Validation of a CMS Software

GxP Webinar

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Paul Daniel
Senior Regulatory Compliance Instructor
Vaisala, Inc.

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Vaisala in Brief

- We serve customers in weather and controlled environment markets
- 75 years of experience in providing a comprehensive range of innovative observation and measurement products and services

Vaisala - Life Science

Our Offering

Provides measurement instrumentation, continuous monitoring systems and validation systems for regulated or highly controlled life science environments.

Our Goal is to help customers

- Reduce their risk of lost or adulterated product
- Reduce their risk of failing to meet GxP regulations and/or guidelines

Your Hosts

Speaker:

Paul Daniel
Sr. Regulatory Expert

Chat Moderator:

Janice Livingston
Marketing Specialist

What are you most interested to learn from this webinar?

A. Better understanding of GAMP-style validation
B. How to identify gaps in my current validation program
C. Recommendations for documents such as URS, FS and Traceability Matrices
D. Learn more about Vaisala products in general
E. I forgot… I only joined because an email made me click it
F. Other

What industry do you work in?

A. Pharmaceuticals
B. Medical Devices
C. Biologics, HCT/ps or Blood/Tissue
D. Contract Organization
E. Nutraceuticals
F. Consulting or engineering firm
G. Distribution/Logistics
H. Student
I. Manufacturing other than Life Science
J. Industry other than Life Science

Have you attended a Vaisala webinar before?

A. No
B. Yes
C. Not sure, it's all a blur…

Validation of a CMS Software

Using GAMP principles in monitoring system validation

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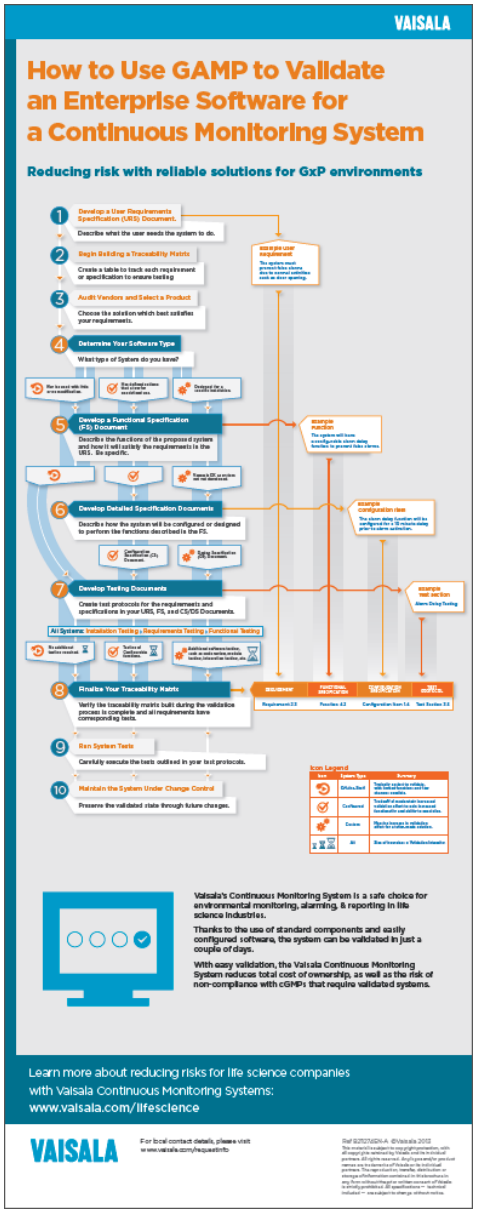
Goal of this Webinar

- Review the GAMP process for CMS validation.
- Break it into easy to understand steps.


VAISALA
How to Use GAMP to Validate an Enterprise Software for a Continuous Monitoring System
Reducing risk with reliable solutions for GxP environments
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Preserve the validated state through future changes.
example user requirement
example function
example configuration item
example test section
Alarm Delay Testing
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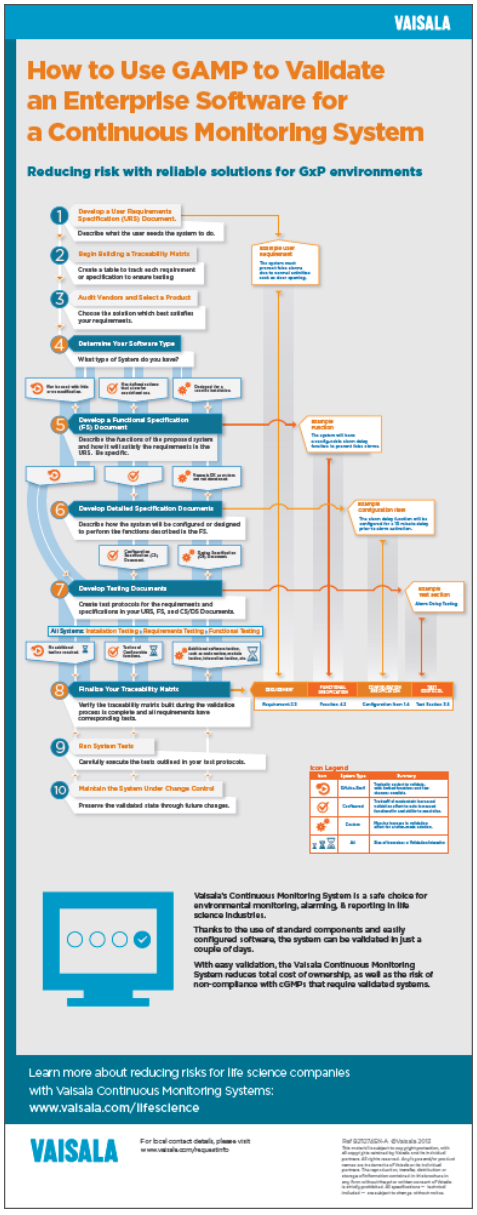
For local contact details, please visit
www.vaisala.com/requestinfo



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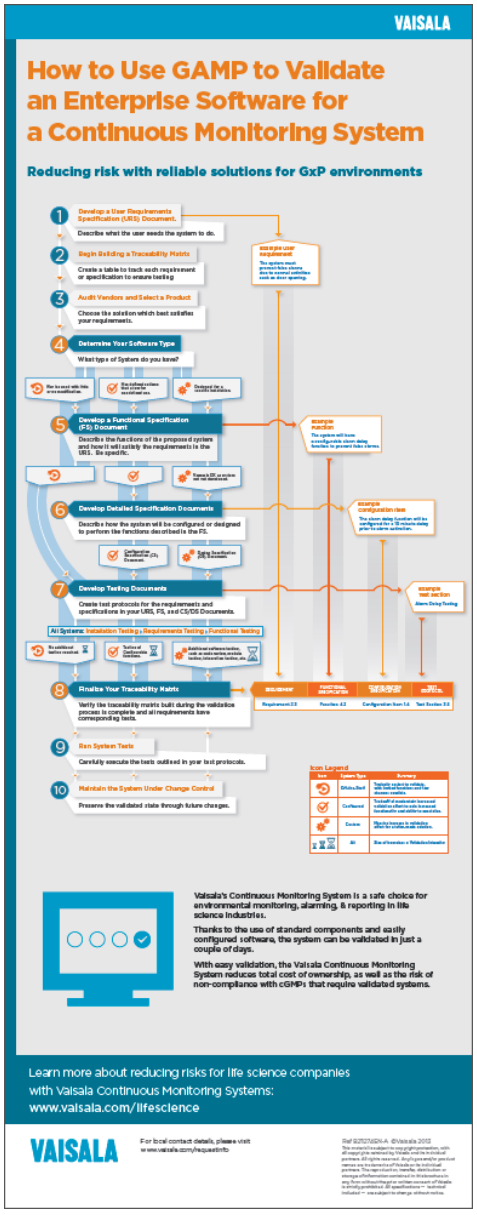
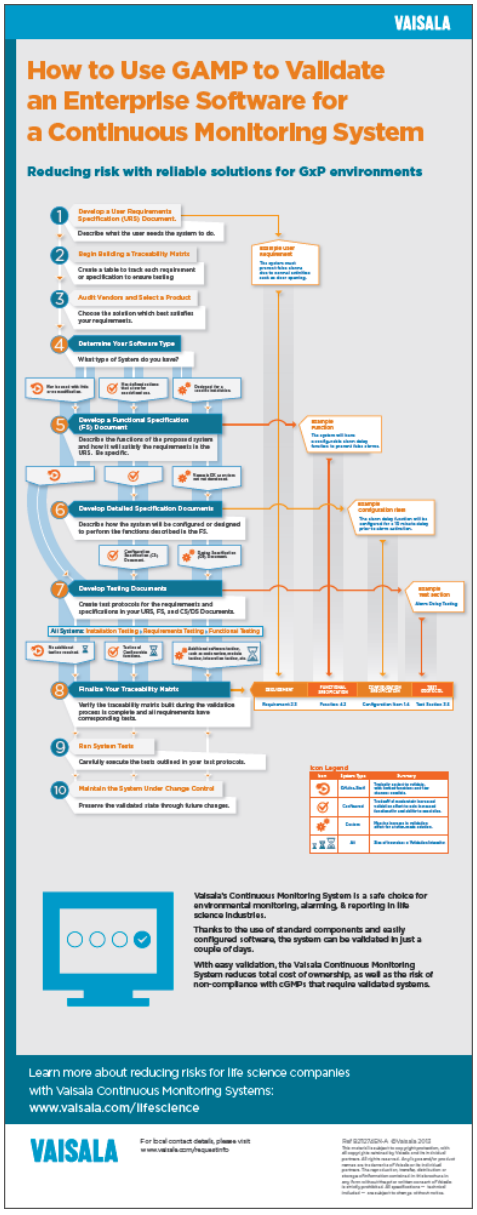


Icon	System Type	Summary
	Off-the-Shelf	Typically easiest to validate, with limited functions and few changes possible.
	Configured	Tradeoff of moderately increased validation effort to gain increased functionality and ability to specialize.
	Custom	Massive increase in validation effort for a tailor-made solution.
	All	Size of hourglass = Validation Intensity.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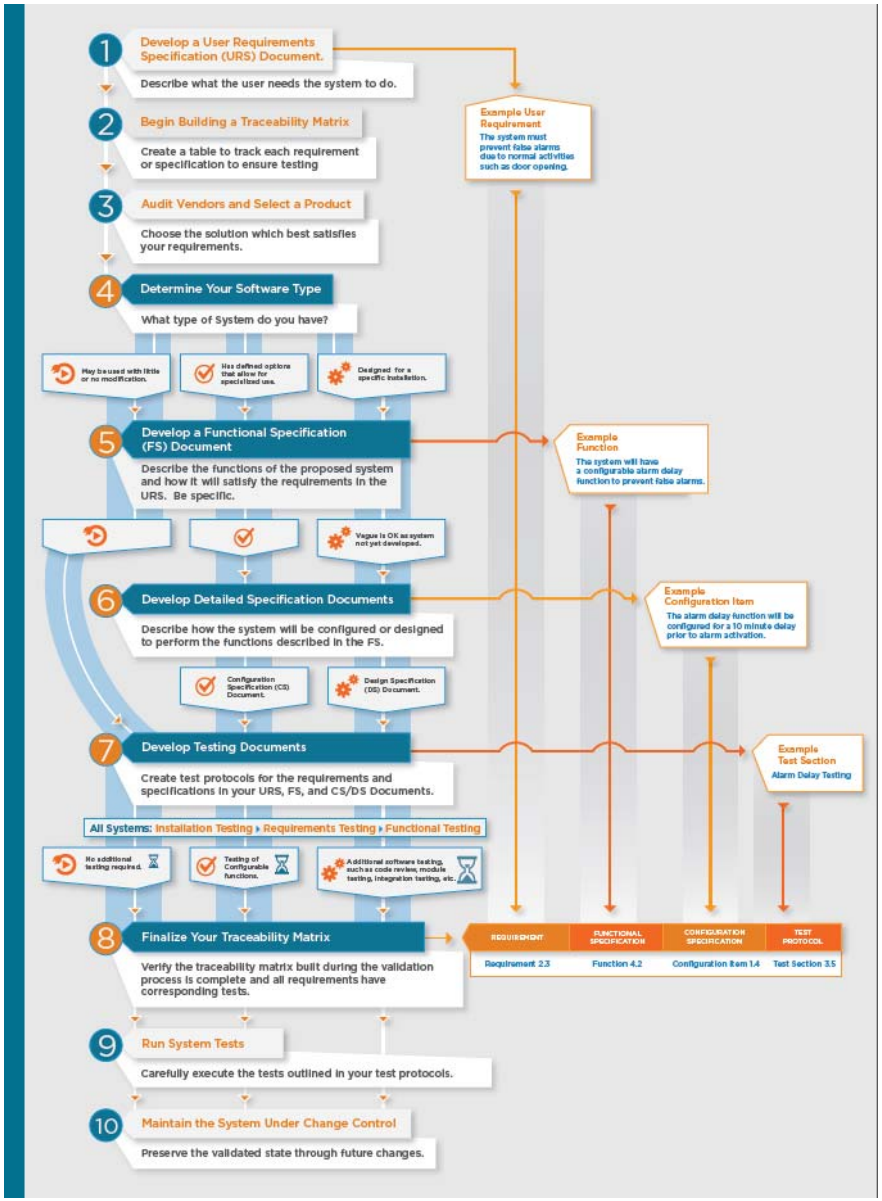
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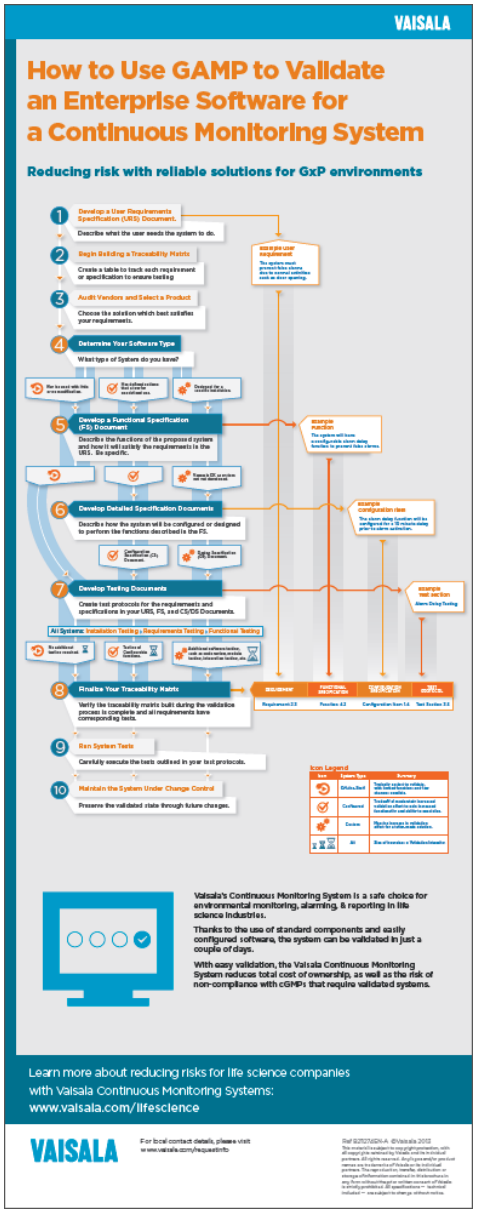
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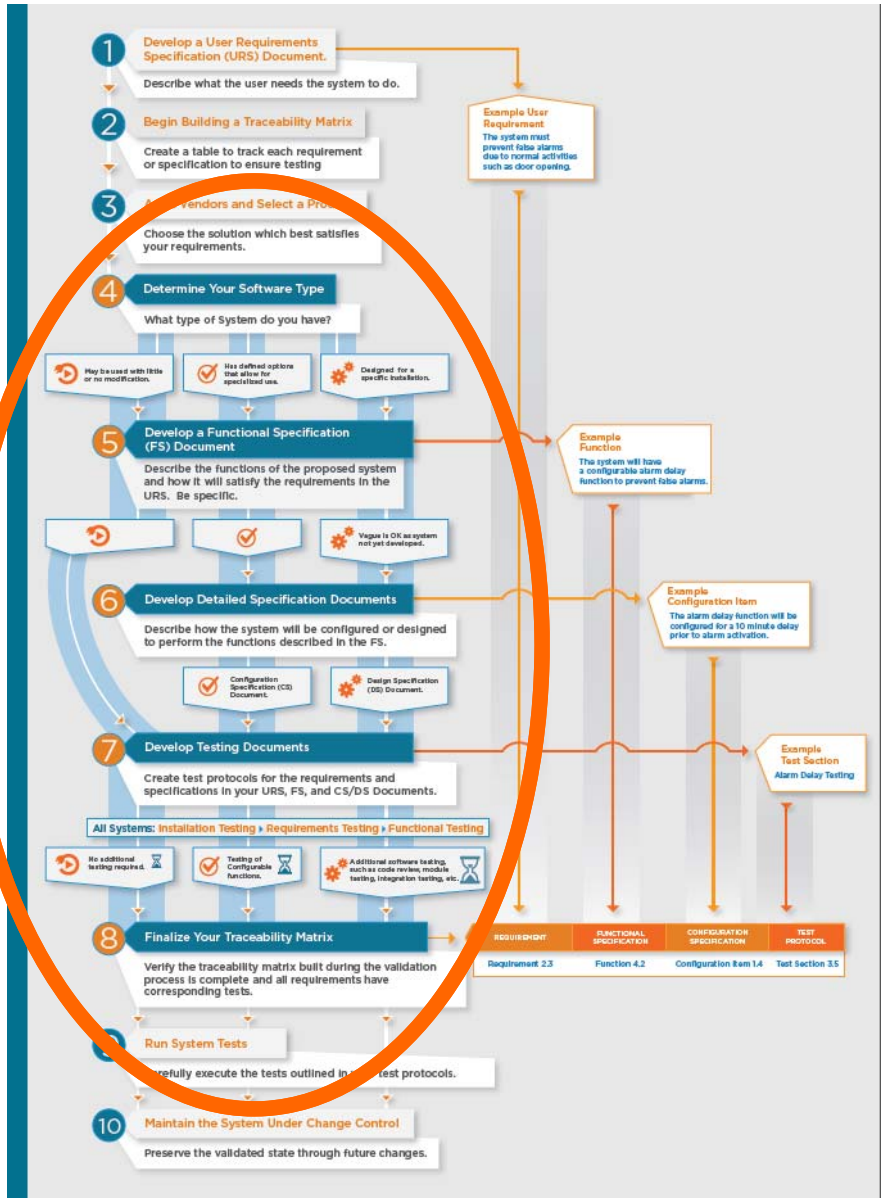
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May be used with little or no modification.
Has defined options that allow for specialized use.
Designed for a specific installation.
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Vague is OK as system not yet developed.
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Design Specification (DS) Document.
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Testing of Configurable functions.
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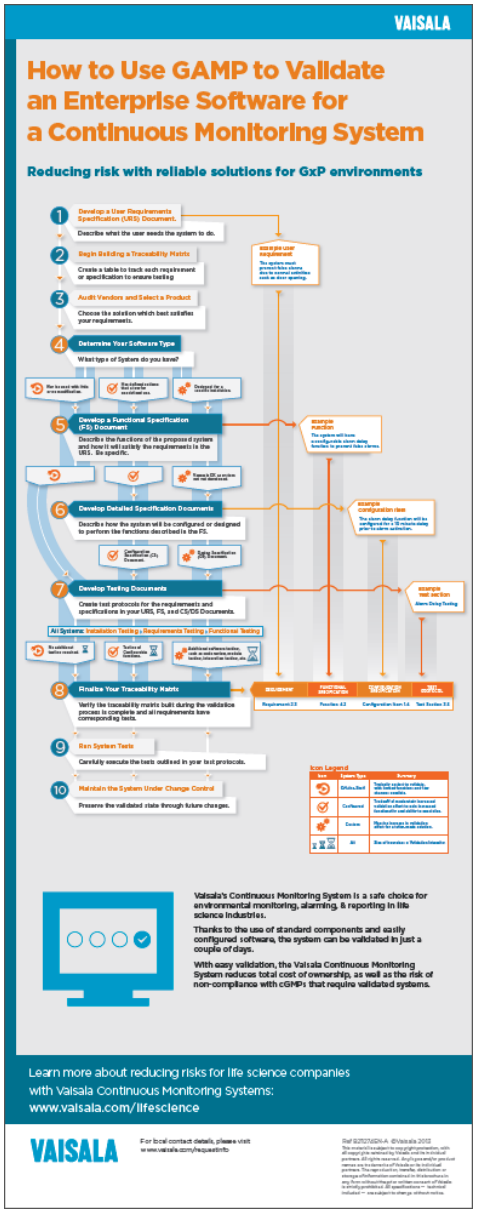
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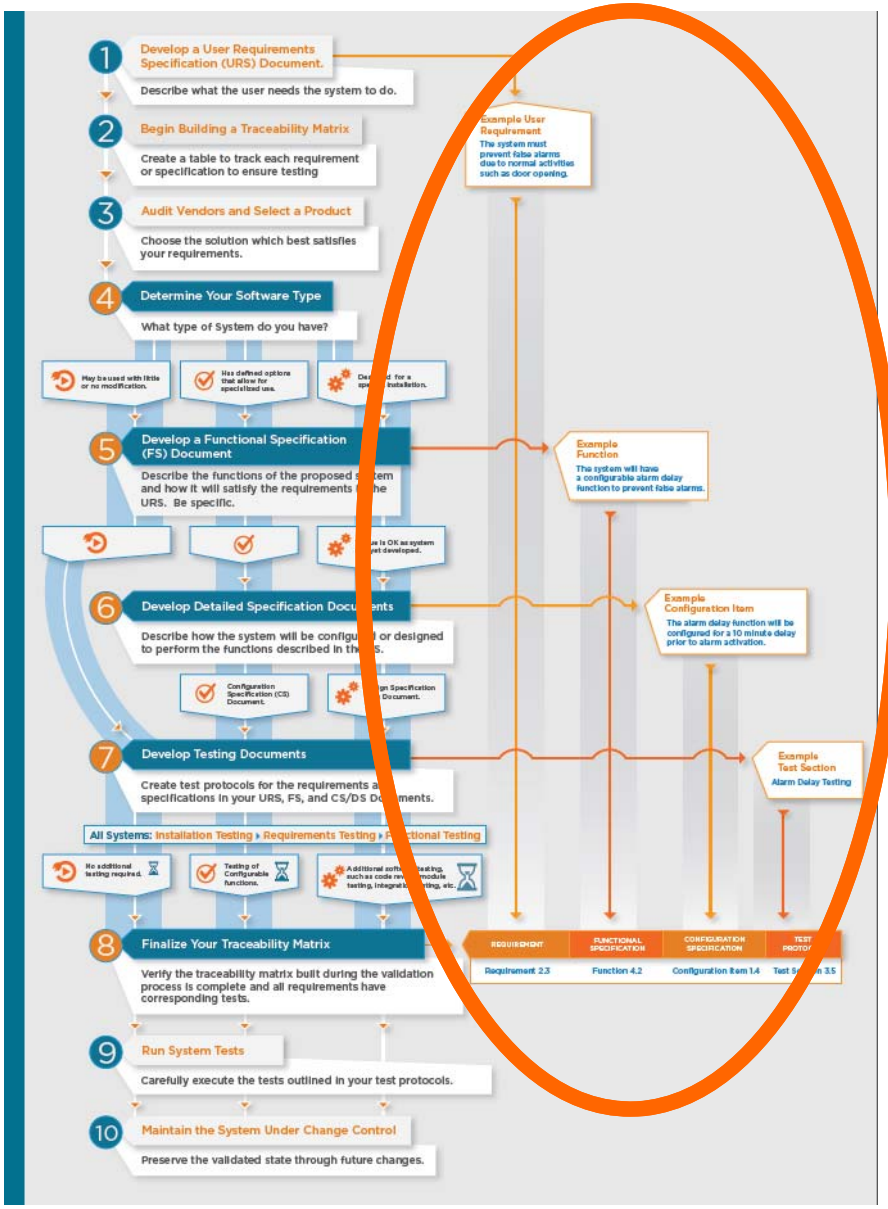
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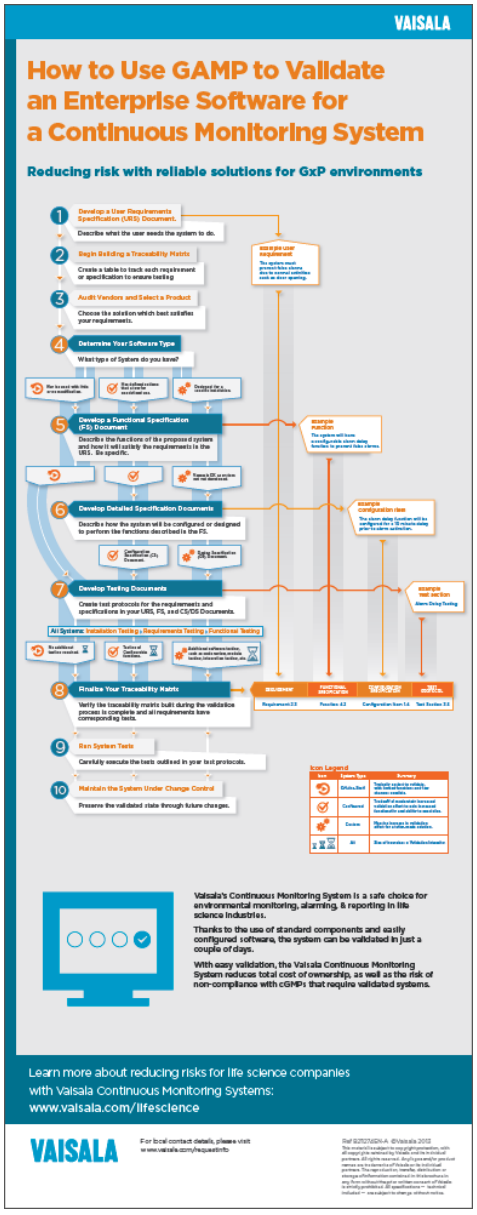
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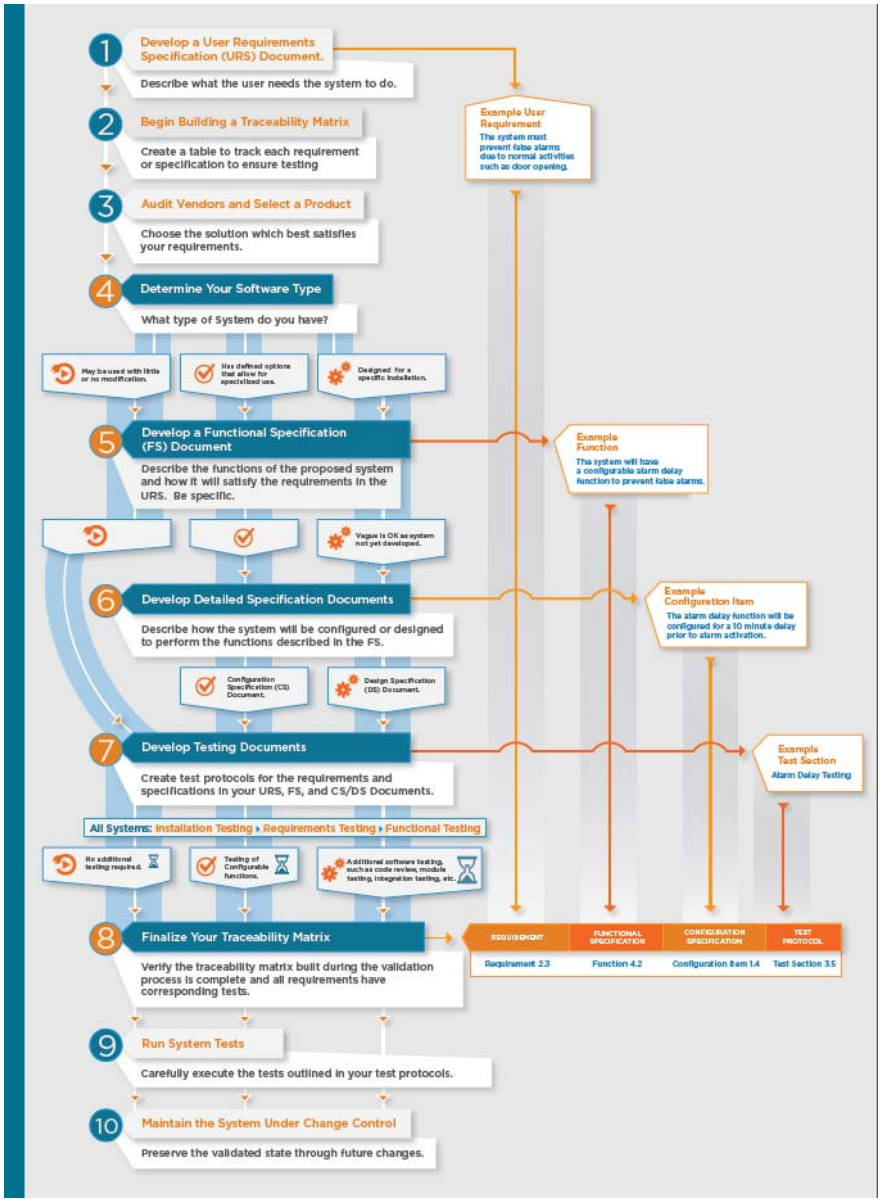
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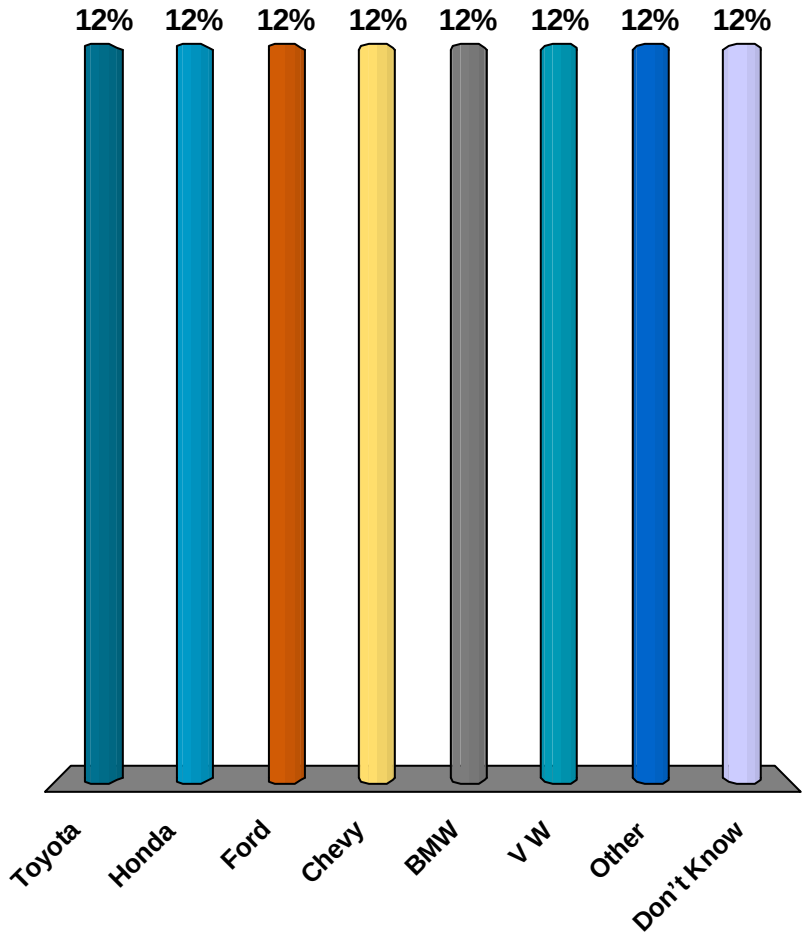
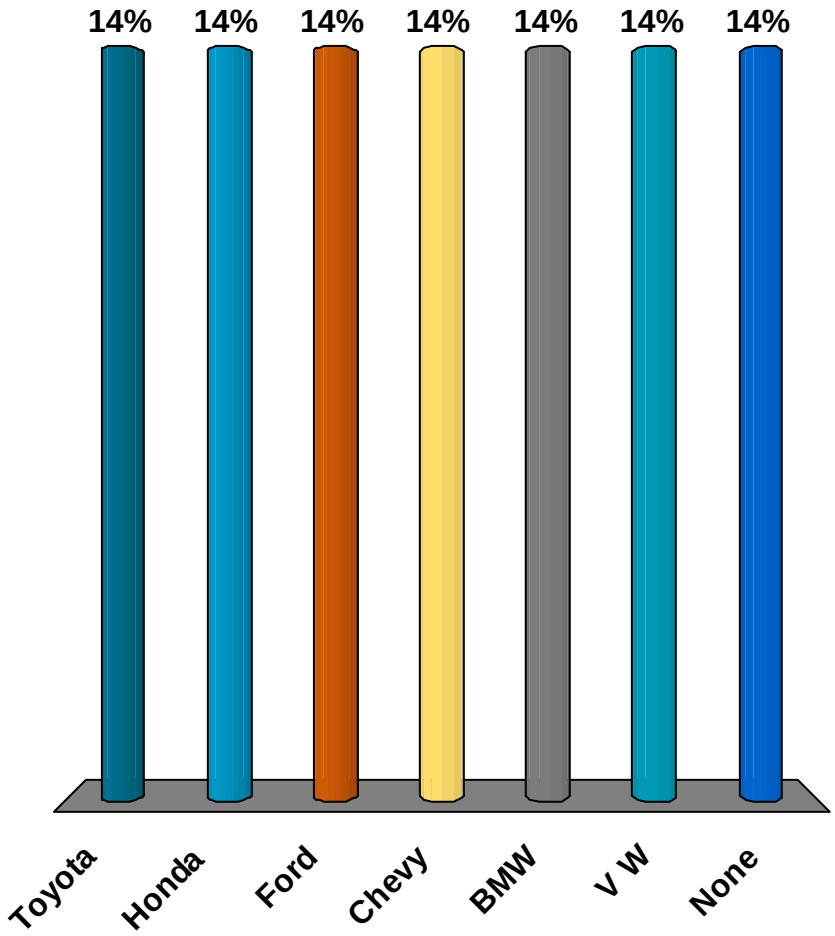
What brand of automobile do you own?

A. Toyota
B. Honda
C. Ford
D. Chevy
E. BMW
F. VW
G. Other
H. Don’t Know



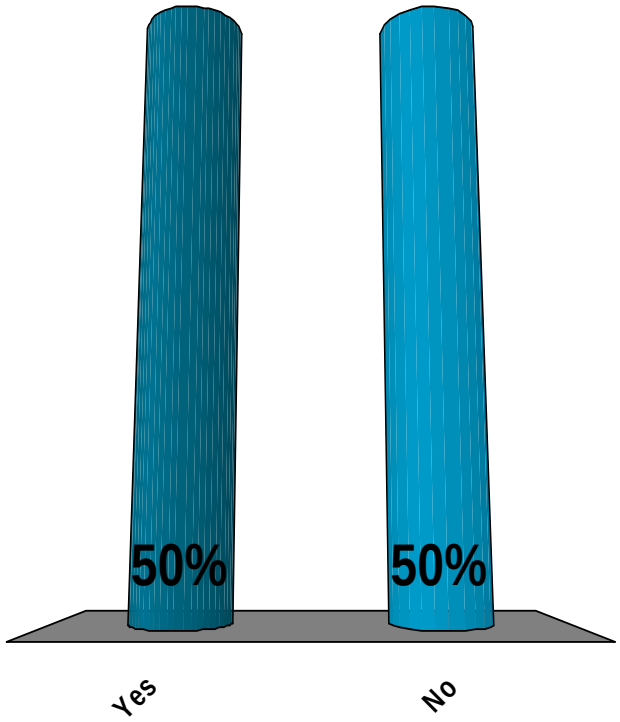
What brand names do you recognize?

A. Toyota
B. Honda
C. Ford
D. Chevy
E. BMW
F. VW
G. None



Do you know what car you would buy?

A. Yes
B. No




ISPE
GAMP 5
A Risk-Based Approach to
Compliant GxP Computerized Systems
Management
Development
Operation
Special Interest
General
Enabling Innovation

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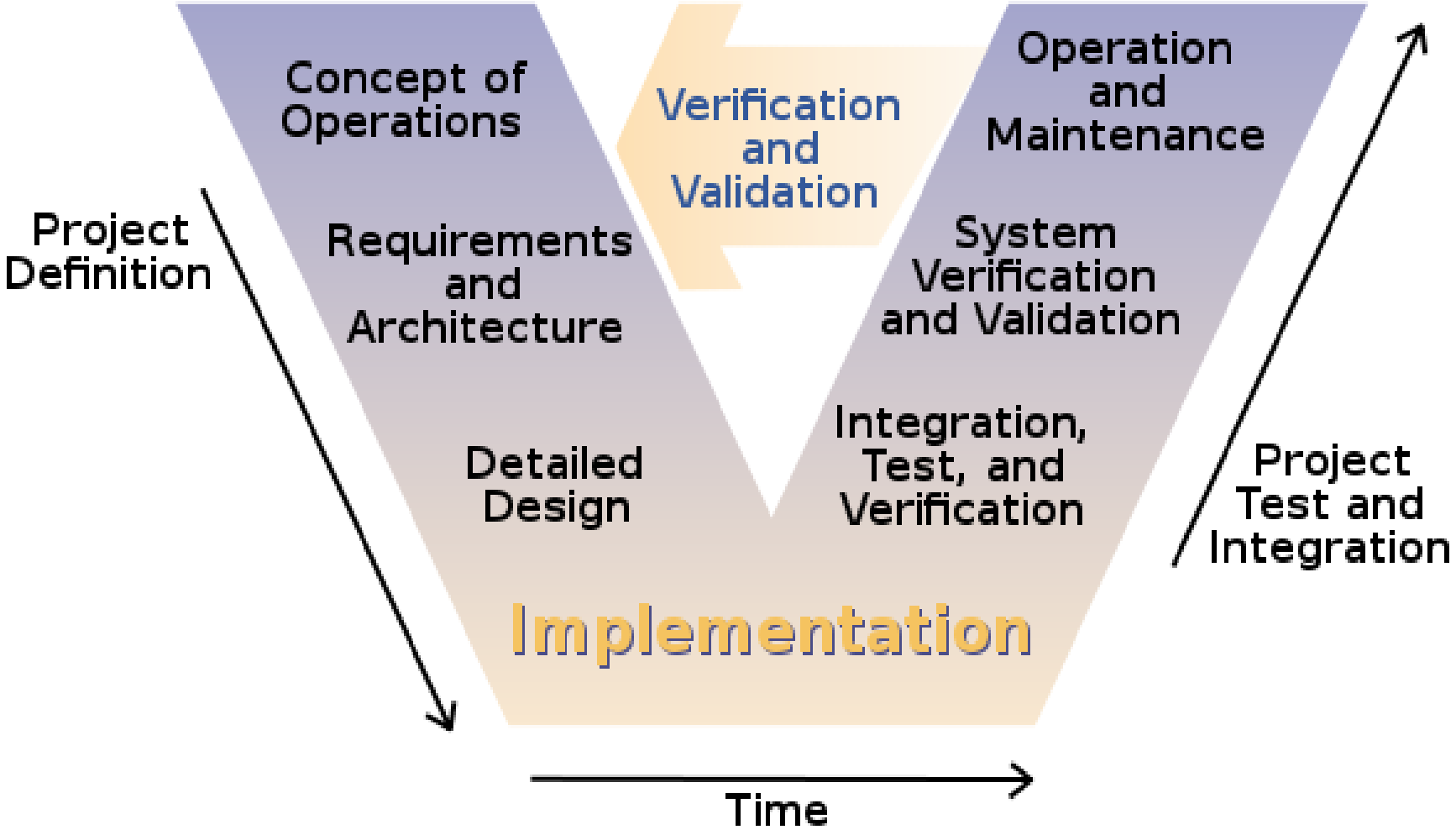
Concept of Operations
Verification and Validation
Operation and Maintenance
Project Definition
Requirements and Architecture
System Verification and Validation
Detailed Design
Integration, Test, and Verification
Project Test and Integration
Implementation
Time

CMS LIFE CYCLE

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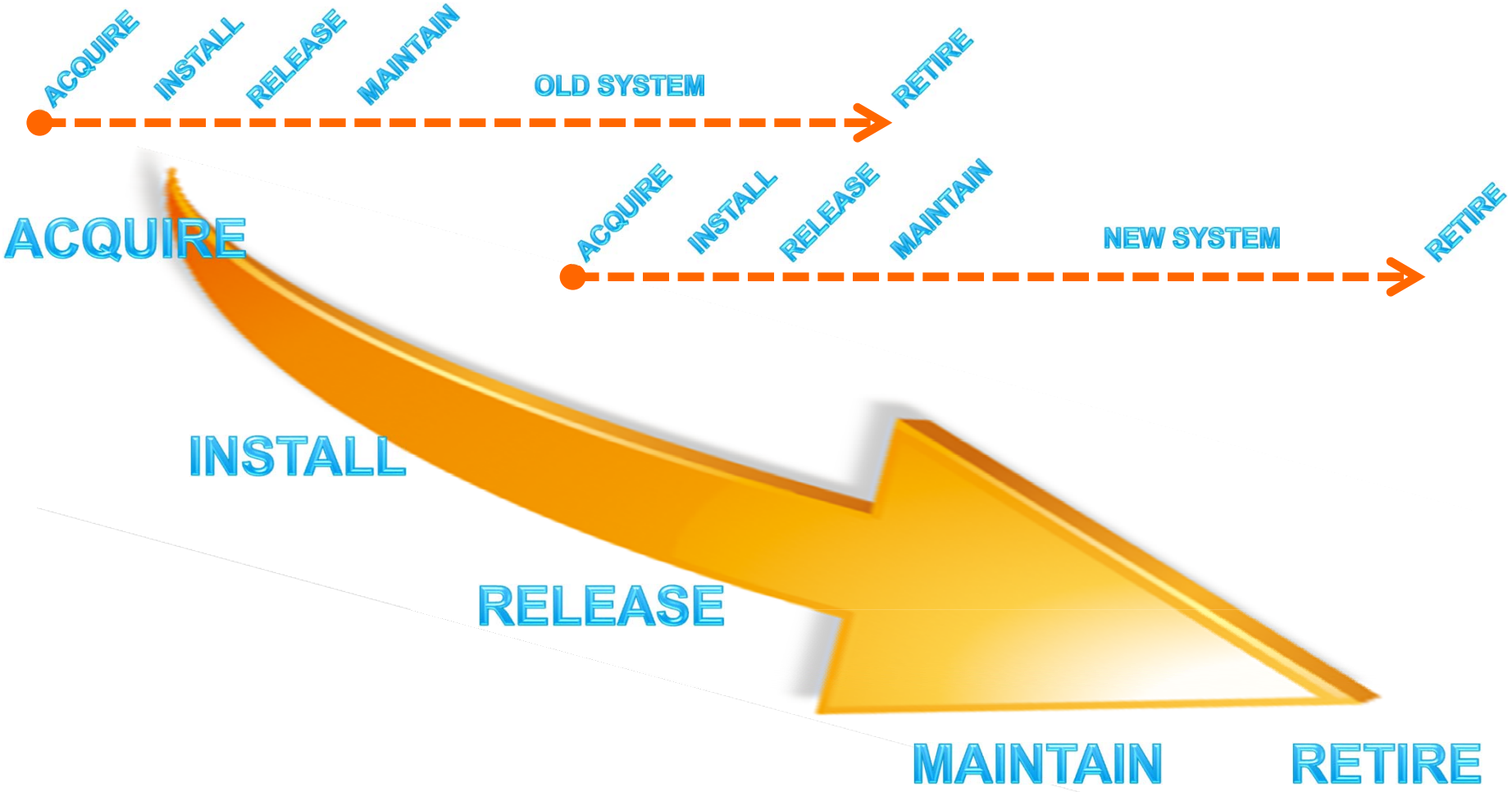

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Step 1 Develop a User Requirements Specification (URS) Document.

- Describes what system needs to do.

- or -

- Identify stakeholder needs to create consensus and guide system selection.

Most important step in entire process!!!

The Quality System Puzzle

URS – What does it look like?

- Standard Approved Document

- What makes it different?
  - System Description
  - Requirements

- Sensors
- Network
- Utilities
- Infrastructure
- Security
- Alarming
- Reporting
- IT
- ?????

Example User Requirement

The system must prevent false alarms due to normal activities such as door opening.

Make your Requirements “SMART”

TESTABLE

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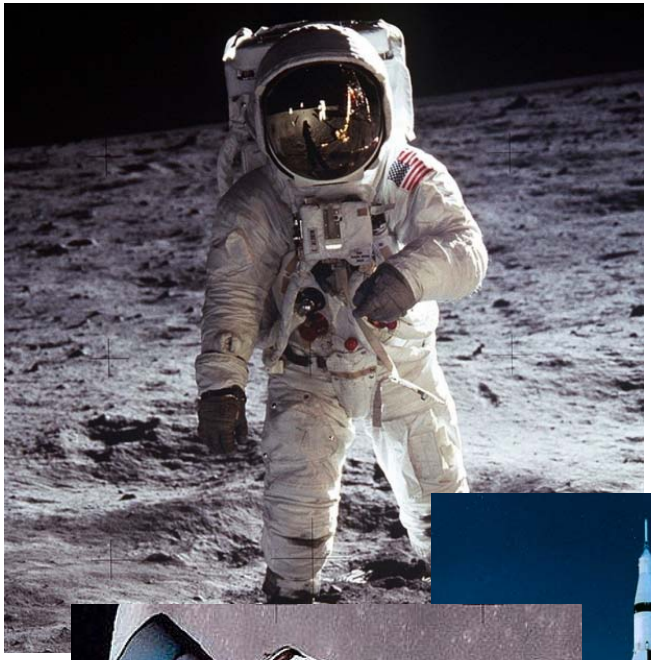
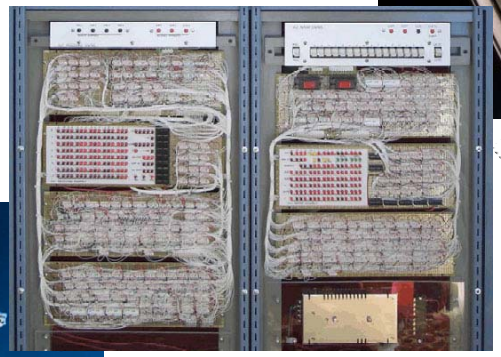
Other Sample Requirements

- Alarming – The system must…
  - …have the capability to notify facility personnel when sensor readings exceed threshold values.
  - …have configurable delays from 0 to 60 minutes before alarm generation and notification.
  - …allow multiple high and low thresholds.
  - …communicate alarm states by SMS text, email, and phone.

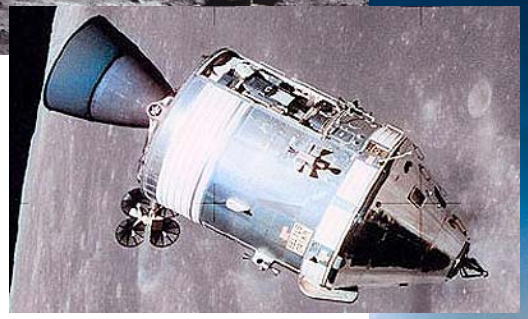
Approval of the URS by stakeholders

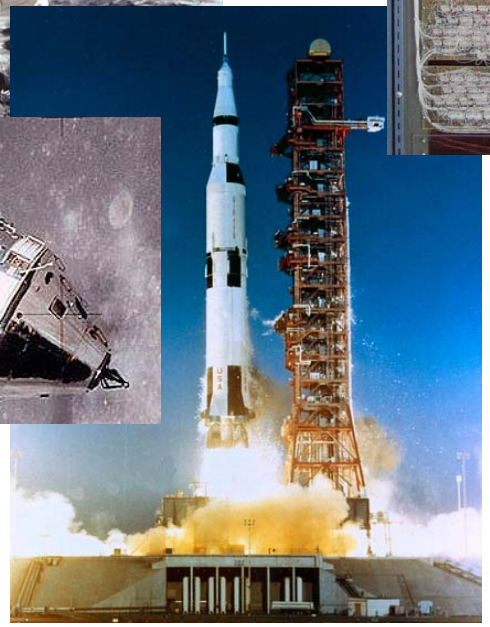
- Developed by “Committee”
- Easy to approve if stakeholders are included.
  - Expect some rounds of revision.
- You will have more requirements than you can meet.
  - Retain unsatisfied requirements for traceability and transparency of “work-arounds”.
  - System selection will be a compromise.





1,000,000x Memory





1,000x CPU Power

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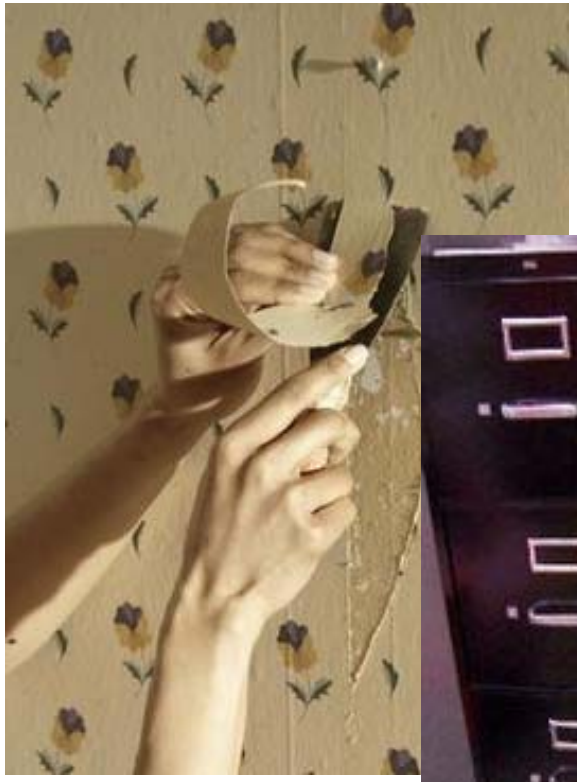


Step 2 Begin Building a Traceability Matrix

- Traceability Matrix (TM)
  - Simple table to track our requirements.
    - There is a function that fulfills each requirement.
    - Each function is tested.
  - Just a spreadsheet, populated with the requirements.

Start it now, so that can be used as a tool!!!

Trace Matrix Example

REQUIREMENT	FUNCTIONAL SPECIFICATION	CONFIGURATION SPECIFICATION	TEST PROTOCOL
The system must prevent false alarms due to normal activities such as door opening.			

Finding a System

- Not like a car – don't know what is out there…

- Influential Persons
- Web Searches
- Existing Relationships

- Other Constraints
  - Acquisition Budget
  - Long-Term Cost of Ownership
  - Validation Capabilities

Step 3 Audit Vendors and Select a Product

- Audit the Vendors (2 ways!)
  - Quality System
  - CMS Solution
    - Compare your requirements to the candidate systems.

- Goal
  - Identify multiple candidate systems for further examination.

Step 4 Determine Your Software Type

What type of System do you have?

Category	Name
3	Off-the-Shelf
4	Configured
5	Custom

Category 3: Off-the-Shelf

- GAMP 4 - Standard Software
- GAMP 5 - Non-configured

- There are important distinctions for other types of software, but for CMS, we know it will be software on a server with a sensor network.

KEY: Run-time configuration ONLY.

No additional configuration!

Category 4: Configured

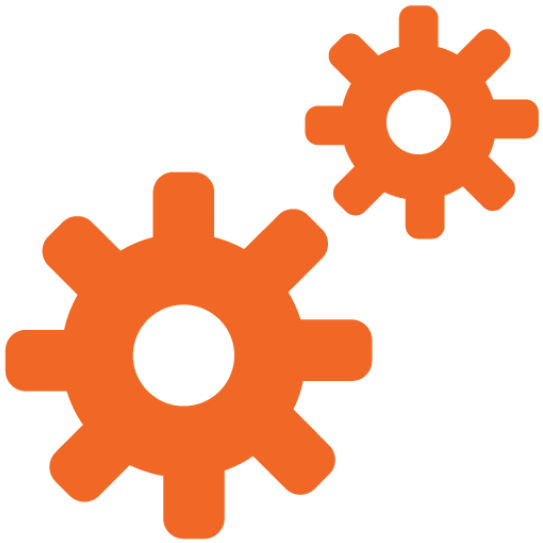
- GAMP 4 - Configured Software
- GAMP 5 - Configured Products

- These products don't do what you want out of the box. Parameters must be set to match your business process.

KEY: Any configuration beyond run-time.

But, no custom code, even when constructed using the application itself.

Category 5: Custom



- GAMP 4 - Custom Software
- GAMP 5 - Custom Products

- These products are made bespoke for your business process. They did not exist before, and were not tested.

KEY: This includes code created using the functions within an application that is not custom, such as Macro functions in Excel.

For our purposes…

Category	Name
3	Off-the-Shelf
4	Configured
5	Custom

Step 5 Develop a Functional Specification (FS) Document

- Describes the system functions.
- Describes how the system will fulfill the requirements.

FS should be detailed, and may be available from vendors.

FS may be vague, as system doesn't exist.

Note: Use FS for system selection by comparing to URS.

Example Function

The system will have a configurable alarm delay function to prevent false alarms.

Sample Functions - WILL

- Alarming – The system…
  - …will notify facility personnel when sensor readings exceed threshold values.
  - …allows configurable delays from 0 to 60 minutes before alarm generation and notification.
  - …allows multiple high and low thresholds.
  - …communicates alarm states by SMS text, email, and phone.

Trace Matrix Example (cont'd)

REQUIREMENT	FUNCTIONAL SPECIFICATION	CONFIGURATION SPECIFICATION	TEST PROTOCOL
The system must prevent false alarms due to normal activities such as door opening.	The system will have a configurable alarm delay function to prevent false alarms.		

Thoughts so far…

- There won't be 1:1 correlation from URS and FS.
  - Populate the TM to see if requirements are met.
  - Some requirements will not be met.
  - Not all requirements are created equal.
  - We should be ready to make our final system selection.

The Road not Taken…

The system type you choose will have a large impact on the required validation effort, and on the return on your investment.

Step 6 Develop Detailed Specification Documents

Not necessary.

- System already in final form.

Configuration Specification (CS)

- Describes the configuration necessary to match the system functions to the business process.

Detailed Design Specification (DDS)

- How the system will be designed. It still needs to be built.

Note: DDS is out of scope for this presentation.

Example Configuration Item

The alarm delay function will be configured for a 10 minute delay prior to alarm activation.

Other Sample Configurations

- Alarming
  - For refrigerator Alert alarms, the “delay before activation” is set at 5 minutes; Action alarms have a “delay before activation” set at 30 minutes.
  - Refrigerator alarms are set at Alert levels of 3 and 7ºC and Action levels of 2 and 8ºC.
  - For refrigerators, Alert alarm notifications are sent by text to the Lab Manager (555-1212), and Action alarm notifications by email to QA (john.doe@vaisala.com).

Trace Matrix Example (cont'd)

REQUIREMENT	FUNCTIONAL SPECIFICATION	CONFIGURATION SPECIFICATION	TEST PROTOCOL
The system must prevent false alarms due to normal activities such as door opening.	The system will have a configurable alarm delay function to prevent false alarms.	The alarm delay function will be configured for a 10 minute delay prior to alarm activation.	

Step 7 Develop Testing Documents

Necessary for all system types.

- Testing required increases **GEOMETRICALLY** with system complexity.

- Goal
  - Make sure every GMP item identified in URS/FS/CS is tested.
    - Use risk assessment activities to lighten the load.
  - This is where SMART requirements pay-off.
  - Use TM to ensure all items are tested.

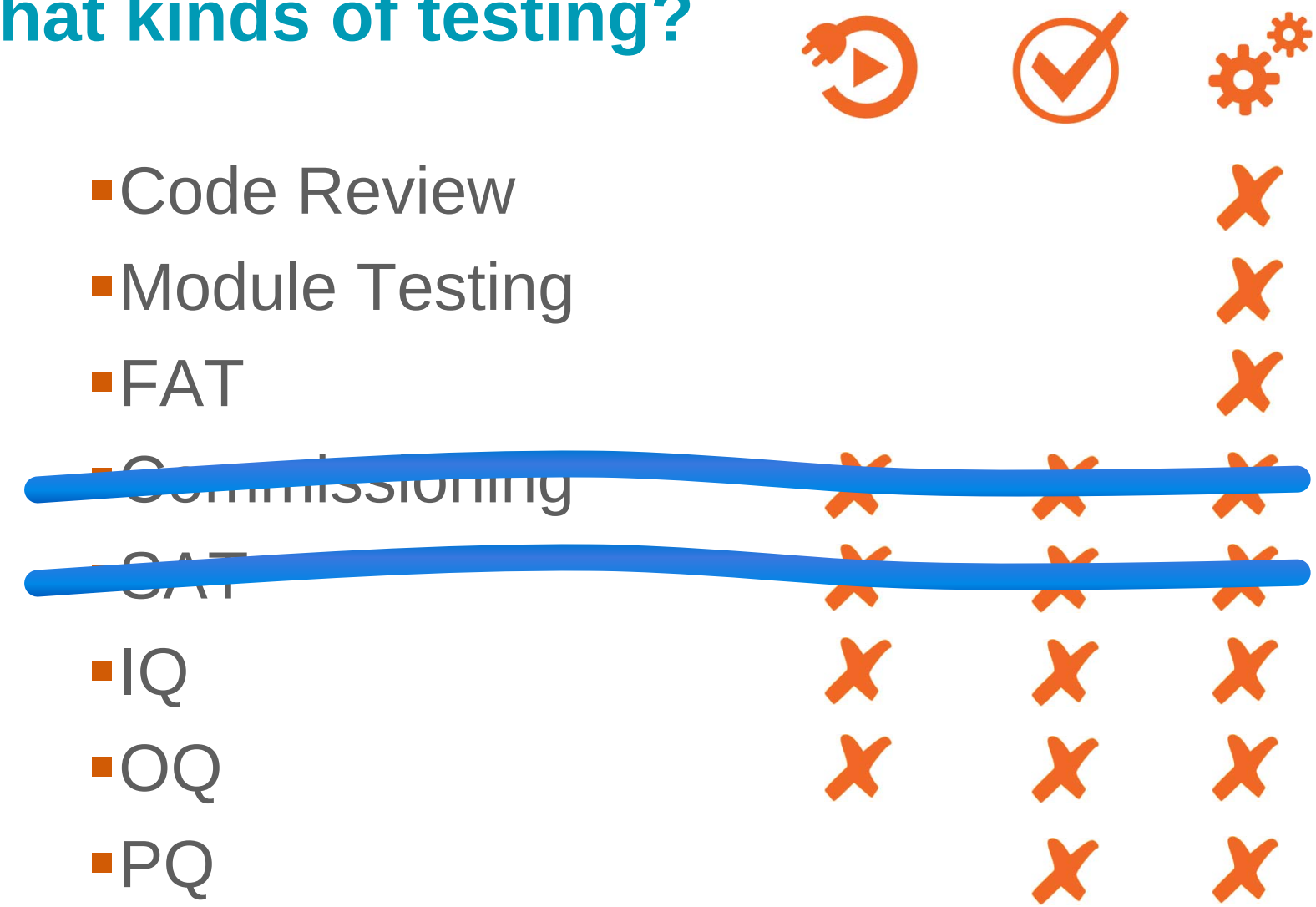
Trace Matrix Example (cont'd)

REQUIREMENT	FUNCTIONAL SPECIFICATION	CONFIGURATION SPECIFICATION	TEST PROTOCOL
The system must prevent false alarms due to normal activities such as door opening.	The system will have a configurable alarm delay function to prevent false alarms.	The alarm delay function will be configured for a 10 minute delay prior to alarm activation.	Alarm Delay Testing

What kinds of testing?

Code Review			X
Module Testing			X
FAT			X
Commissioning	X	X	X
SAT	X	X	X
IQ	X	X	X
OQ	X	X	X
PQ		X	X

What kinds of testing?



- Code Review
- Module Testing
- FAT
- ~~Commissioning~~
- ~~SAT~~
- IQ
- OQ
- PQ

Icon	System Type	Summary
	Off-the-Shelf	Typically easiest to validate, with limited functions and few changes possible.
	Configured	Tradeoff of moderately increased validation effort to gain increased functionality and ability to specialize.
	Custom	Massive increase in validation effort for a tailor-made solution.

Step 8 Finalize Your Traceability Matrix

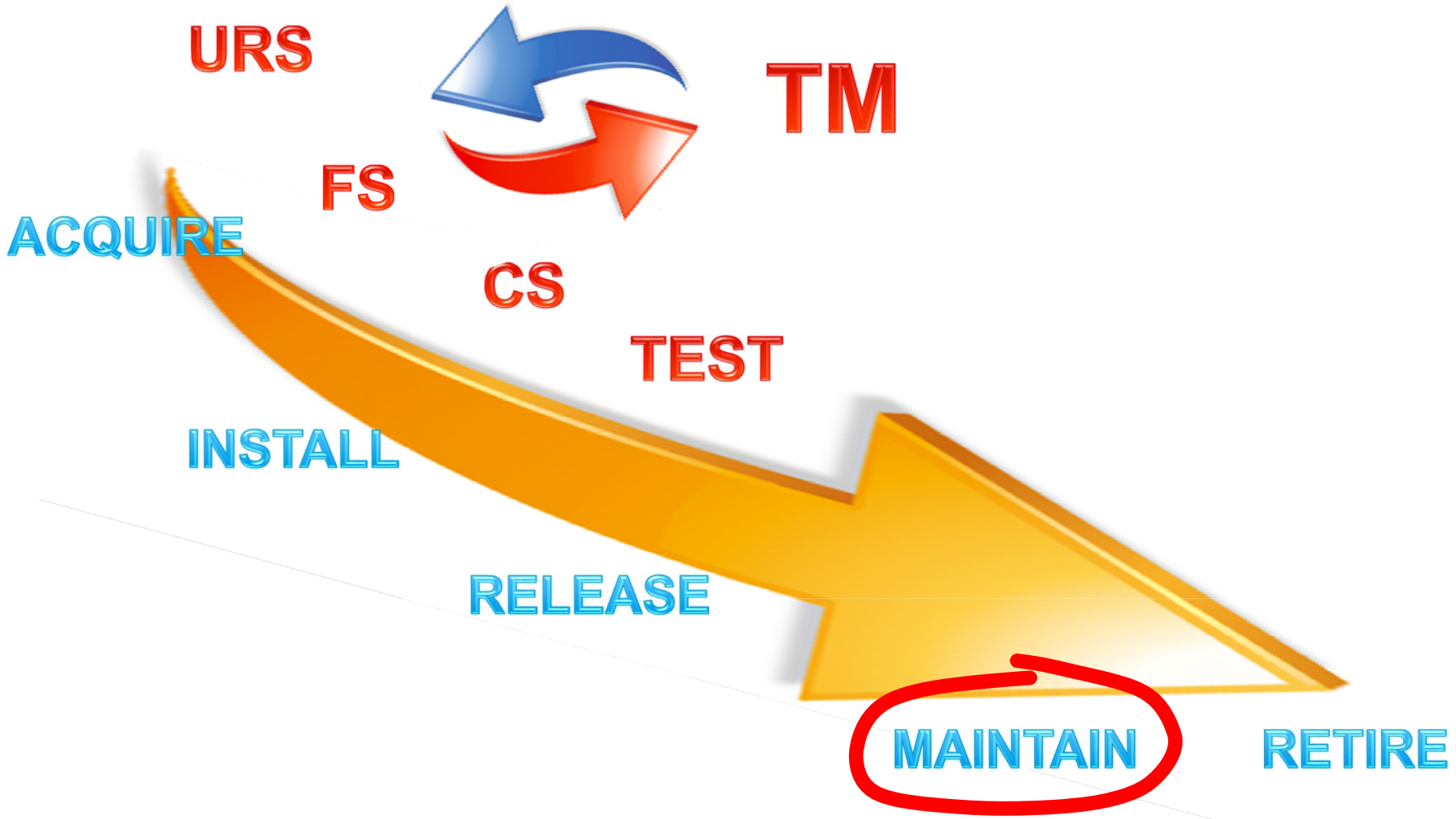
- We have been adding to this all along…
  - URS, FS, CS, Test Documents…
  - Verify each item is tested.
    - There may be tests with no requirement..
      - Do we need the test?
    - There may be requirements with no test…
      - Justification or rationale to not test.

Final check. All docs approved, entered in TM. TM checks out.

Step 9 Run System Tests

- The hard work is done. This is the fun part!
- Real life doesn't follow the plans.
  - There will be deviations.
  - Most of them will be resolved.
- If something just doesn't work..
  - Revise the requirement.
  - Develop a work-around.
  - Get a fix from vendor.

CMS LIFE CYCLE



Step 10 Maintain the System Under Change Control

- SOPs
- Training
- Calibration
- Validation
- Change Control

How to Use GAMP to Validate an Enterprise Software for a Continuous Monitoring System

Reducing risk with reliable solutions for GxP environments

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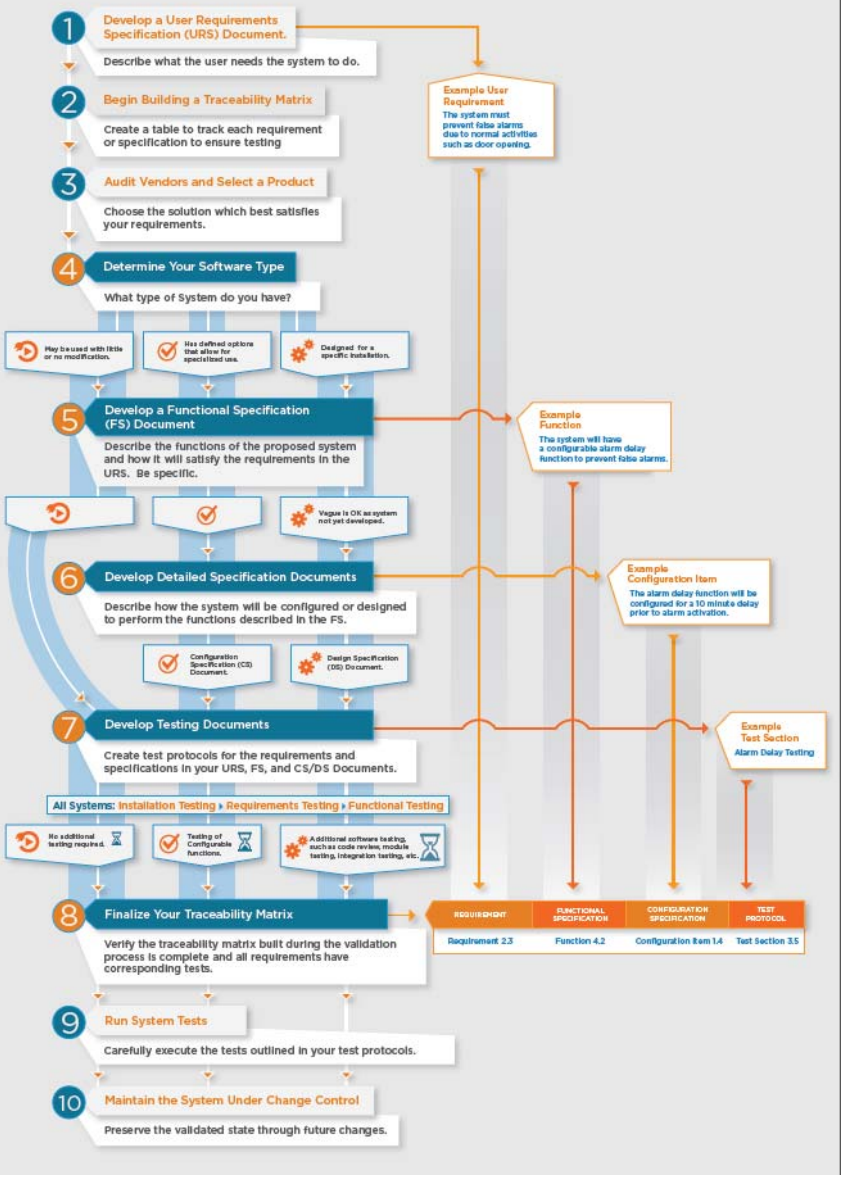
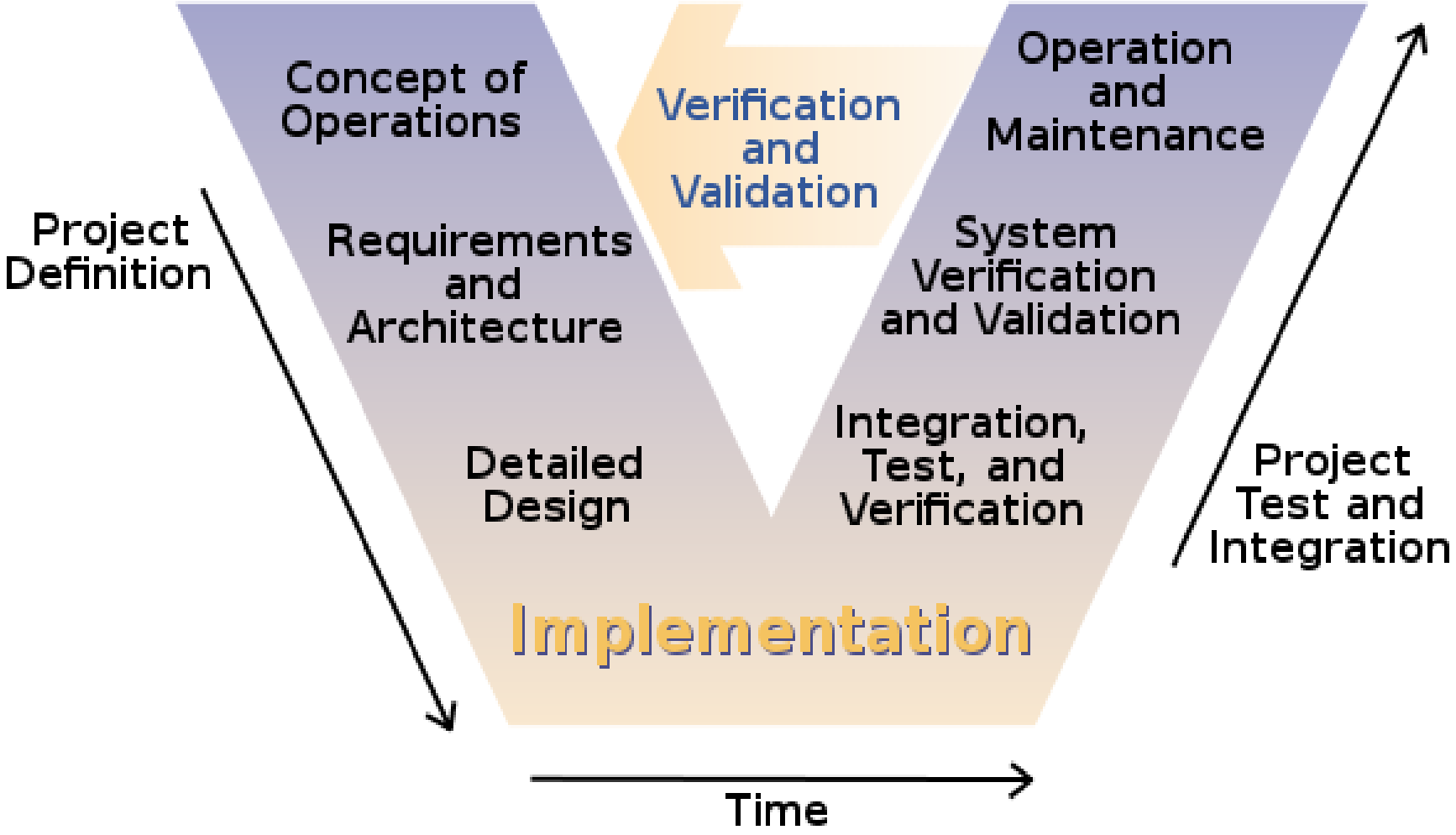
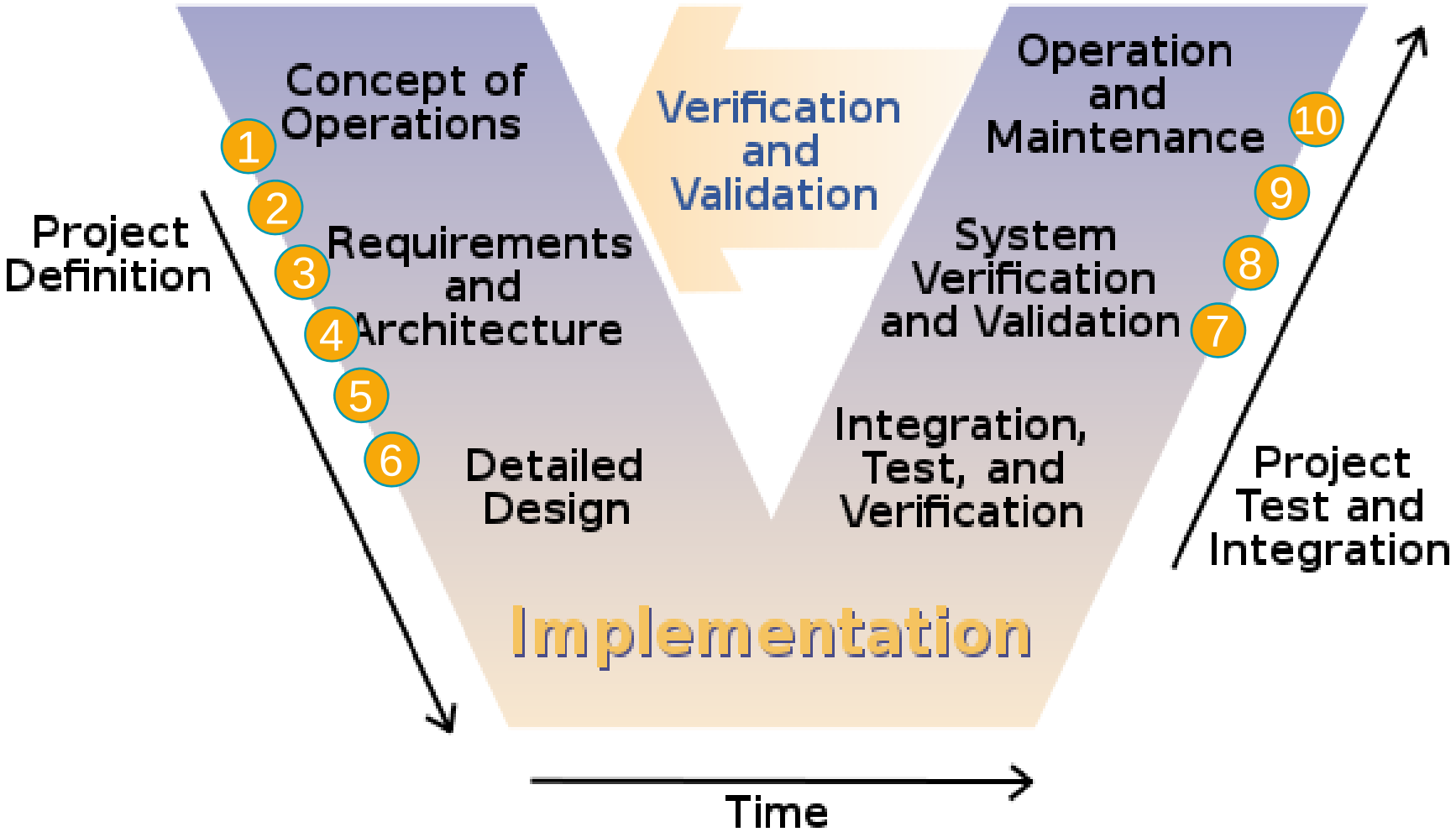



Concept of Operations
Verification and Validation
Operation and Maintenance
Project Definition
Requirements and Architecture
System Verification and Validation
Detailed Design
Integration, Test, and Verification
Project Test and Integration
Implementation
Time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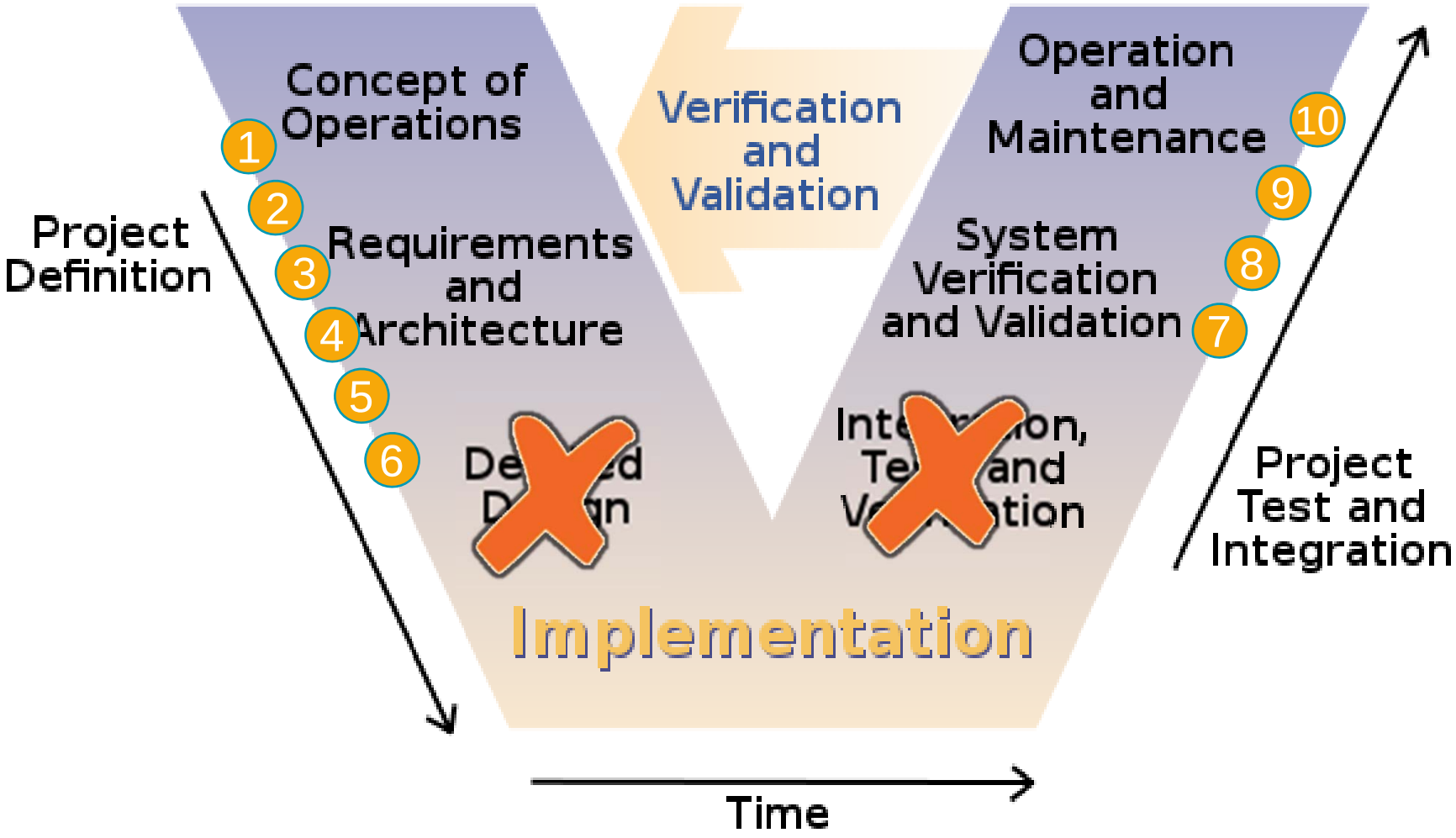
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Time

Summary of this Webinar

- Review the GAMP process for CMS validation.
- Break it into easy to understand steps.

Check us out

- The blog is a great place to post questions and get feedback from our experts and industry contacts.

- http://www.vaisala.com/en/lifescience/blog/default.aspx

Want more information?

- Would you like to speak with a Vaisala Application Engineer about a Vaisala product?
  - A. Yes – Continuous Monitoring System
  - B. Yes – Mapping/Validation System
  - C. Yes – Data loggers
  - D. Yes – Process Instrumentation
  - E. Yes – Handheld devices
  - F. Yes – Other
  - G. Not at this time

Thanks for Attending!

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