



Improve
QUALITY SERVICES

Lean development in the medical domain

June 2019, ICT Developer day

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adviseren.



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doen.

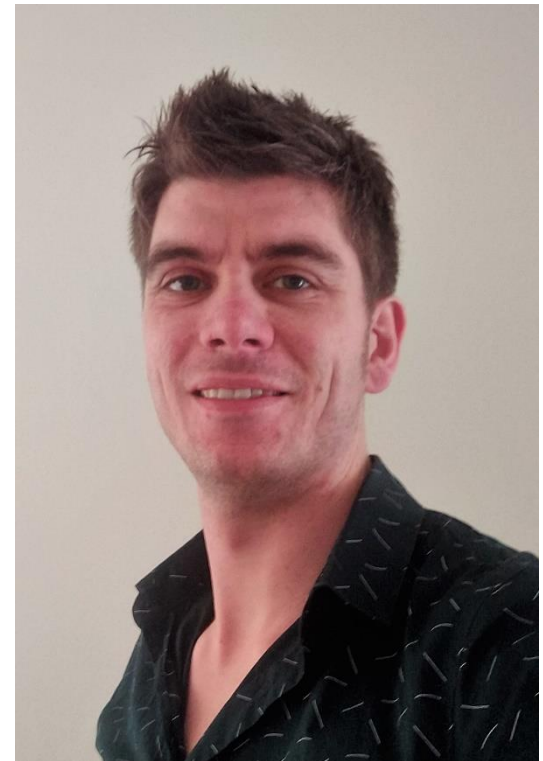
About Patrick Duisters CTEL

- 20+ years experience
 - Software Testing & Quality Assurance
 - Administrative, Technical, Medical, Financial, Governmental, Automotive
- Medical experience:
 - Interventional X-Ray (tester & process mgt)
 - Refurbished Systems (tool validation)
 - Philips Innovation Services (test architect)
 - Biocartis (test architect & usability)
 - Image Guide Therapy: Business Incubation (test architect & usability)
- Test Consultant & Trainer



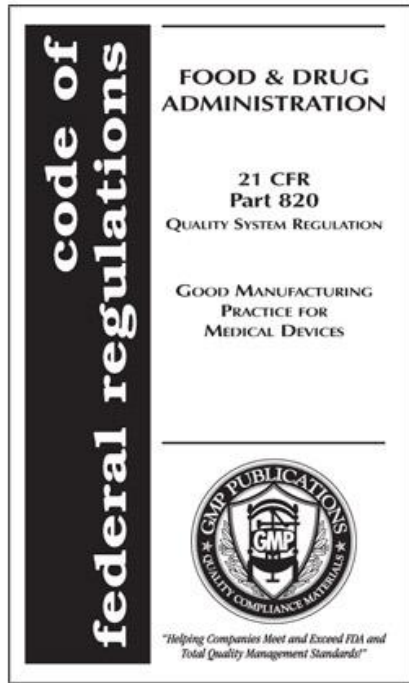
About Johan van Berkel

- 13 years experience
 - Software and Hardware Testing
 - Embedded and Medical domain
- Medical experience
 - Image Guided Therapy Philips
 - Test Designer Geometric domain
 - Digital Computational Pathology
 - Verification Lead ART Scanner
 - Coaching of requirements engineers
- Test Consultant



Background

Medical devices impact human lives for better... or worse:



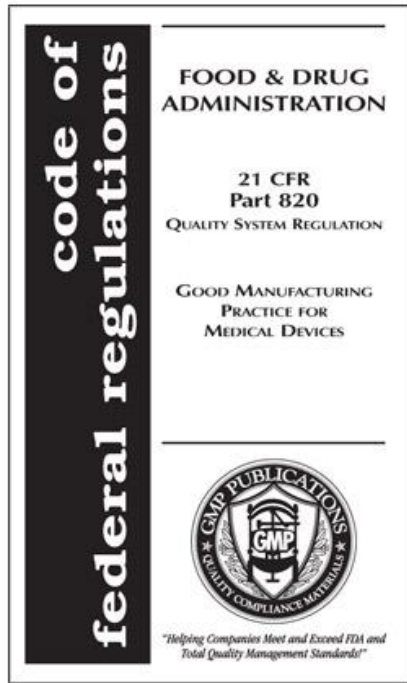
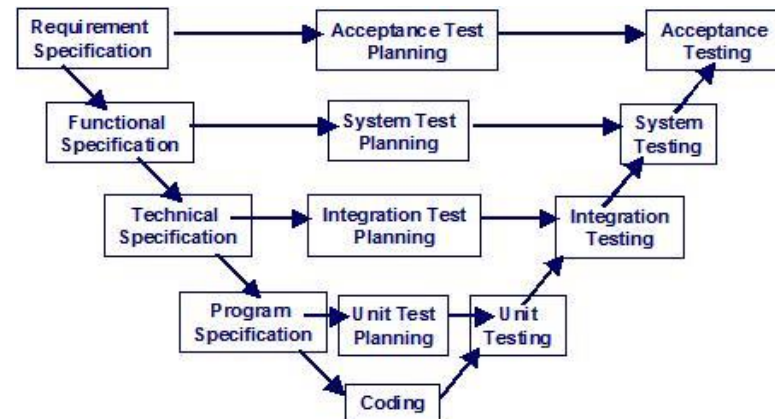
Which is why we need



Therac-25: 2 deaths

Background

Introduced
in the 80's

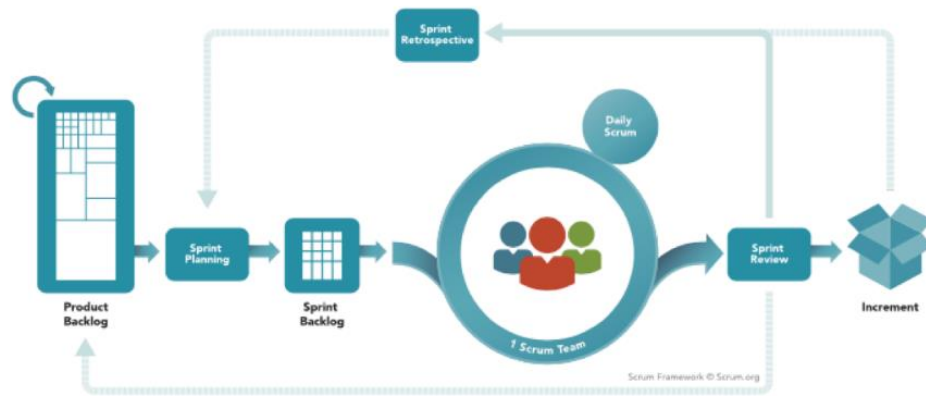
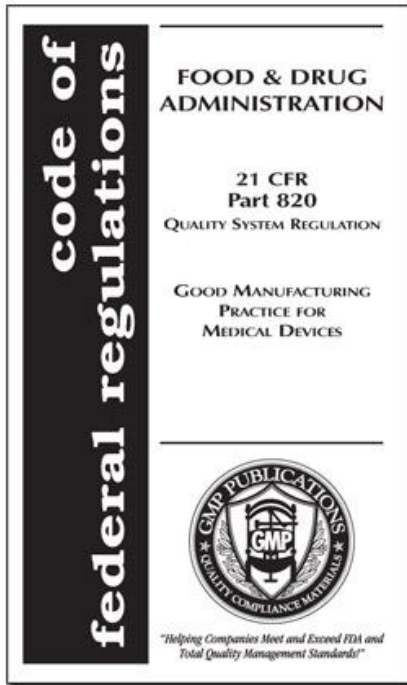


Background

But times change...



NETFLIX



Background

First – some definitions:

Incremental

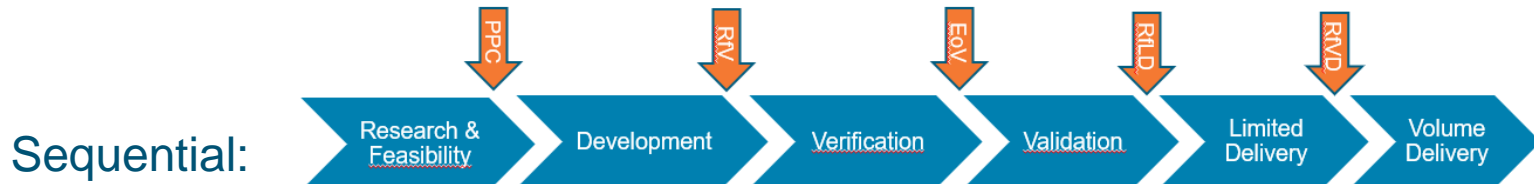


Iterative

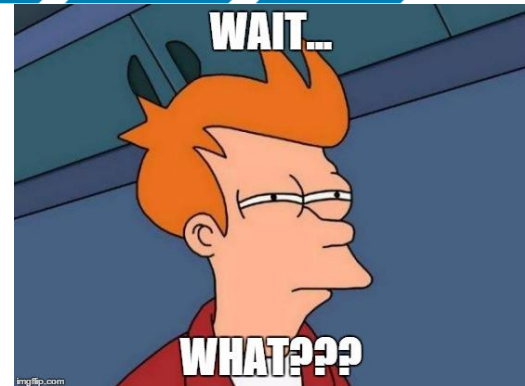
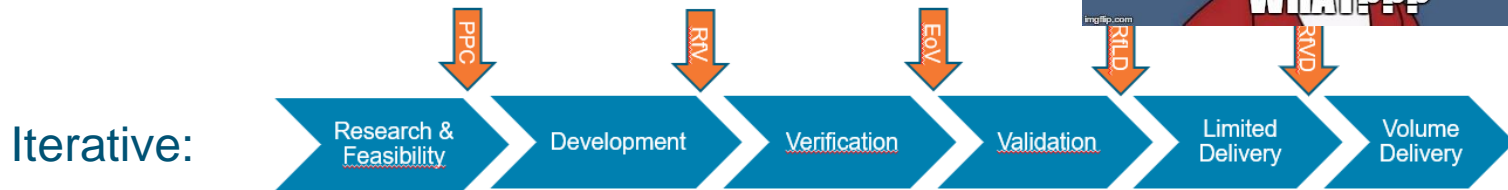


Background

How does that translate to the development process?



VS



Background

Submission teams on
short iterations



Background

The difference is in the details...



Shifting perspective

Lean principles for software development

-  01 Eliminate Waste
-  02 Create Knowledge
-  03 Decide As Late As Possible
-  04 Deliver Fast
-  05 Empower The Team
-  06 Build Integrity In
-  07 See The Whole

Principles are things that are considered worth pursuing, without describing how they should be pursued.

Shifting perspective

Limited number of principles covered in this context



Definition:

Source of confusion:



01 Eliminate Waste



Waste (verb) : “To use or expend carelessly, extravagantly, or to no purpose”



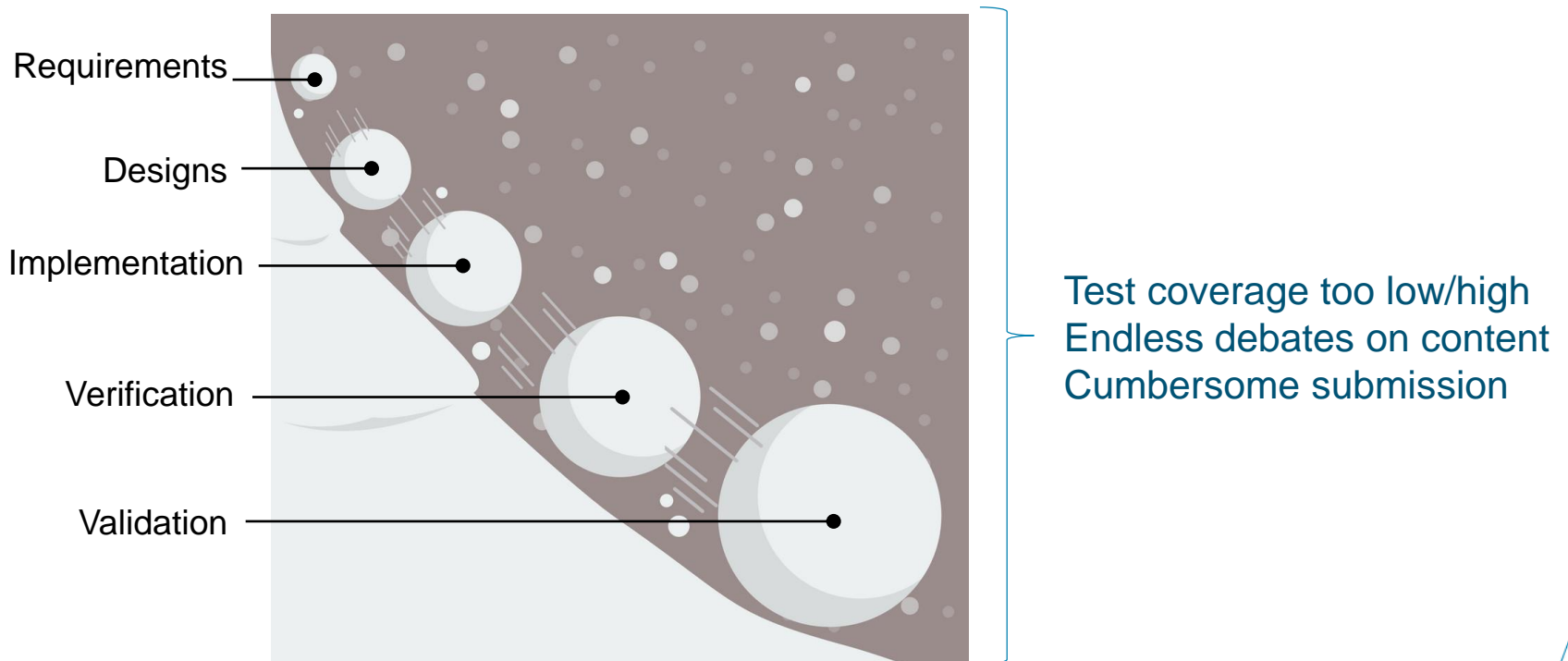
Waste (noun) : “Unwanted or unusable material, substances or byproducts

Symptoms:



01 Eliminate Waste

Waste in requirements is most impactful:



Solutions:



01 Eliminate Waste

Consider the purpose of a requirement:

Why do we create requirements:



Business requirements

Process requirements

What auditors need

What customer wants

Product requirements

Solutions:

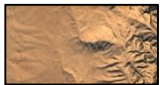
01 Eliminate Waste

Decompose your requirements systematically

Mutually Exclusive, Collectively Exhaustive



High level goal or characteristic of the product

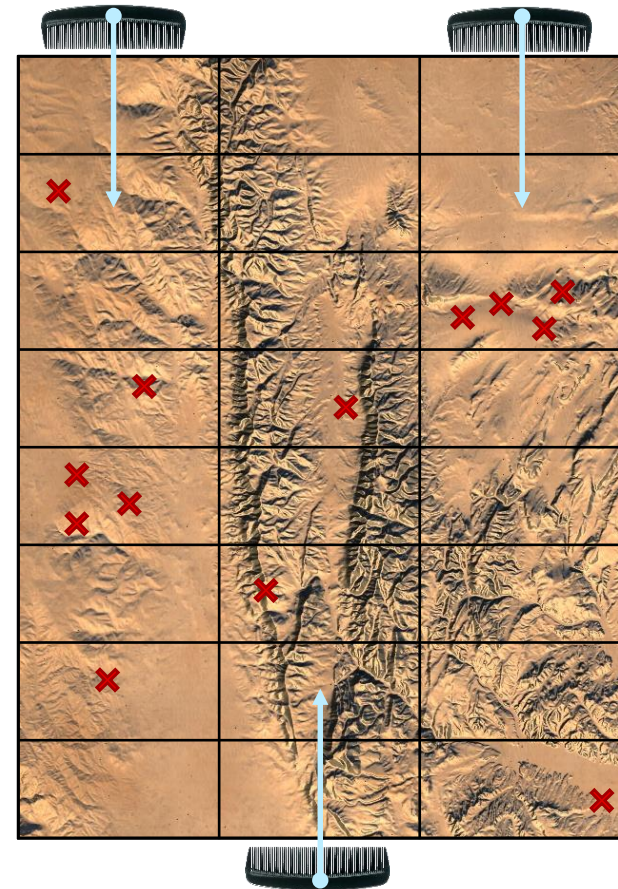


Capability supporting the intended use



(Non-)functional requirement

- Use characteristics that are useful for you
- Define capabilities at high level
- Use customer/user terminology
- Allow requirements to emerge ad-hoc
- Requirement doesn't fit? Tweak the model!



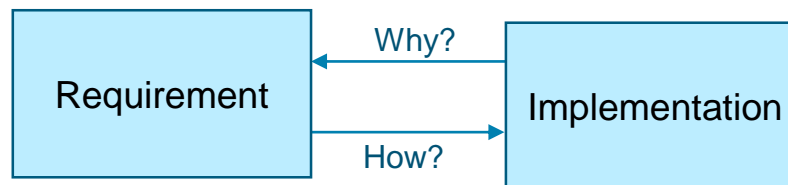
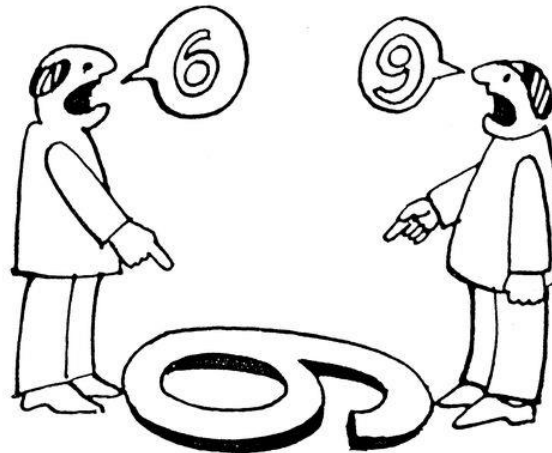
Solutions:



01 Eliminate Waste

Define what constitutes as a requirement:

The how/what paradigm trap:



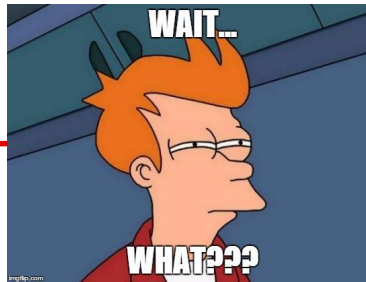
Solutions:



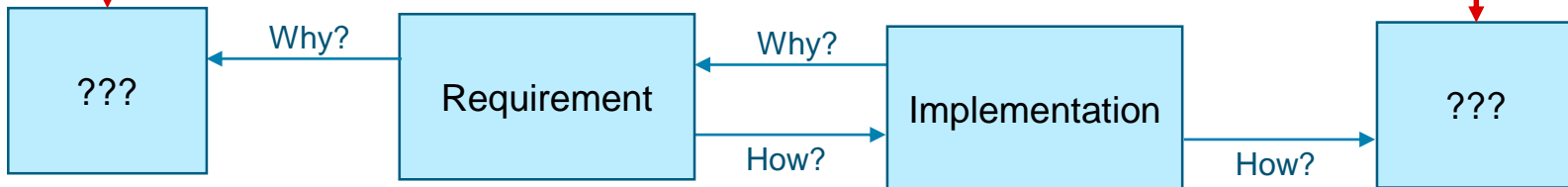
01 Eliminate Waste

Define what constitutes as a requirement:

The how/what paradigm trap:



Requirements are expected to contain "some degree of implementation"



Solutions:

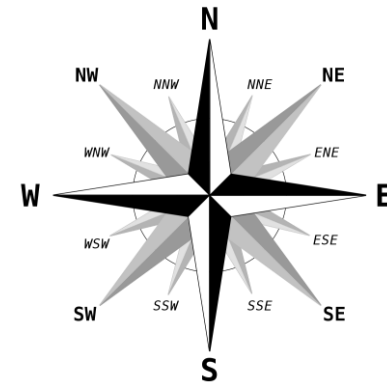


01 Eliminate Waste

Define what constitutes as a requirement:

Some direction:

- Serves a purpose (product, process, business)
- Executable or observable by its user(s)
- Detailed at the level it is expected to be tested
- Can be tested in isolation



There will be opposition:

- Higher number of changes!
 - No: regression is better isolated
- More effort when changing!
 - No: Applying a changing < Discussing changes

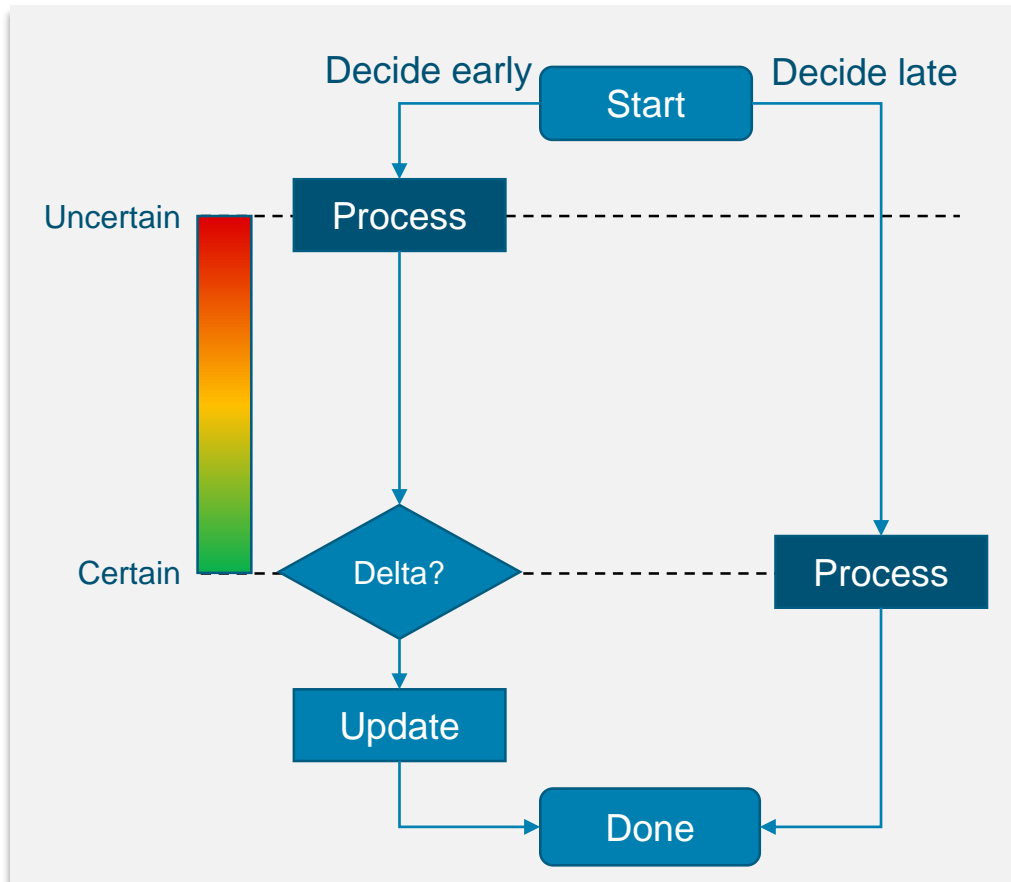


Definition:



03 Decide As Late As Possible

Avoiding decisions for as long as possible in order to save rework:



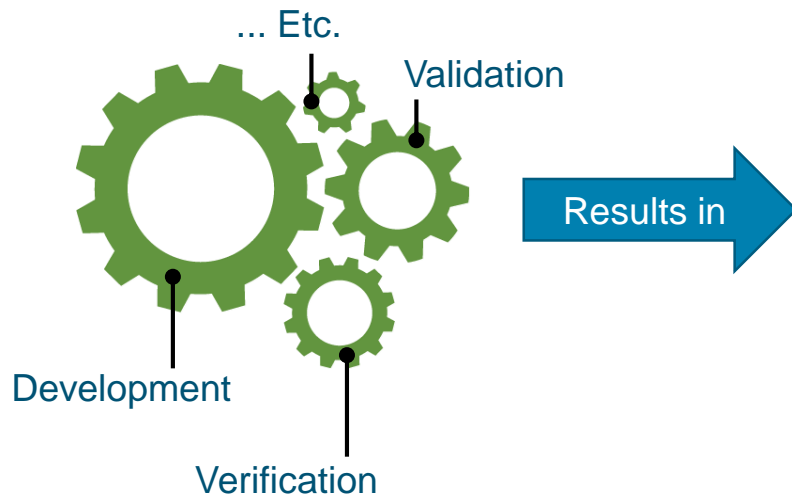
$$\text{Process} + \text{Update} > \text{Process}$$

Definition:

Introducing two key concepts in medical device development:

Quality Management System

How do we create our evidence?



Design History File (DHF):

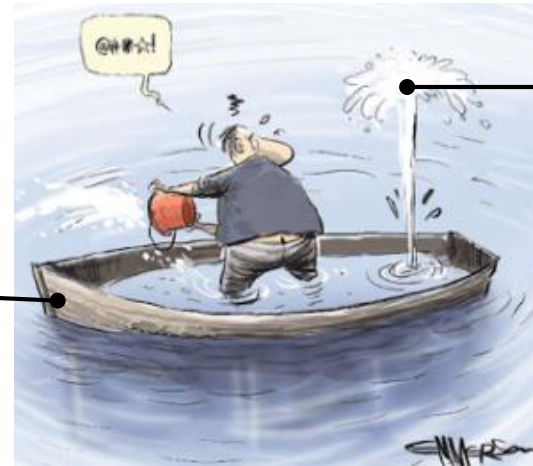
Evidence on safety and effectiveness



Symptoms:

Focusing on the wrong thing...

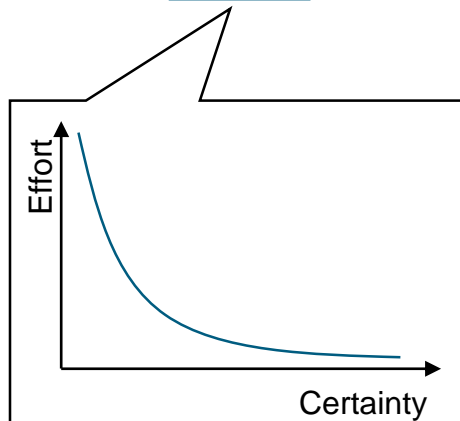
Design History File (DHF)



Risks

...causes heavy refactoring...

$$\text{Process} + \text{Update} > \text{Process}$$



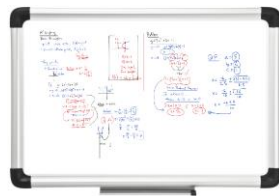
...or worse...



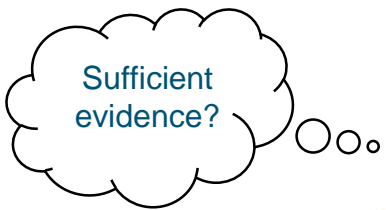
Solutions:

Differentiate between formal and informal processes and documentation

Sprint Backlog			
Forecast	To-Do	In-Progress	Done
1x 1hr Meeting	2x 1hr Meeting	3x 1hr Meeting	4x 1hr Meeting
2x 1hr Meeting	3x 1hr Meeting	4x 1hr Meeting	5x 1hr Meeting
3x 1hr Meeting	4x 1hr Meeting	5x 1hr Meeting	6x 1hr Meeting



Formal process



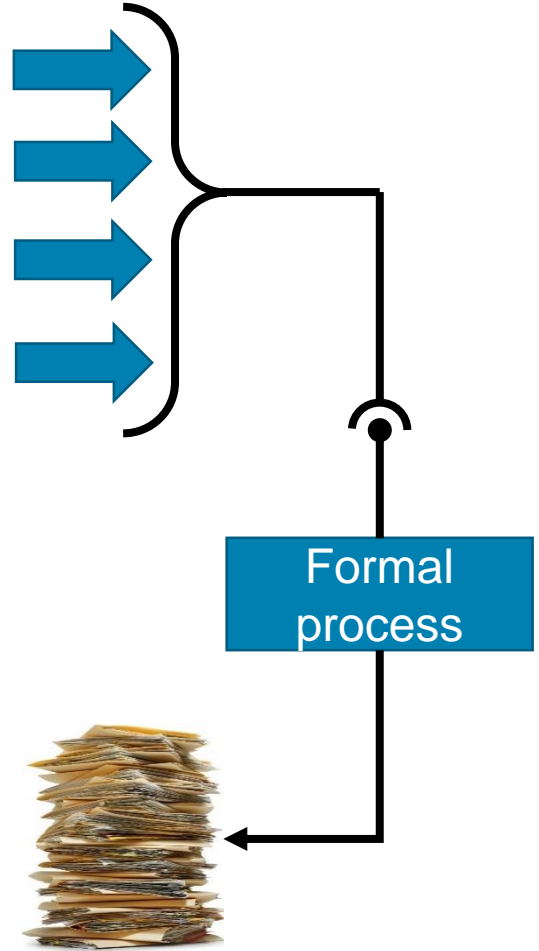
Solutions:

Differentiate between formal and informal processes and documentation

Milestones don't trigger formal processes...

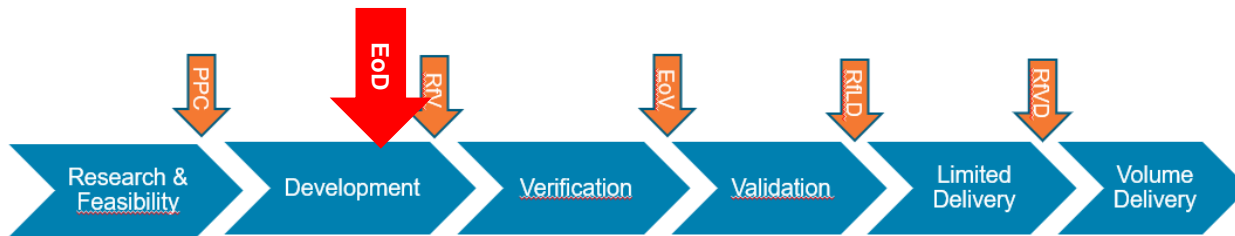


...But updates to the DHF do!



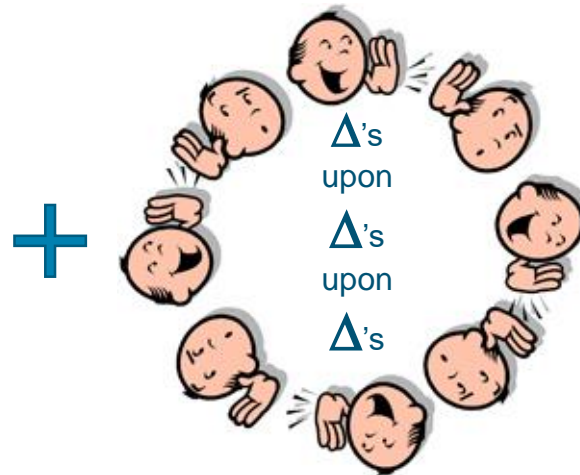
Solutions:

Introduce an informal “End Of Development” milestone



- Mitigates the risks of iterative development:

Narrow view during sprints



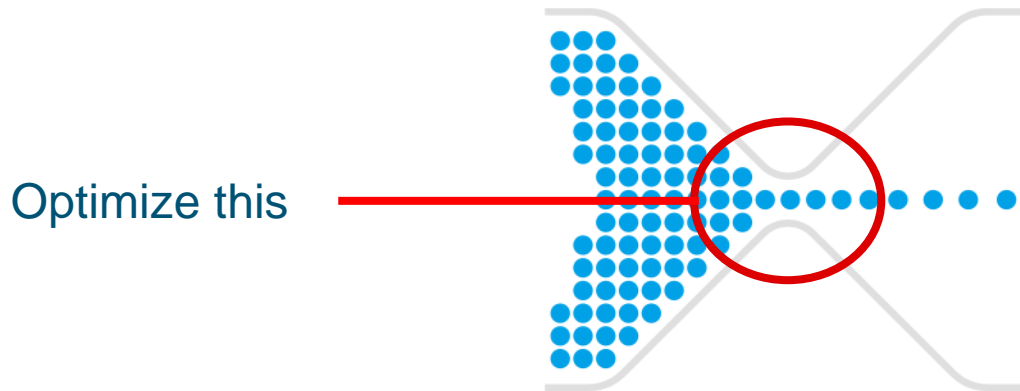
 03 Decide As Late As Possible



 07 See The Whole

Definition:

Optimizing processes and actions,
based on the impact it has on the entire chain:



To avoid doing this →



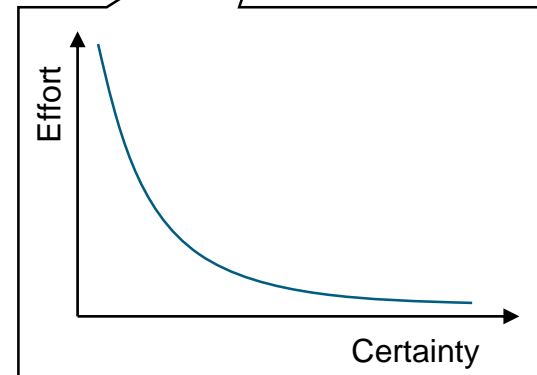
Symptoms:

Forcing formal test cases to be created on immature requirements

Inefficient test execution



Refactoring due to assumptions:



Solutions:

- Write requirements / tests conform their maturity
- Learn and adapt



- Exploratory modeling
- Exploratory testing



- Create test design
- Define traceability



- Create test cases

High effort

Informal

Formal

Low effort

Symptoms:

Prioritizing of product implementation over product maturity

Increases test execution time



Obstructs drawing conclusions

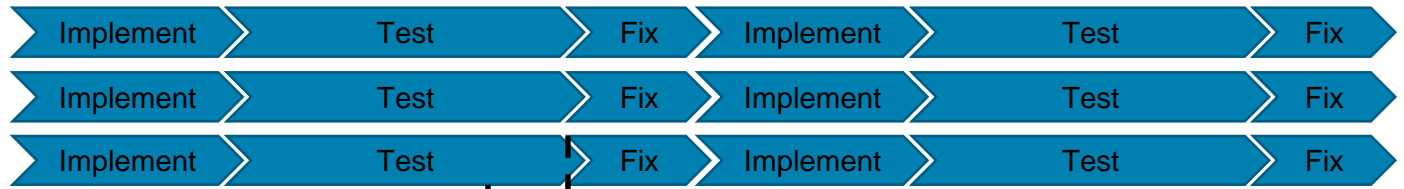


Solution:

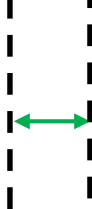


Prioritize test lead time over new implementation

Leave in

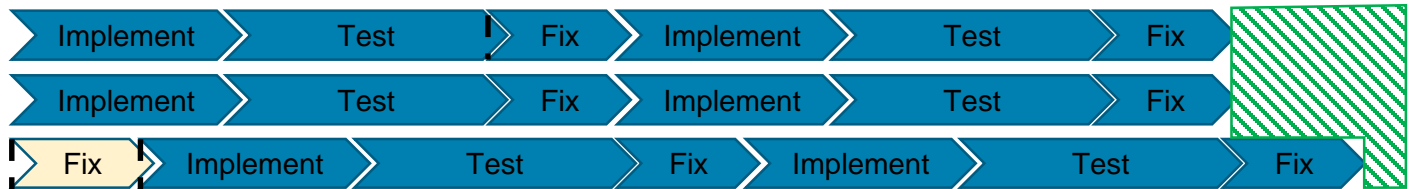


Decreased time needed to test



Increased velocity

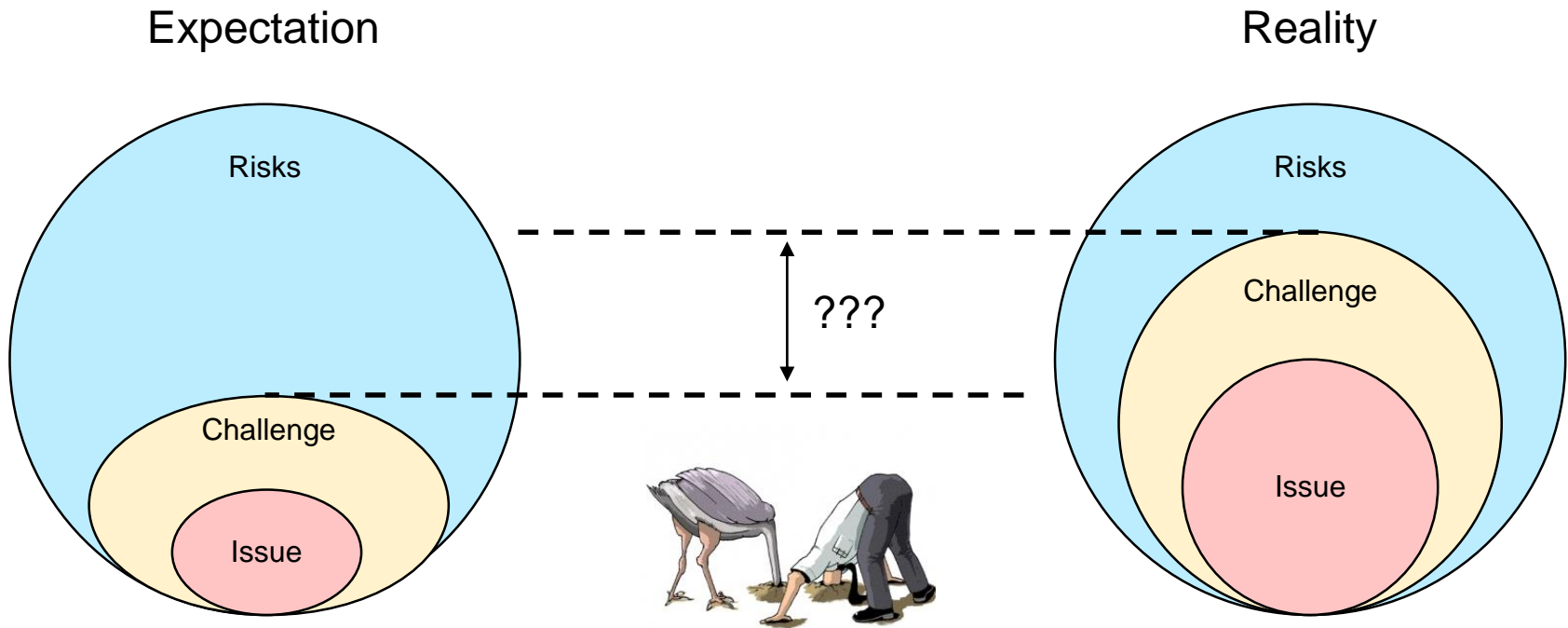
Fix



Cost

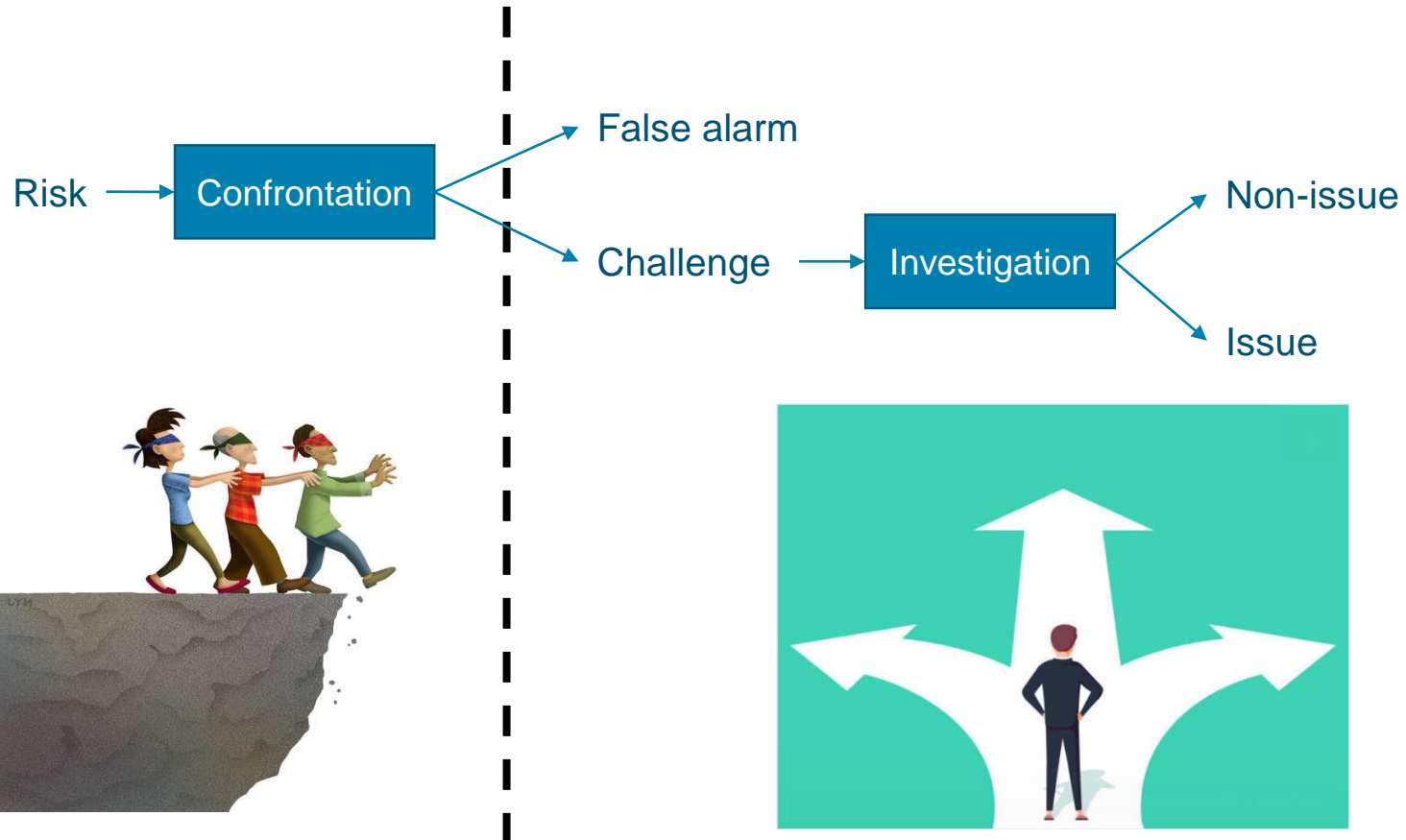
Symptoms:

Risks related to later phases are missed or downplayed



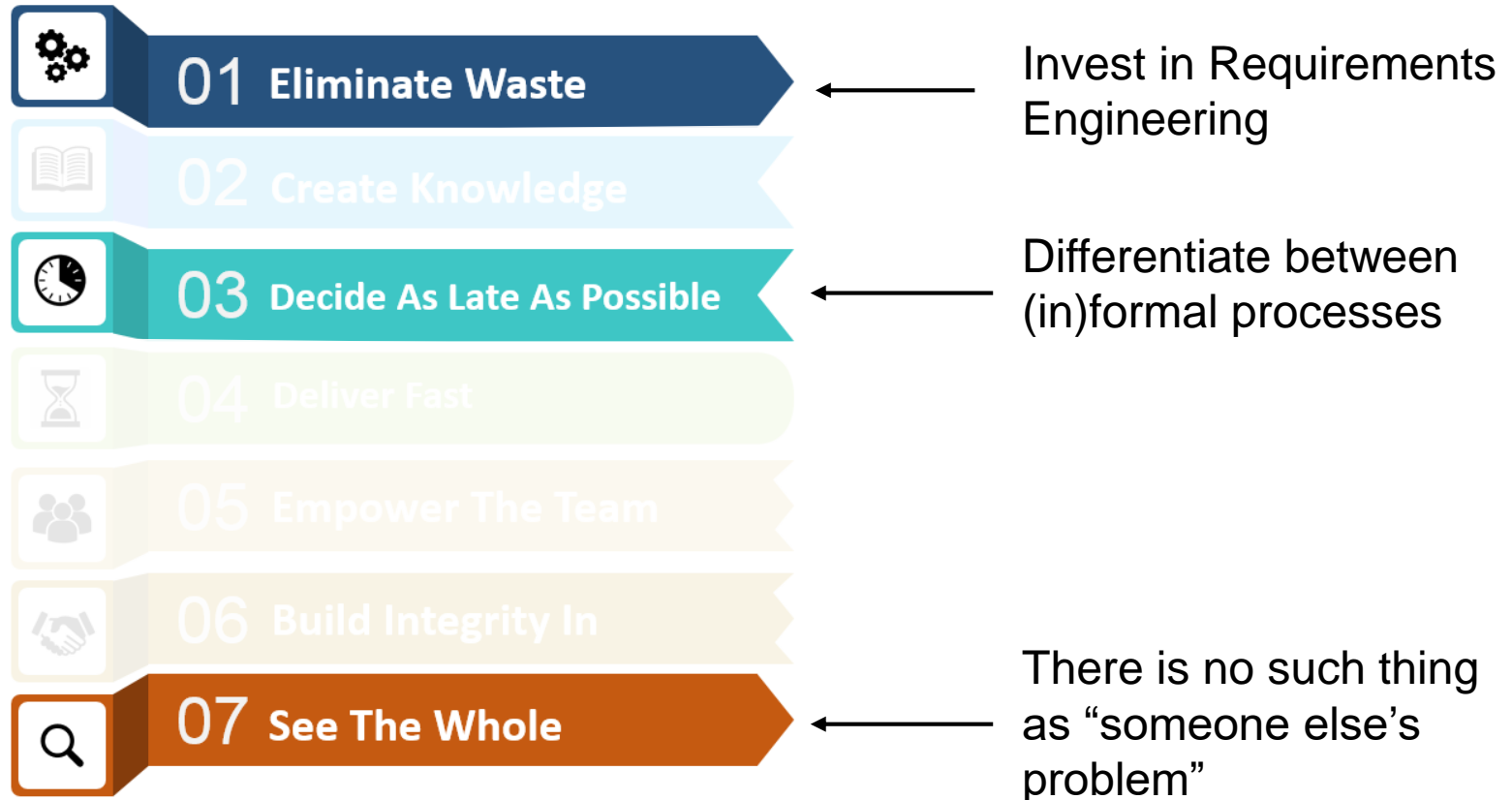
Solution:

Involve stakeholders as earlier as possible



Take home message

If anything, remember this:



Opening the floor for discussion...

