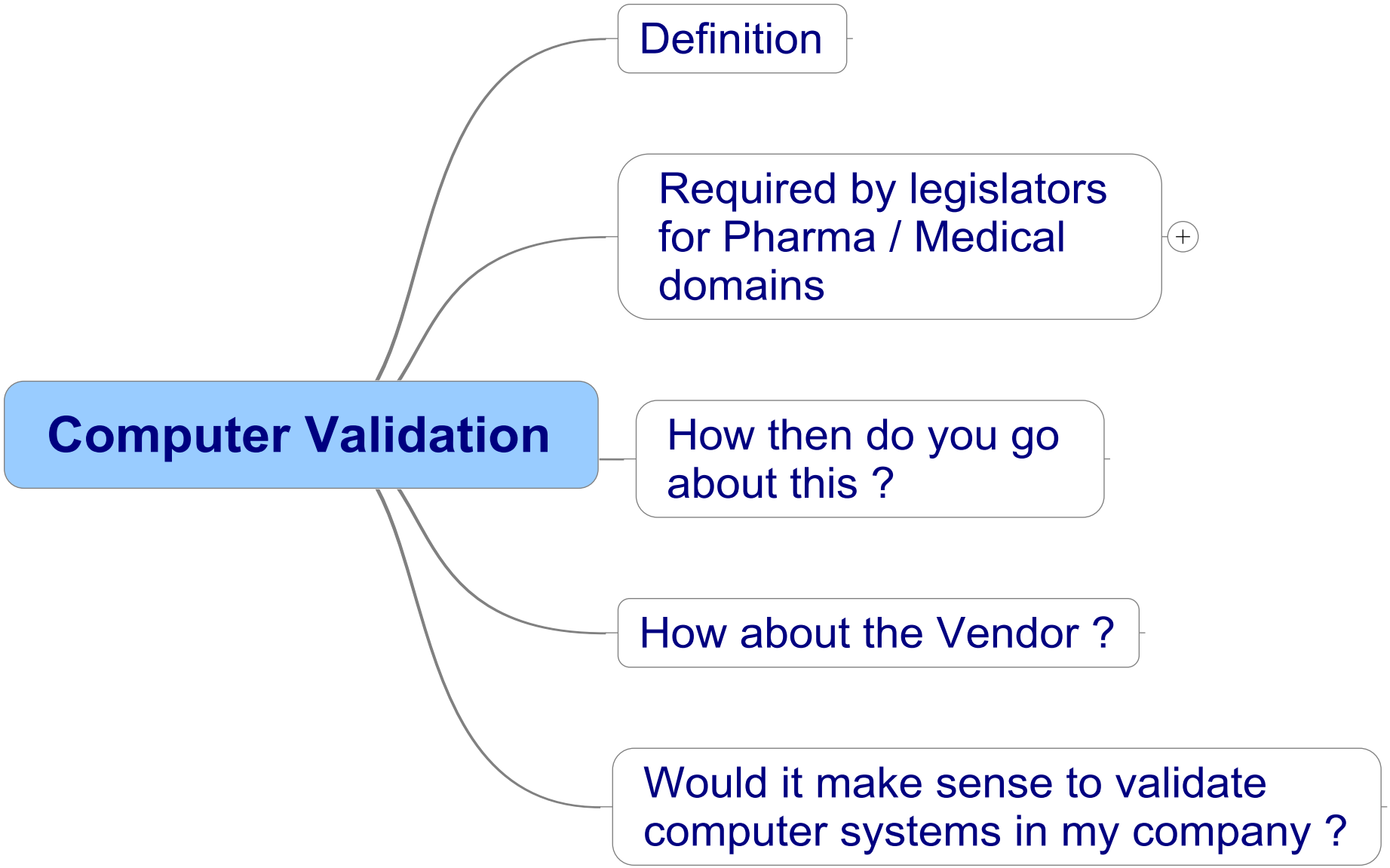
Computer System Validation

Embedding quality into Automated Processes


Computer Validation
Definition
Required by legislators for Pharma / Medical domains
How then do you go about this ?
How about the Vendor ?
Would it make sense to validate computer systems in my company ?

Validation definition

“Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting it’s pre-determined specifications and quality attributes”.

FDA definition 1987

Validation

1. Documented evidence
2. high degree of assurance
3. specific process
4. consistently produce
5. pre-determined specifications

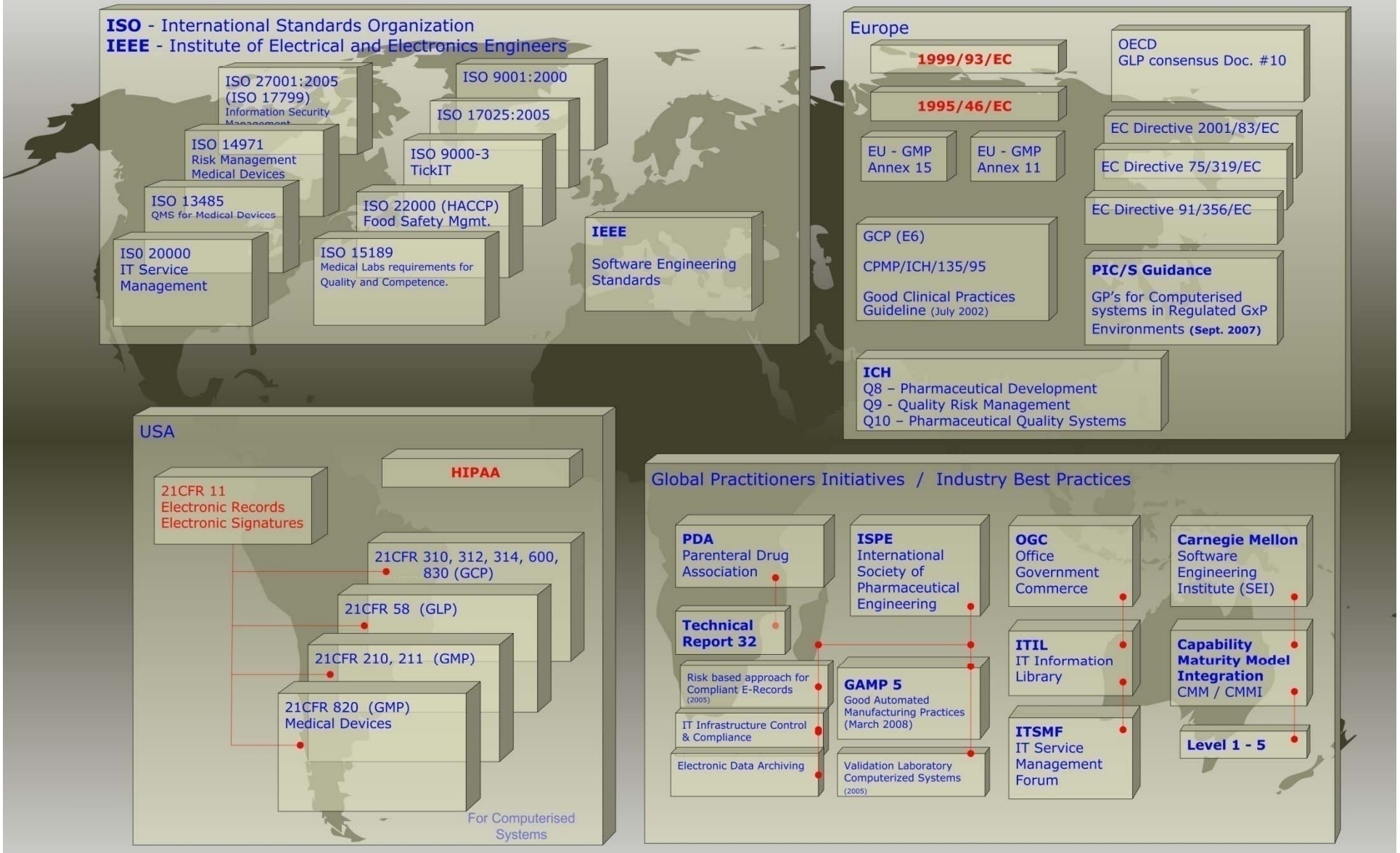
Required by Legislators

Compulsory Good Practices
(i.e. imposed Quality System)

The GxP's

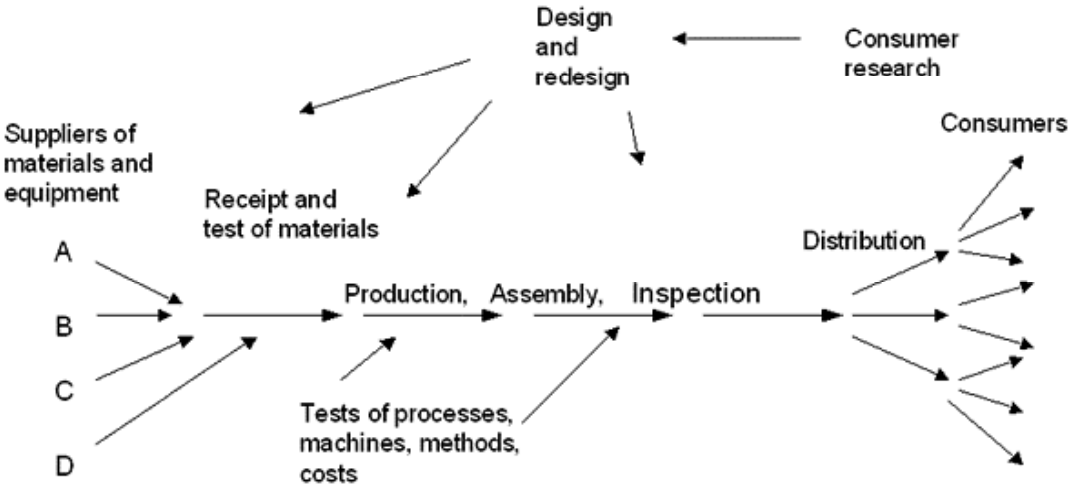
Laboratories – GLP
Clinical Studies – GCP
Manufacturing – GMP

EU and USA Regulations - International Standards - Global Practitioners & Industry Best Practices



Understand the System

- What is the system
- What does the system consist of
- What does it do for whom

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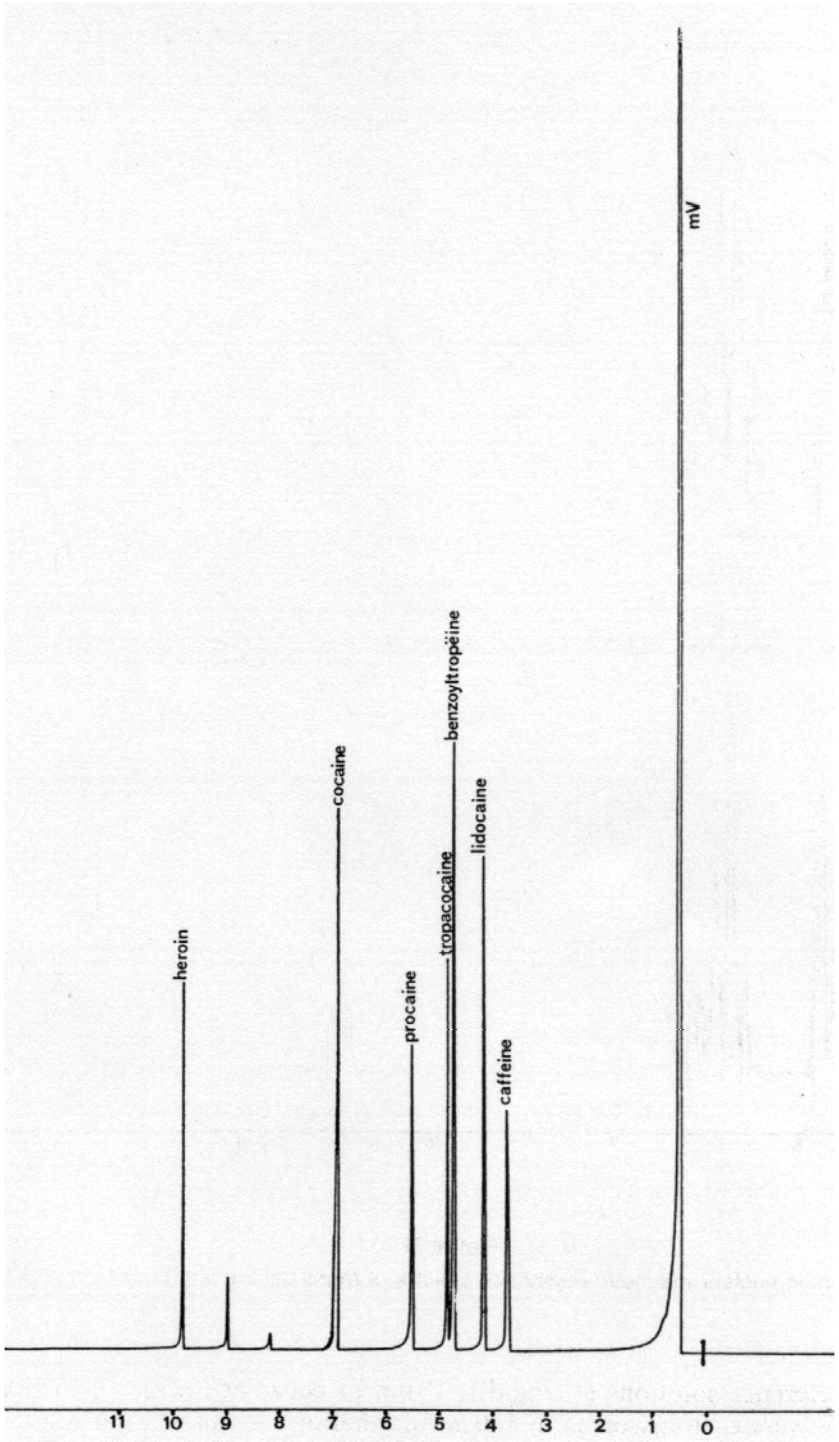
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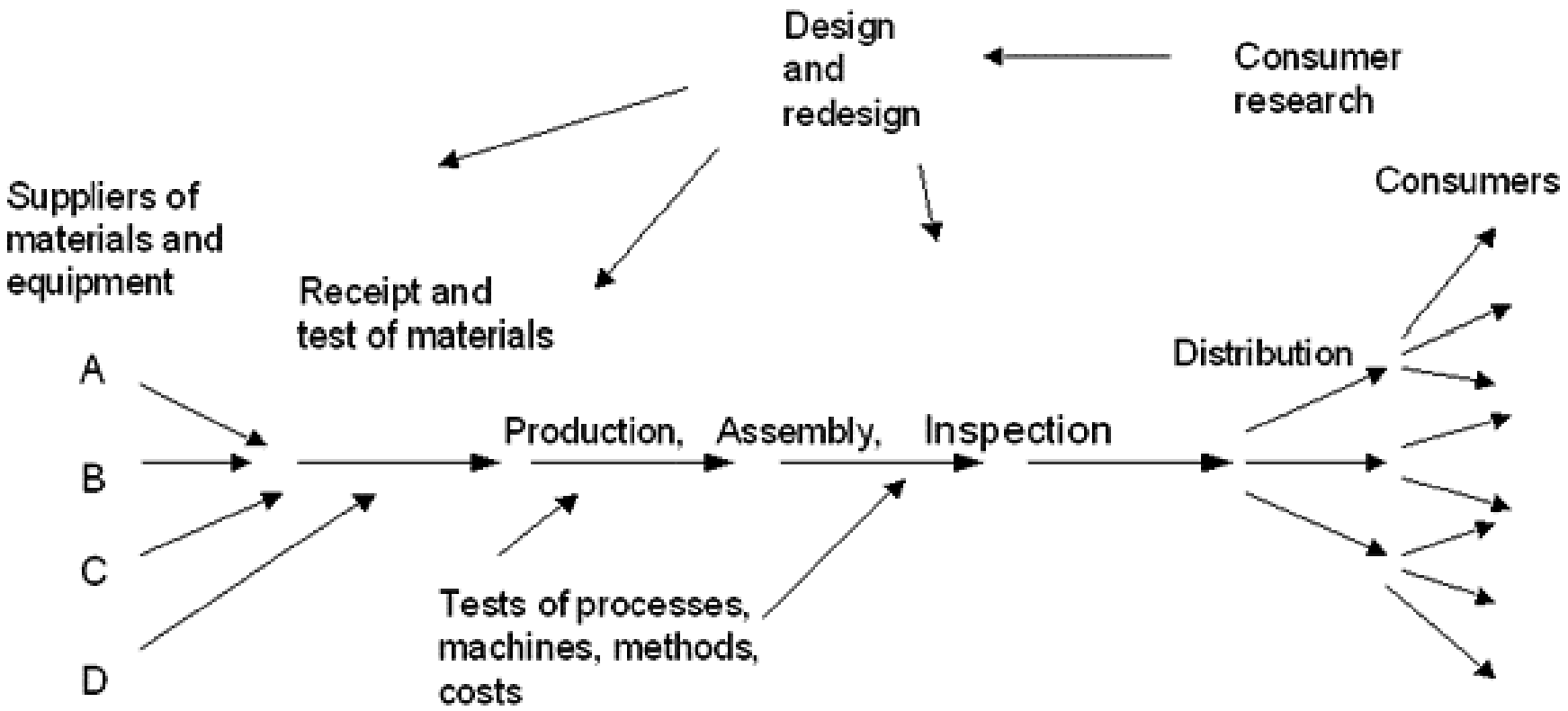
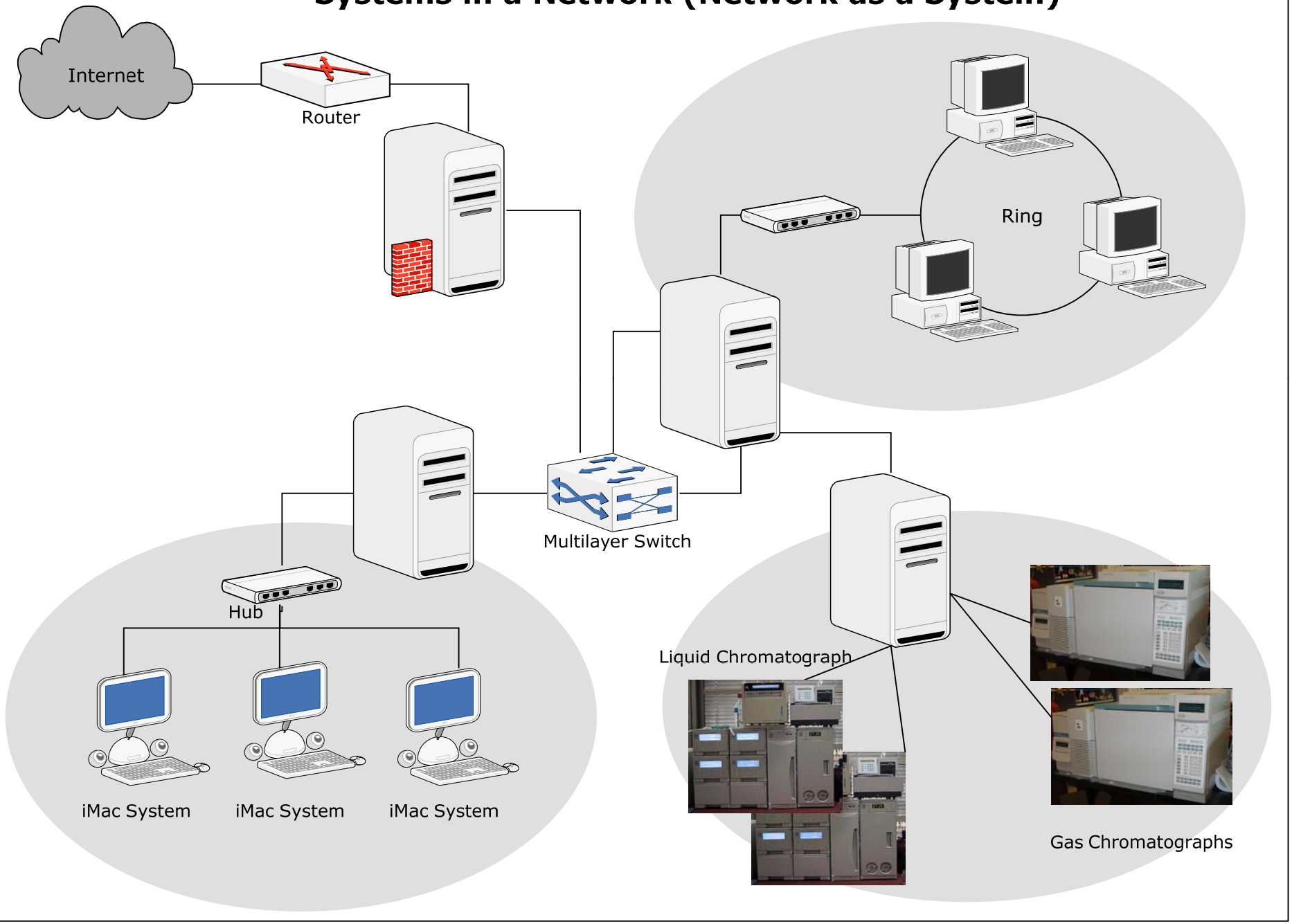
Understand the system



Production as a system
W.E. Deming - Out of the Crisis

Systems in a Network (Network as a System)



Validation

1. Documented evidence
2. high degree of assurance
3. specific process
4. consistently produce
5. pre-determined specifications

General validation activities

planning — **Prepare written Validation plan**

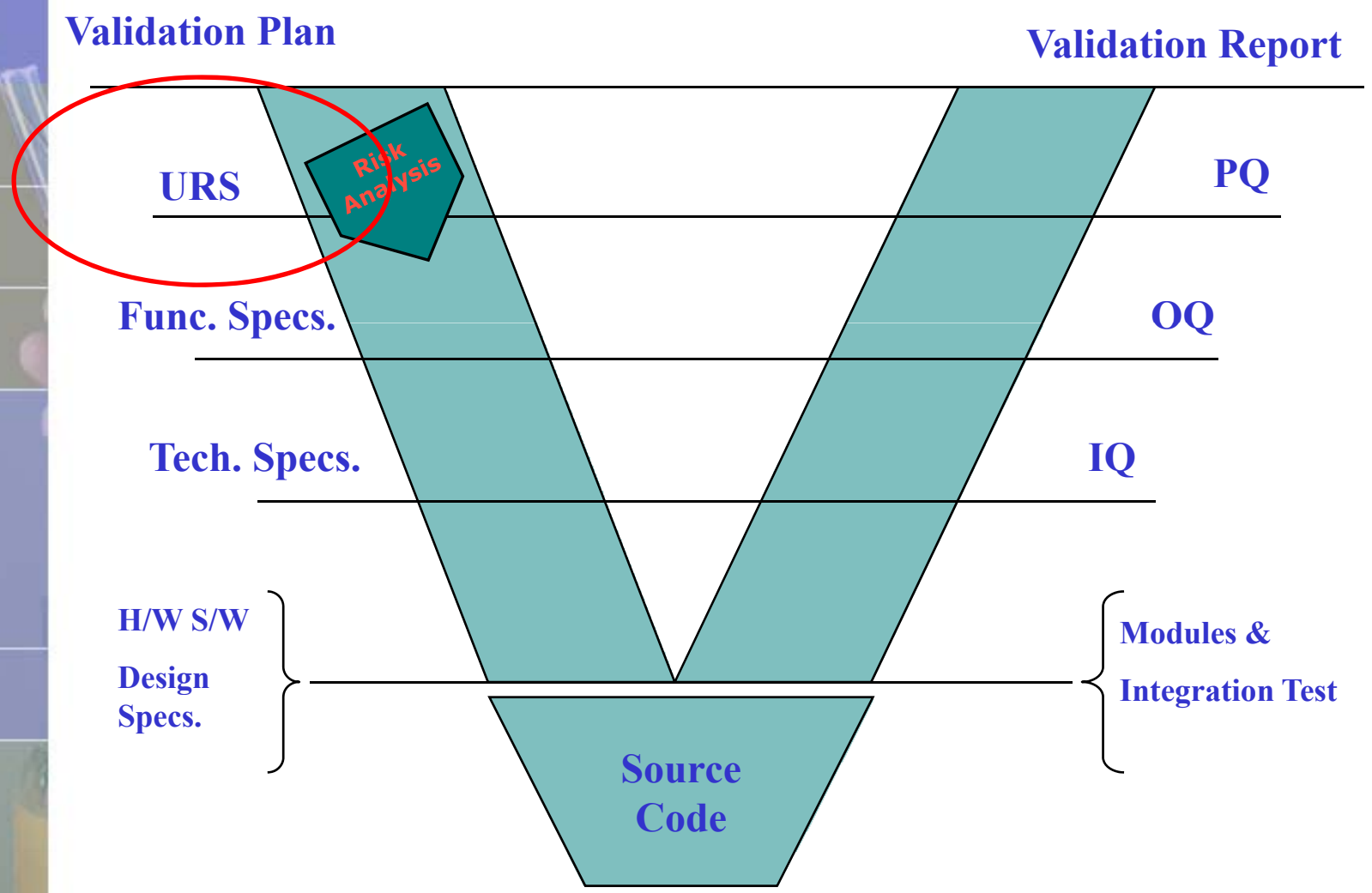
specification — **Specify and agree what is required**
(what does the system do for whom)

test planning
IQ
OQ
PQ — **Write document to describe what is to be verified**

testing
IQ
OQ
PQ — **Perform test and collect results**

review and report — **Review and report conclusions**

Validation Pathway (1)



User Requirements Specification

Purpose

- Documents what the user wants the system to do
- Contract between Customer and Vendor
- Sets project scope
- Foundation for remainder of project plan
- Basis for PQ testset

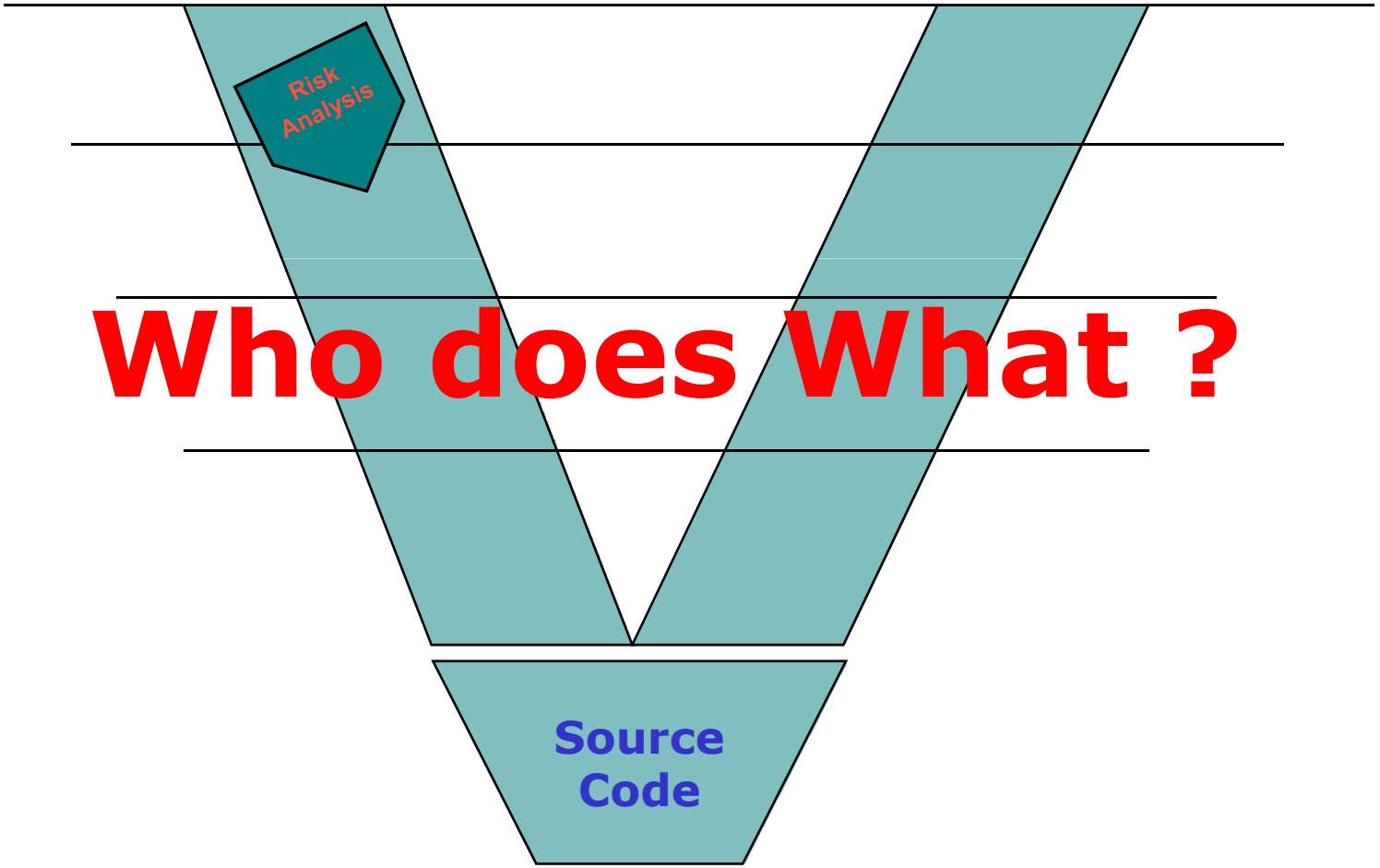
Validating a system without URS is impossible

About the Vendor

Establish sound relationship

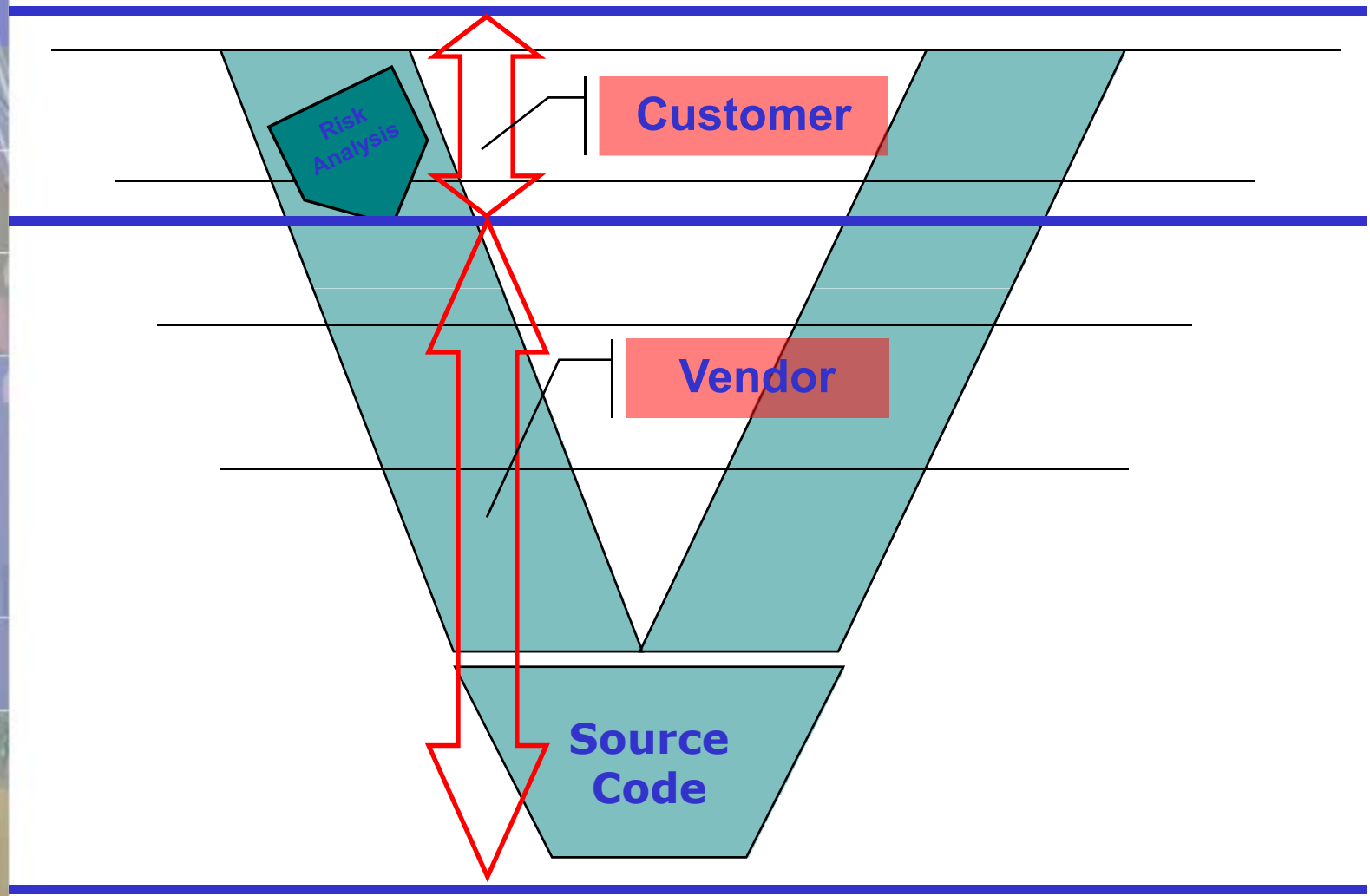
- E-data is a corporate asset
- Business cannot survive without sound vendor support
- Vendor can partly qualify the system (IQ/OQ)

Customer & Vendor

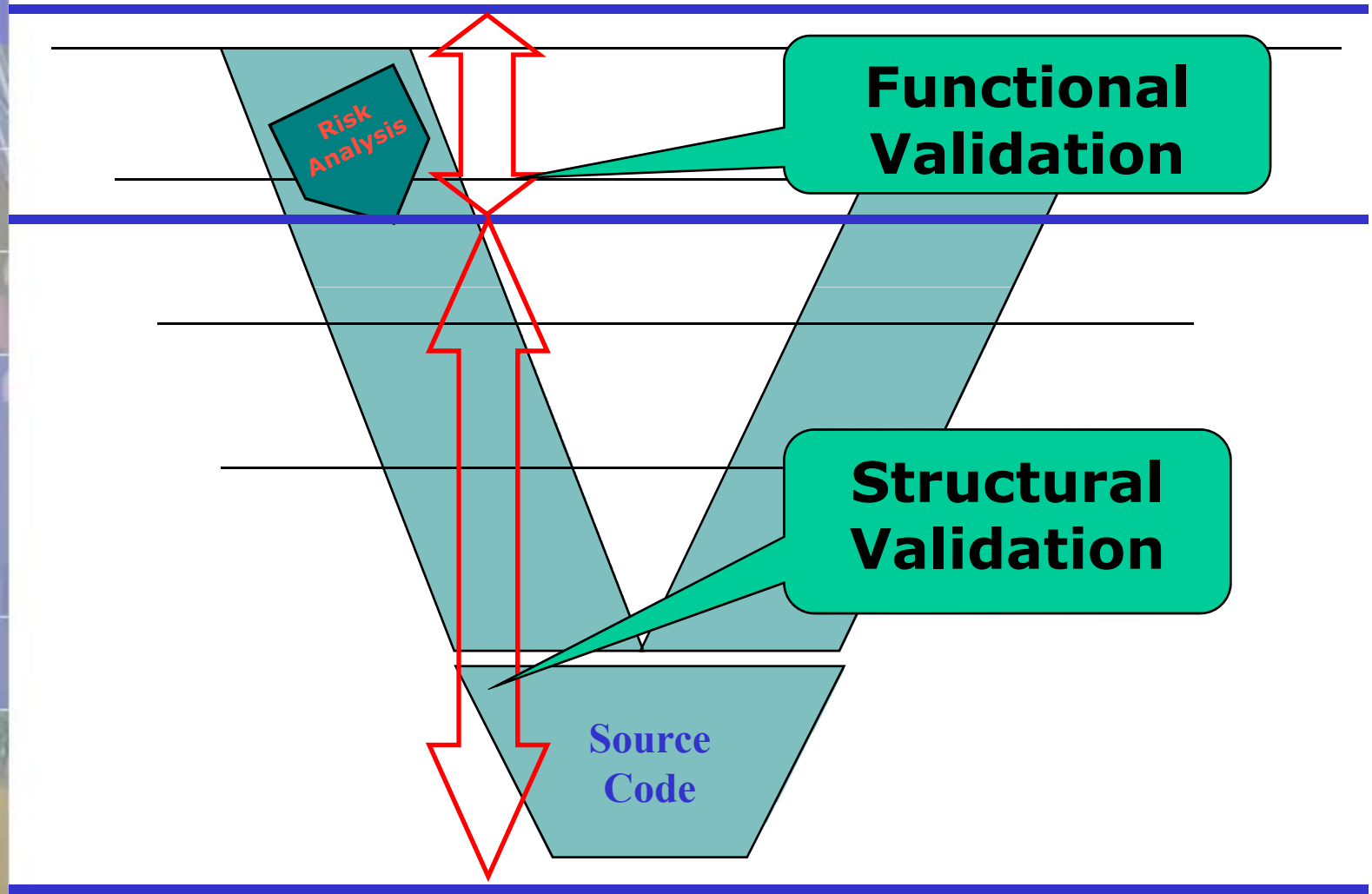


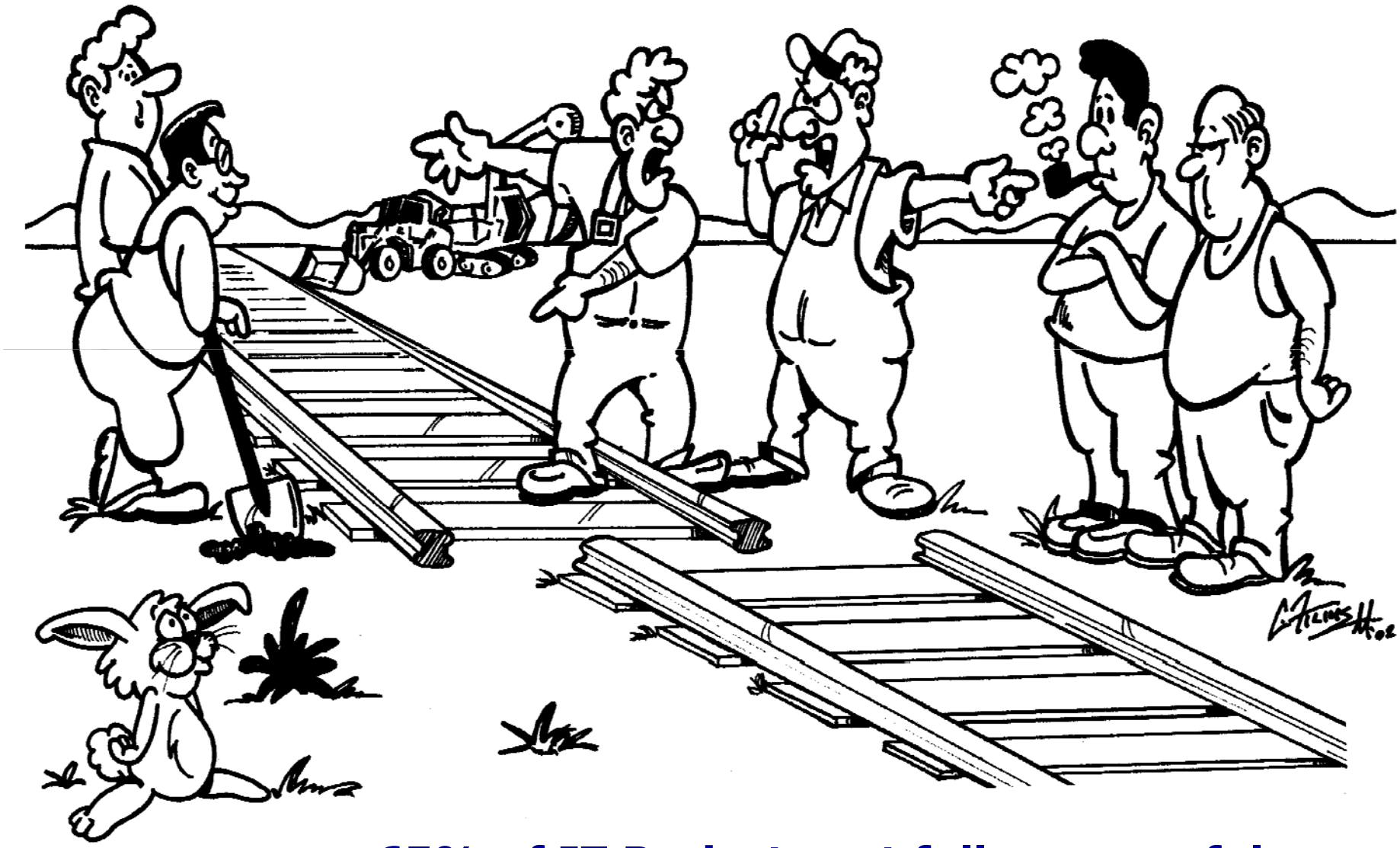
Who does What ?

Customer & Vendor



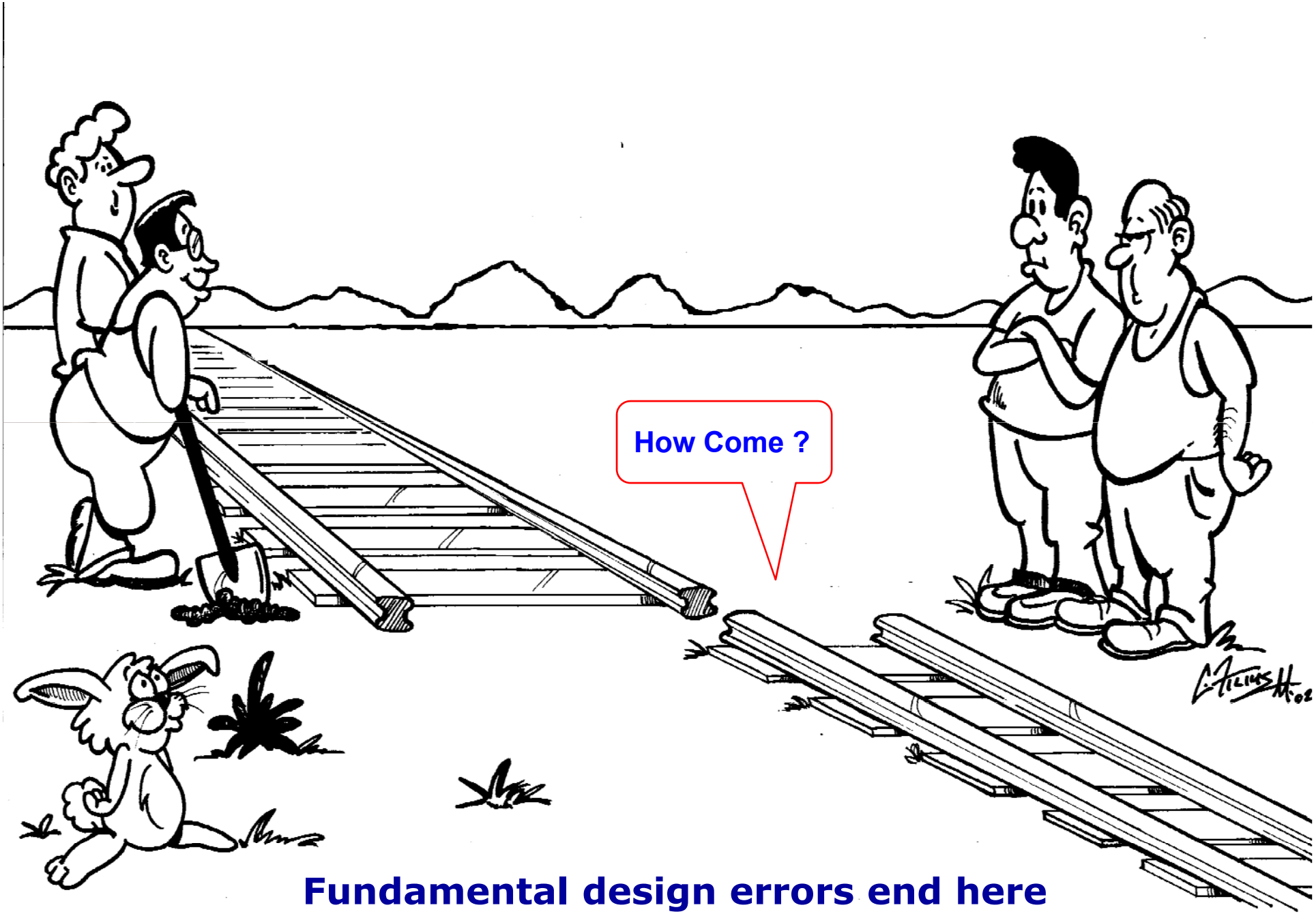
System from Vendor





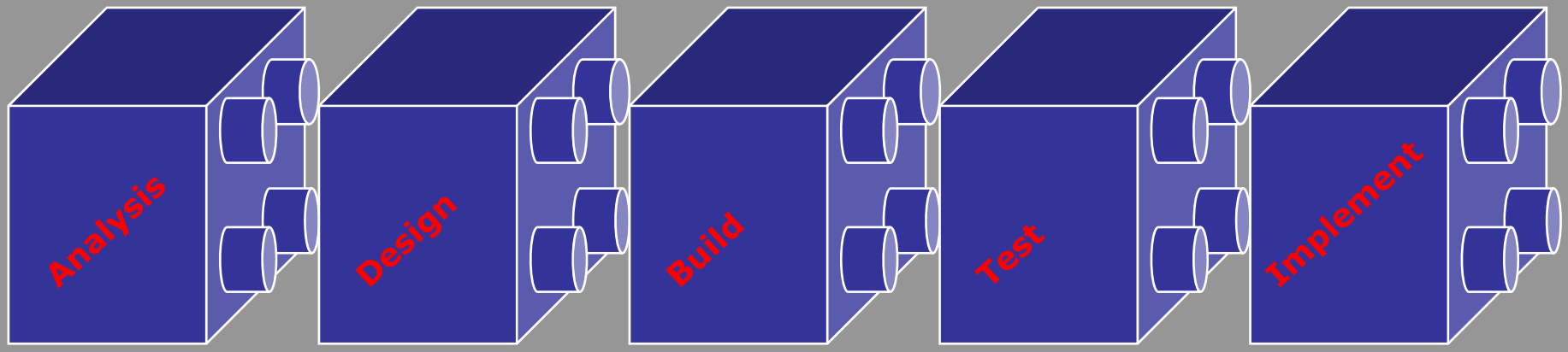
~ 65% of IT Projects not fully successful

The Standish Group: CHAOS Report 2006

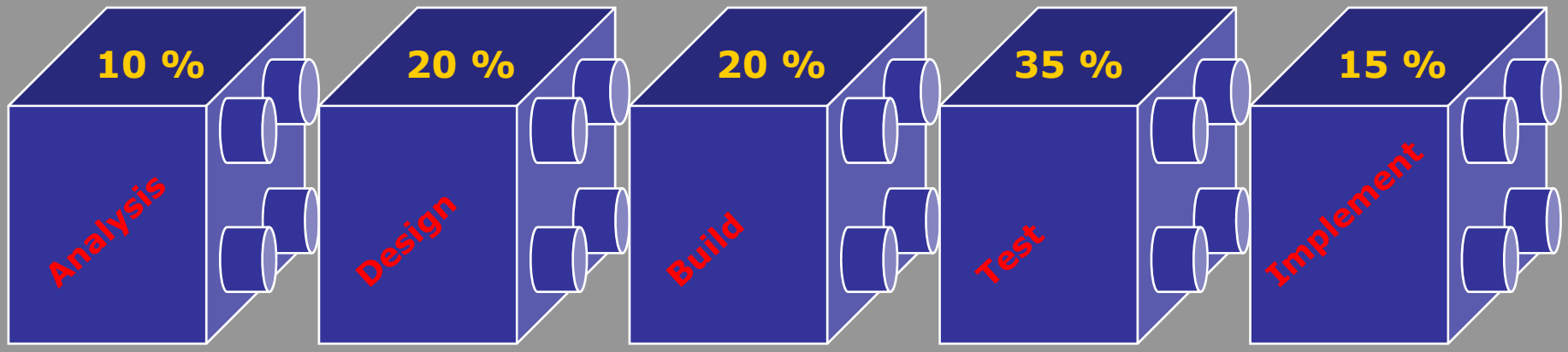


Fundamental design errors end here

Building process for IT systems
Development phases



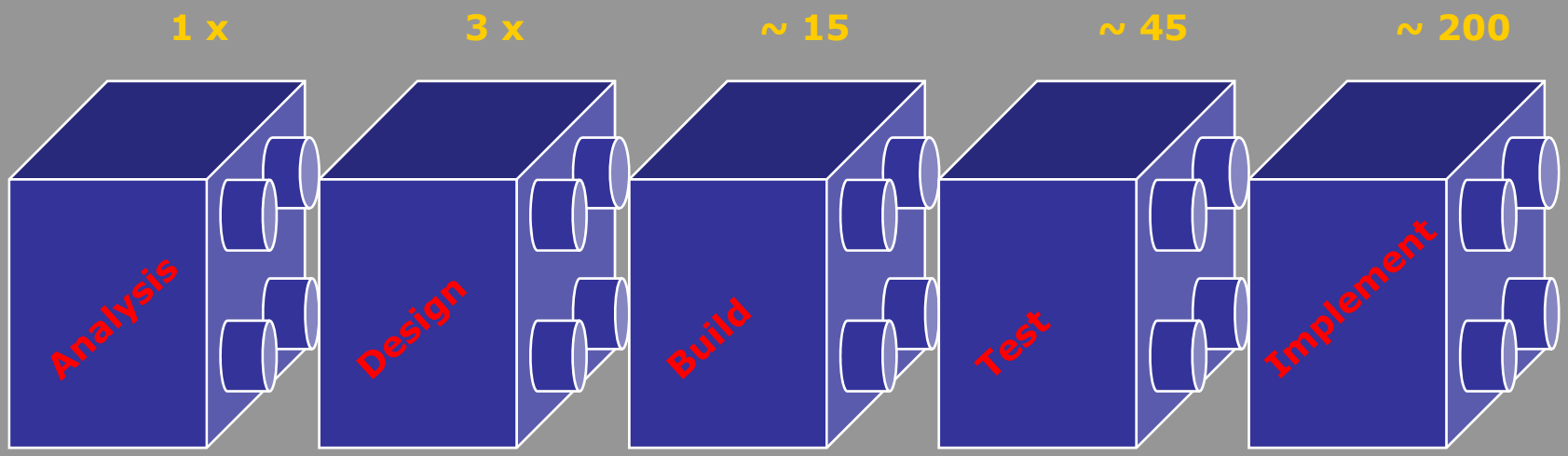
Project cost for standard IT system



Datasource: Accenture

Cost aspects

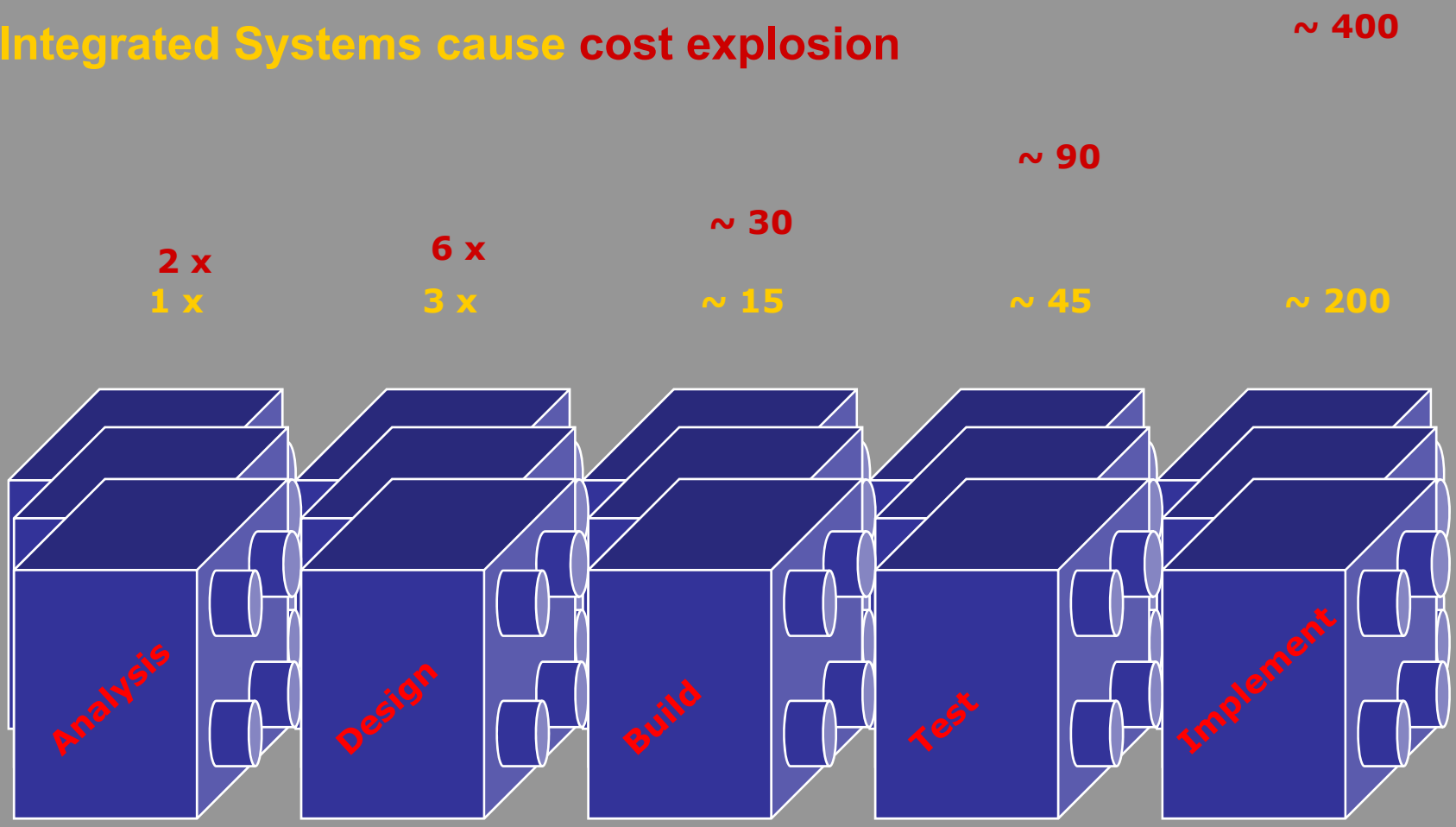
- **Cost of Non Quality**
  - correcting errors



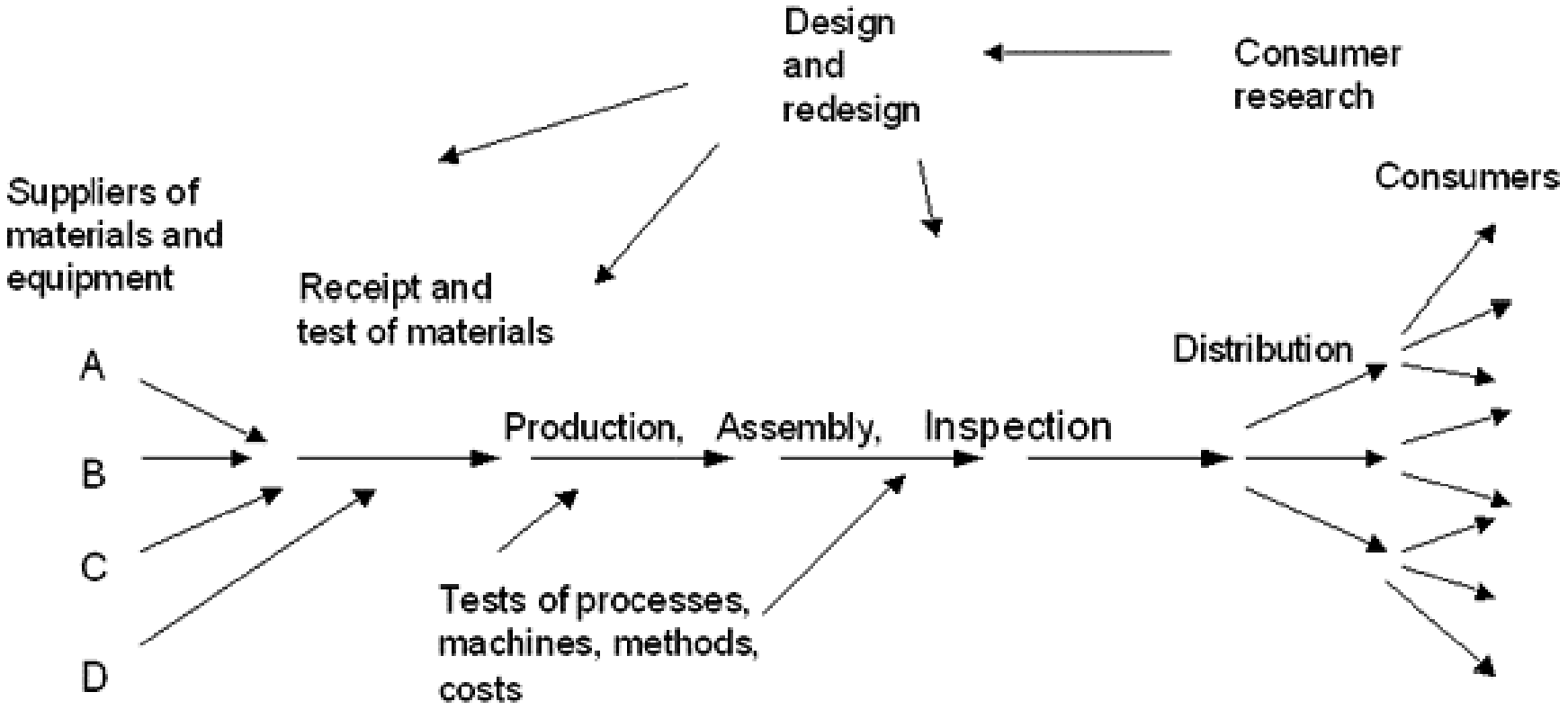
Datasource: Pharmaceutical Education and Research Institute

Potential cost of non quality

Integrated Systems cause cost explosion



It takes Time and Planning to understand the system



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Page 4

About not planning..

The best thing about doing no planning is that failure comes as a complete surprise, and is not preceded by a period of worry, depression and panic.'

Sir John Harvey-Jones

Take Home

Understand the business as a system (Hospital, Laboratory, Production Plant)

Understand the underpinning processes

Understand what needs to be automated and why (build URS)

Write Business Case