	The supplier should manage the replacement or withdrawal of products/ services in accordance with a documented process and plan. The supplier also may support the regulated company with the retirement of computerized systems in accordance with regulated company procedures.

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