



PhUSE, Conference 2010

Berlin, 17-20 October 2010

Vendor Selection & Management in GxP critical IT projects

Claus le Fevre, Consulting Director, NNIT A/S

NNIT

Conscience driven. Value adding

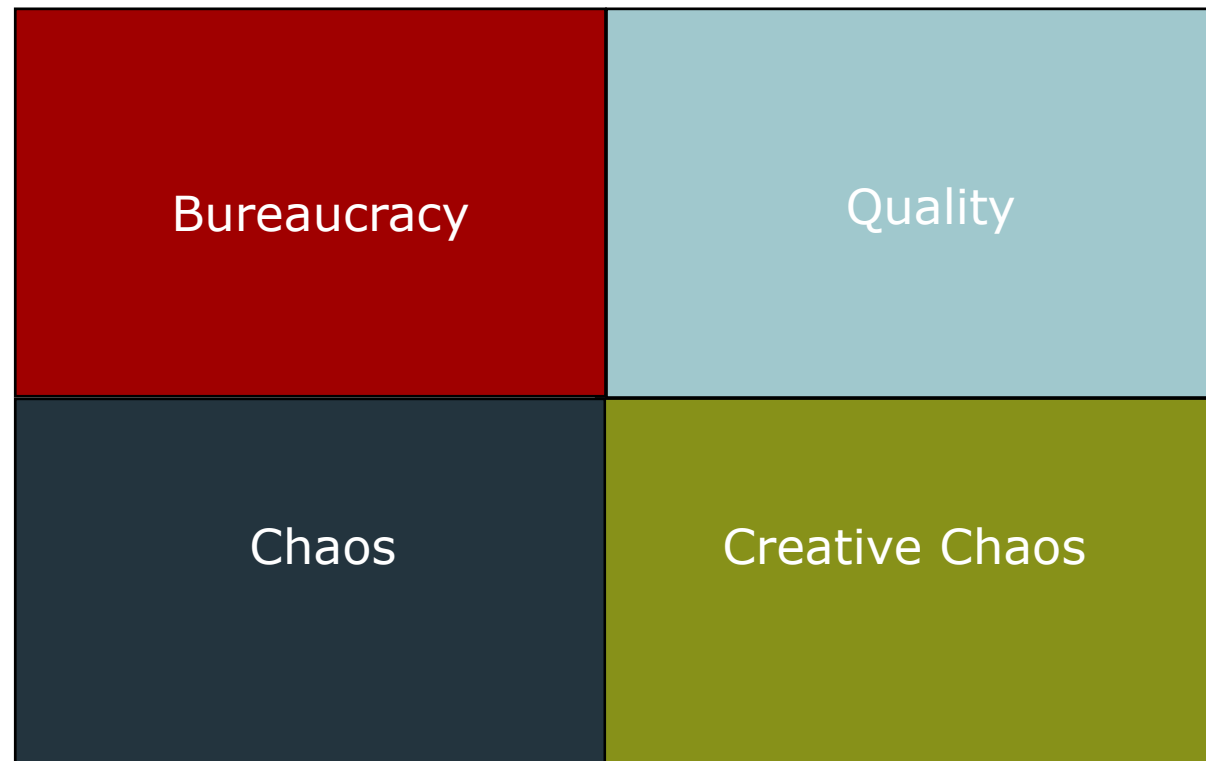
Agenda

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

The Right Quality Level...

No ← Common Sense → **Yes**

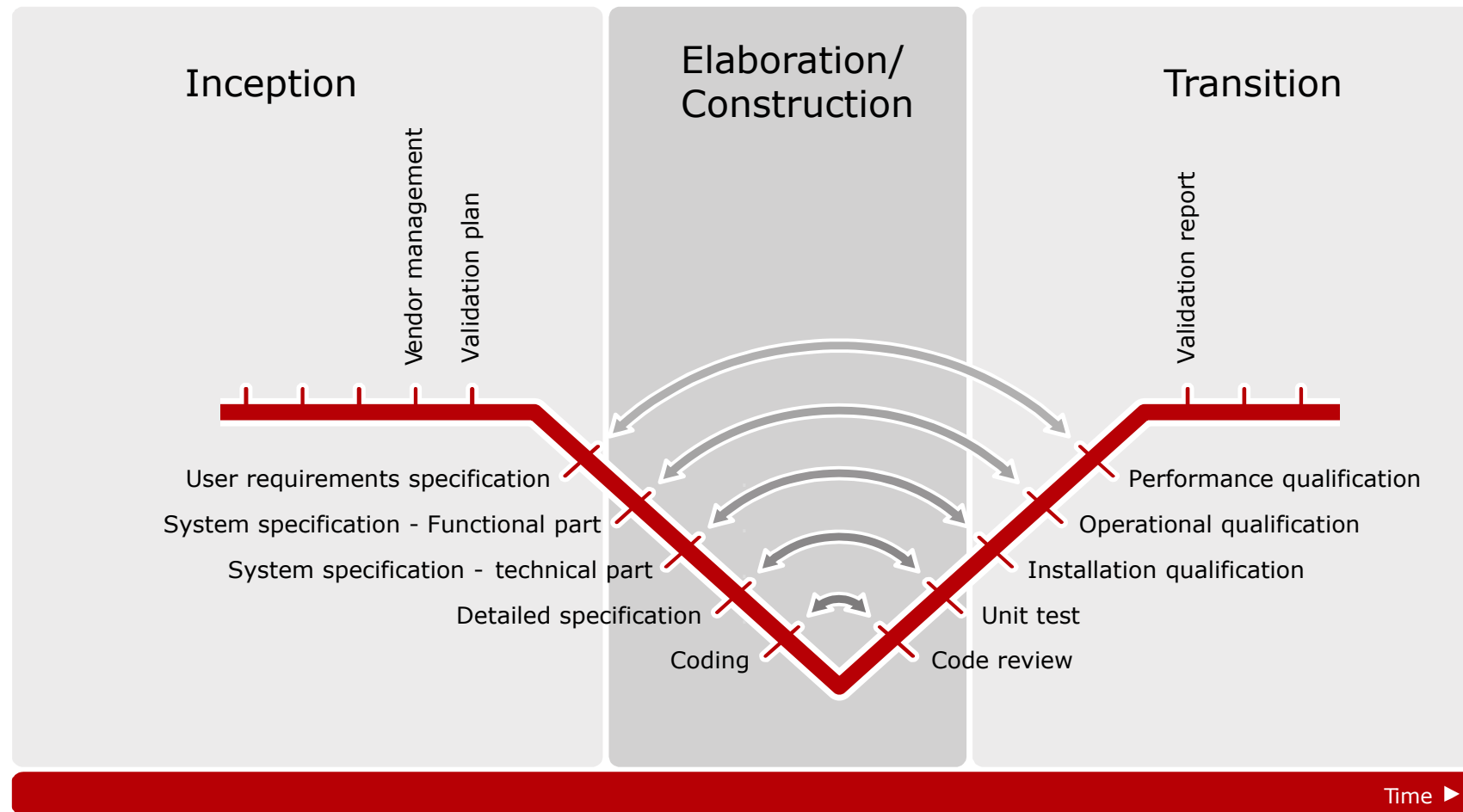
Yes
↑
Standards &
Methods
↓
No



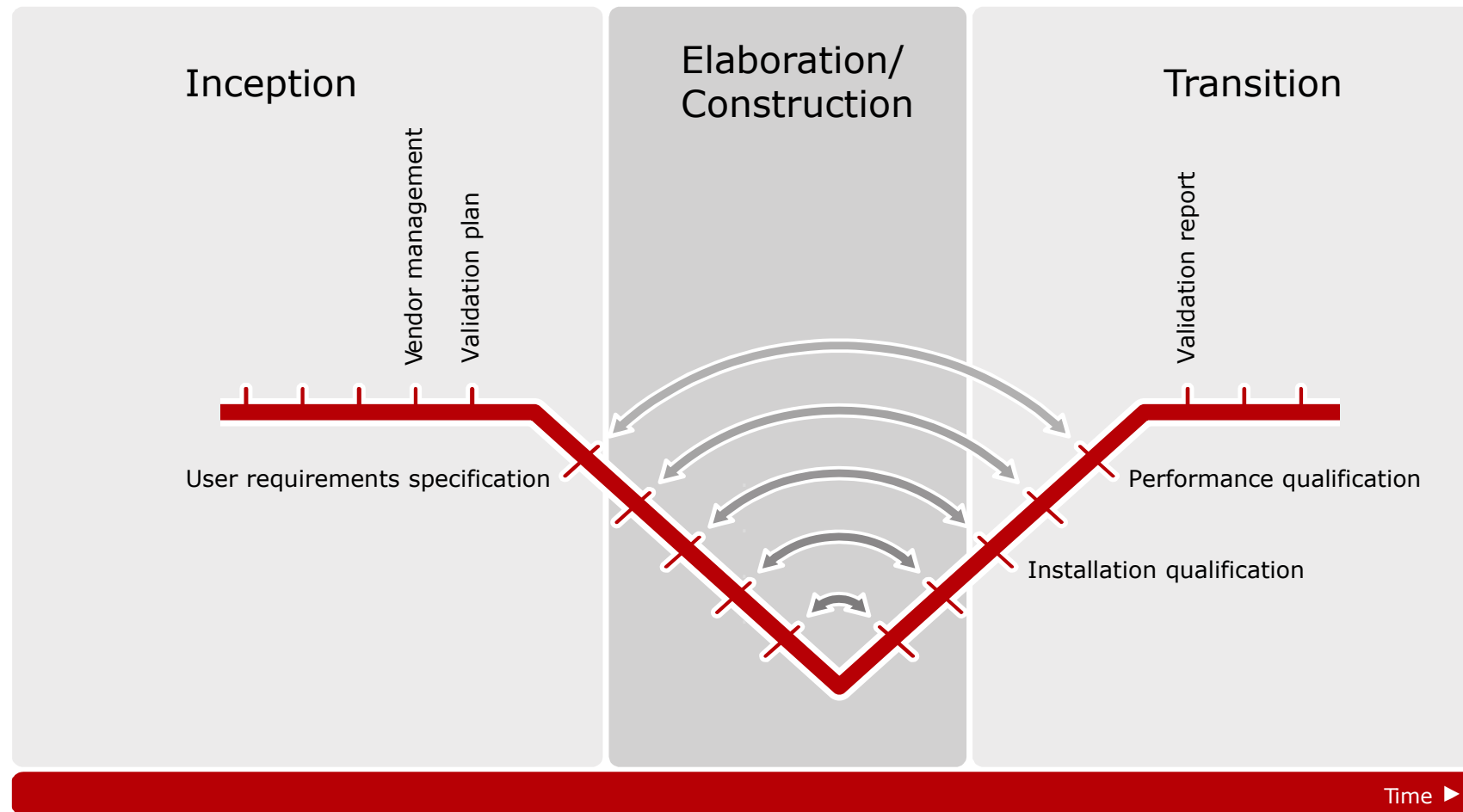
Agenda

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

Computer validation model

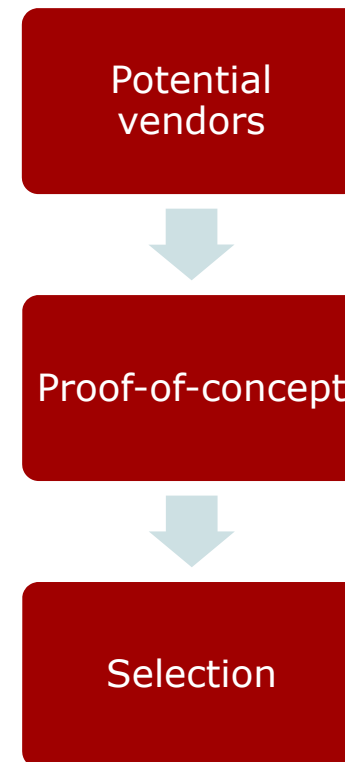


Computer validation model



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)
- Demonstration and discussion of validation deliverables
 - content & walkthrough of package
 - the full portfolio of documents (e.g. plans, protocols, reports, test cases & CILs)
- 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

Proof-of-concept workshop – an example

- Demonstration of tool for automatic OQ test generation and test execution
 - structure and functionality of the tool
 - validation of the tool and relevant documentation
- Presentation of activities to prepare and execute the automated OQ test cases
 - how are the OQ test cases (TCs) built and what guidelines are used
 - what kind of reviewing and approval activities are performed of the OQ TCs
- Known challenges of using the tool in projects?

Value of the proof-of-concept?

- Significant knowledge of vendor strengths and weaknesses
 - What are the risks
 - 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

How to select the vendor

Evaluation Topic	Subject	Overall conclusions comments		Vendor score (0-3)	
		Vendor A	Vendor B	A	B
Validation and test management	Quality Management and organization from required validation perspective	Extensively documented quality system with high transparency...	Quality processes defined and documented in QMS...	2	1
	Competence development, planning and execution	Job descriptions and competencies are defined and available for review. Validation training defined and executed...	Competencies are defined and training schedule are planned and executed. Training of project members...	1	1
	Validation approach	Validation approach well defined and based upon the classical V-model approach...	Validation approach defined broadly according the to V-model. Testing performed according to procedures...	3	1
	Pre-developed test cases (IQ, OQ, PQ)	Portfolio of test cases for OQ testing of core functionality fully developed. 90 % automated test cases. 10% manual test cases.	Full portfolio of OQ test cases for core functionality provided. OQ test cases must be manually executed...	3	2
	Customized test script packages	PQ test cases for preconfigured workflows available. Based upon best practices...	Selection of PQ test cases available for reference...	2	1
	Tool(s) for semi- or automatic test case generation and execution	Automatic test tool for both generation and execution of OQ test cases. Documentation for validation of tool demonstrated...	No automatic test tool available for test...	3	0
IT Operation	Vendor internal IT operation (backup, server room, disaster recovery)	Server room and back up recovery in place. Key restricted access to server room and fire control implemented...	Server room organized and the physical arrangement of the room well planned and logically set-up. Physical restricted key access...	1	2

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 & configuration management
 - Can you still minimize your validation when upgrading to next releases
- Accept terminology other than IQ, OQ, PQ
 - As long as content complies with requirements
- Use vendor documentation by referencing it in your own validation documents
- Get behind the surface – talk to employees

Agenda

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

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



QA activities for vendor deliverables (GAMP cat. 5)

– an example

- Vendor deliverables
 - Software modules
 - IQ, OQ, PQ test cases
 - Traceability matrix (to FRS)
- Design walk-through-meeting
 - Formal walk-through meeting where vendor presents design and test approach
 - Conclusion whether design can start
- Defect walk-through meeting
 - Review of vendor deliverables
 - Evaluation of fulfilment of acceptance criteria
- Input for formal design review
- Reuse of test cases in validation

Agenda

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

Conclusion

- Evaluate the vendor capability
 - Screening
 - Establish knowledge of vendor strength and weaknesses
 - Face-to-face interaction
 - 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?

Thank you!

Contact data

