Agile: Safety-Critical Too!

Brian Shoemaker, Ph.D.

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Brian Shoemaker, Ph.D.

- 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)
- 13 y as independent validation consultant to FDA-regulated companies – mostly medical device
- Active in: software validation, Part 11 evaluation, software quality systems, auditing, training

Acknowledgement

Part of this material was developed by Nancy Van Schooenderwoert, Lean-Agile Partners Inc., and is based on her work in coaching teams in lean methods for high-quality software development.

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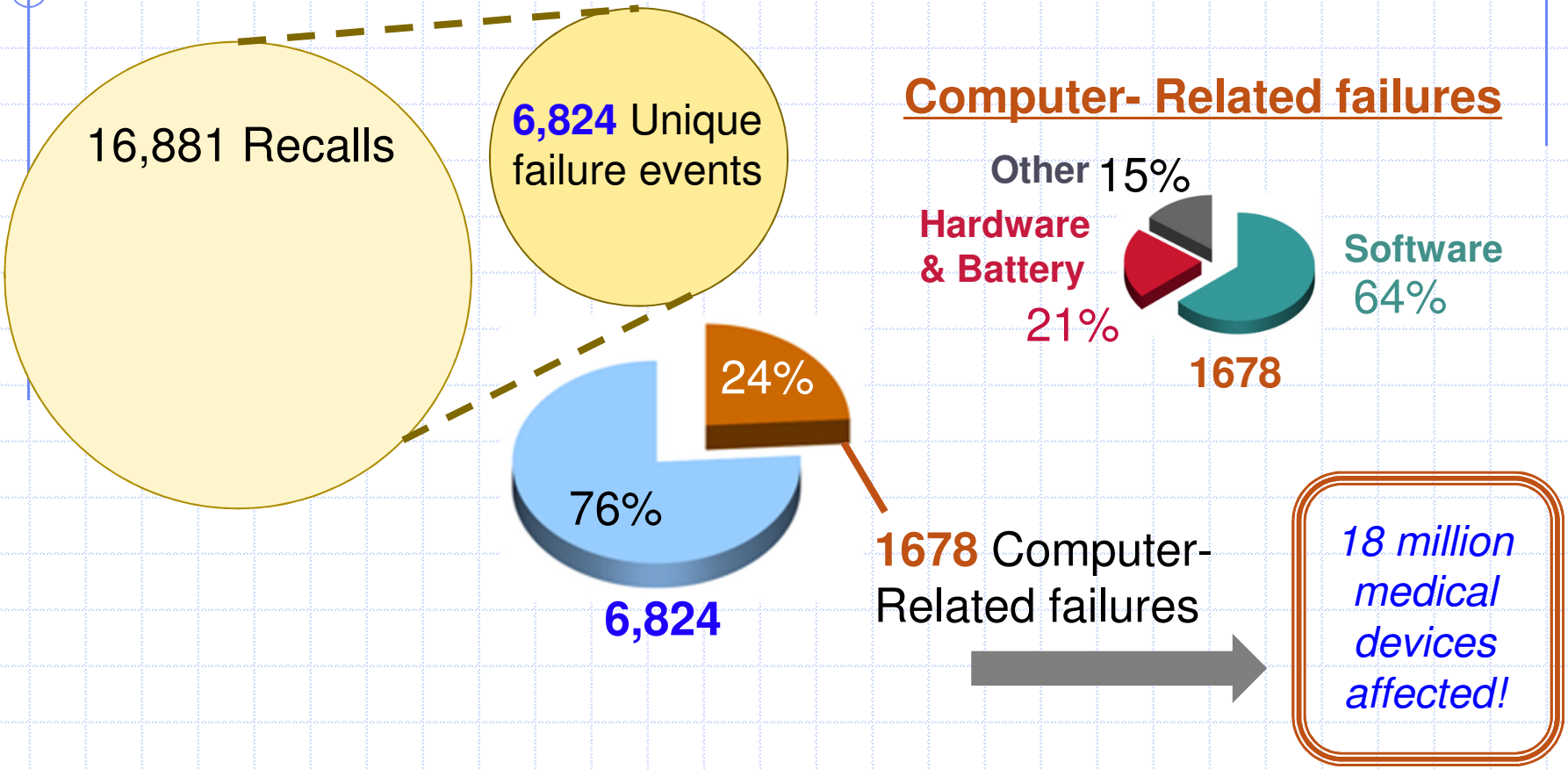
- *Software and hardware - collaborate*
- *Use your mapping to plan*
- *Gradually, Agile is entering the industry*

FDA Recalls, 2007-2013



Note: Free open source tool MedSafe will give you FDA data breakouts by year and type. Visit http://web.engr.illinois.edu/~alemzad1/MedSafe/

Note: Time span for data shown is Jan 1, 2007 through Dec 31, 2013.

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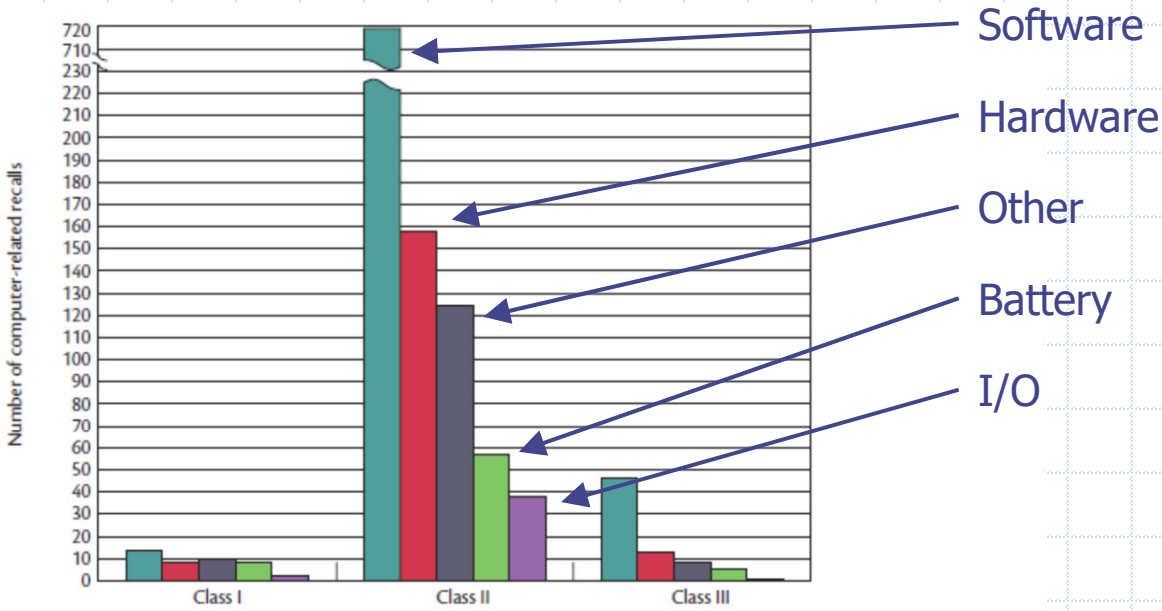
Recalls: SW is a leading cause



	Class I: high risk	Class II: medium risk	Class III: low risk	Total recalls	Number of devices
Software	14 (33.3%)	718 (65.6%)	46 (75.3%)	778 (64.3%)	2,303,441 (19.2%)
Hardware	8 (19.0%)	158 (14.4%)	13 (27.4%)	179 (14.8%)	4,228,133 (35.2%)
Other	10 (23.8%)	124 (11.3 %)	8 (12.3%)	142 (11.7%)	2,831,048 (23.5%)
Battery	8 (19.0%)	57 (5.2%)	5 (6.8%)	70 (5.8%)	2,385,613(19.8%)
I/O	2 (4.8%)	38 (3.5%)	1 (2.7%)	41 (3.4%)	276,601 (2.3%)
Total recalls	42 (3.5%)	1,095 (90.5%)	73 (6.0%)	1,210	12,024,836

Source: Alemzadeh et al, 2013.

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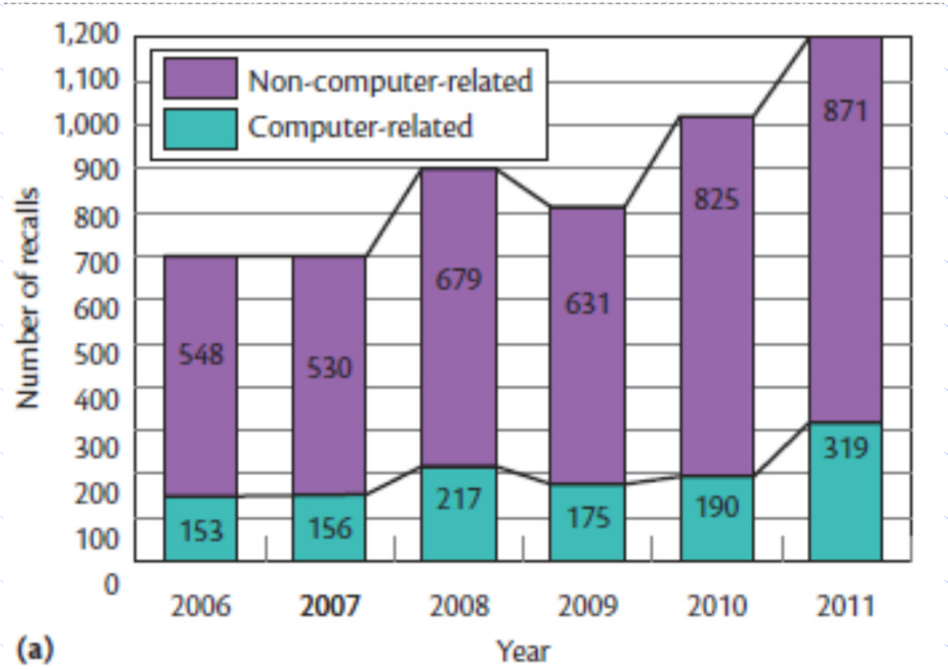
Recalls are growing!



Source: Alemzadeh et al, 2013.

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Why Agile?

- Traditional doc-heavy SW development is expensive, slow, and error prone
- Regulatory bodies rightly concerned with product software vs. safety
- Classic belief: tightly controlled process engineering
- Agile is highly productive, but seems the antithesis of tightly controlled process

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Too many rumors

*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!

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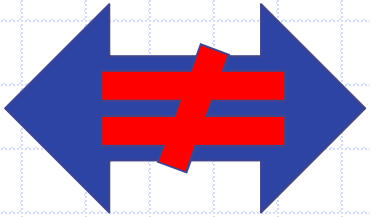
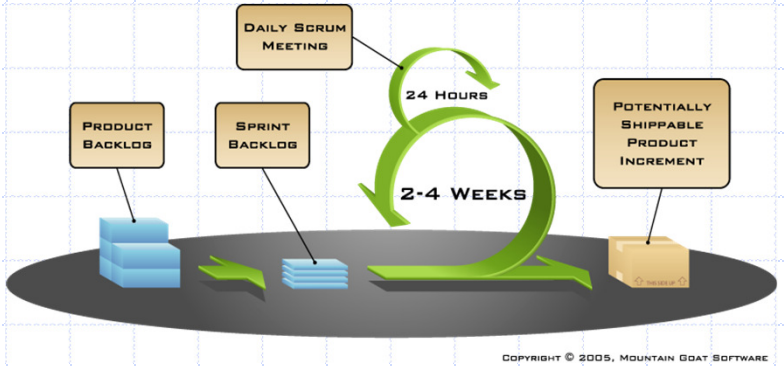
Contradiction?





These aren't inherently incompatible – but documentation and risk management are crucial differences

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

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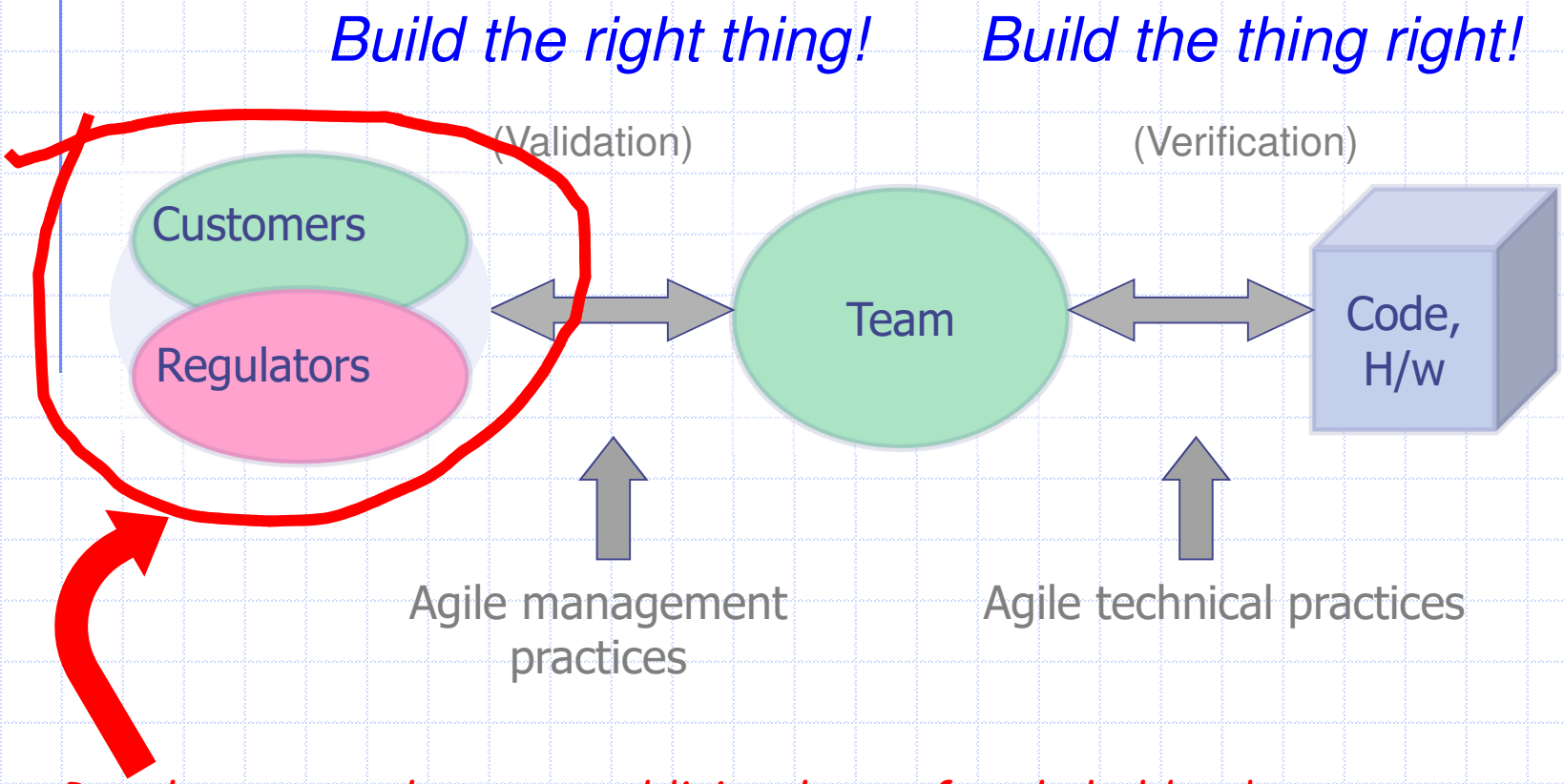
New stakeholders!



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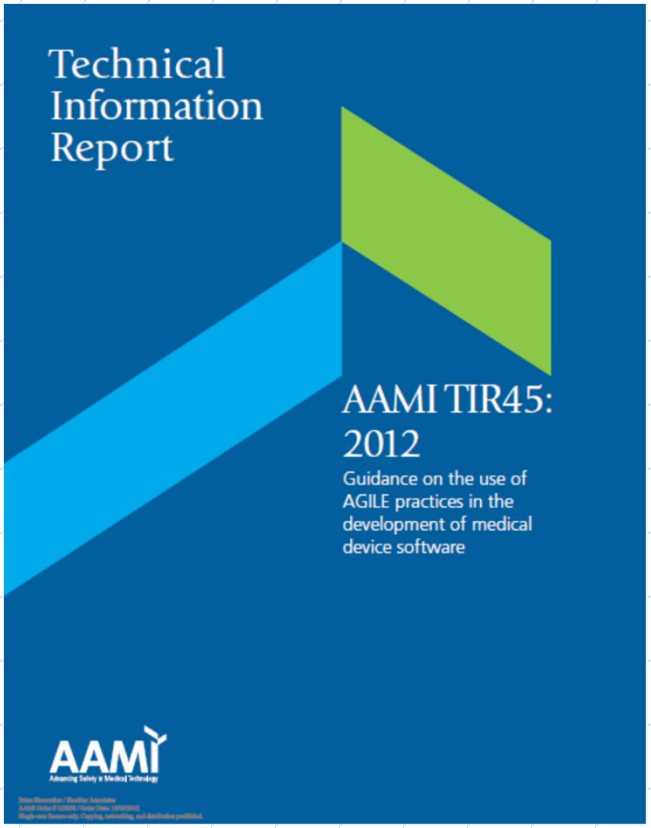
First Came AAMI TIR 45



- Published in 2012
- Authors include industry experts, Agile experts, and FDA personnel
- Gives guidance on using Agile methods for medical device SW development
- Covers key concepts and practices

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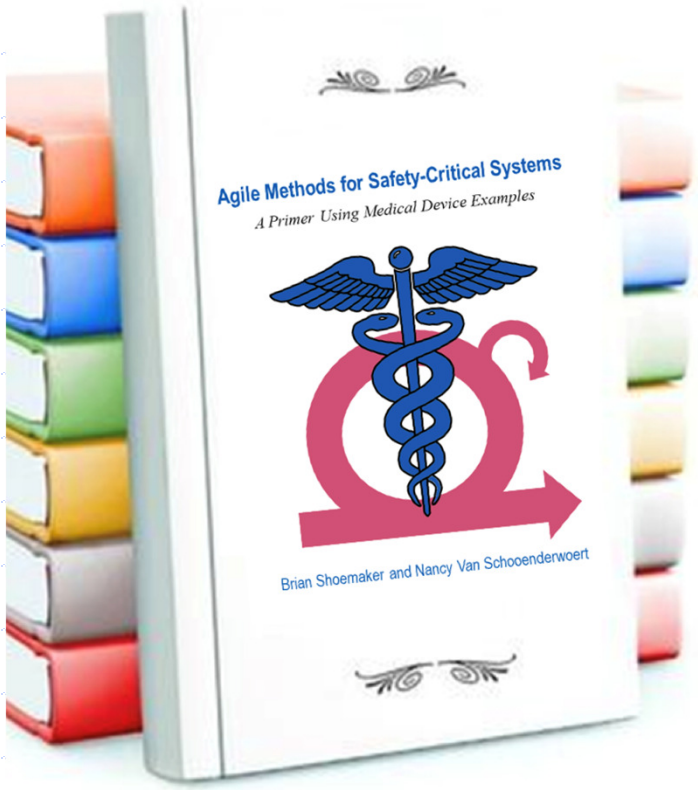
Picking Up From There . . .



Agile Methods for Safety-Critical Systems:

A Primer Using Medical Device Examples

By

Nancy Van Schooenderwoert

And Brian Shoemaker

Topics go beyond what I'll discuss here.

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Agile – Safety-Critical Too!

- *Traditional response: Agile won't fly here!*
- **Risk Management must be integral**
- *Documentation? Do it incrementally*
- *Software and hardware - collaborate*
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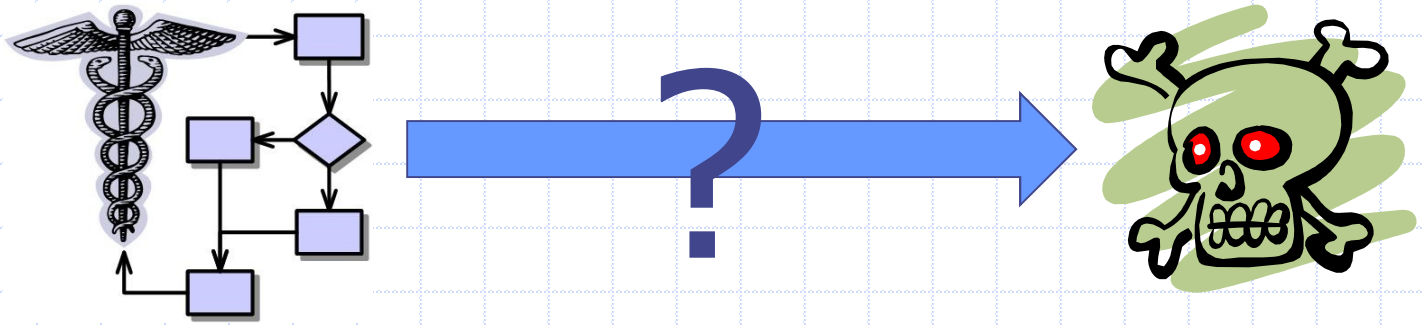
- *Gradually, Agile is entering the industry*

What is a software safety hazard?



Some ideas - sources?

- Direct failure
- Permitted misuse
- User Complacency
- User Interface confusion
- Security vulnerability

- *Incorrect algorithm / logic*
- *No input checking*
- *Inadequate warnings*
- *Poor UI design, no validn*
- *No attention to security*

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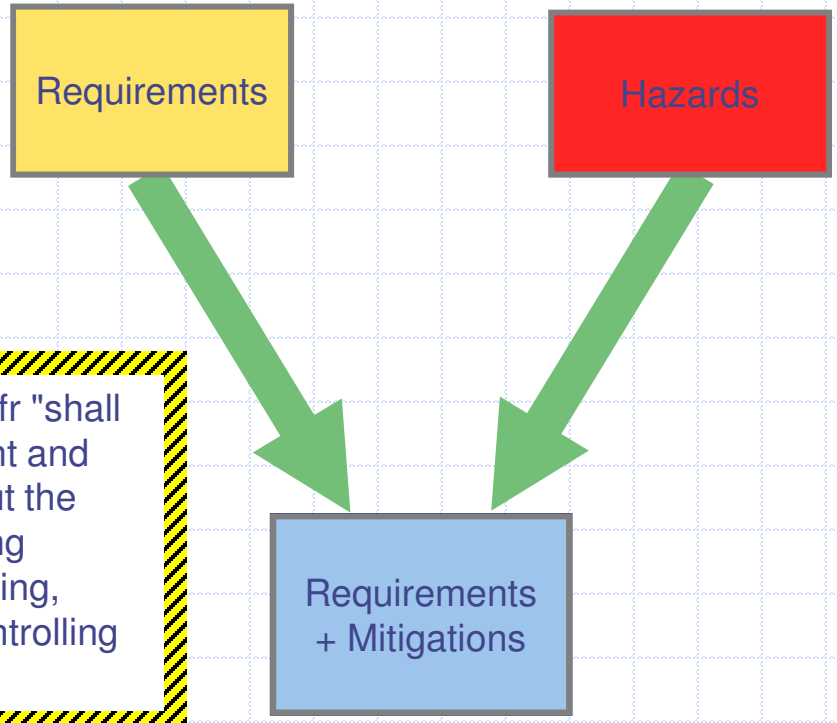
Who Should Help Evaluate?

- Electronic / Mechanical engineers?
- Physicians / Nurses?
- Patients who have used other TENS devices?
- Researchers who work on pain relief?
- Regulatory experts (review of other devices on market)?

Risk Management *MUST* Iterate



Early in project
- Preliminary
- High-level
- Approximate

Late in project
- Refined
- Detailed
- Specific

ISO 14971 §3.1: Mfr "shall establish, document and maintain throughout the life-cycle an ongoing process" for analyzing, evaluating, and controlling risks.

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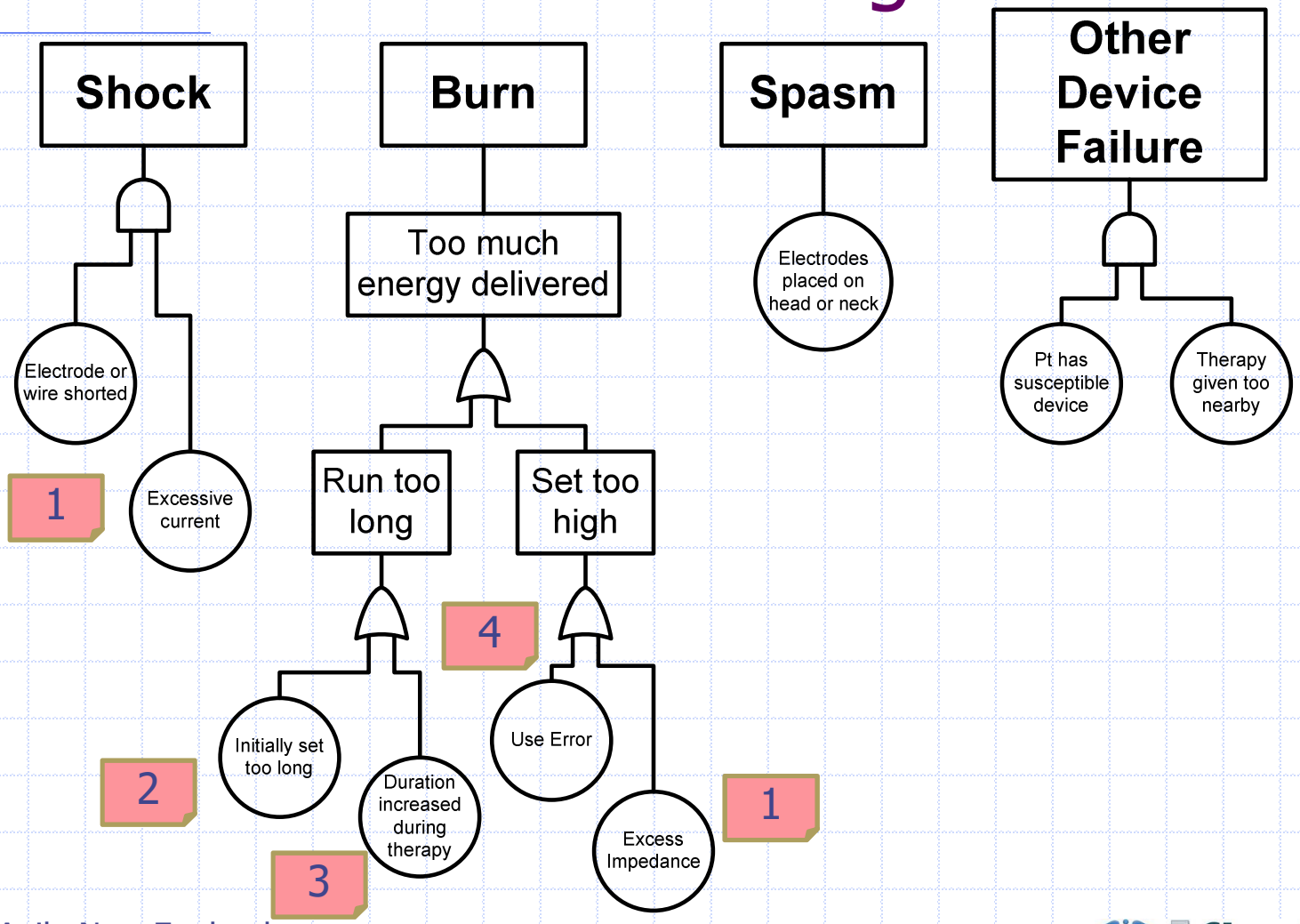
Predict Risks Before Design?



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Risk Stories

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.

As a caregiver,
I want the unit to prevent setting duration longer once therapy has begun,
to avoid harming the patient.

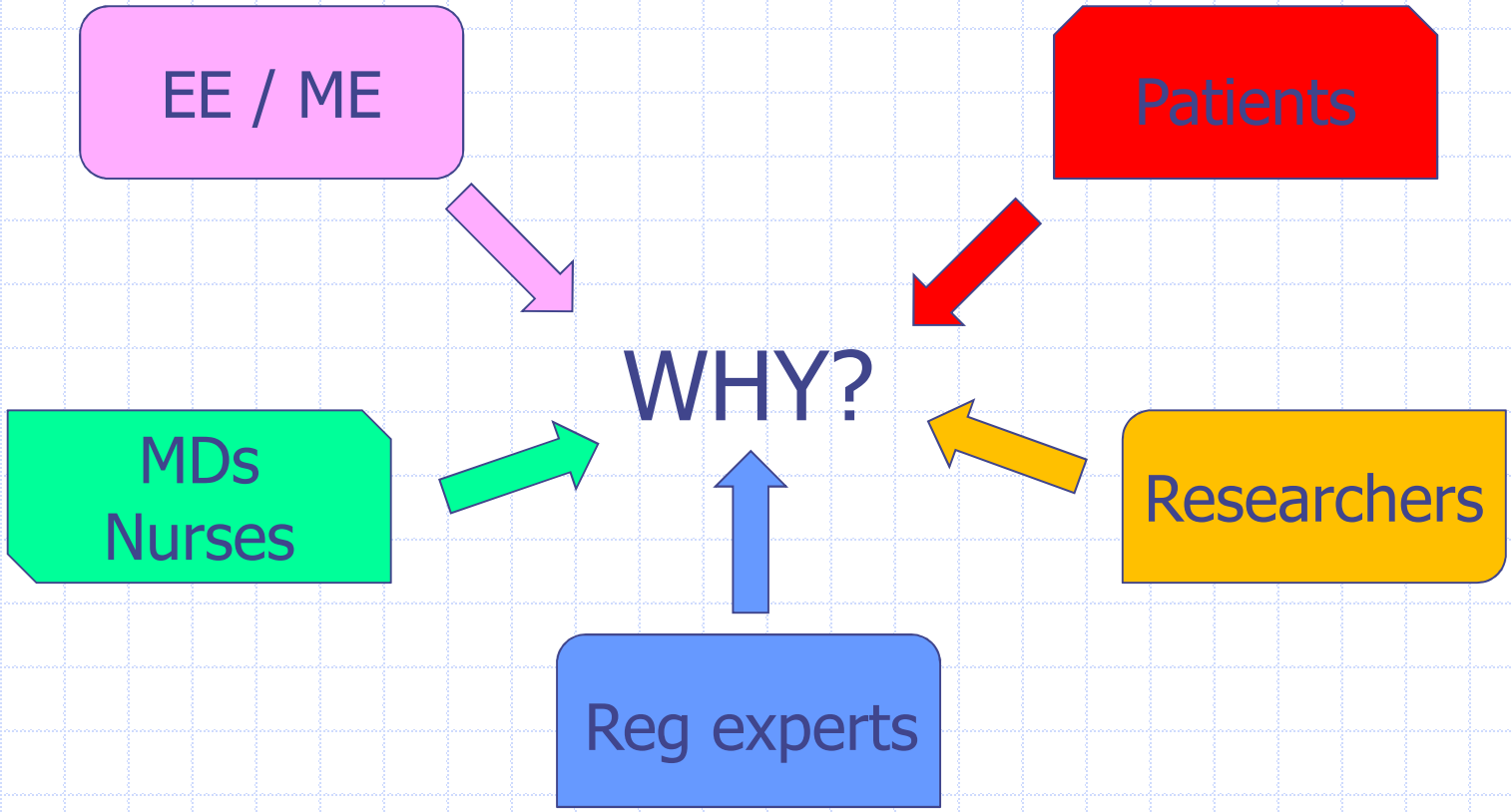
As a caregiver,
I want the unit to limit the therapy duration,
to avoid harming the patient.

As a caregiver,
I want the unit to prevent setting output too high,
to avoid harming the patient.

Is This Ever "Complete"?

- Do we know enough about hazards when a project begins?
- Will we learn as potential users try out our design?
- What other analyses can we do when we have a detailed design?
- Might we bring in other stakeholders later in development?

Team Diversity → Questions



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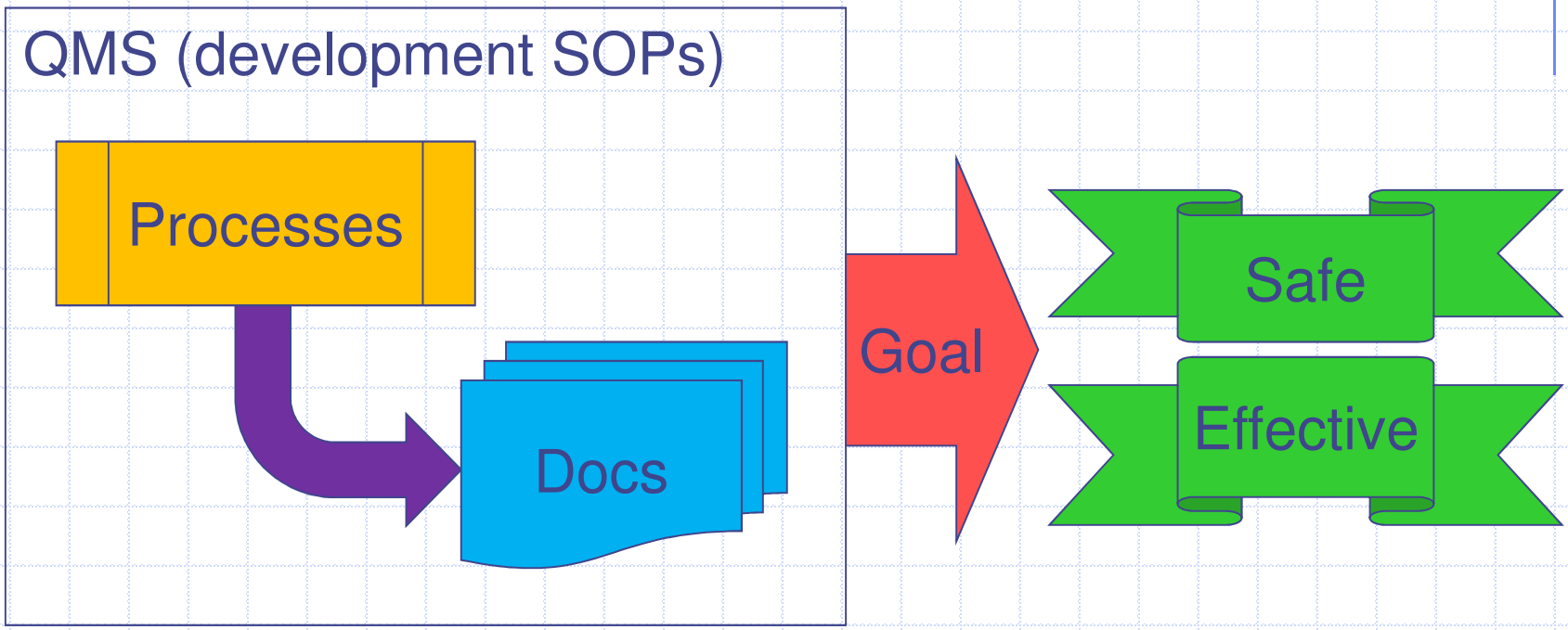
Documents = evidence



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

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Docs required for Design Control

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.

Docs need to provide . . .

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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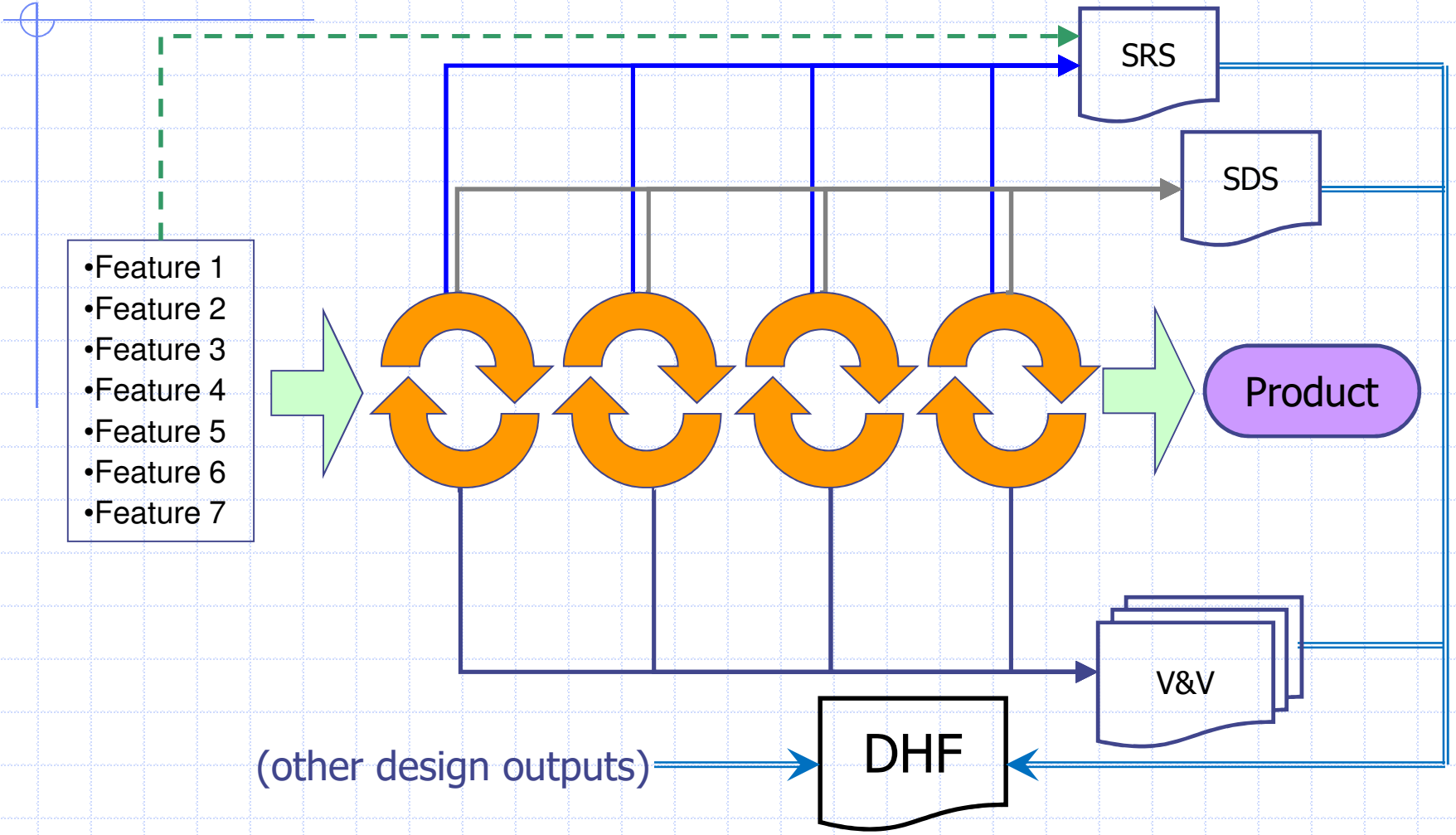
Document Cumulatively



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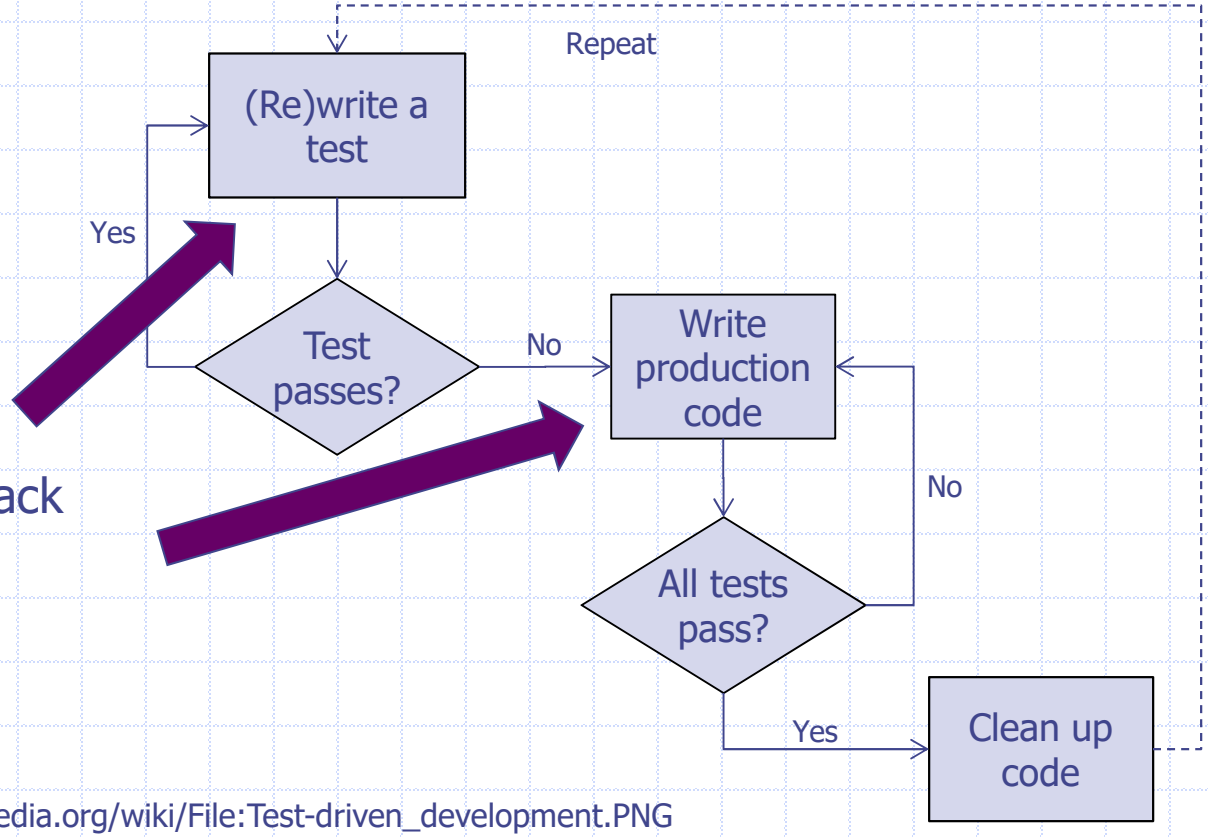
How about Traceability?

Consider TDD:



Just keep track of these!

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

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Documentation – what was done

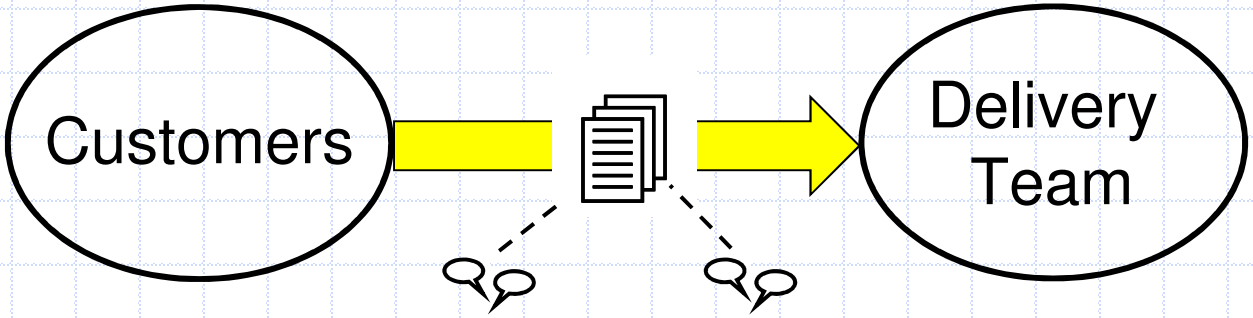
From TIR 45:

'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").'

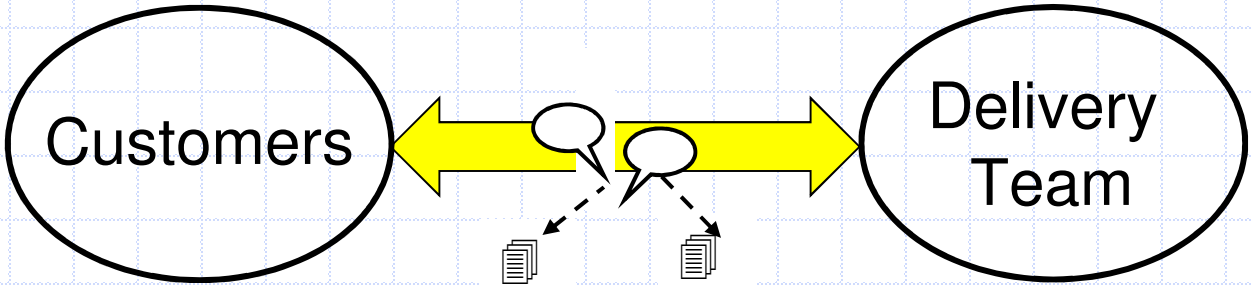
Jeff Patton describes this as "taking vacation photos" so that the team can remember what they agreed on.

Let Documents Be Output

- From **Document-centric**, supported by Conversation



- To **Conversation-centric**, supported by documents



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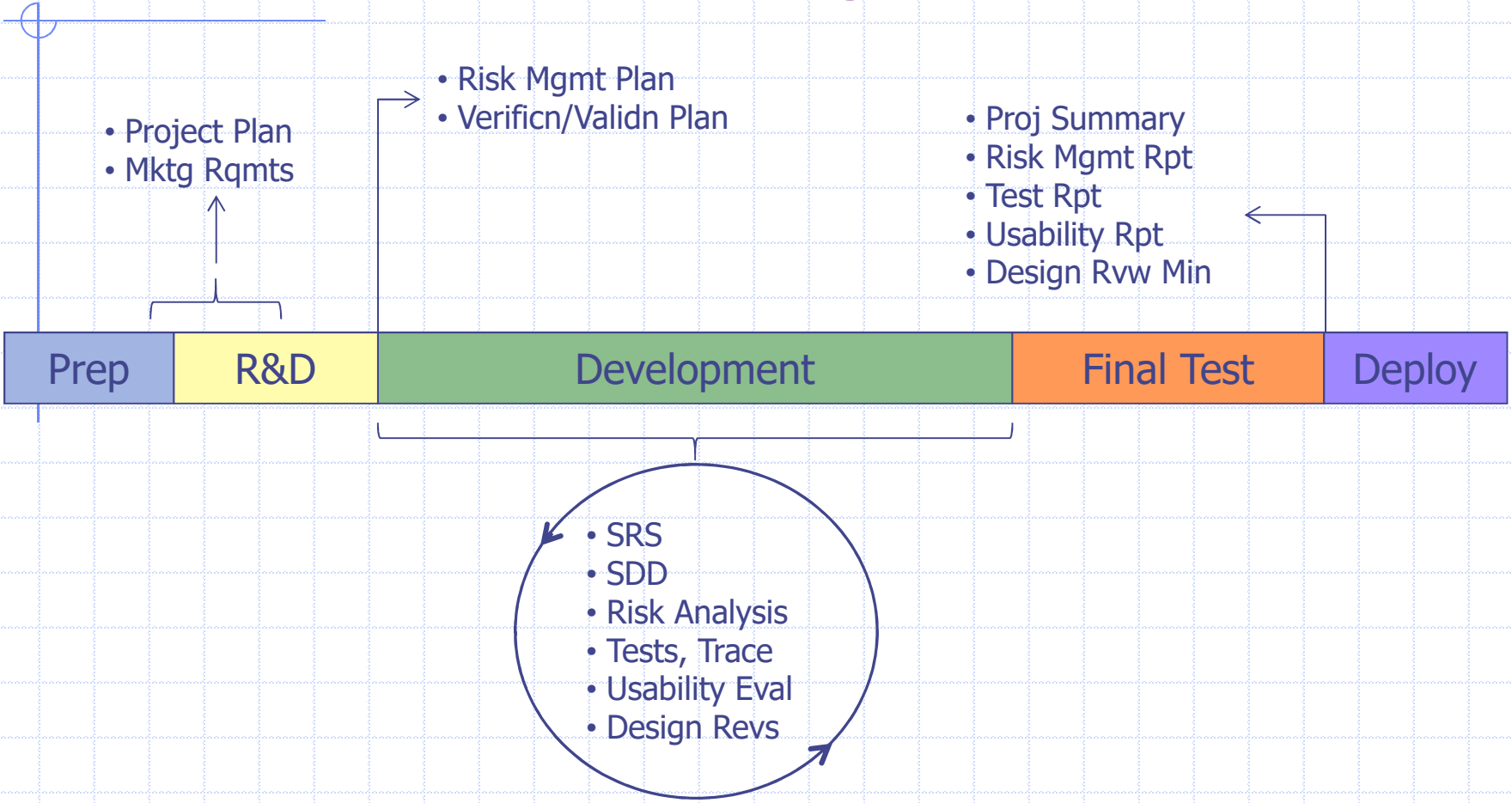
Document at time of generation



Source: N. Van Schooenderwoert.

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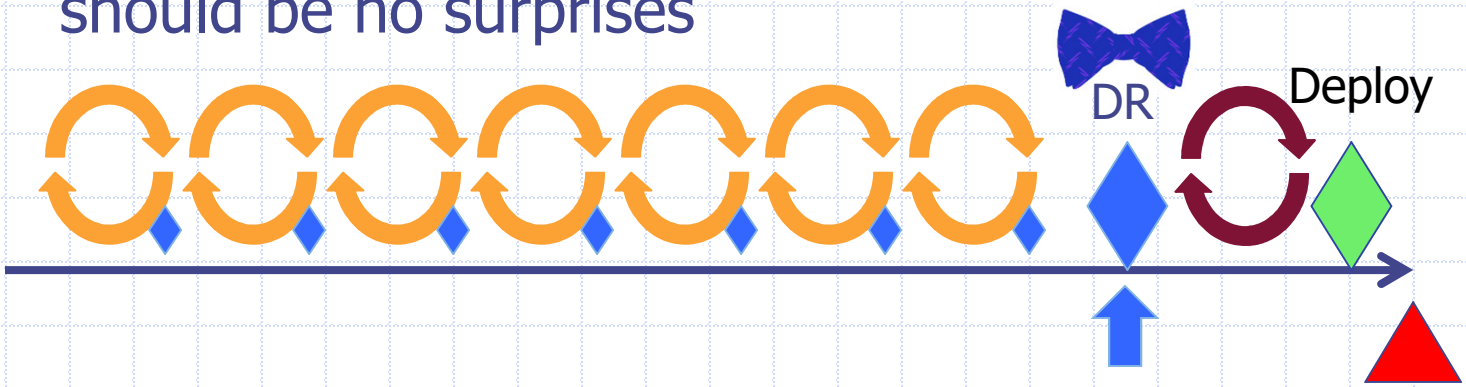
Demos can be design reviews

- Each iteration has design, dev, test, demo (♦)
- Each demo an incremental design review
- Document via memo to file – attendance, topics covered, issues/action items
- We'll hold the complete Design Review at the end – should be no surprises



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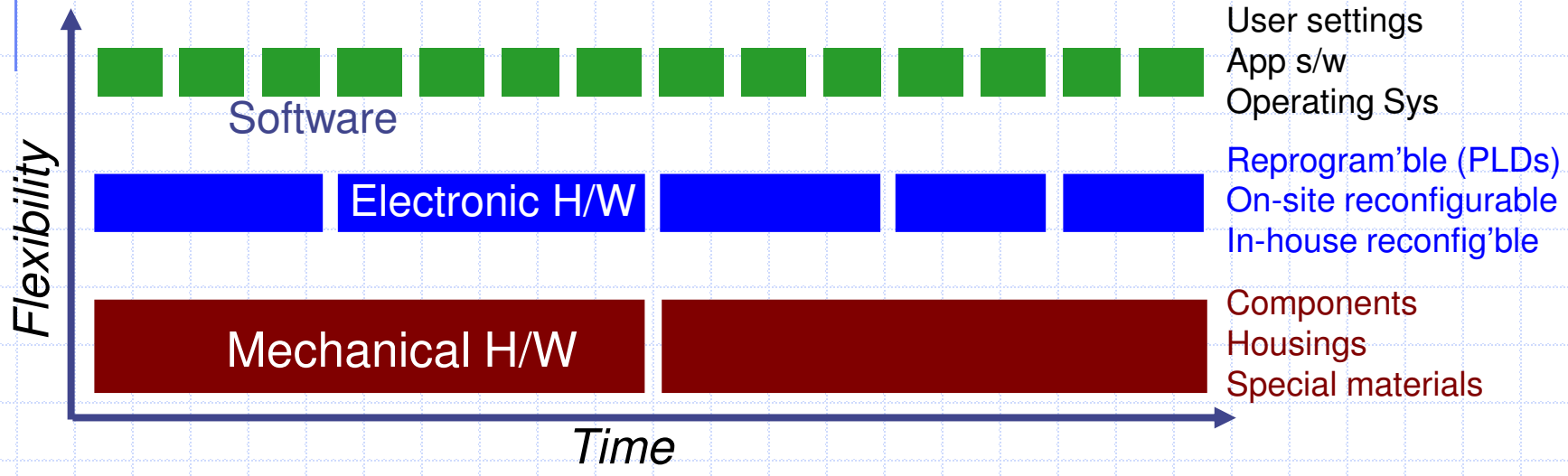
Iterations work differently

- Less frequent iterations for hard-to-change items
- Aim for *working hardware* at each iteration boundary
- Misconception: To be Agile, h/w dev has to fit inside of 2-wk or 4- wk iterations



Source: N. Van Schooenderwoert.

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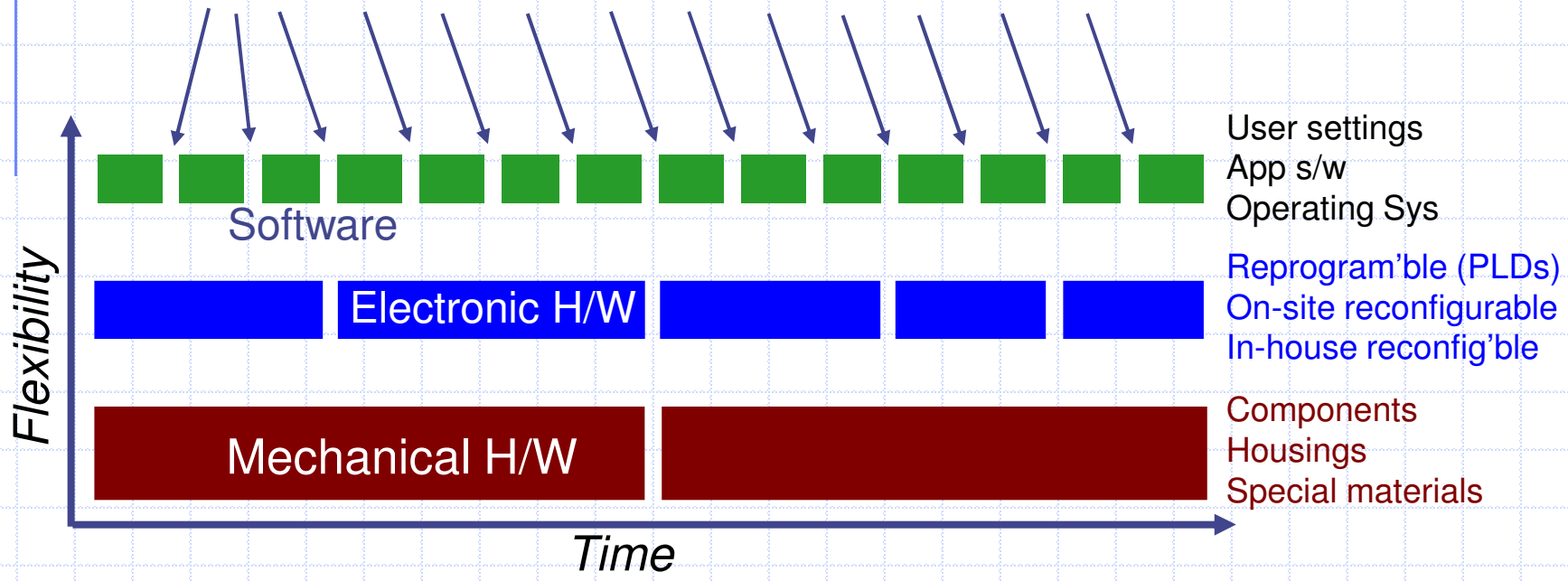
Sprints: A Learning Culture

- Each junction gives tangible baseline each person sees
  - Enables peer-to-peer work, less need for hierarchy



Source: N. Van Schooenderwoert.

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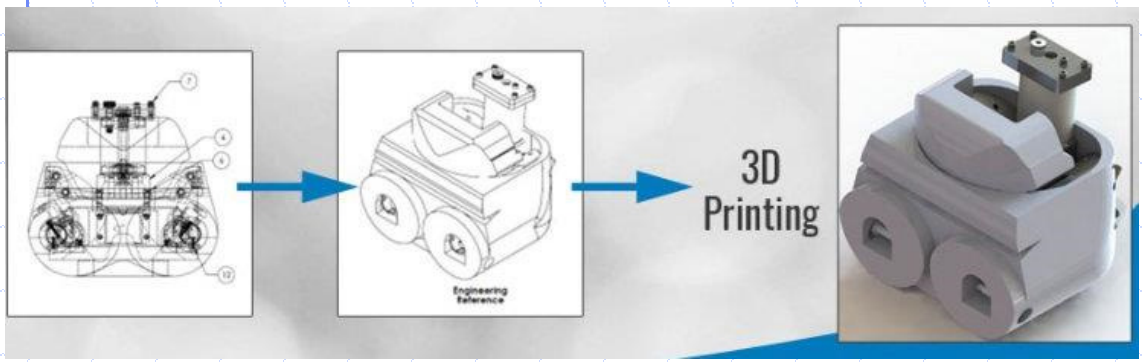
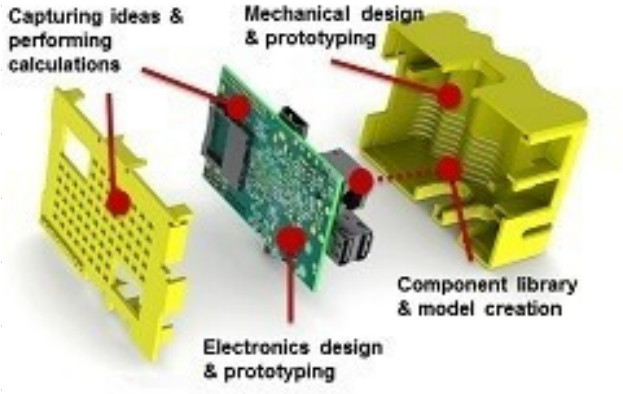
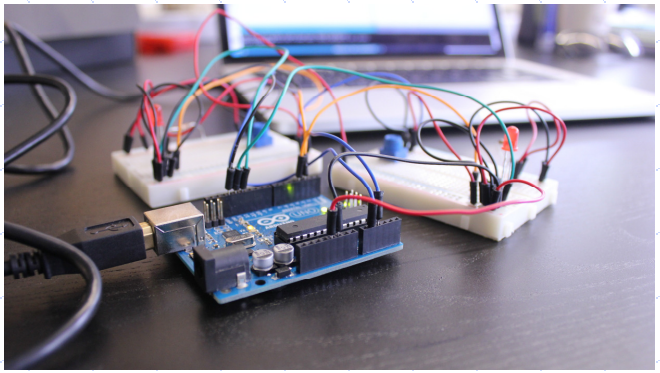
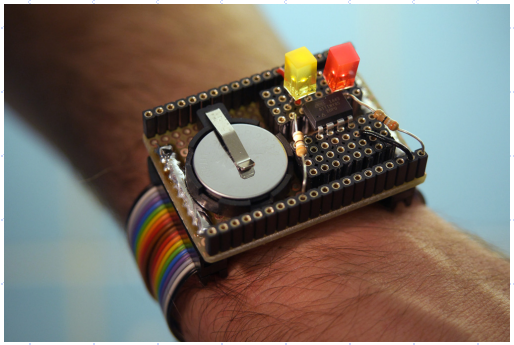
Mockups / Prototypes

Mechanical / electrical engineers have designed iteratively for decades …









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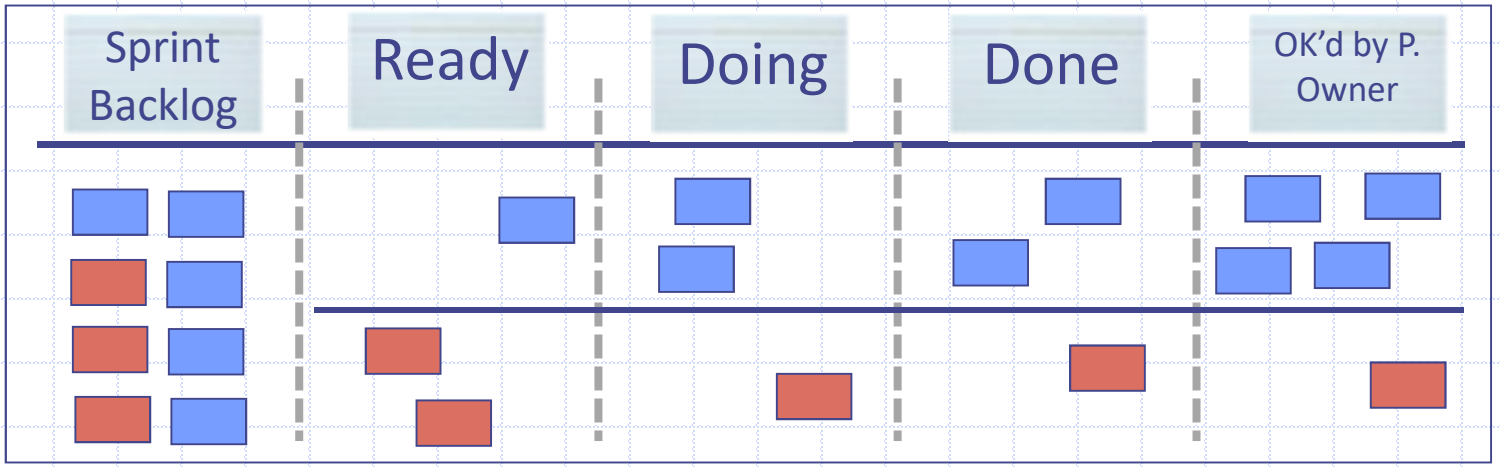
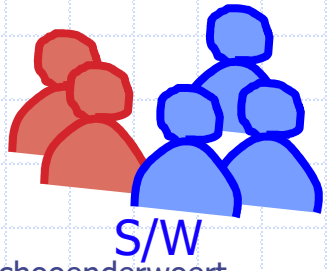
Mixed team skills

- Story board can be divided…





We're still *one* team, now with different workstreams visible

Source: N. Van Schooenderwoert.

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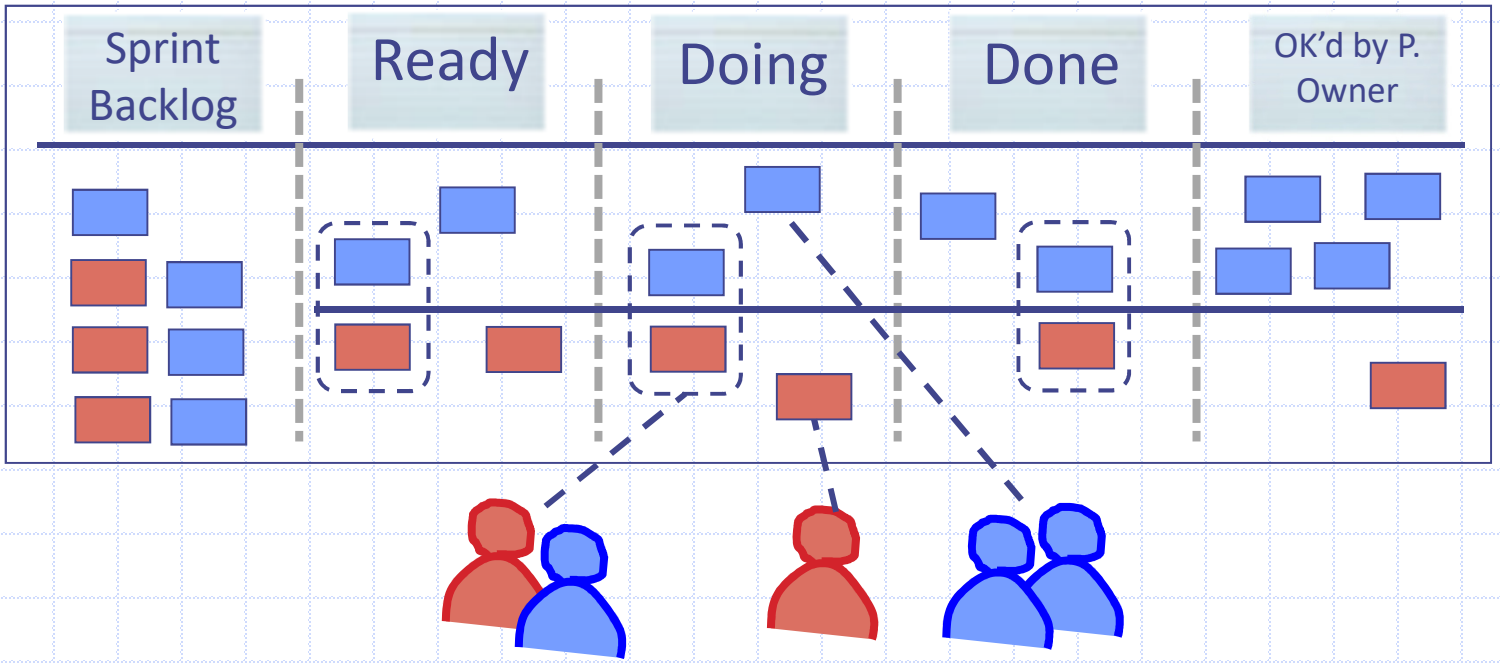
Lanes not independent

- Keep focus on whole features; don't merely fit work to skill siloes



People pair to do their parts of features that span disciplines

Source: N. Van Schooenderwoert.

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Experience with collaboration

- Project: grain monitor system – all new HW, math, SW
- Only the SW team was using Agile practices, but…
- Frequent SW releases created many more opportunities to improve HW-SW interaction
  - Some measurements inconclusive due to voltages out of range – so added SW monitoring of HW key areas
  - Field problems that could not be isolated to one area (opto, sensor, electronics) could be investigated thru special s/w releases for troubleshooting
  - Hand assembly of field units improved by downloadable collection of SW drivers with command-line menu
- Result was HW became more Agile "without trying"

Source: N. Van Schooenderwoert.

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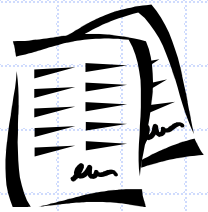
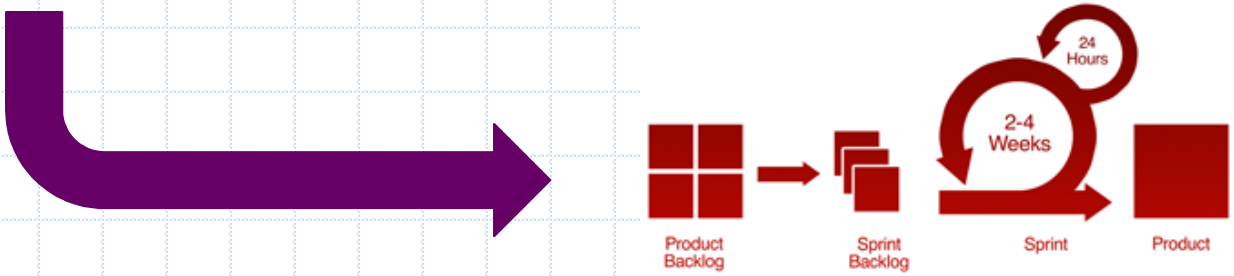
Plans – avoid the bottleneck

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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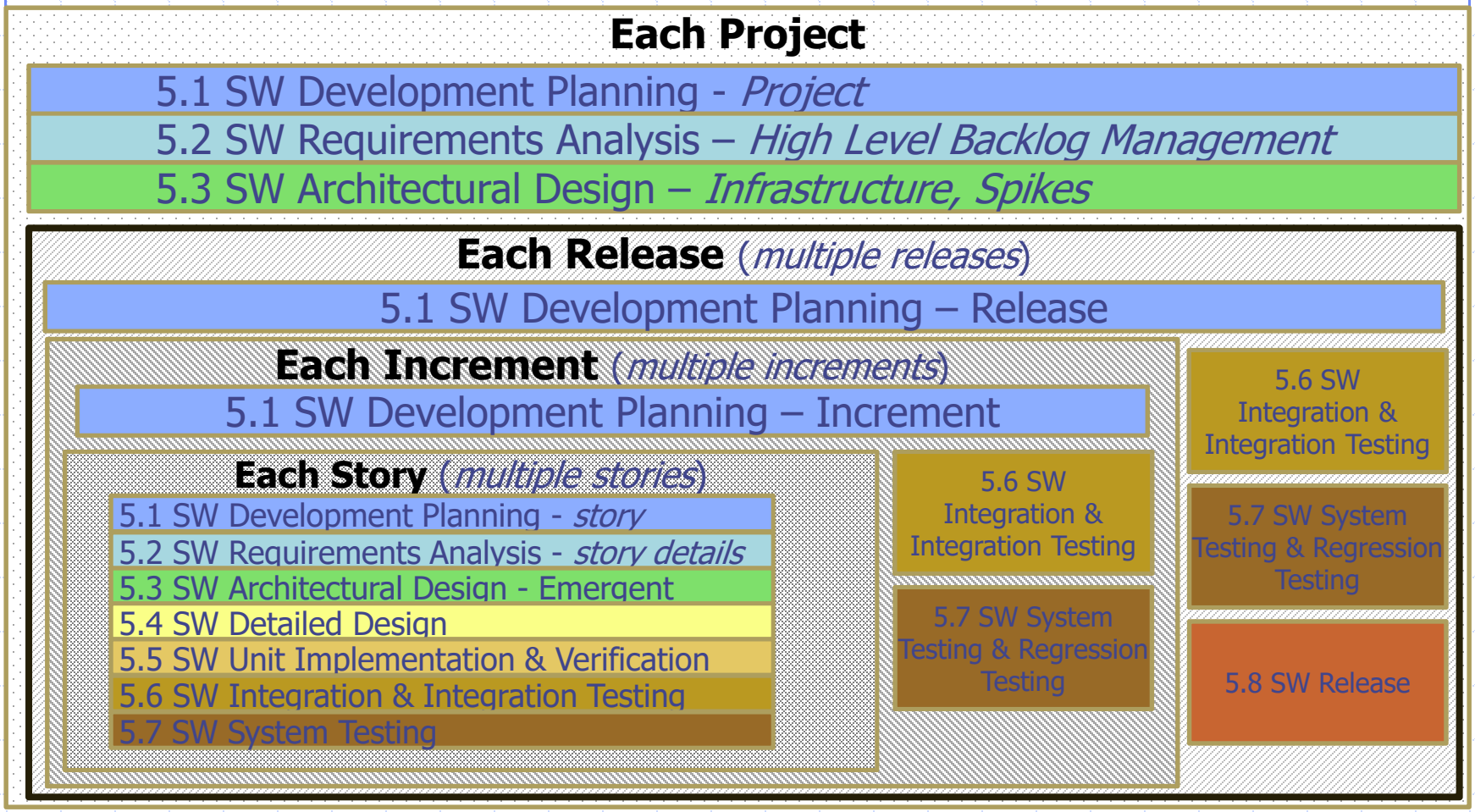
Plan in "Layers"



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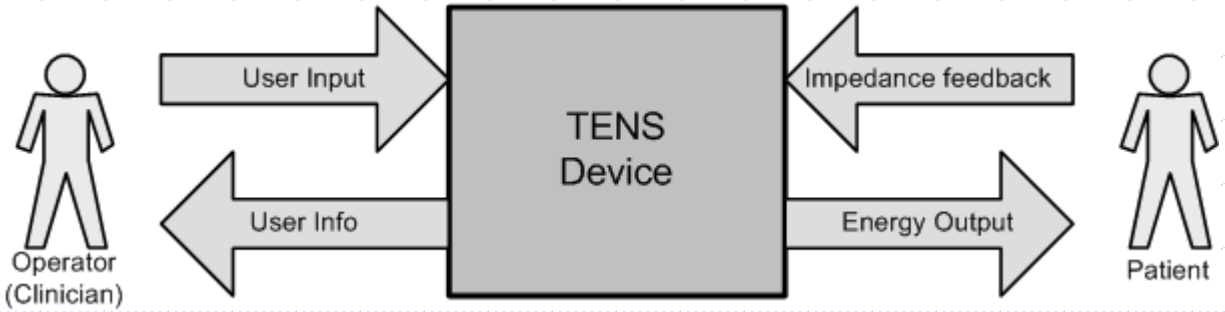
TENS – A Compact Example

TENS, or transcutaneous electrical nerve stimulation, is a pain-relief therapy in which weak electrical signals are applied to a patient via standard skin electrodes.

The goal is for treatment to be fully automated: working parameters are to be set dynamically, with no manual adjustment required other than regulating stimulus intensity, which is manually set at the perception threshold.



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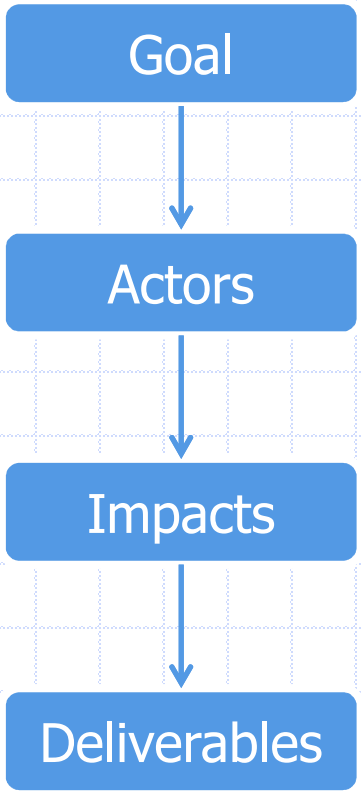
Impact Mapping – Include All Parties



What is our goal?

Sell 2000 units in the first 3 years on the U.S. market

Who can help or prevent us reaching our goal?

Physicians, Patients, FDA, Support

Behavioral change helping/obstructing our goal

[Physician] Can adopt this TENS system with confidence
[Patient] Cannot be shocked or burned; experience lasting pain relief; willing to provide testimonial about relief
[FDA] Grant clearance to sell device

Features supporting/preventing impact:

- *Prompted setup sequence; limits on intensity, duration*
- *Therapy stop if electrical malfunction detected*
- *Proprietary pulse algorithm (from extensive research)*
- *Convincing safety profile*

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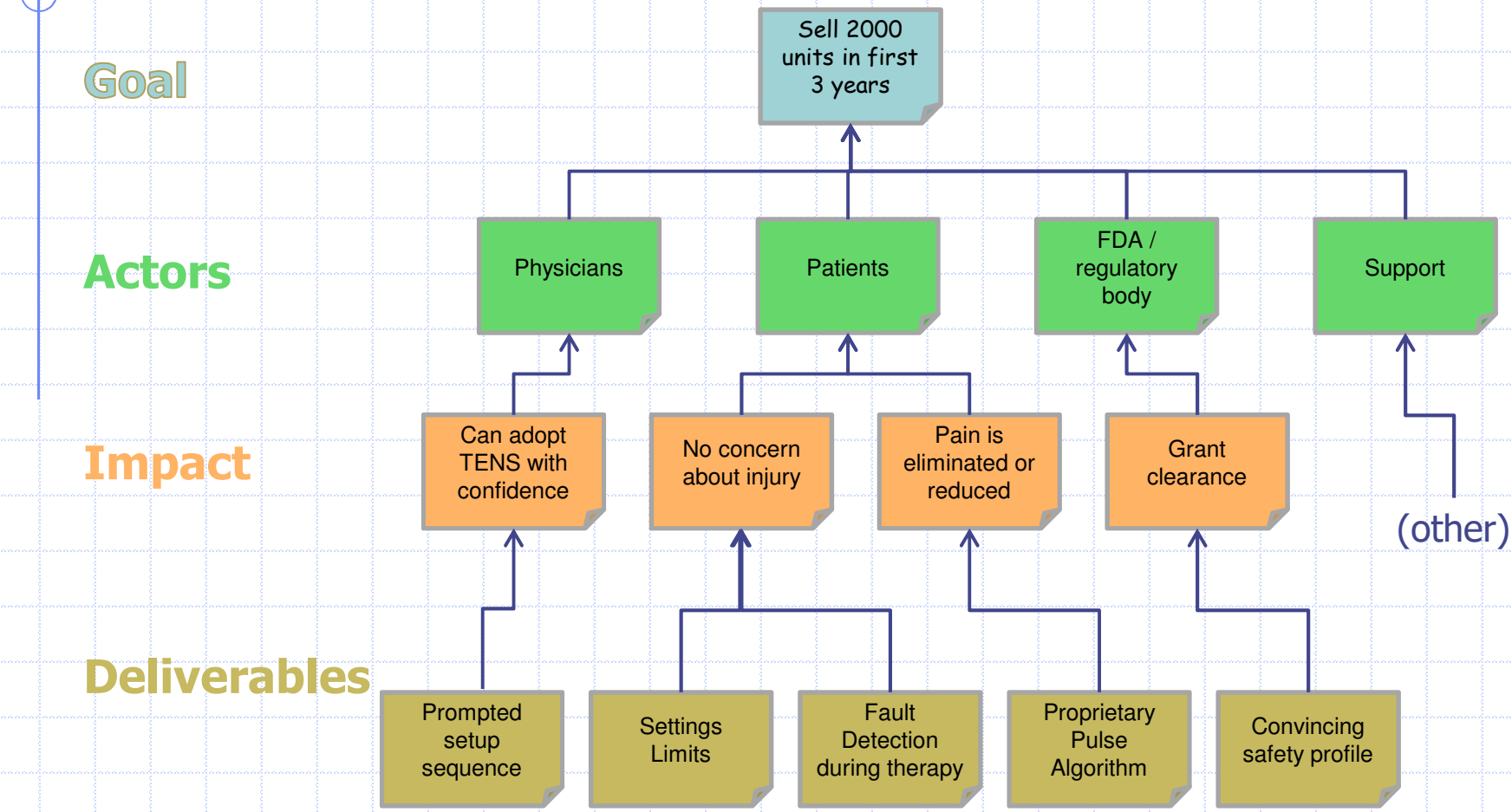
Example Impact Map, TENS Device



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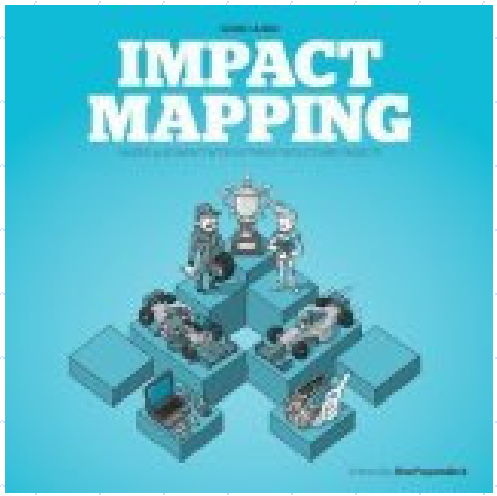
Impact Mapping – There's More



- *Have covered only a portion of impact mapping – enough to get you started*
- *Have found the method extremely useful for linking marketing and customer requests to development*
- *Highly recommend reading the Gojko Adzic book to understand the questions to ask.*

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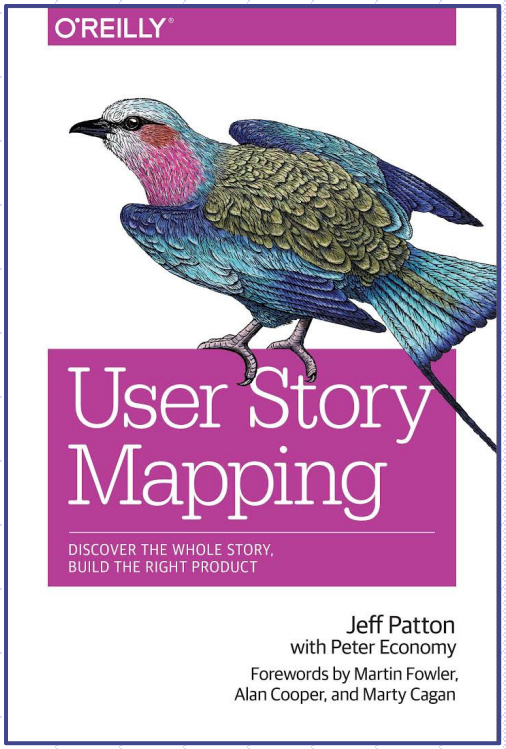
Story Mapping – Flexible Framework



Purpose

- Ensure product will fit user needs
- Envision minimum viable product
- Plan releases
- Communication – Marketing, QA, RA, Development

Who uses it?

- Product managers/ marketers and hands-on technical teams

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

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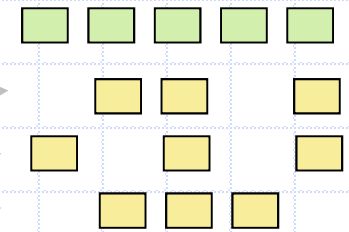
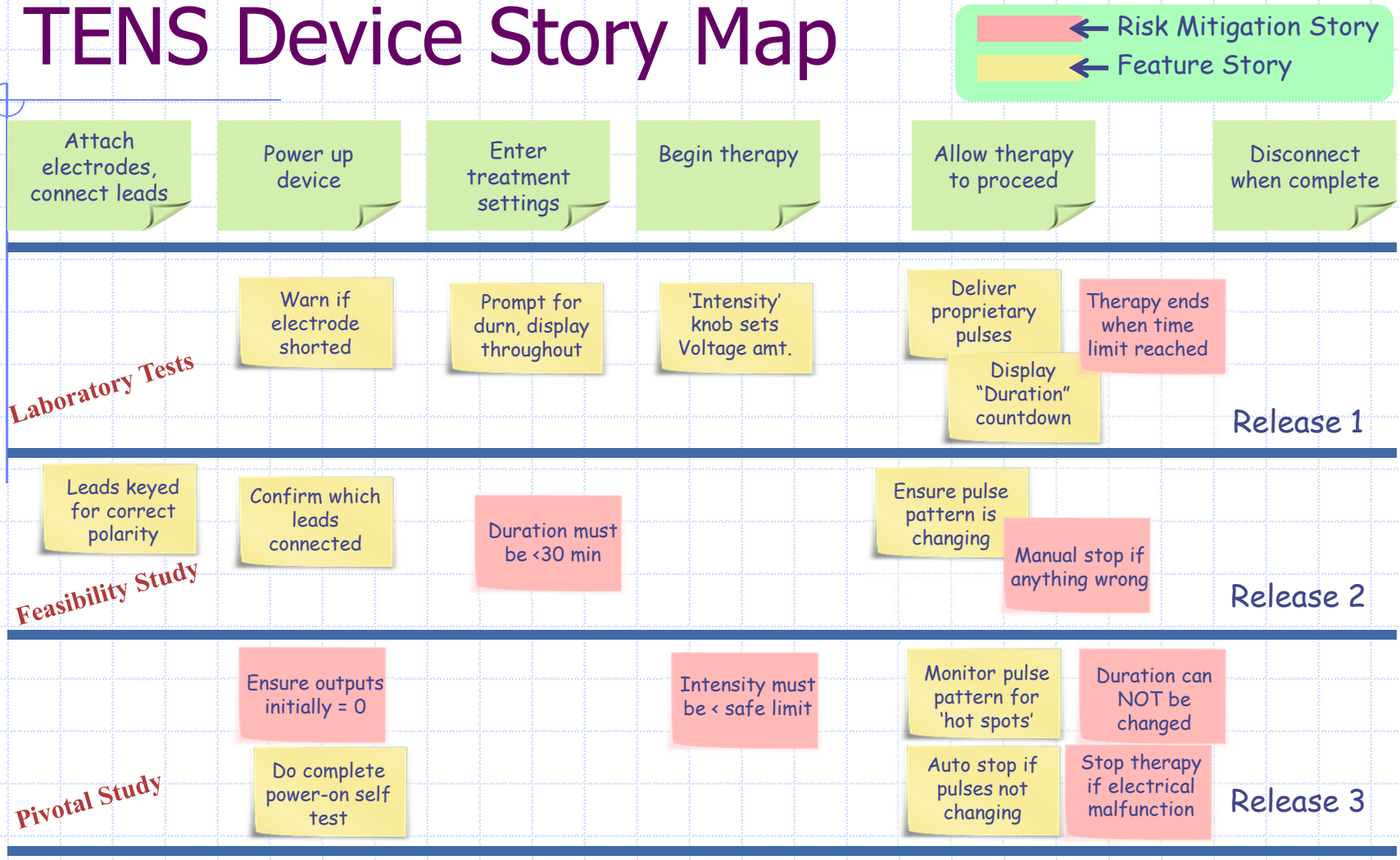
Building a Story Map

- Start with your customer's activities using your envisioned product (horizontal axis)
- Vertical axis: increasing levels of completeness in implementation
  - First level is a releasable "walking skeleton"
  - Next levels flesh out more features



- Benefit: Avoids releases that are unusable due to dependence on less urgent stories not yet implemented

TENS Device Story Map



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Agile – Safety-Critical Too!

- *Traditional response: Agile won't fly here!*
- *Risk Management must be integral*
- *Documentation? Do it incrementally*
- *Software and hardware - collaborate*
- *Use your mapping to plan*
- **Gradually, Agile is entering the industry**

SDMD Attendees Using Agile

- Dräger Medical
- Elekta
- Given Imaging
- Medidata Solutions
- Philips Healthcare
- Renishaw
- Siemens
- Systelab Software

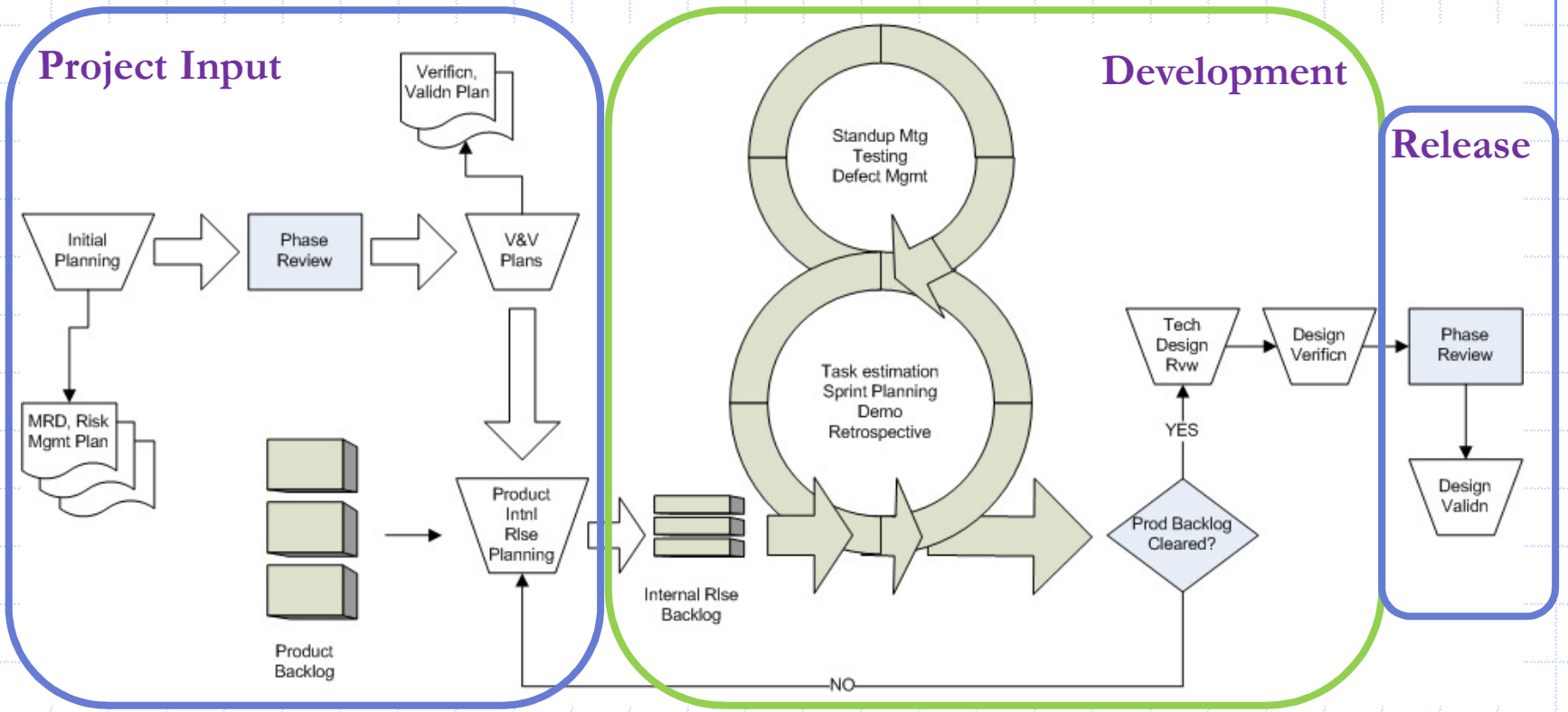
INCOSE Agile in HC Conference

- Attendees included reps from:
  - Battelle Memorial Institute
  - Boston Scientific
  - Cook Medical
  - GE Healthcare
  - Medtronic
  - Roche
- All were there to share successes!

We've Worked With Others

- Clinical trial data mgmt software (2 companies)
- ICU aggregated-data risk prediction SW
- Histology / pathology networked slide imaging & assessment system
- Clinical diagnostics
- IVUS
- Optical measurement systems

Agile in a Product Lifecycle Process



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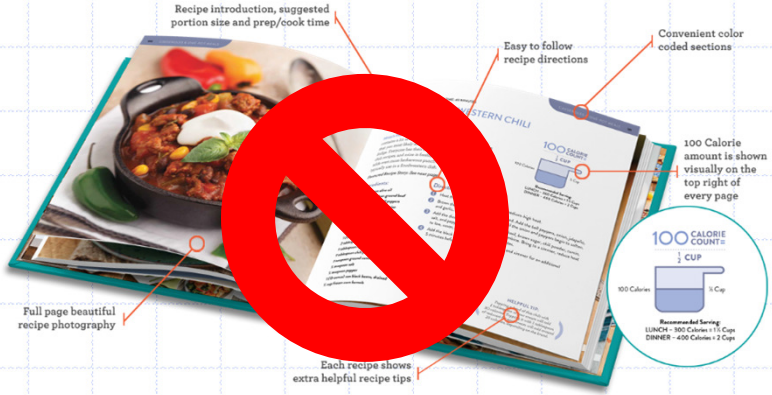
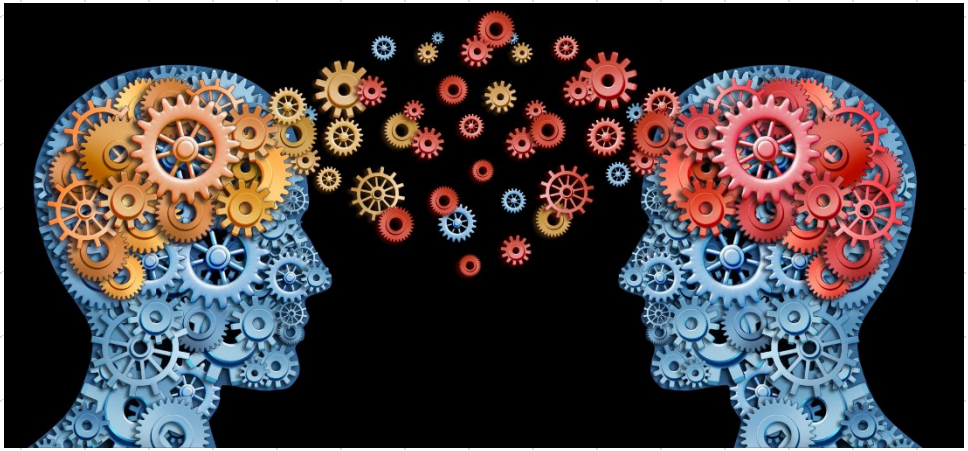
Challenge: the SOP Mindset

NOT this:



But this:



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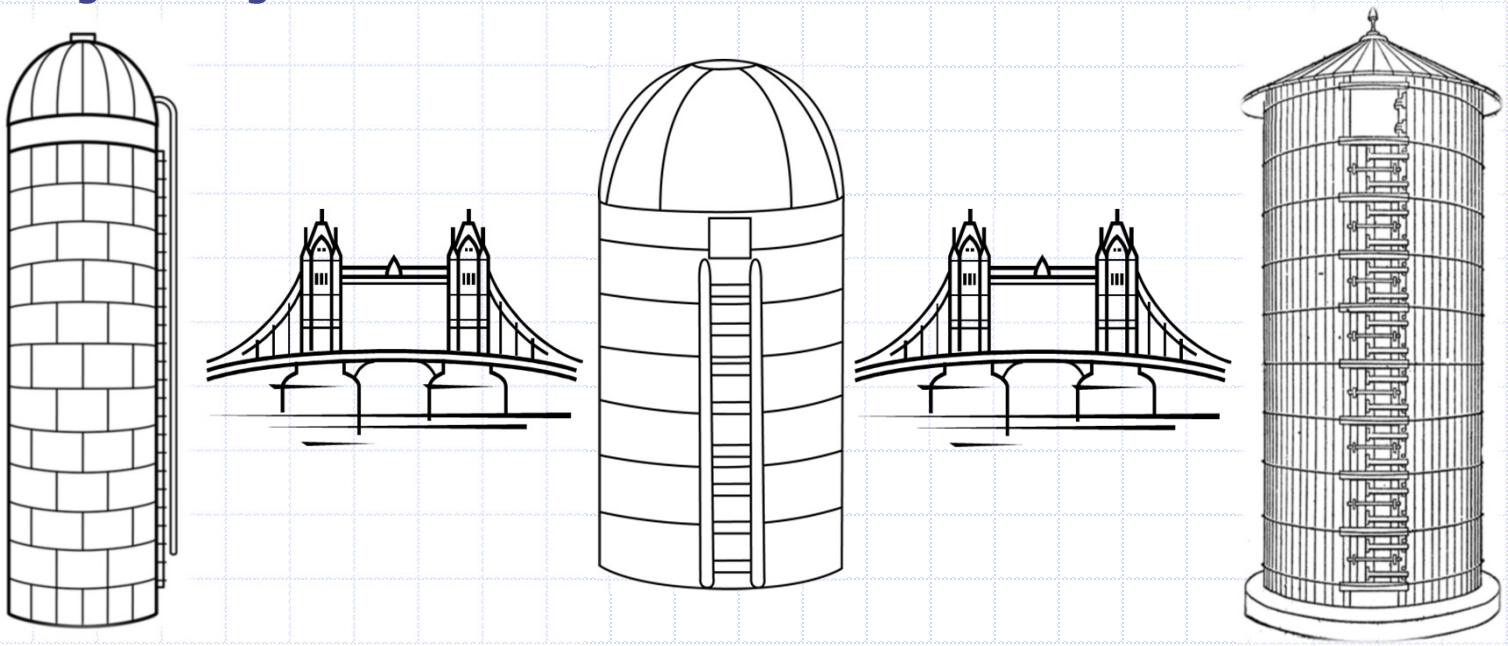
Bridging Silos is Difficult

R&D / Engineering

Clinical / Support

Marketing



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Essential Elements

- High level product vision
- Access to REAL CUSTOMERS
  - Hospital med techs – Radiologists – Nurses - Patients, e.g. diabetics
- Collaboration across functions
  - SW, HW, UI design, marketing
- Managers need to participate!
  - Remove roadblocks, keep team focus

What HAVEN'T I Discussed?

- Standards and their interrelations
- Human factors (NOT the same as UX!)

These elements are also crucial in medical product development – we cover them in more detail in other presentations.

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