



IVT Computer and Software Validation

Dublin, 27-29 September 2010

Optimize CSV by Selecting Qualified Vendors

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NNIT

Conscience driven. Value adding

Agenda

- 1** Introduction
- 2** Approach to vendor selection
- 3** Risk based validation
- 4** Conclusion

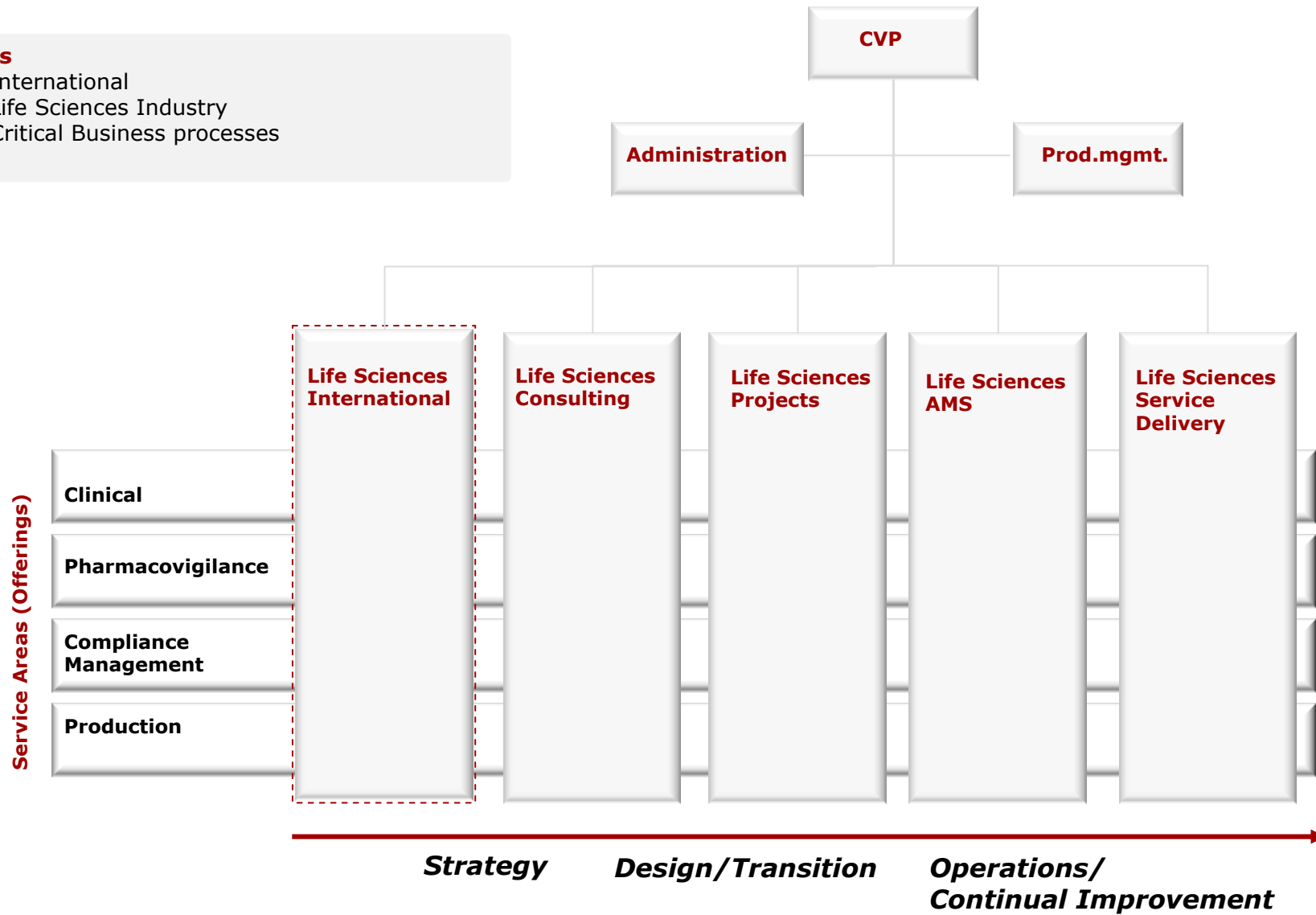
NNIT - In brief

- NNIT is one of the four largest providers of IT services in Denmark
- Focus areas: It consultancy, development, implementation and operations for regulated industries
- Approx. 1,450 employees
- Turnover in 2009 - EUR 213 million
- Head office in Lyngby, Denmark
 - offices in five countries including China and the Philippines
- Customers throughout Europe
- Subsidiary of Novo Nordisk A/S



NNIT Life Sciences Organisation

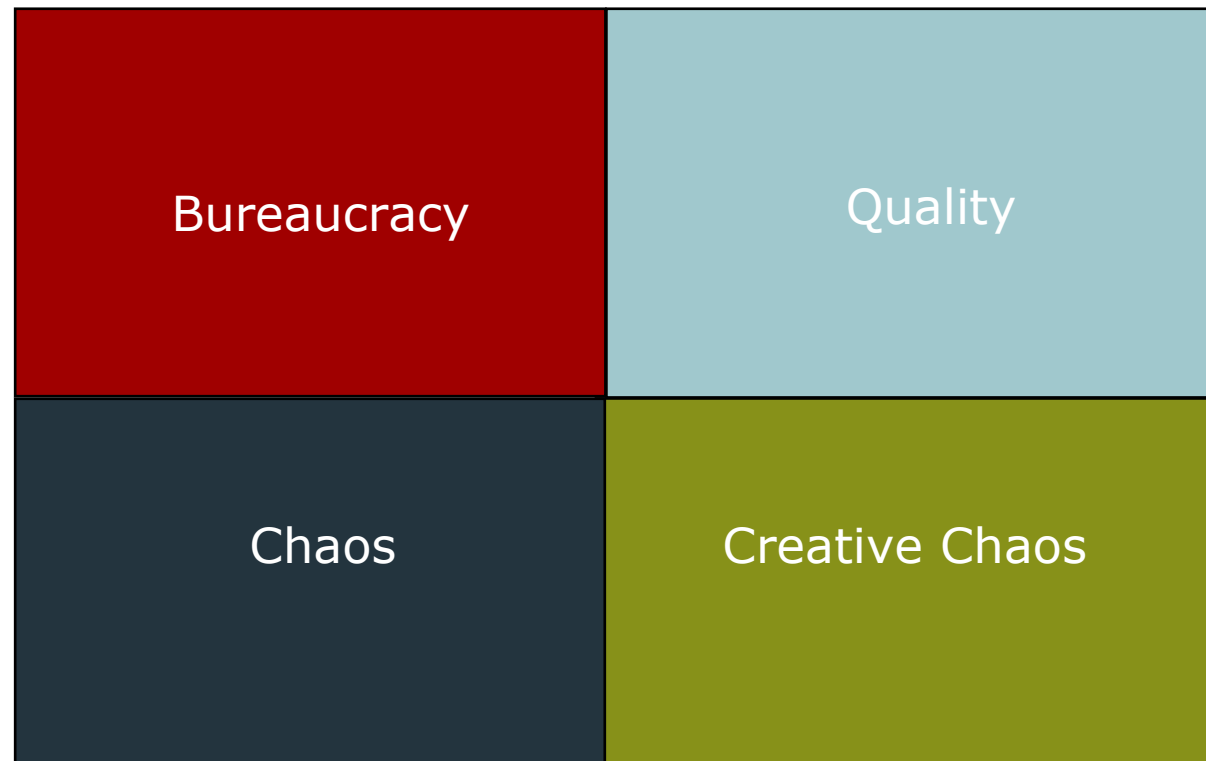
- Focus**
- ▶ International
 - ▶ Life Sciences Industry
 - ▶ Critical Business processes



The Right Quality Level...

No ← Common Sense → Yes

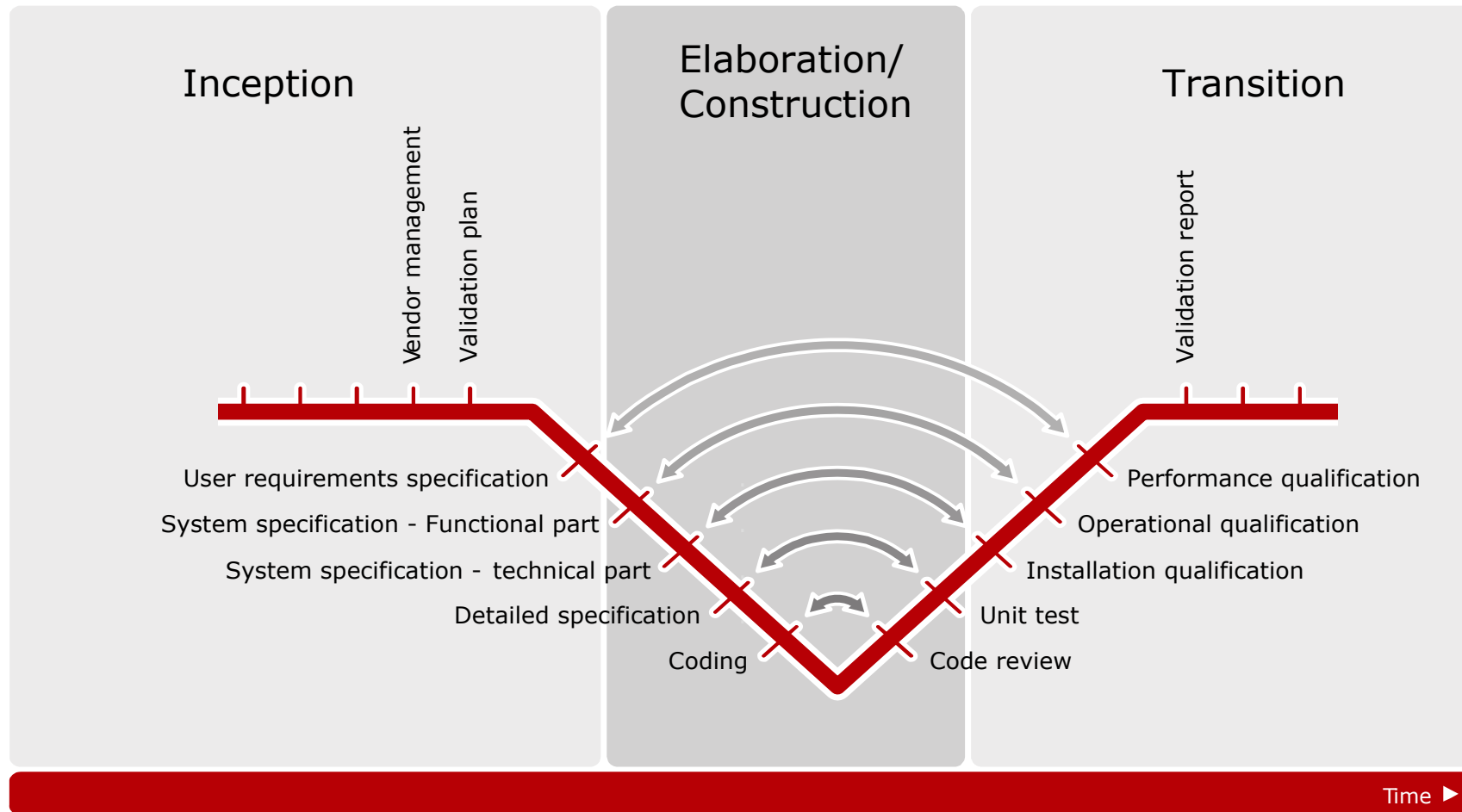
Yes
↑
Standards &
Methods
↓
No



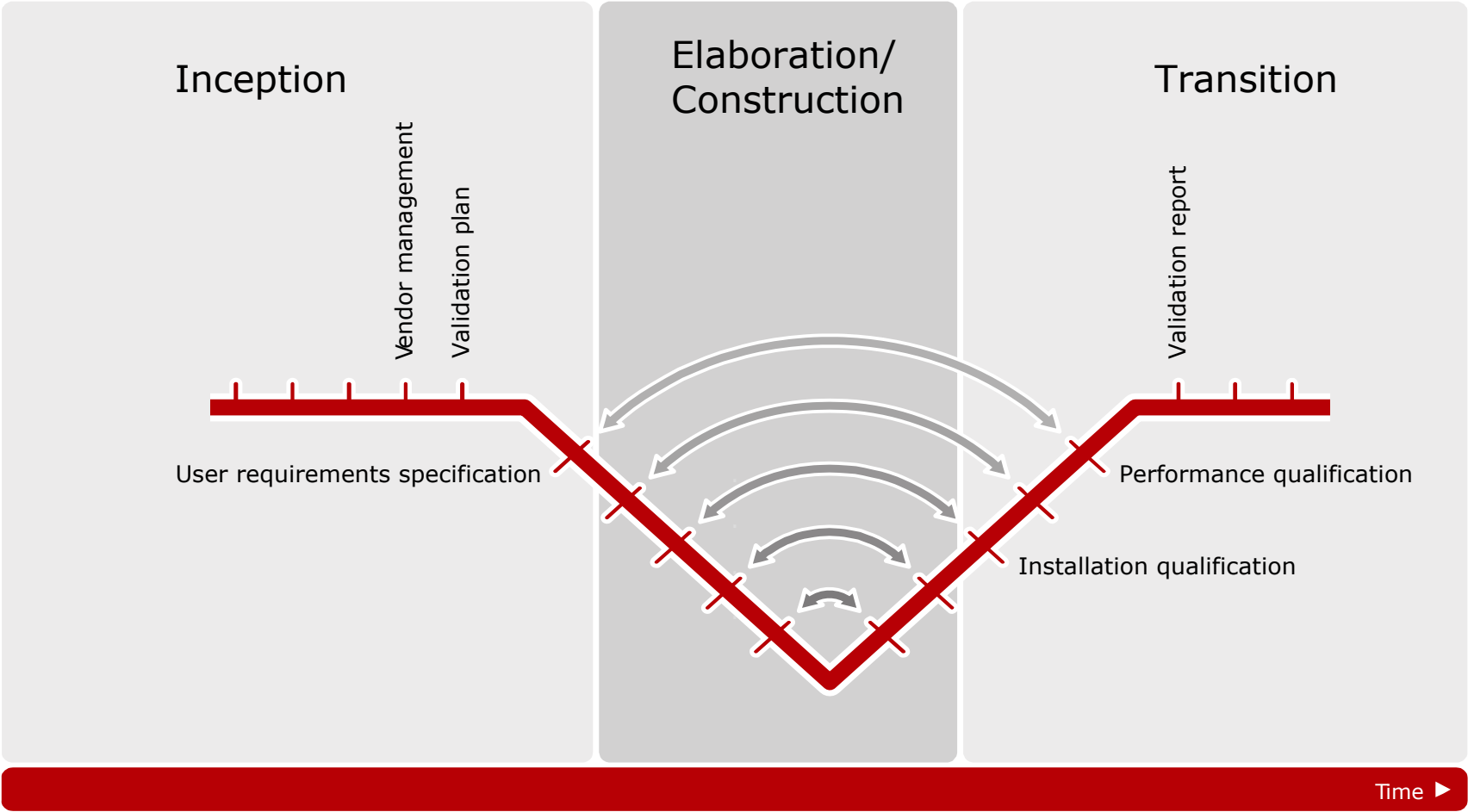
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Computer validation model

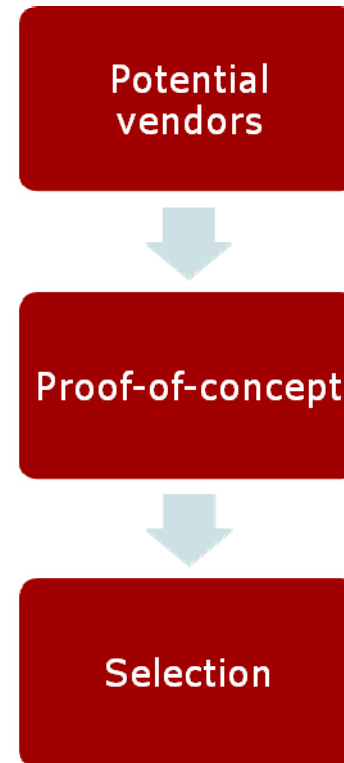


Computer validation model



Selection of vendor

- Identification of potential vendors
 - Business application
 - Prior experience
 - Indication of capabilities
- Vendors chosen for proof-of-concept
 - Functionality of application
 - Capabilities and competencies
 - Knowledge of business processes
 - Technical competencies
 - Validation Management
 - Test Management
- The selection of vendor
- The formal vendor audit



Proof-of-concept workshop – an example

- Demonstration and discussion of general validation approach
 - content of and interfaces between processes (workflows) used for validation activities (for example Computer system validation SOP, Test Management SOP and handling of non-conformities SOP)
- Presentation and discussion of general development approach
 - content of processes for development of user requirements, functional and technical design requirements
 - how are design reviews and code reviews performed and documented
- Presentation and discussion of release management activities
 - content of processes (workflows) used for releasing of upgrades and patches
 - content of deployment activities

Value of the proof-of-concept?

- Significant knowledge of vendor strengths and weaknesses
 - What are the risks
 - Where do we need to pay increased attention
 - To what extent can we reuse vendor validation deliverables
 - Input to which quality assuring activities to implement
- Vendor better able to understand our requirements
 - How do we approach validation
 - Which requirements do we have regarding validation deliverables
- Increased openness between the parties
- Strengthened personal business relationship
- Input for special focus areas in the formal audit

The formal vendor audit

- Use knowledge from proof-of-concept activities
- Focus on evidence of efficient QMS
 - Select carefully what to scrutinize
- Focus on critical SW development and maintenance aspects
 - Project management
 - Software development practices
 - Release and configuration management
 - Ongoing maintenance and support
 - Can you still minimize your validation when upgrading to next releases
- Get behind the surface – talk to employees

The formal vendor audit

- Look for consistency and accuracy of specifications and test evidence
 - Use auditor specialised in IT audit
- Accept tools, e.g. automated test
 - Look for qualification of tools
- Accept terminology other than IQ, OQ, PQ
 - As long as content complies with requirements
- Emphasize in audit report and validation plan if vendor specification and test is adequate
 - Supports that you only need to specify and test your own configuration.
- Use vendor documentation by referencing it in your own validation documents.

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Right methods and tools reduces validation effort

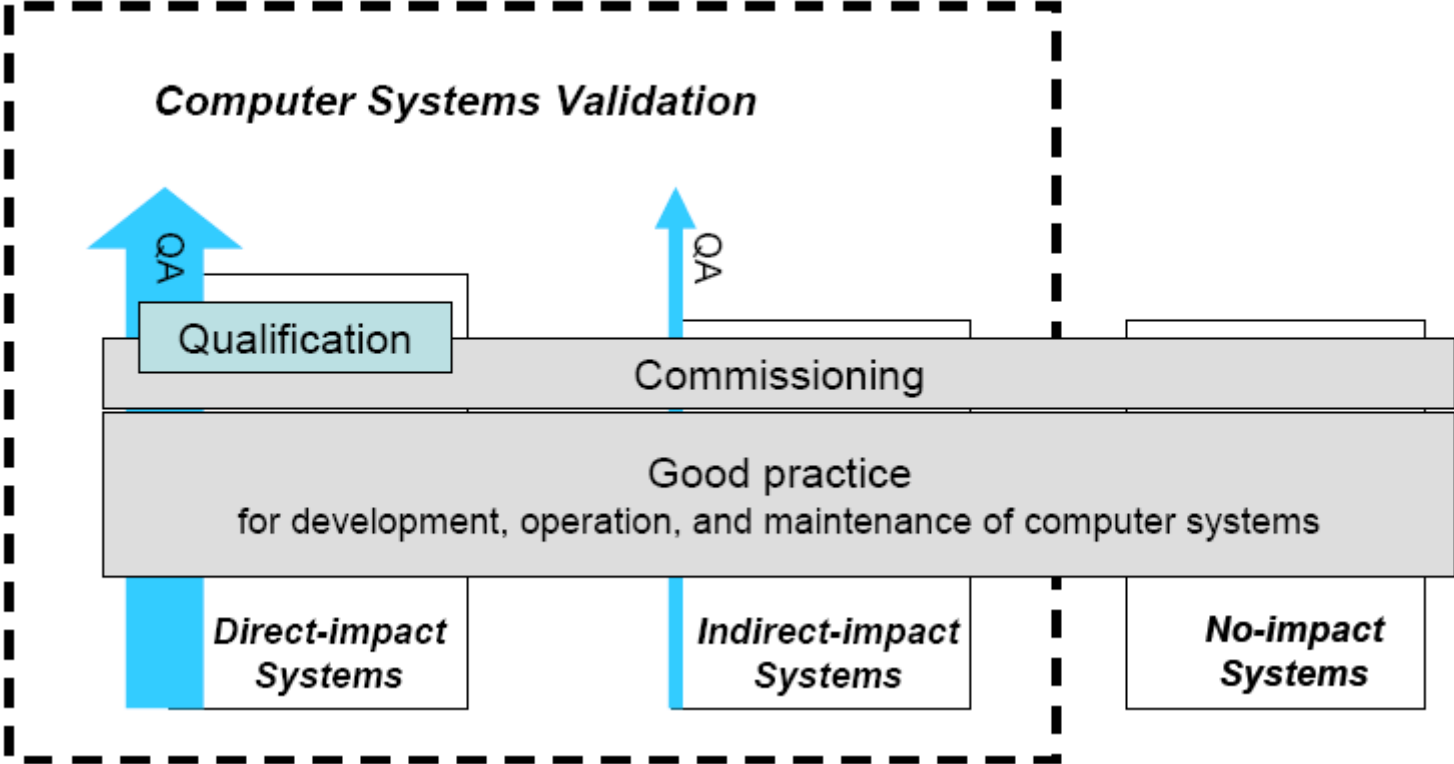


Risk based validation

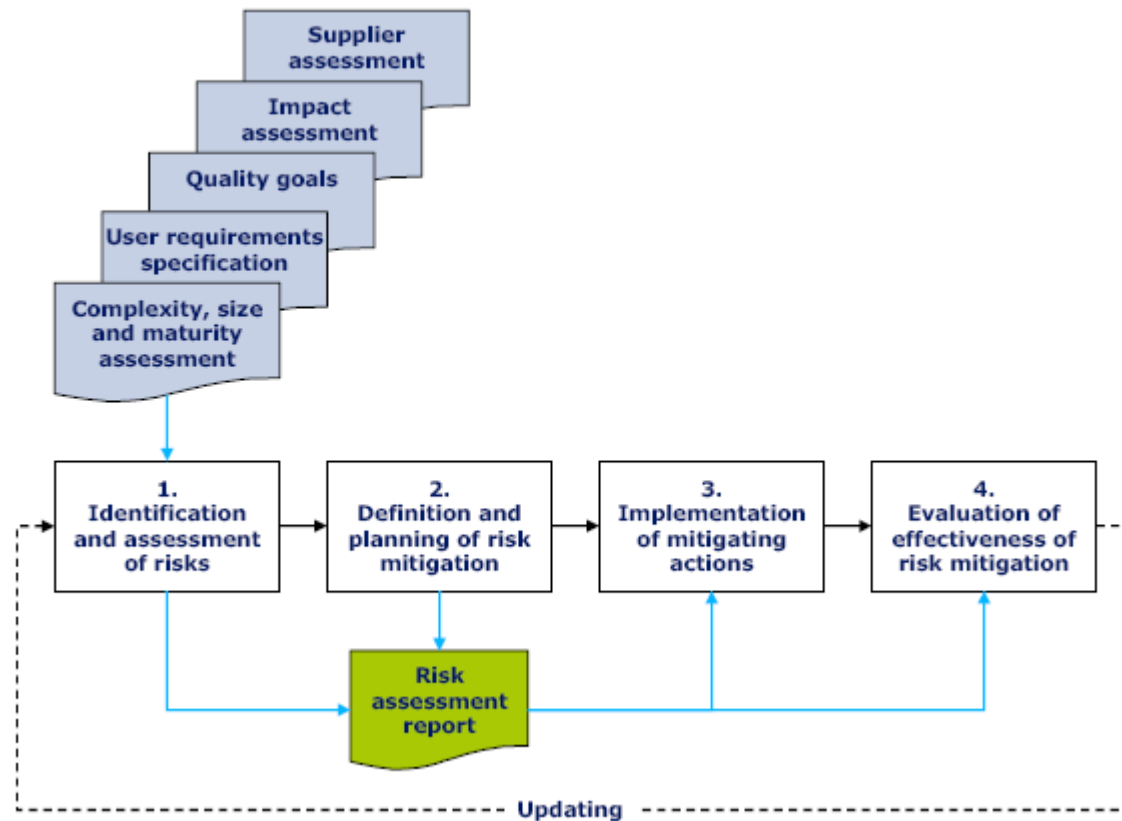
- Risk based approach
 - Risk based approach starts identifying risks associated with selected vendor
 - Risk based approach includes identifying impact on aspects of regulatory concern
- Base risk analysis on GAMP 5 categories
 - Different levels of risk analysis dependent on GAMP category
 - Different levels of GxP criticality in same system
- Different levels of risk analysis during the project phases
 - Initial phase: Identify GxP modules and function
 - Design phase: Identify GxP critical record and control
 - Test phase: Identify different levels of testing



Impact assessment



Risk management process



Risk assessment – small system example

- Risk assessment part of URS - appendix

Hazard Category	Description/ impact	Risk Assessment	Mitigating Actions/Barriers	Test Approach
Programme errors: Incorrect Control Chart Reports	Conversion calculation errors/errors in algorithms.	Programme errors are not likely to occur as the system is mature and as SAP JMP is a standard system running in a validated Citrix environment. However, the scripts (which are not standard) are being upgraded during this project.	<ul style="list-style-type: none"> • Design Review • Code review 	Unit testing & OQ-PQ testing.
Data Load	Programme error - error in data transfer from Excel to CCS.	System is mature and experience says that this is not likely to occur.	<ul style="list-style-type: none"> • Review of control charts 	OQ-PQ testing.
Data Integrity: Incorrect Definitions Files	Theoretically a definition file can be erroneous.	The probability of this occurrence is low, but the potential harm is significant.	<ul style="list-style-type: none"> • New definition files are subject to Change Control. • SOPs • Training 	N/A

Examples of Quality Assurance activities for vendor deliverables (category 5)

- Design walk-through-meeting
 - Vendor receives FRS
 - Formal walk-through meeting where vendor presents design and test approach
 - Conclusion whether design can start
- Defect walk-through meeting
 - Review of vendor deliverables
 - Defect-logging
 - Evaluation of fulfilment of acceptance criteria
- Input for formal design review
- Reuse of test cases in validation

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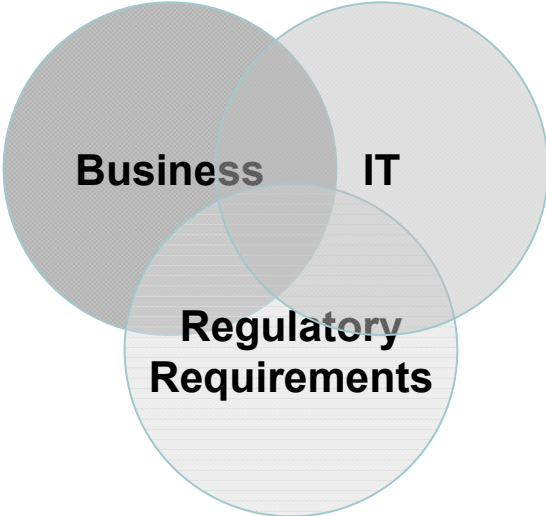
Conclusion

- Evaluate the vendor capability
 - Screening
 - Establish knowledge of vendor strength and weaknesses by evaluation of
 - capabilities and competencies
 - documentation
 - results
 - Face-to-face interaction
 - proof-of-concept sessions
 - business visit
 - Structured selection of the vendor
- Formal audit
 - Focus especially on areas for special scrutiny
- Risk based approach
 - Which parts will the vendor be involved in?
 - Which QA activities will we implement to be able to benefit from vendor capabilities?

Most important - Cooperation between stakeholders



Chief "Business" Officer



Chief Information Officer



Chief Quality Officer