3rd Annual ComplianceOnline

Medical Device Summit - 2017

June 8-9, 2017 | Boston, MA

Documentation for Agile Development

Shared Understanding, Vacation Photos, and Compliance

Brian Shoemaker, Ph.D.
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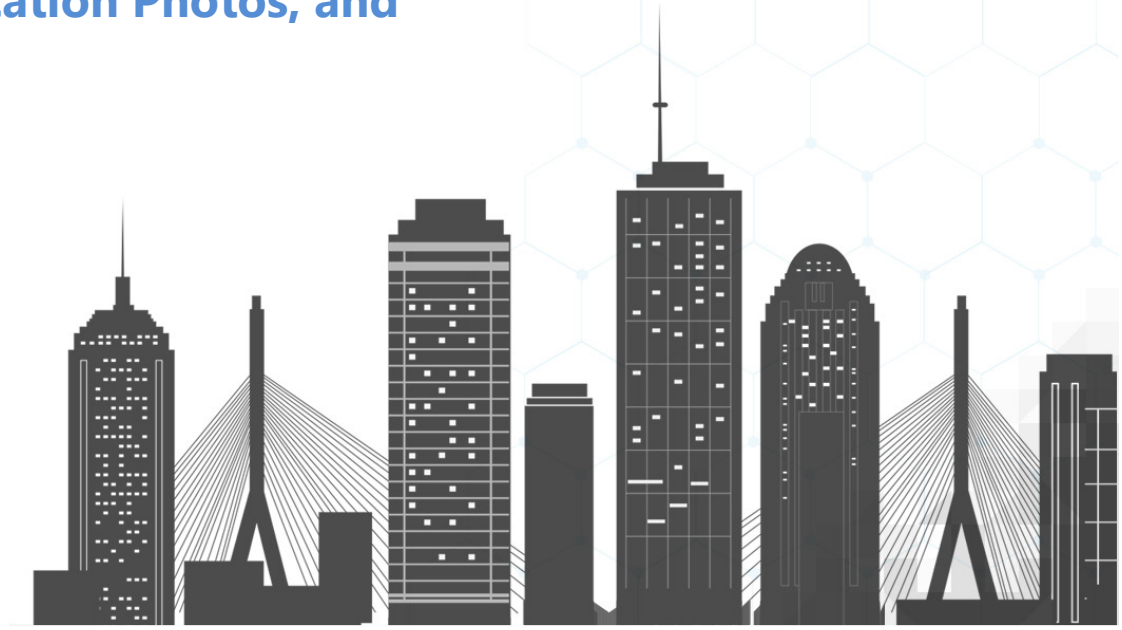

Who I Am

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- Originally an analytical chemist
- 15 y in clinical diagnostics (immunoassay):
  analytical support → assay development → instrument software validation
- 6 y as SW quality manager (5 in clinical trial related SW)
- 12 y as independent validation consultant to FDA-regulated companies – mostly medical device
- Active in: software validation, Part 11 evaluation, software quality systems, auditing, training

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Thesis

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If created efficiently, compliant documentation doesn't drag down development, but adds value.

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Shared Understanding, Vacation Photos, and Compliance

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- Are the demands contradictory?
- *What do regulatory bodies REALLY require?*
- *Where do most companies get bogged down?*
- *Practices let us bridge the apparent gap*
- *The core values align*

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Documents … Documents …

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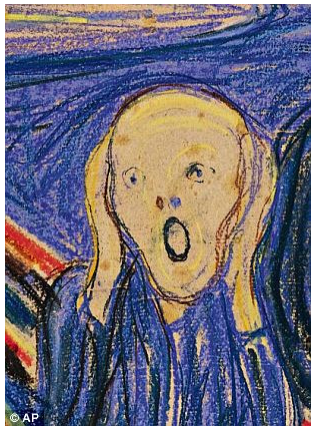
Project Plan

User Requirements

Design Document

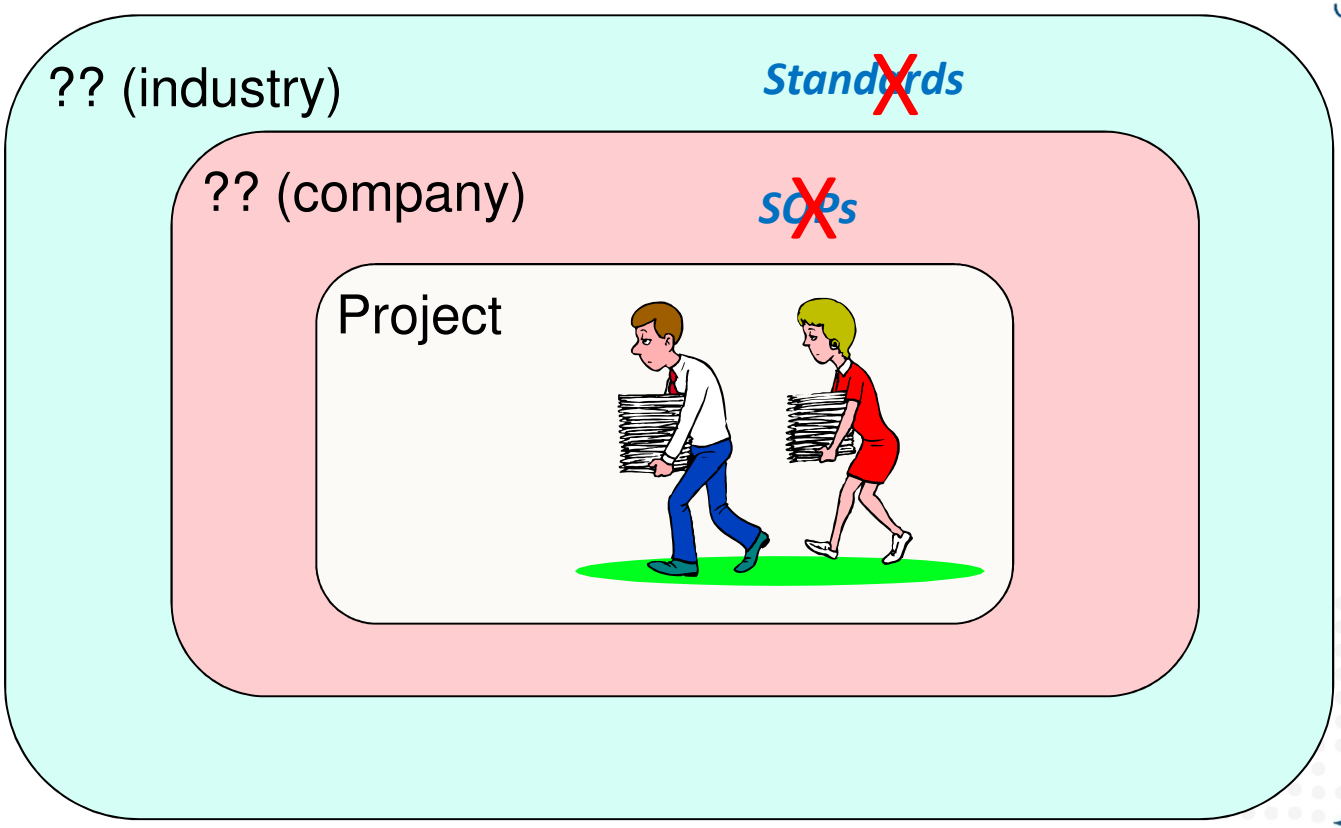


Tests and traceability

Hazard Analysis

Image: http://www.dailymail.co.uk/news/article-2138678/Edvard-Munch-The-Scream-painting-fetches-119m-Sothebys-auction.html

Topic here: output docs, not process



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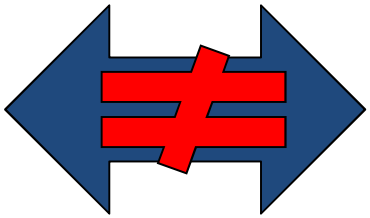
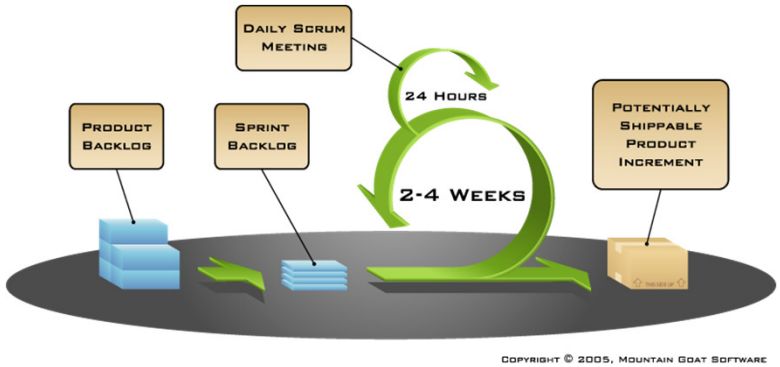
Contradiction?





These aren't inherently incompatible – but documentation is the big struggle for many teams!

Scroll Image: http://www.nifter.com/free_clipart_downloads.htm

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Different Focus

- ***Agile perspective***:
  Maximize delivery of customer / stakeholder value
- ***Regulatory perspective***:
  Quality
  Safety
  Effectiveness

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Agile Manifesto Says?

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Agile 12 Principles?

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- Satisfy customer: deliver software which has value.
- Welcome changing requirements.
- Deliver working software frequently.
- Business and development must work together throughout.
- Allow motivated individuals to get the job done.
- Communicate face-to-face!
- Working software is the primary measure of progress.
- Develop at a sustainable pace.
- Being Agile also means technical excellence and good design.
- Keep it simple - maximize what you ***DON'T*** do.
- Self-organizing teams produce the best work.
- Teams must regularly reflect and adjust how they work.

Paraphrased from http://agilemanifesto.org/principles.html

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AAMI Agile TIR: Valuable Discussion

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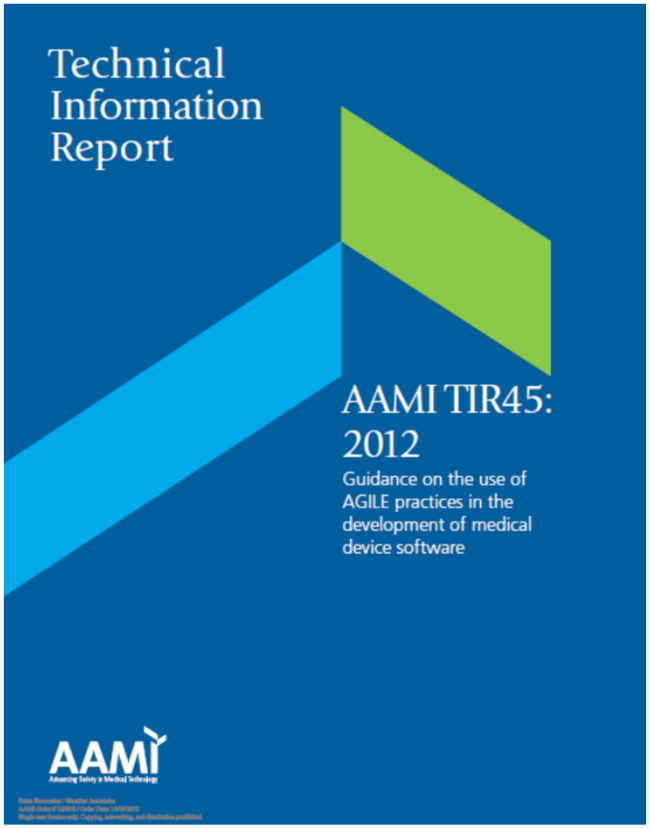

- Document issued in August 2012
- Discusses how Agile approach, regulatory demands can coexist
- Authors came from industry, Agile community, regulators

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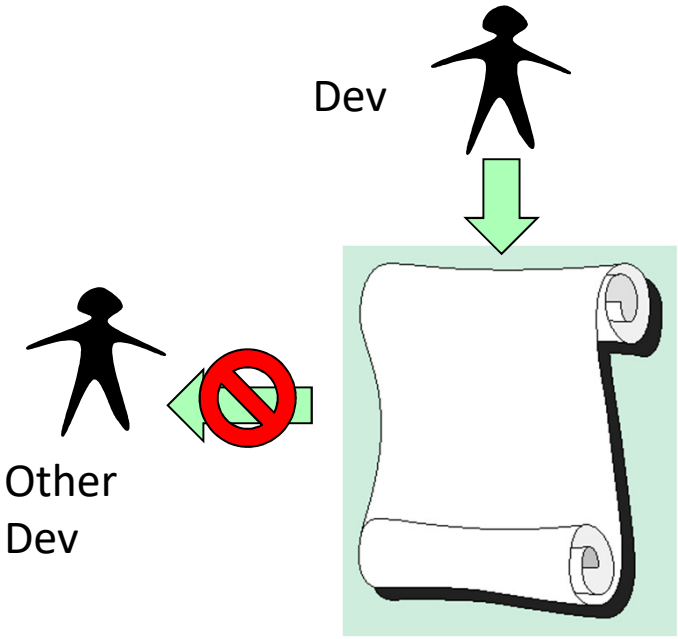
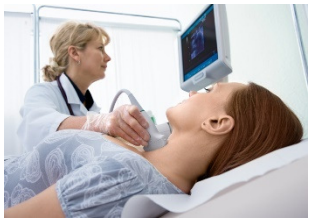
Who is the Audience?



Internal: QA, RA, mgmt

External: Regulatory, Certification



Customers (sometimes)

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Shared Understanding, Vacation Photos, and Compliance

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- *Are the demands contradictory?*
- What do regulatory bodies REALLY require?
- *Where do most companies get bogged down?*
- *Practices let us bridge the apparent gap*
- *The core values align*

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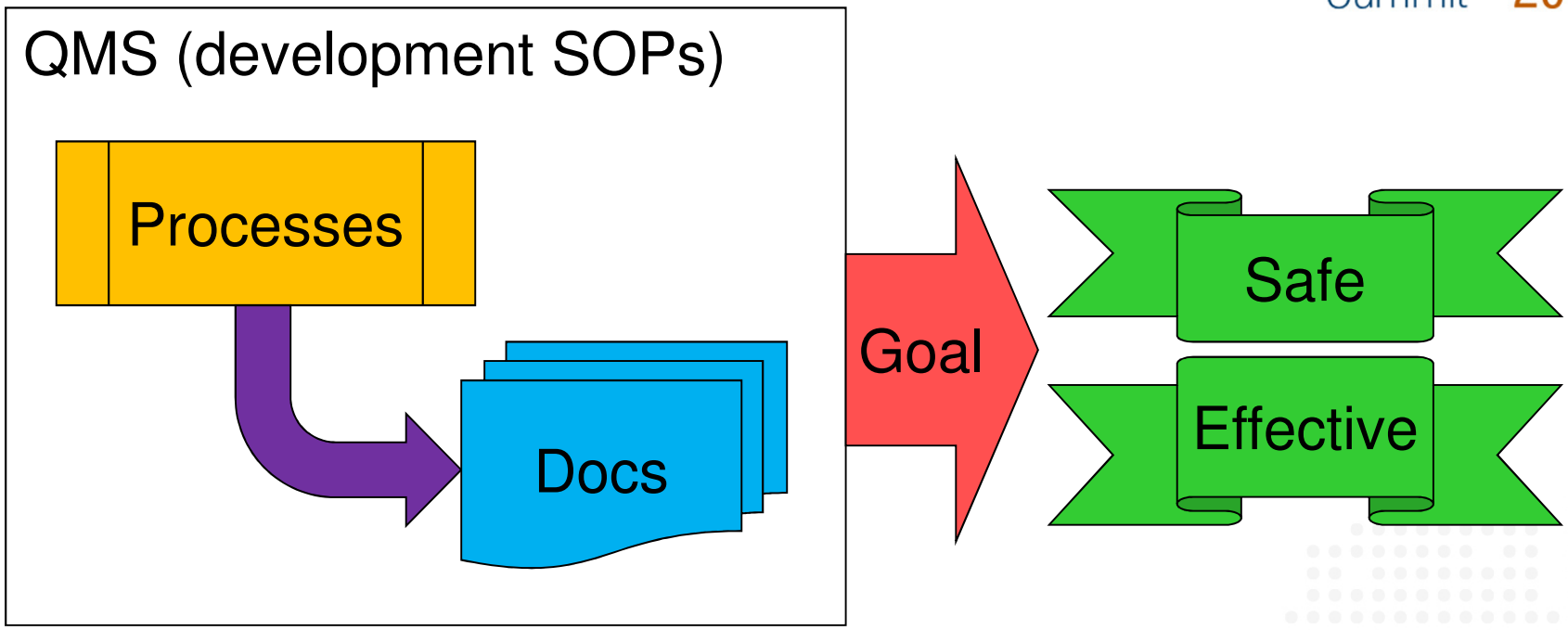
Documents as Evidence



GOAL is crucial; docs provide evidence. *Process* is up to you.

Docs need to provide . . .

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This

NOT This!

GPSV* discusses development TASKS, but never lists a specific set of required documents!

* FDA, General Principles of Software Validation

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Docs are required for Design Control

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Elements to be documented for design control*:

- Design and development planning
- Design input
- Design output
- Design review
- Design verification
- Design validation
- Design transfer
- Design changes
- Design history file

These are activities – not specific documents!

* From 21 CFR Part 820. ISO 13485 lays out similar expectation, though not as explicitly.

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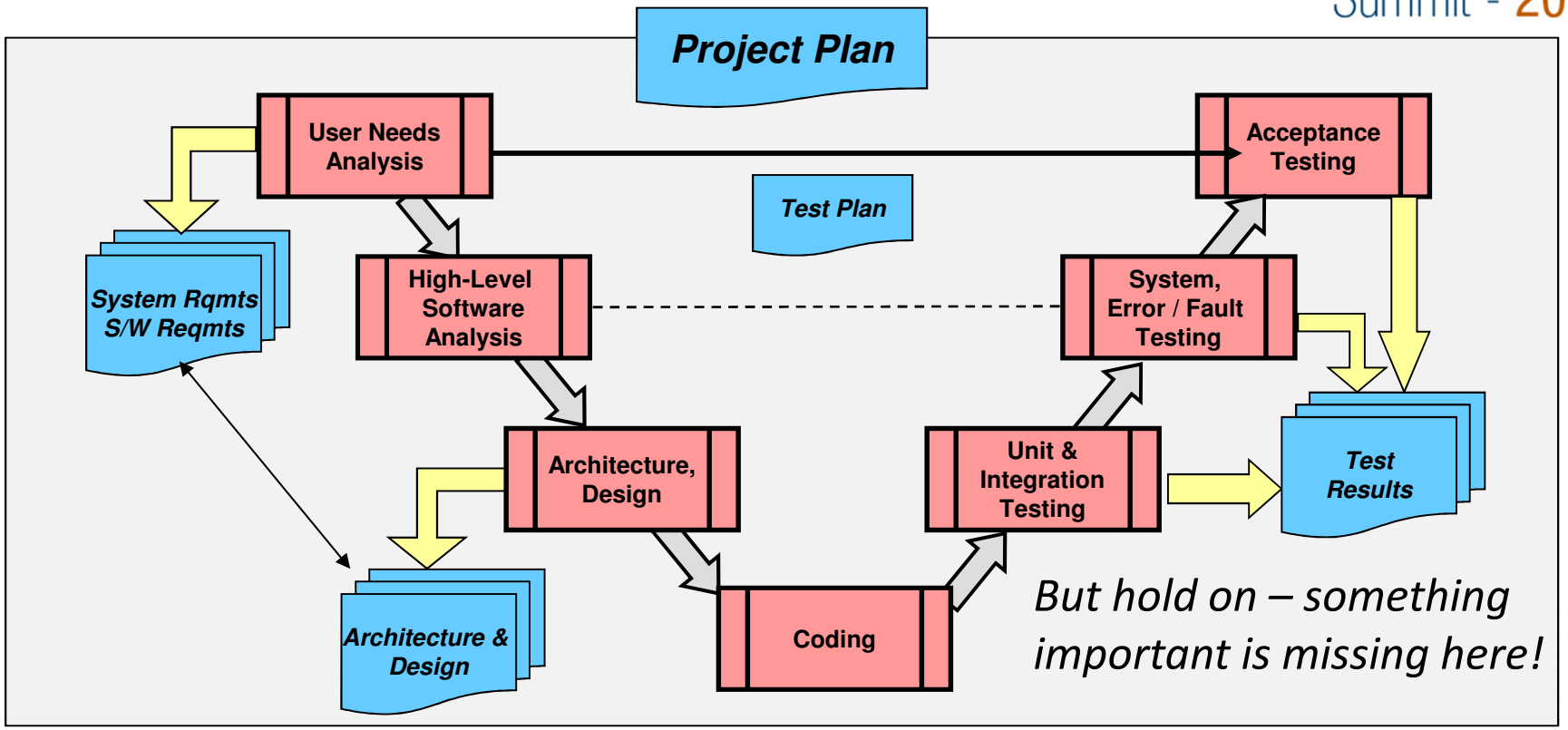
Typical Docs: Linked to Processes



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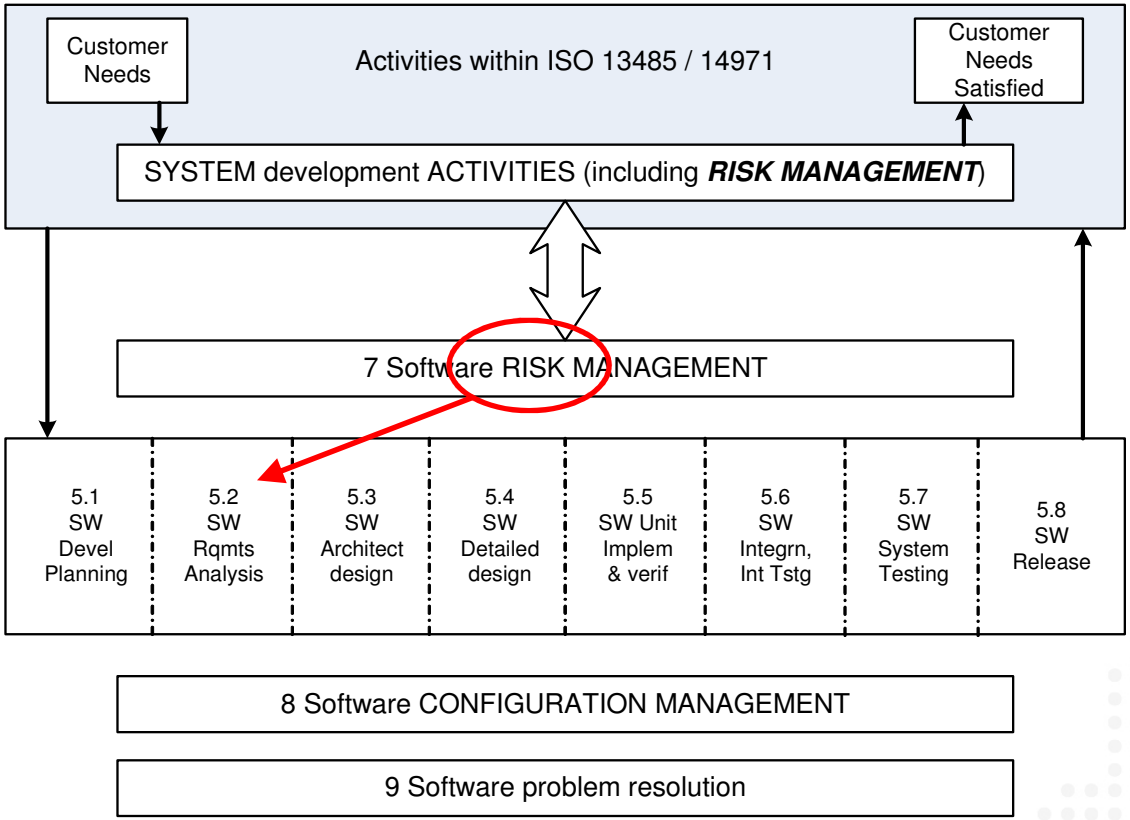
62304: Manage RISK in Development



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What Your Documents Show

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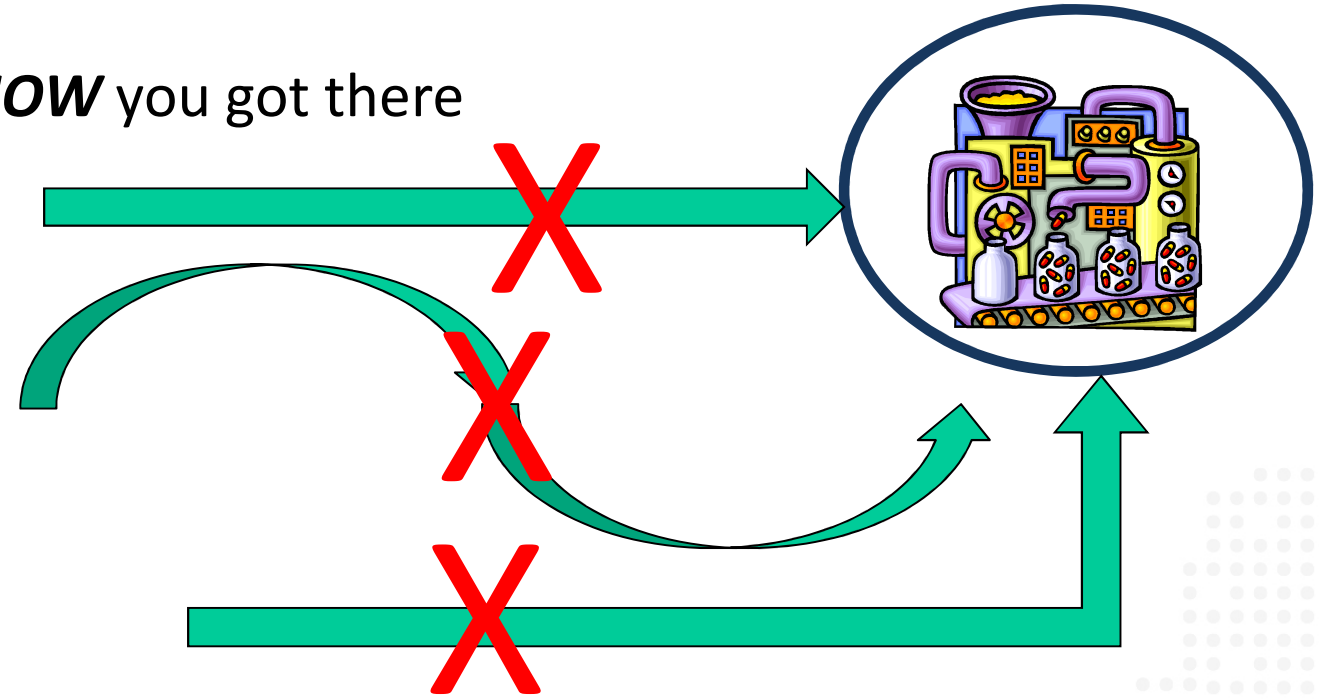
WHAT you generated

Not ***HOW*** you got there



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Top Seven Myths

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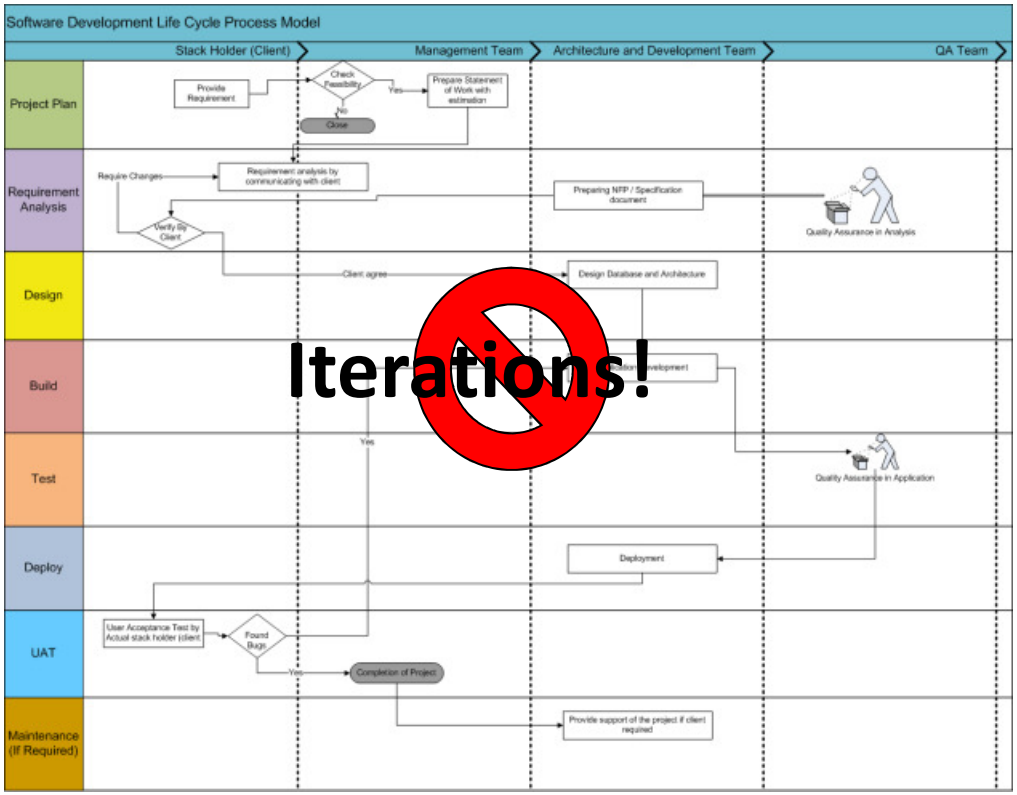
- You must complete the design before you build
- You must document and approve all your requirements before you start your design work
- Developers will build the wrong things unless we prescribe every detail for them
- You cannot meet a fixed deadline unless you know all your specifics ahead of time
- A plan has to define explicitly all the activities (design, development, test) that will be carried out
- We are required to review and sign a document any time we make any change
- A design review only 'counts' if all stakeholders are present and there is a complete and through review of the entire design

Restrictive Development Process



- Development SOP like this?
- Can't change all at once
- Look for deviations / exceptions clause
- Start with one or a few projects

Figure source: www.amipatelit.com/tag/sdlc-diagram

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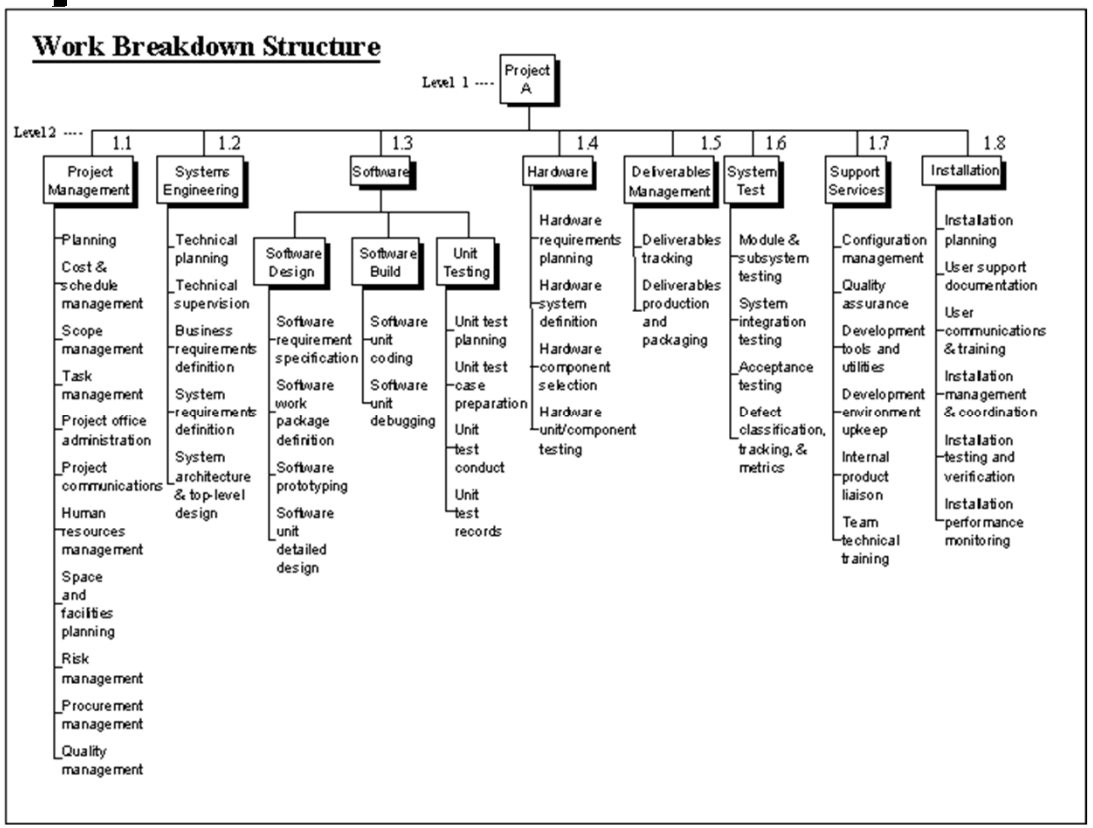
Upfront Plans – Excessive Detail



How can details for all stages of a project be planned before the specifics are explored and known?

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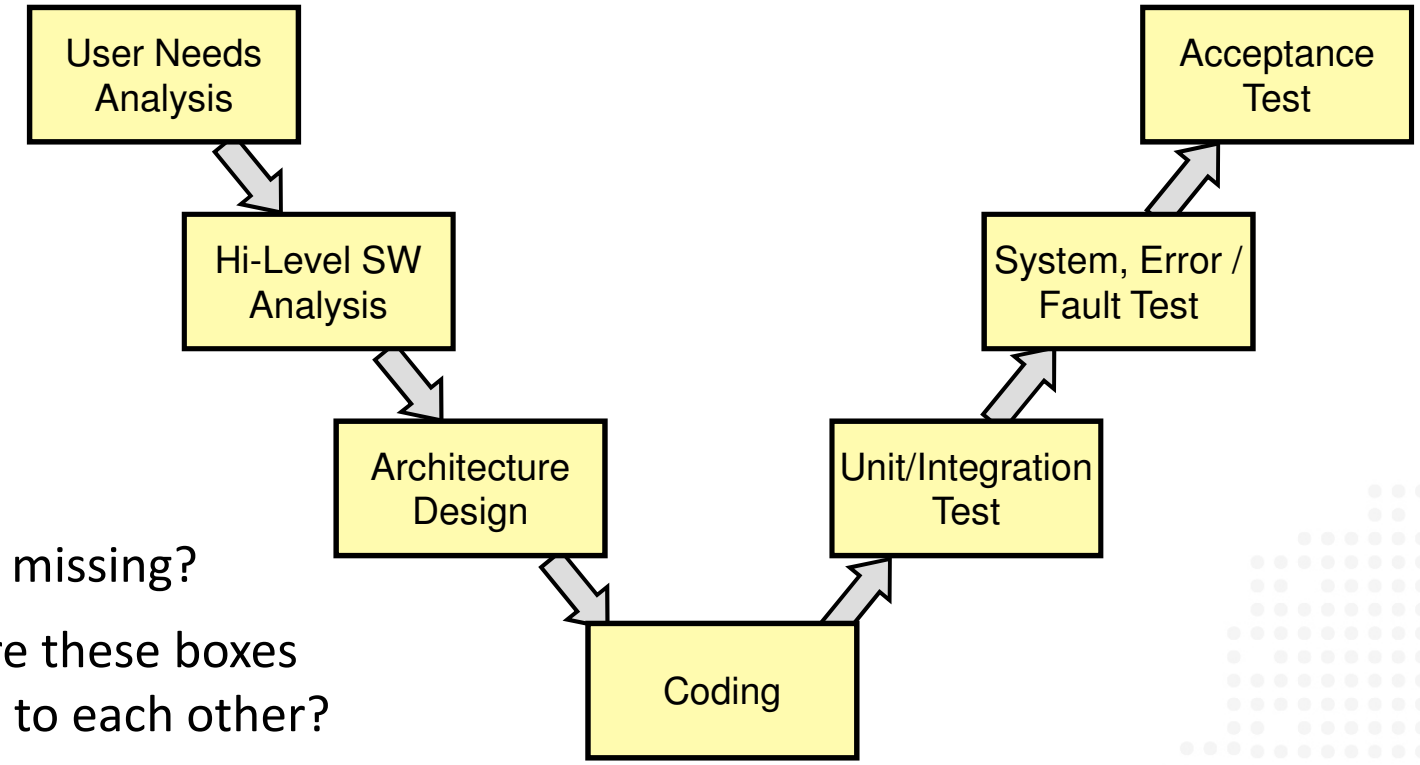
"Linear" Thinking



- What's missing?
- How are these boxes related to each other?

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Reqmts / Design = Prose?

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- Is this what software documents should look like?
- How will many engineers view developing documents like this?
- What happens to prose documents as design is modified during development?
- When is traceability usually established?

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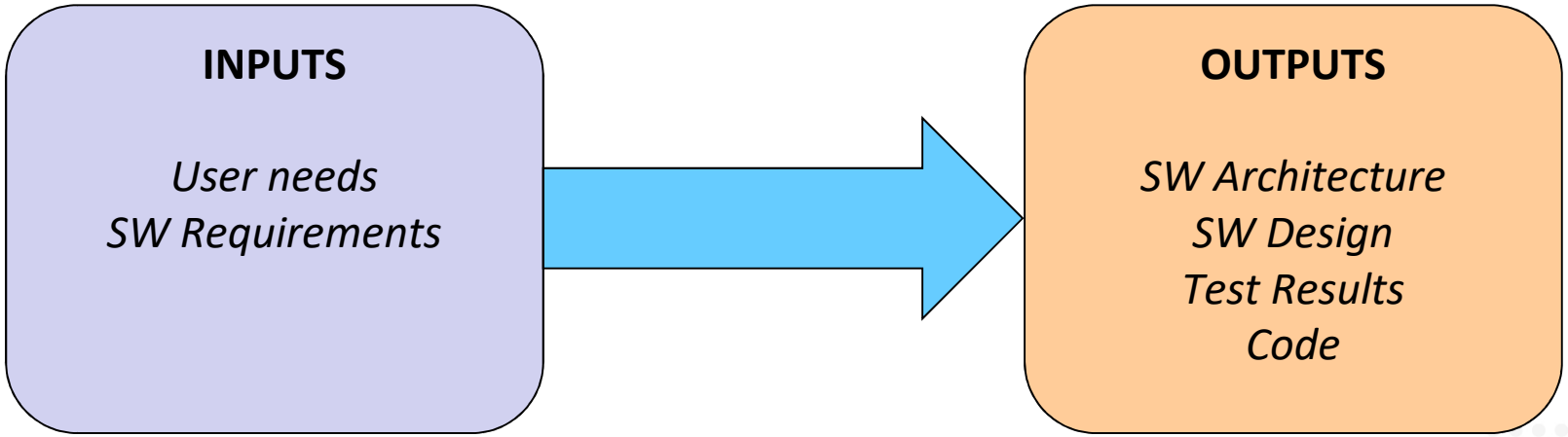
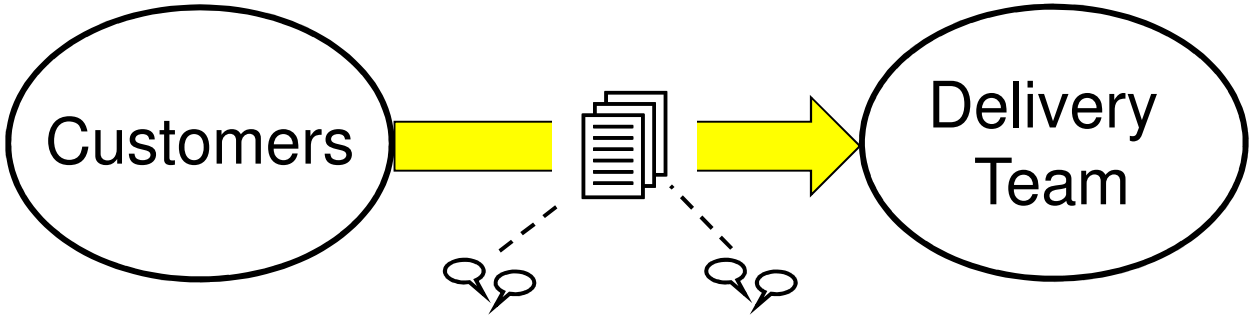
Concurrent, not Subsequent



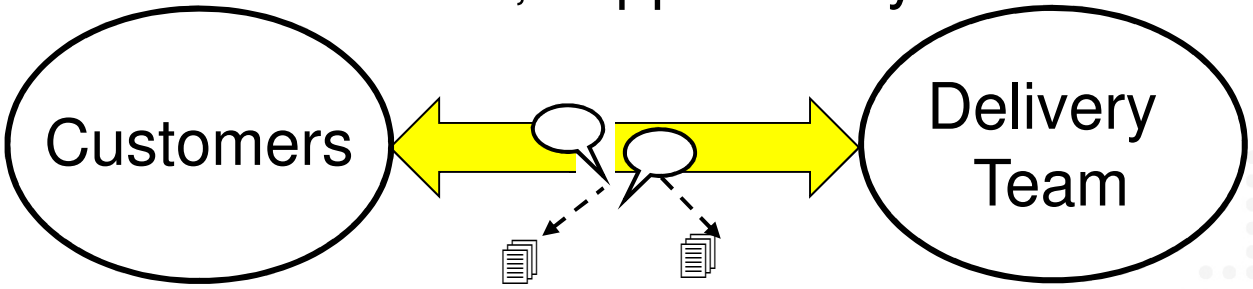
Consider: Do good documents result if we try to write them after everything else is done?

Using documents to communicate

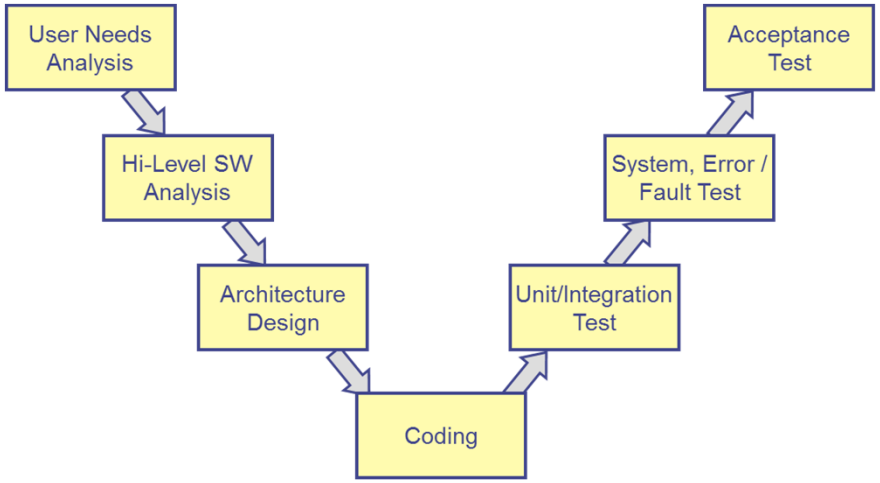
- Document-centric, supported by Conversation

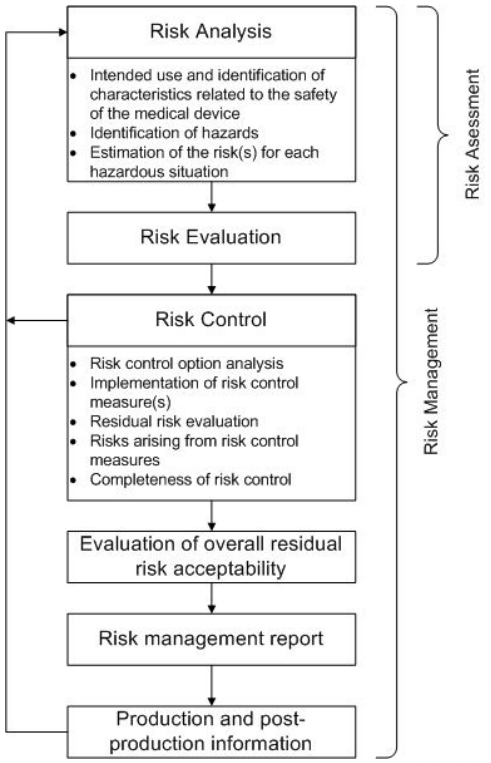


- Conversation-centric, supported by documents



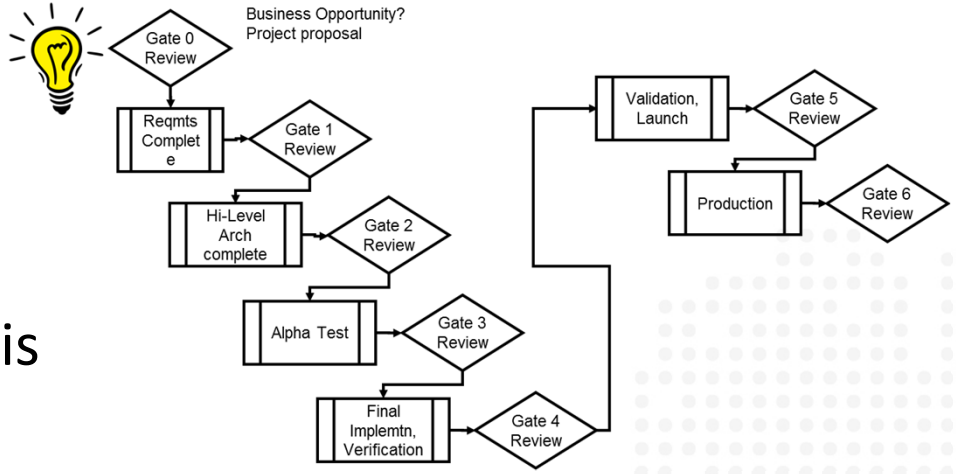
Risk Mgmt / Development Disjoint





"Big Bang" Design Reviews

Do design reviews usually look like this?



Does your process mandate this many reviews ?

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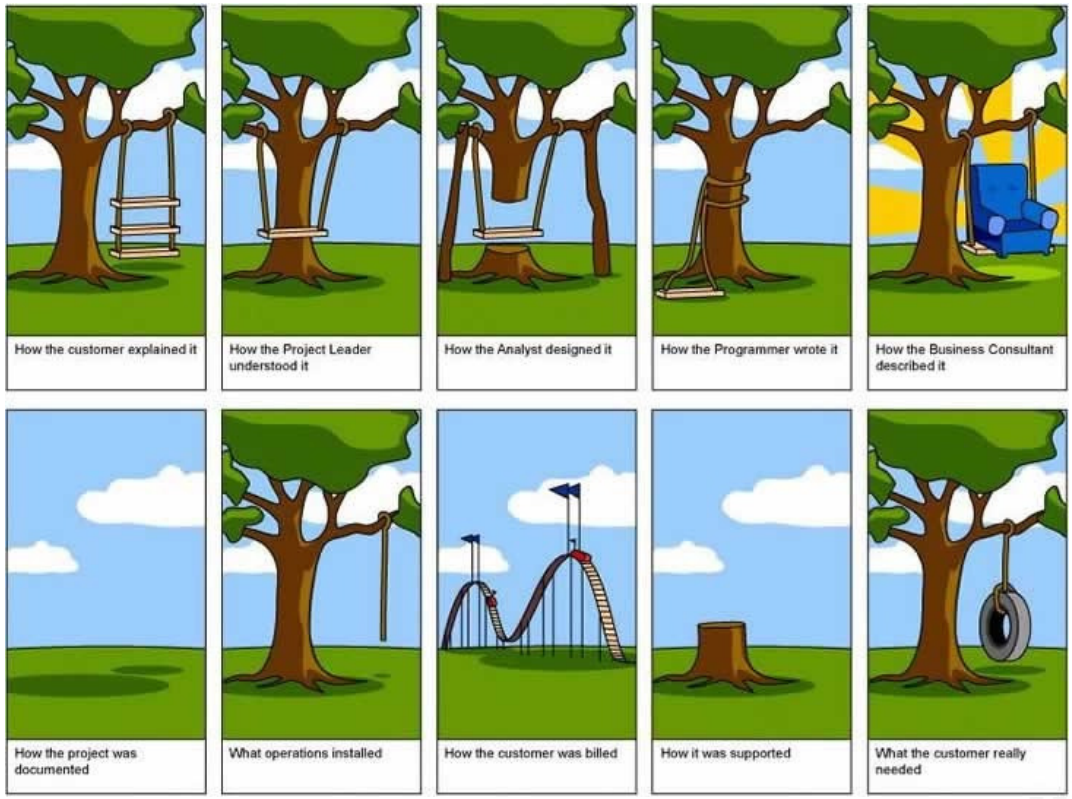
Have you ever experienced this?



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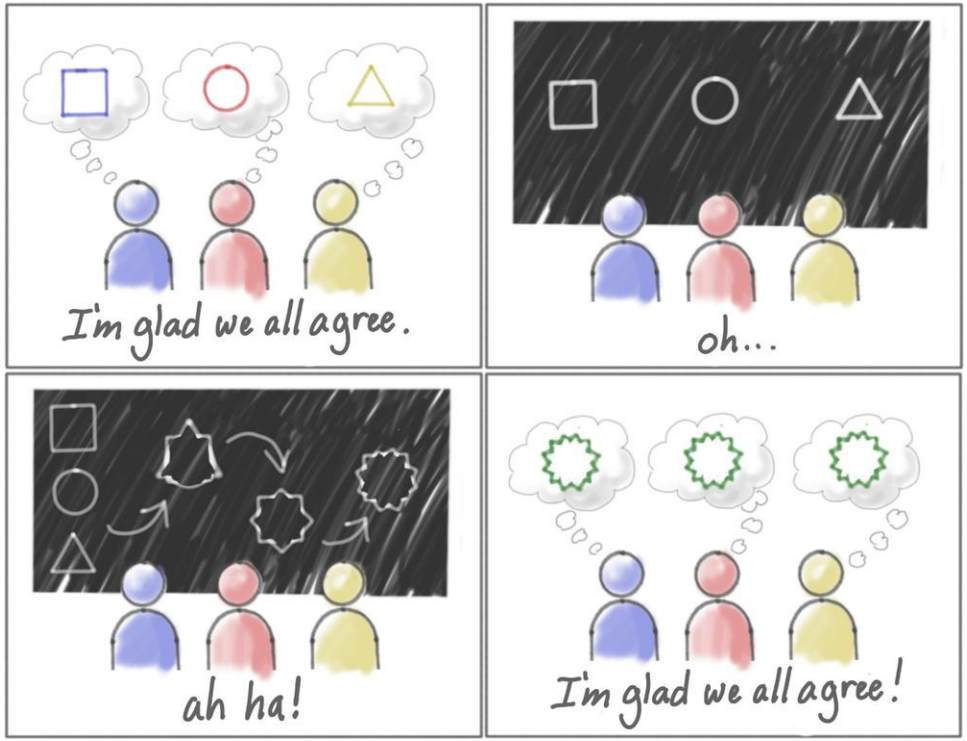
The Goal: Shared Understanding!



Source: Patton, Jeff, and Peter Economy, *User Story Mapping: Discover the Whole Story, Build the Right Product*, Sebastopol CA, O'Reilly Media Inc, 2014.

Documentation: What was done

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From TIR 45:

'In an AGILE model, where a team is working together on a set of activities, documentation is less important to initiating an activity ("when we begin") and guiding an activity ("while we are working"), but documentation is still important to communicating the results of the activity ("when we are done").'

Jeff Patton describes this as "taking vacation photos" so that the team can remember what they agreed on.

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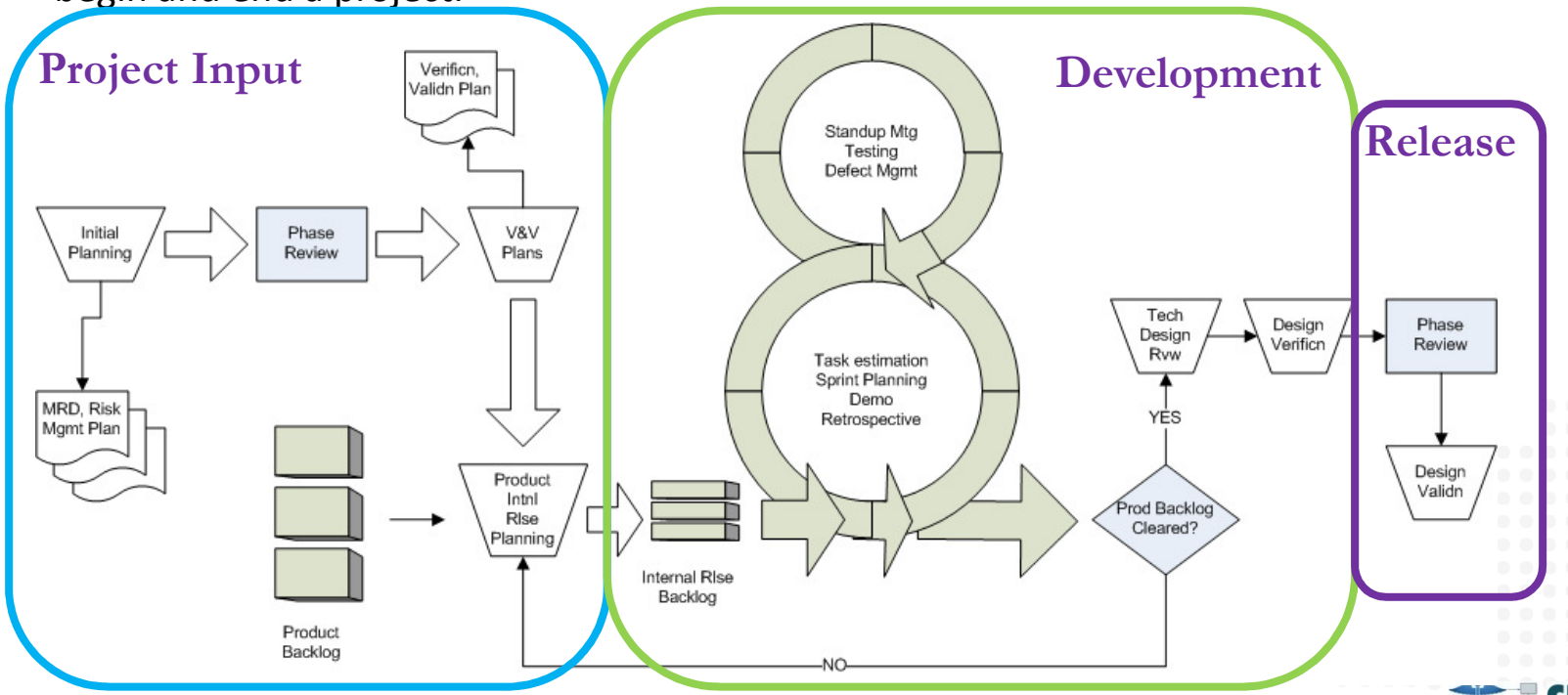
Get Lifecycle Model Out of the Way

Allow flexibility in the development process, while still requiring the important gates to begin and end a project.



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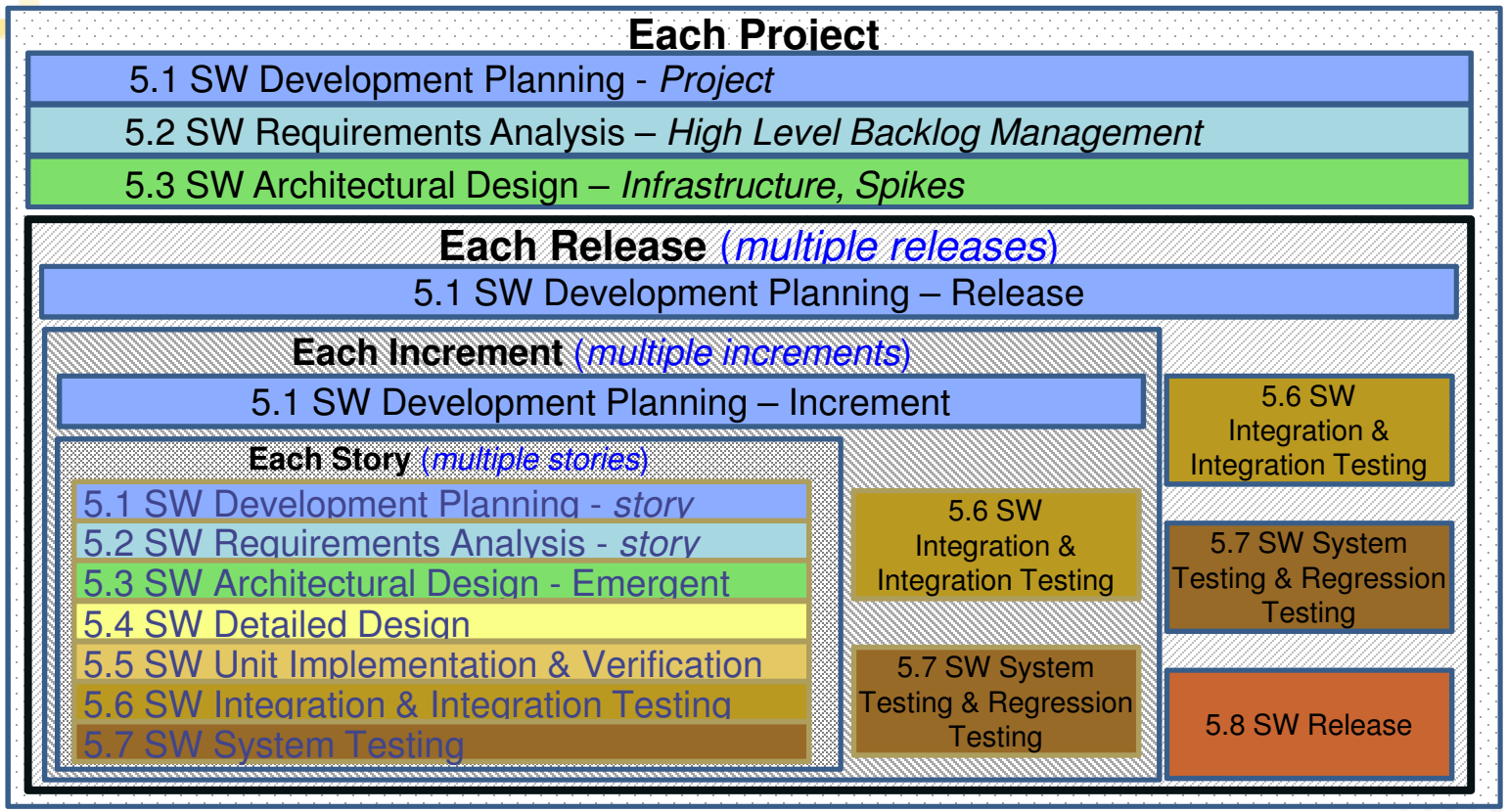
Plan at MANY Levels!



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Plans can be more formal or less

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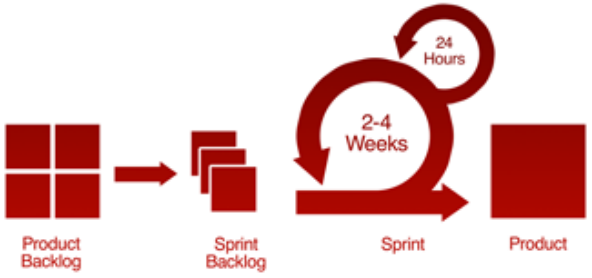
Formal – high level

Goals
Resources
Milestones
Deliverables

An Agile team will find that they need more than a backlog and release strategy to cover some of these planning topics. They now will have to write formal plans around such subjects as testing (at all levels), risk management, and software configuration management. A good way to remain Agile is to document the high-level strategy / resources / schedules / milestones and use the story creation / backlog / increment / release management to plan and execute detailed tasks. Together, they form the software development plan for a project.



Less formal
(emergent details)

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Generate Requirements Naturally

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Is there any reason your requirements need to look like this?

Gauge Data

R_D1	The metrology lab needs to maintain an up-to-date list of all gauges.
R_D2	The metrology lab needs to store properties, calibration dates, and calibration data for each gauge.

Gauge Operations

R_O1	The metrology lab needs the ability to set and track status of each gauge (in lab, checked out, out for repair, out for calibration, inactive).
R_O2	The metrology lab needs to be able to calibrate any gauge which is considered available (i.e. in lab and Master Gauge calibration is in date.)
R_O3	The metrology lab needs to have the calibration routine set a calibration to PASS only if all measurements are within tolerance.
R_O4	The metrology lab needs to prevent any gauge from being checked out for use if a calibration has not been carried out and passed within the calibration period.
R_O5	The metrology lab needs to record a history of all calibrations and status changes for every gauge.

How about like this?

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Function:

"As a runner I want to upload my paces with one button press so I can compare with my coworkers."

Hazard Mitigation:

"*As a caregiver,*
I want to ensure that therapy will stop if short, open circuit, or high impedance is detected,
to avoid harming the patient."

What other formats could arise directly from your development work? Executable specification? Structured test?

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User Stories as Requirements

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Advantage: You're generating them already!
Potential Drawback: They can be large, covering many different functions or elements.

Jeff Patton warns us to learn how to break the rocks into very small ones!

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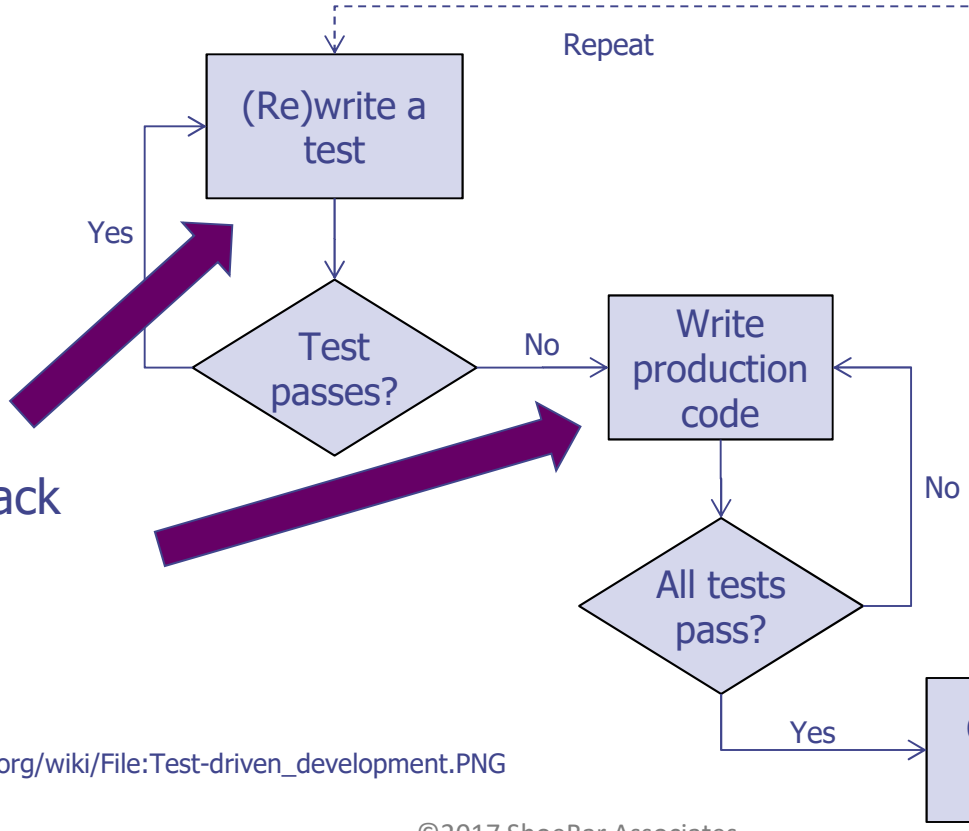
Generate Story Maps

- Purpose
  - Ensure product will fit user needs
  - Envision minimum viable product
  - Plan releases
- Who uses them?
  - Product managers/ marketers and hands-on technical teams
- How do they help?
  - Give context for each feature

Source: http://www.agileproductdesign.com/presentations/user_story_mapping/ Blog post describing Story Mapping. Jeff Patton's book describes the story mapping technique in detail.

TDD: Traceability comes naturally



Just keep track of these!

Source: http://en.wikipedia.org/wiki/File:Test-driven_development.PNG

Define – and enforce – "Done"

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When can we say with confidence that a story is DONE?

- When the story is refined and accepted (and documented).
- When the code is implemented & checked in.
- When the implementation is unit tested.
- When system / functional tests have passed.
- And??

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Documents: Capture As You Work

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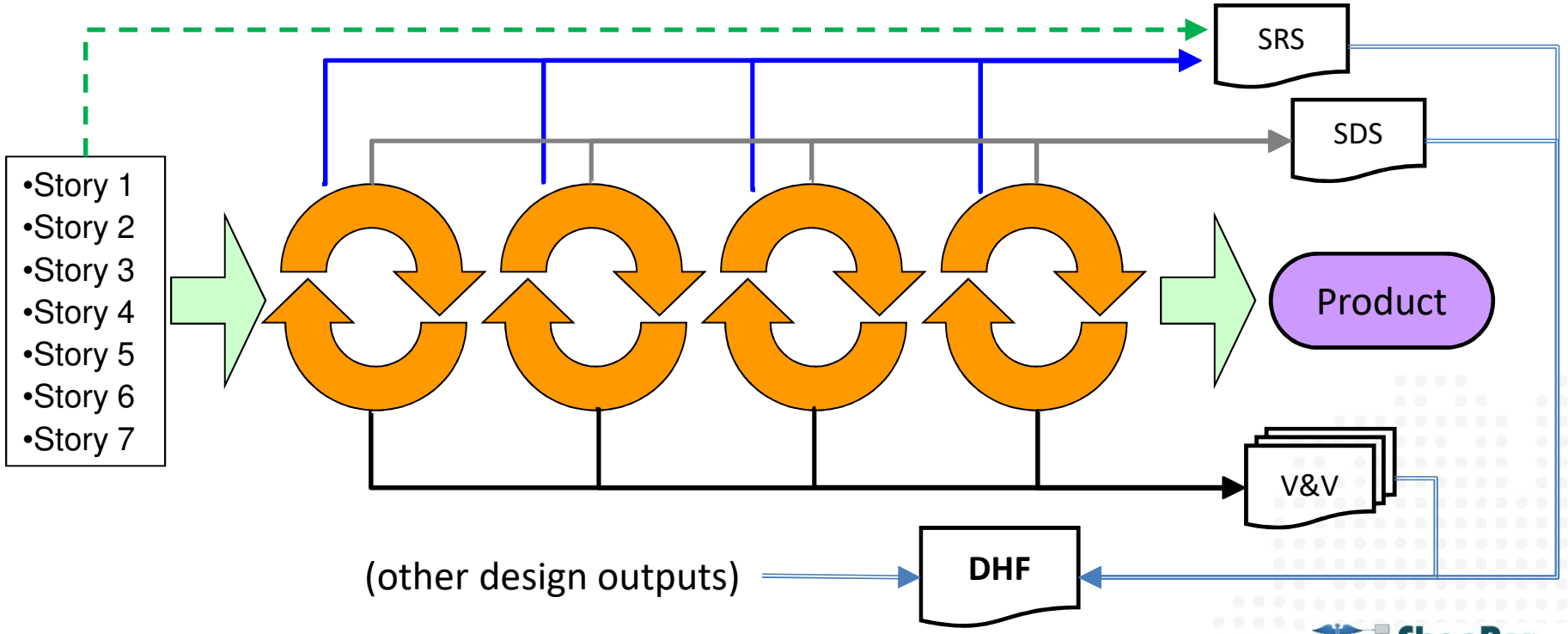

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Time to dispel the myths

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Too many rumors in the medical device village.

*The standards say we **must** use a waterfall model*

Agile isn't suitable for safety-critical work!

TRUE Agile means you don't plan and don't write documents.

Agile is just an excuse for sloppiness!

Beware the "But"

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Have you ever heard "We're Agile but . . .

". . . Detailed requirements are written and approved before iterations begin" or

". . . We don't conduct demonstrations" or

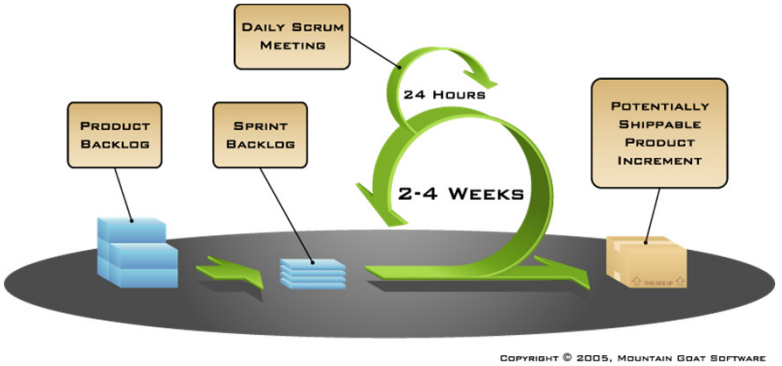
". . . After all features are implemented, we conduct an integration sprint" or

". . . We use every [Nth] iteration to catch up our documentation" or

". . . Software isn't runnable until many iterations into the project"

Approaches like these are ***Agile in Name Only***

Common Values



Fulfilling medical need
Safety / Effectiveness

=

Customer Satisfaction
High Quality

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Several Thoughts

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- *Discipline* is a key - documented process, and continuous improvement
- Documentation can arise out of conversations, but can't replace them
- Plans are important - but recognize that they change
- *Good Engineering* is our goal – compliance follows

In Summary

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- Document to prove what you agreed on and generated – “vacation photos”
- Have, and follow, a definition of DONE
- Plan at multiple levels. Formal, written plans should be very high level.
- Generate documentation naturally from the work you’re already doing.

References

AAMI TIR45:2012 "Technical Information Report: Guidance on the use of AGILE practices in the development of medical device software", Association for the Advancement of Medical Instrumentation, August 2012. (available at http://my.aami.org/store/)

Patton, Jeff, and Peter Economy, *User Story Mapping: Discover the Whole Story, Build the Right Product*, Sebastopol CA, O'Reilly Media Inc, 2014.

Contact Information

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Thank You