ISPE

XAAS GOVERNANCE MODEL:

Managing the role of vendors and service providers

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Guest Presenter

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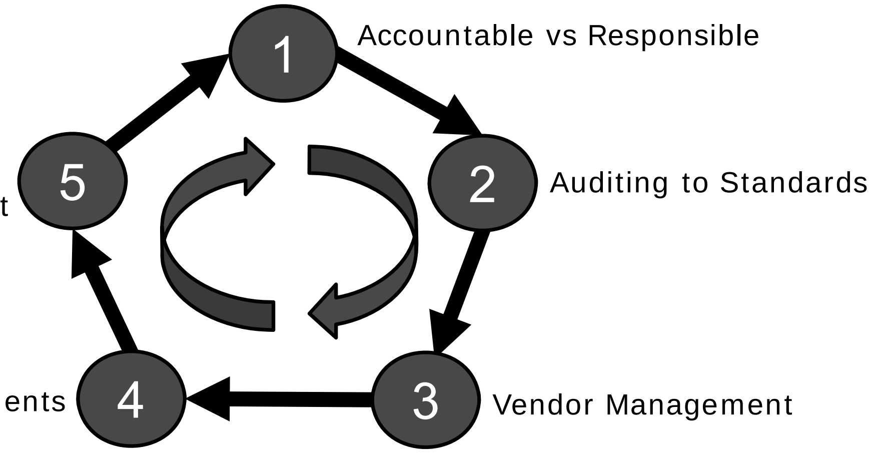
XaaS Governance Model 5 Key Concepts



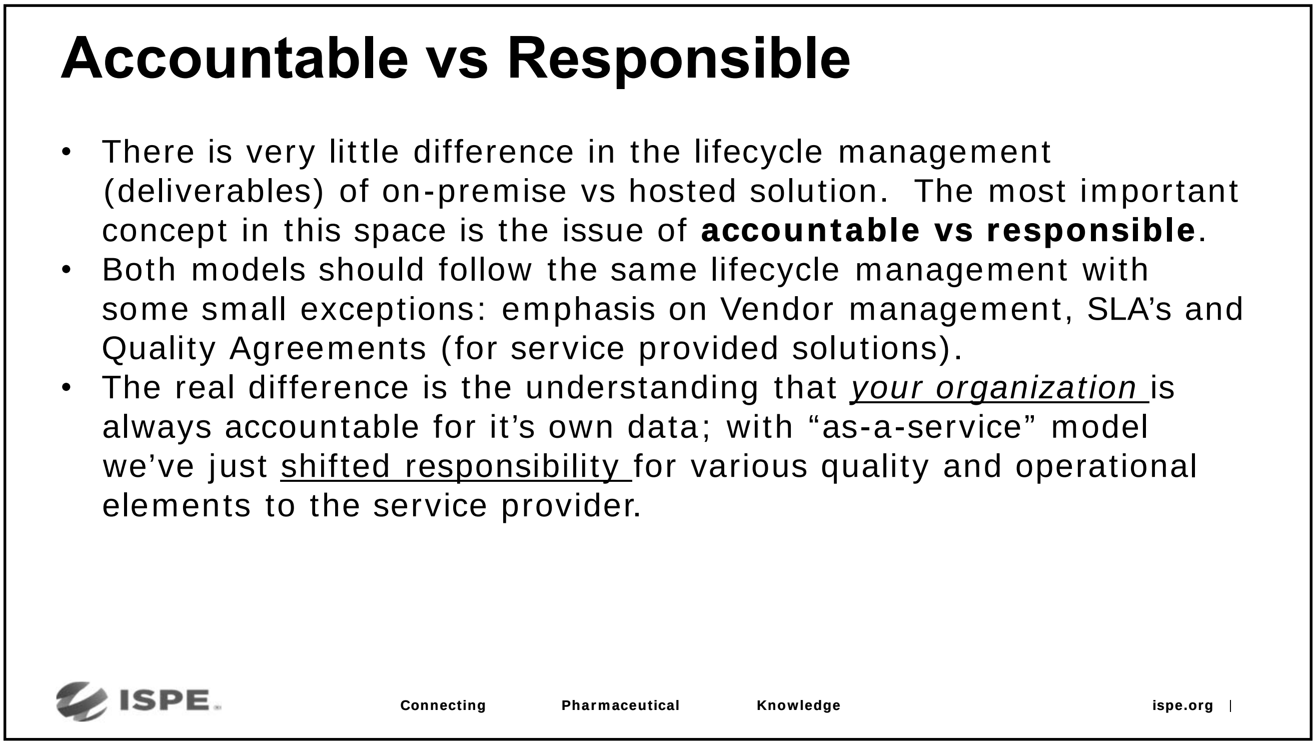
1 Accountable vs Responsible

2 Auditing to Standards

3 Vendor Management

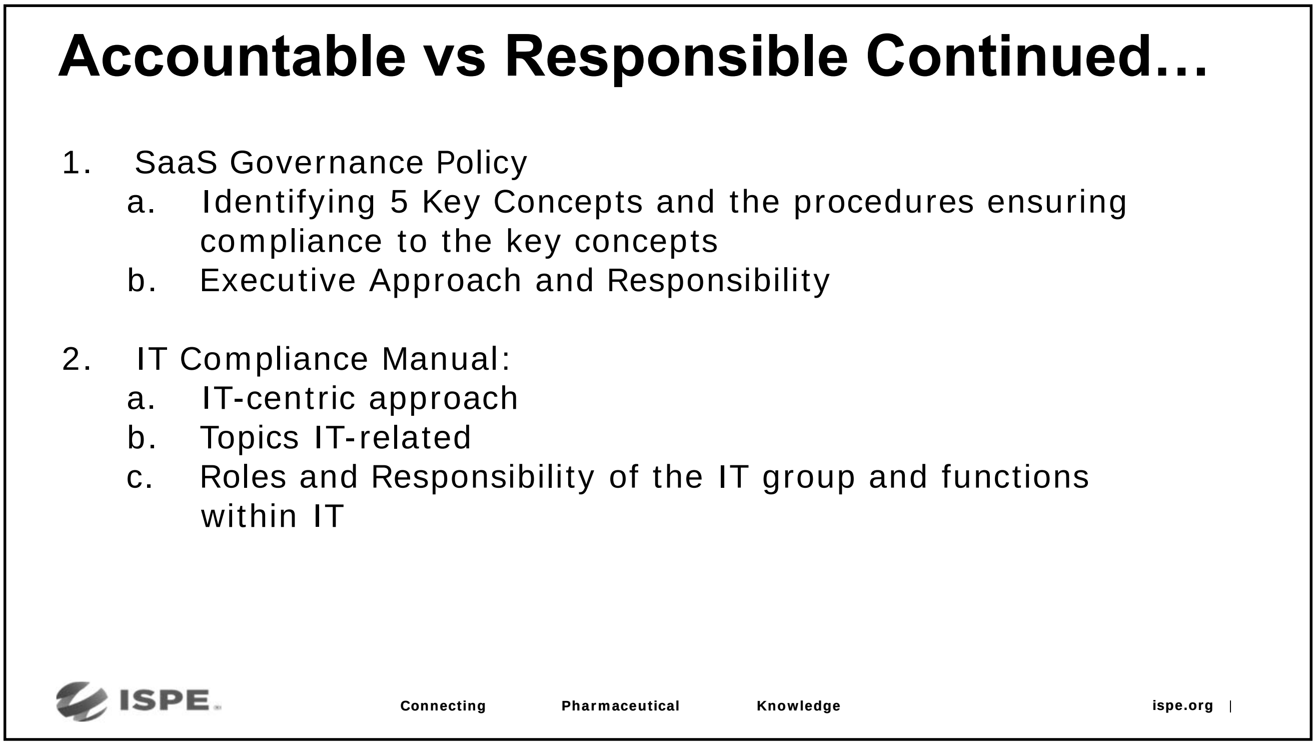
4 SLA/Quality Agreements

5 Computer System Lifecycle Management



Accountable vs Responsible

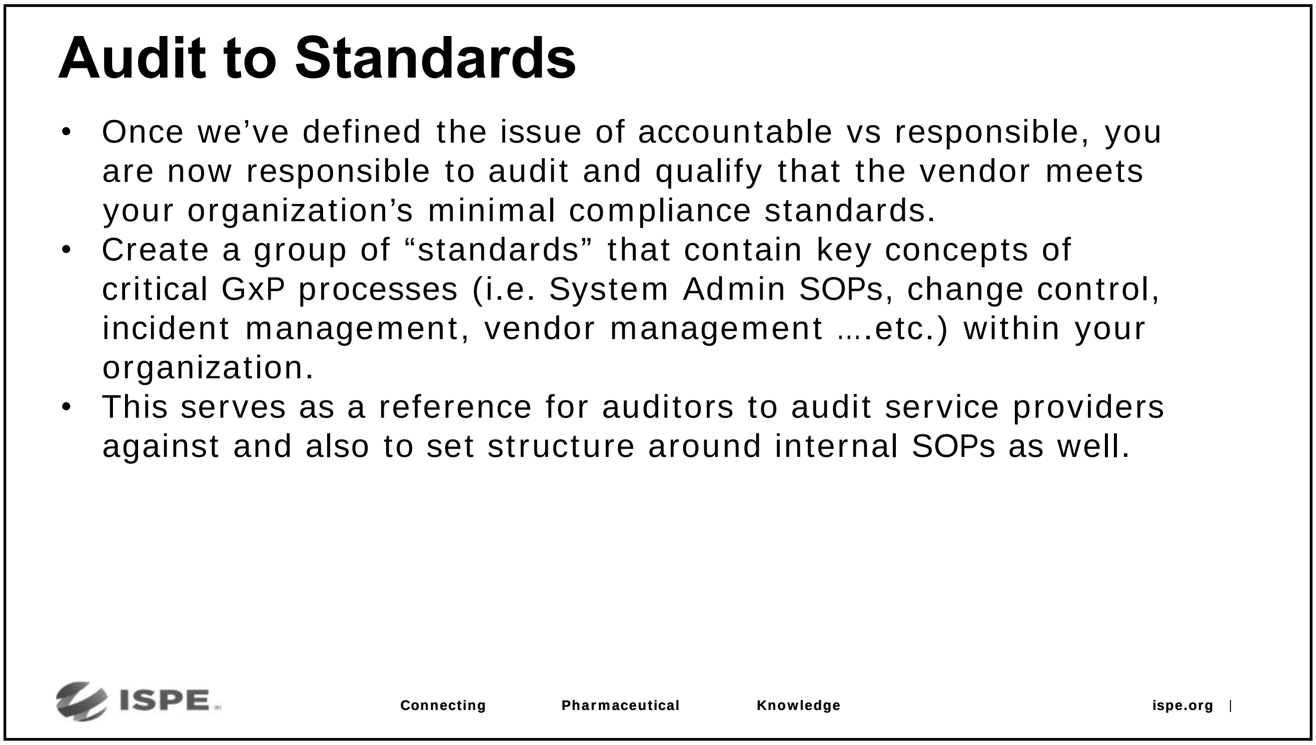
- There is very little difference in the lifecycle management (deliverables) of on-premise vs hosted solution. The most important concept in this space is the issue of **accountable vs responsible**.
- Both models should follow the same lifecycle management with some small exceptions: emphasis on Vendor management, SLA's and Quality Agreements (for service provided solutions).
- The real difference is the understanding that *your organization* is always accountable for it's own data; with "as-a-service" model we've just shifted responsibility for various quality and operational elements to the service provider.



Accountable vs Responsible Continued…

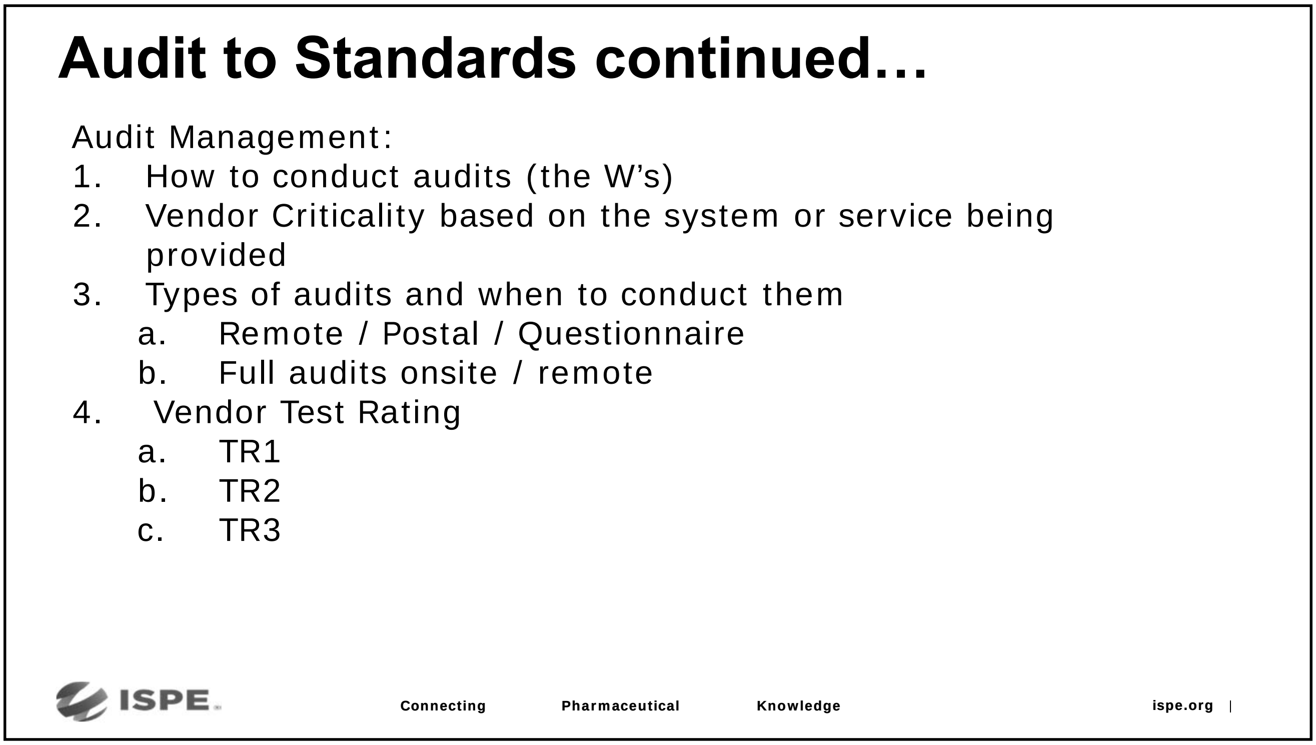
1. SaaS Governance Policy
   a. Identifying 5 Key Concepts and the procedures ensuring compliance to the key concepts
   b. Executive Approach and Responsibility

2. IT Compliance Manual:
   a. IT-centric approach
   b. Topics IT-related
   c. Roles and Responsibility of the IT group and functions within IT



Audit to Standards

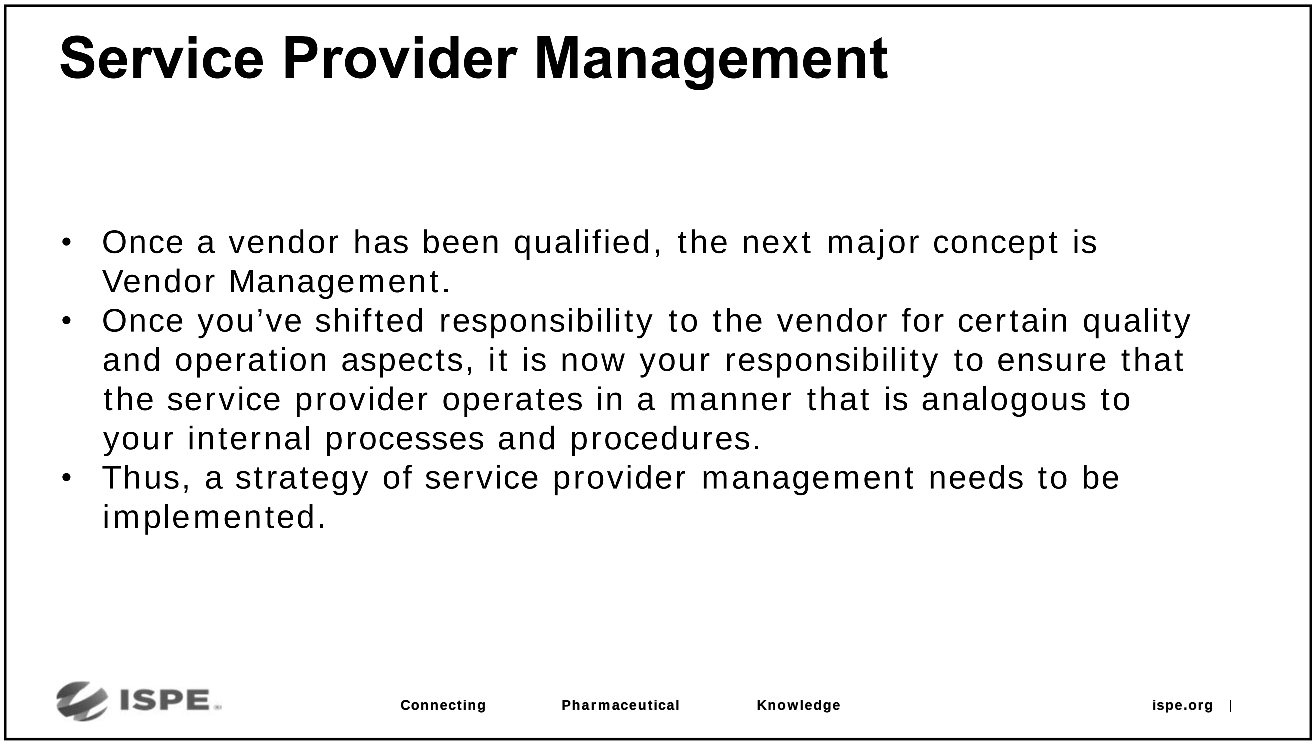
- Once we've defined the issue of accountable vs responsible, you are now responsible to audit and qualify that the vendor meets your organization's minimal compliance standards.
- Create a group of "standards" that contain key concepts of critical GxP processes (i.e. System Admin SOPs, change control, incident management, vendor management ….etc.) within your organization.
- This serves as a reference for auditors to audit service providers against and also to set structure around internal SOPs as well.



Audit to Standards continued…

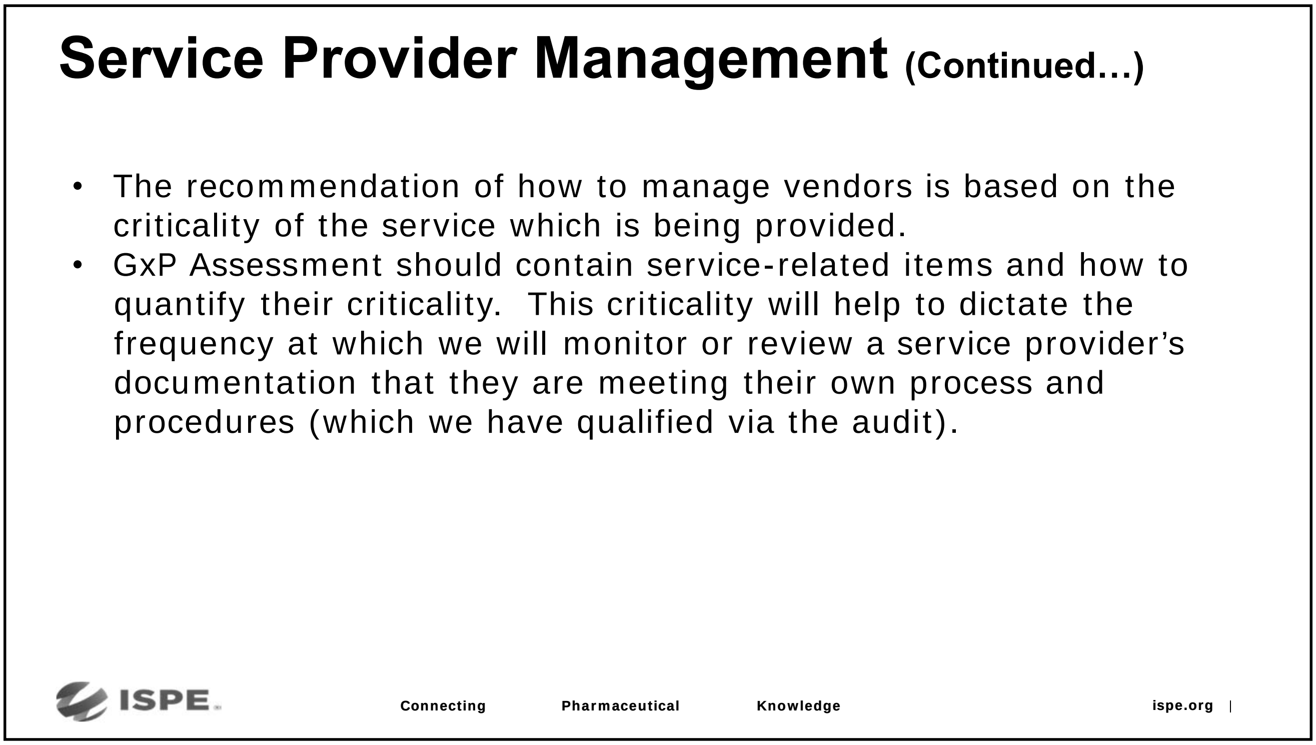
Audit Management:

1. How to conduct audits (the W's)
2. Vendor Criticality based on the system or service being provided
3. Types of audits and when to conduct them
   a. Remote / Postal / Questionnaire
   b. Full audits onsite / remote
4. Vendor Test Rating
   a. TR1
   b. TR2
   c. TR3



Service Provider Management

- Once a vendor has been qualified, the next major concept is Vendor Management.
- Once you've shifted responsibility to the vendor for certain quality and operation aspects, it is now your responsibility to ensure that the service provider operates in a manner that is analogous to your internal processes and procedures.
- Thus, a strategy of service provider management needs to be implemented.



Service Provider Management (Continued…)

- The recommendation of how to manage vendors is based on the criticality of the service which is being provided.
- GxP Assessment should contain service-related items and how to quantify their criticality. This criticality will help to dictate the frequency at which we will monitor or review a service provider's documentation that they are meeting their own process and procedures (which we have qualified via the audit).

Service Provider Management (Continued…)

Vendor Management:

- What is the frequency of audits or re-evaluation
- Monitoring process
- Involvement in service providers Quality Operations (i.e. Change / Incident / CAPA management

SLA’s and Quality Agreements

- Since it is your responsibility to manage and verify that the service provider is in compliance to their own processes, you have to ensure that you are able to review on an on-going basis activities that that the service procedure is now responsible for.
- The concept of SLA’s and Quality Agreement is very crucial in setting expectations and the understanding of how your organization plans on approaching the process of managing service providers.
  - For example, if the service provider is providing a critical function (assessed by GxP assessment), your organization should dictate that they are either reviewers or approvers of critical change controls (as opposed to major or minor).
- This is added resource time to the vendor and therefore should be accounted for in the Quality agreement.
- Verify that the supplier’s change management procedure contains an adequate process for impact assessment (this element of change control should be defined in the Change Management Standard).

SLA’s and Quality Agreements Continued

SLA and Quality Agreement Management:

- Based on the criticality of the system or service
- Define and specify communication process
- Quality Dashboards
- Define Vendor Management

ICE &Computer Systems Lifecycle Management

Integrated:

- To give or cause to give equal opportunity and consideration to regulatory impact, business impact and complexity

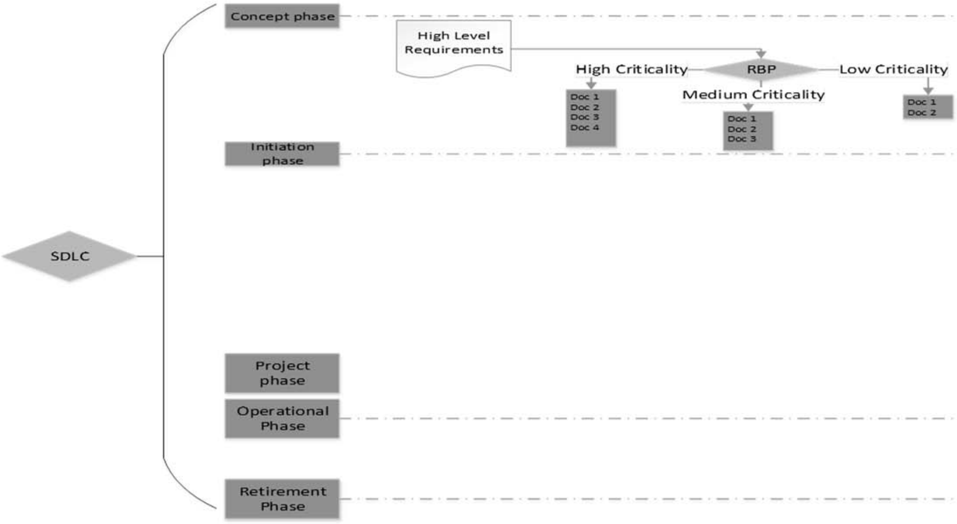
Compliance:

- The act of conforming, acquiescing, or meeting regulatory obligations.

Ecosystem:

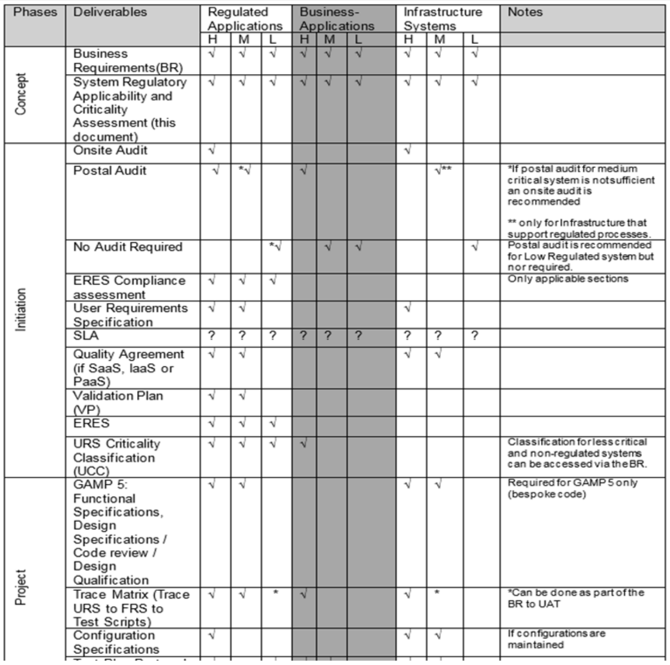
- A system, or a group of interconnected elements, formed by the integration of our methodology.

CSLM Overview

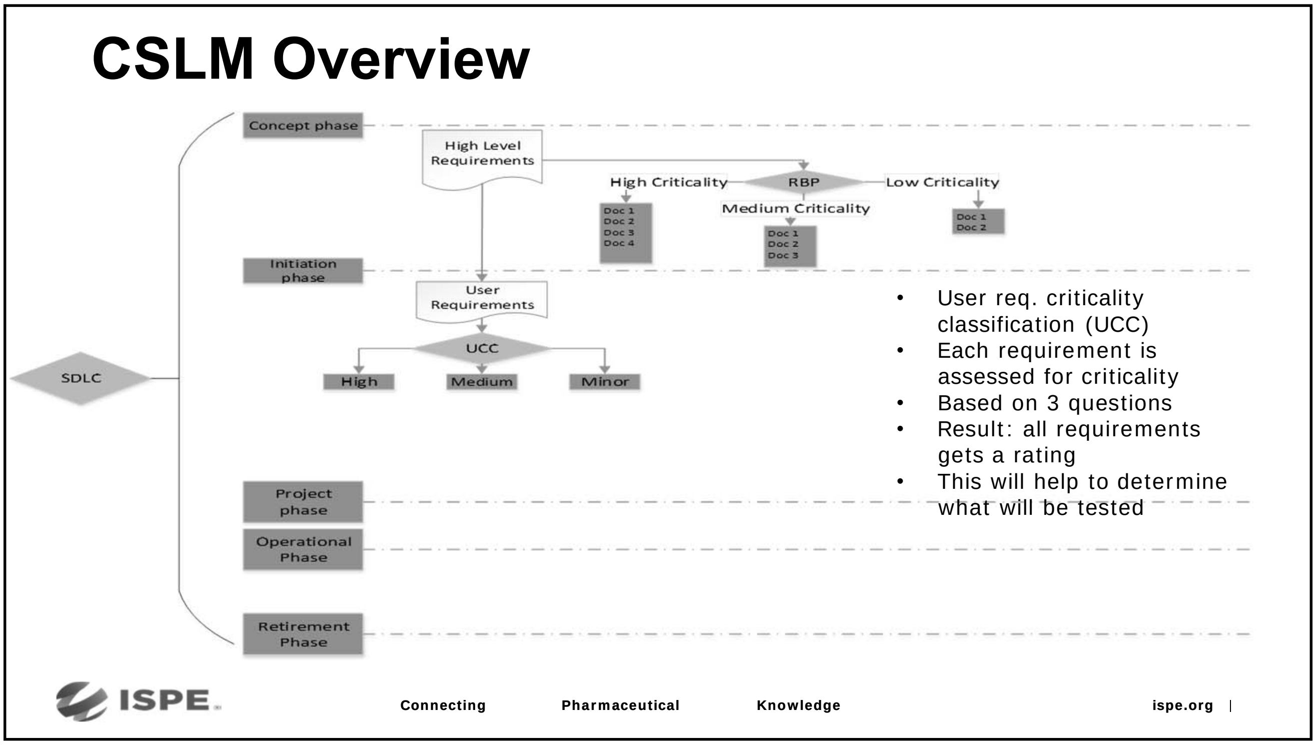


- Based on a scoring system
- Yes/No Questions
- Quantitative over Qualitative

Deliverables Matrix



Phases	Deliverables	Regulated Applications			Business-Applications			Infrastructure Systems			Notes
		H	M	L	H	M	L	H	M	L	
Concept	Business Requirements(BR)	√	√	√	√	√	√	√	√	√	
	System Regulatory Applicability and Criticality Assessment (this document)	√	√	√	√	√	√	√	√	√	
Initiation	Onsite Audit	√						√			
	Postal Audit	√	*√		√				√**		*If postal audit for medium critical system is not sufficient an onsite audit is recommended ** only for Infrastructure that support regulated processes.
	No Audit Required			*√		√	√			√	Postal audit is recommended for Low Regulated system but nor required.
	ERES Compliance assessment	√	√	√							Only applicable sections
	User Requirements Specification	√	√					√			
	SLA	?	?	?	?	?	?	?	?	?	
	Quality Agreement (if SaaS, IaaS or PaaS)	√	√					√	√		
	Validation Plan (VP)	√	√								
	ERES	√	√	√							
	URS Criticality Classification (UCC)	√	√	√	√						Classification for less critical and non-regulated systems can be accessed via the BR.
Project	GAMP 5: Functional Specifications, Design Specifications / Code review / Design Qualification	√	√					√	√		Required for GAMP 5 only (bespoke code)
	Trace Matrix (Trace URS to FRS to Test Scripts)	√	√	*	√			√	*		*Can be done as part of the BR to UAT
	Configuration Specifications	√						√	√		If configurations are maintained



CSLM Overview

SDLC

Concept phase

High Level Requirements

High Criticality

RBP

Low Criticality

Medium Criticality

Doc 1
Doc 2
Doc 3
Doc 4

Doc 1
Doc 2
Doc 3

Doc 1
Doc 2

Initiation phase

User Requirements

UCC

High

Medium

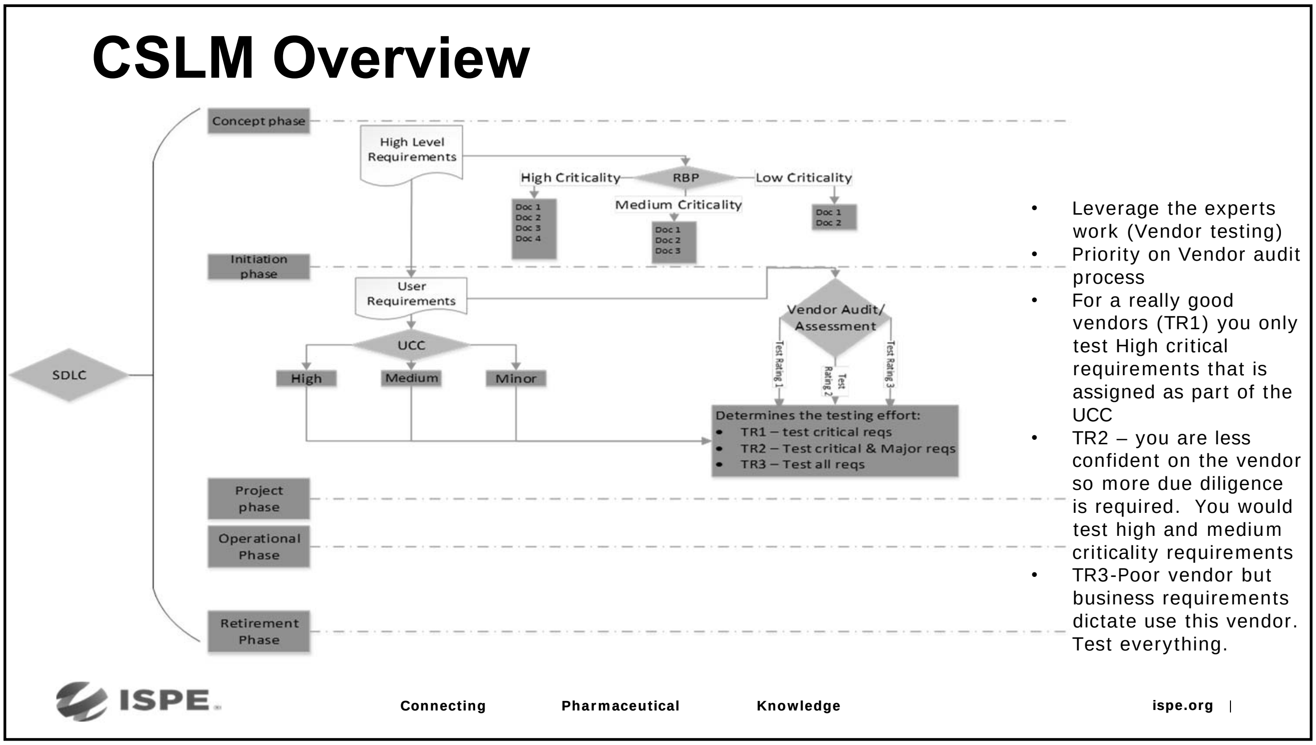
Minor

Project phase

Operational Phase

Retirement Phase

- User req. criticality classification (UCC)
- Each requirement is assessed for criticality
- Based on 3 questions
- Result: all requirements gets a rating
- This will help to determine what will be tested



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Vendor Audit/ Assessment

Test Rating 1

Test Rating 2

Test Rating 3

Determines the testing effort:
- TR1 – test critical reqs
- TR2 – Test critical & Major reqs
- TR3 – Test all reqs

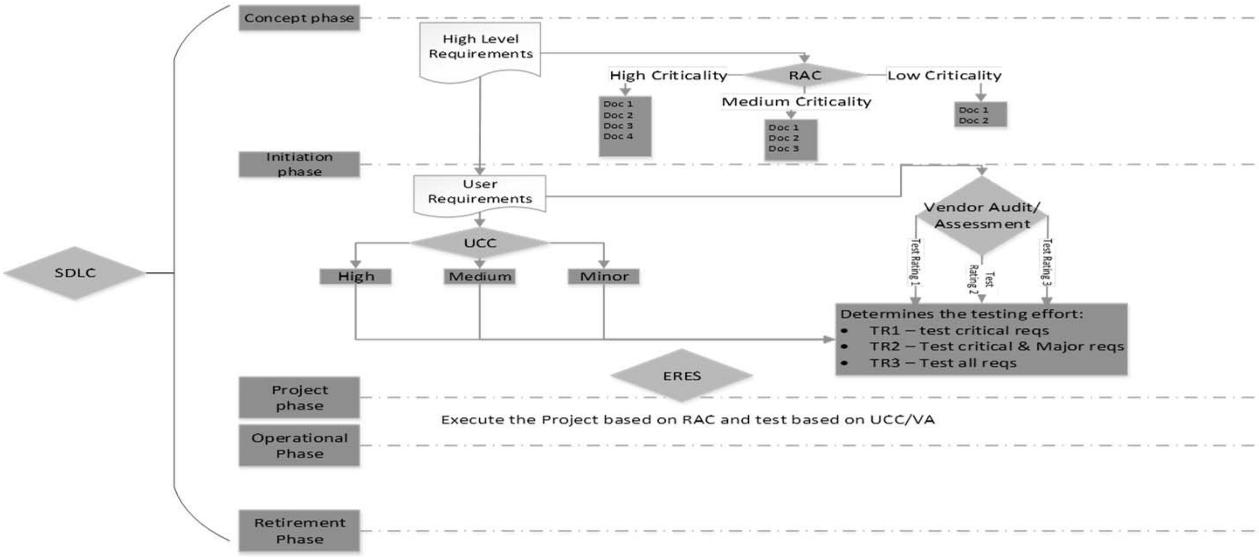
Project phase

Operational Phase

Retirement Phase

- Leverage the experts work (Vendor testing)
- Priority on Vendor audit process
- For a really good vendors (TR1) you only test High critical requirements that is assigned as part of the UCC
- TR2 – you are less confident on the vendor so more due diligence is required. You would test high and medium criticality requirements
- TR3-Poor vendor but business requirements dictate use this vendor. Test everything.

CSLM Overview



Concept phase

High Level Requirements

RAC

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Initiation phase

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ERES

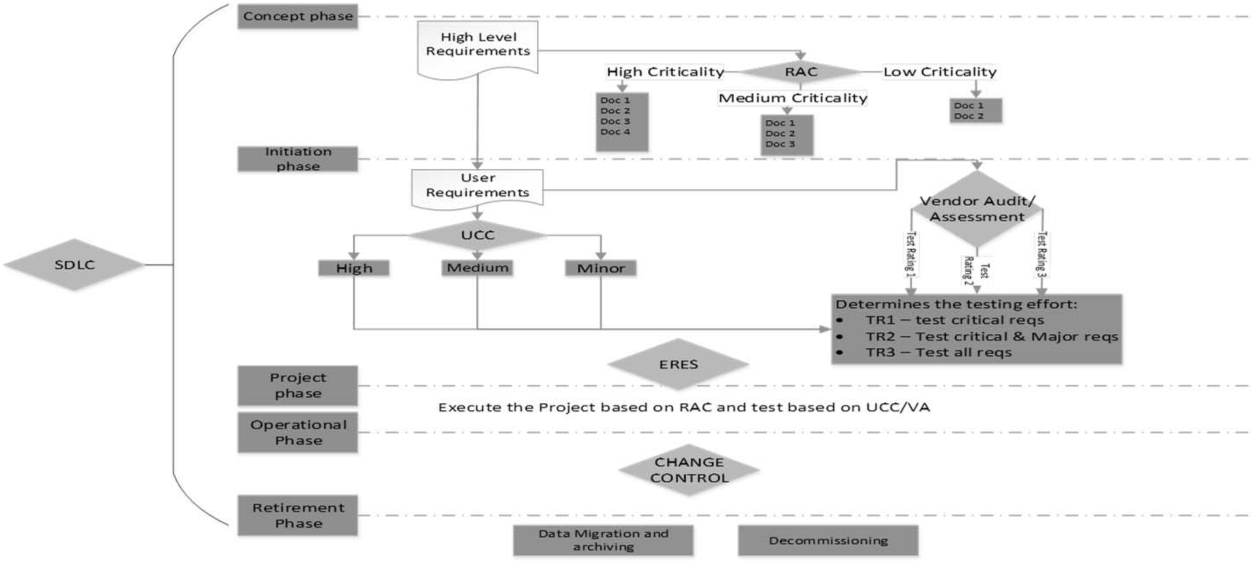
Project phase

Execute the Project based on RAC and test based on UCC/VA

Operational Phase

Retirement Phase

CSLM Overview



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ERES

Project phase

Execute the Project based on RAC and test based on UCC/VA

Operational Phase

CHANGE CONTROL

Retirement Phase

Data Migration and archiving

Decommissioning

Summary

1. Create Standards documents for Key critical GxP and Operational processes
2. Include concept of Accountable vs Responsible for Lifecycle management and Vendor Management SOPs
3. Create frequency and vendor management chart in Lifecycle Management SOP
4. Include ICE concepts in the Lifecycle Management SOPs
5. Include SLA's and Quality Agreements in the Deliverables matrix (should also create a Standard for Quality Agreements)

THANK YOU!

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