



26th annual **INCOSE**
international symposium

Edinburgh, UK
July 18 - 21, 2016

Improve Medical Device Development by Expanding Systems Engineering

Carissa Black

syncronesstm
complex problems inspired solutions



Best Ideas Ever



Water
Roller



Citrus Spritzer



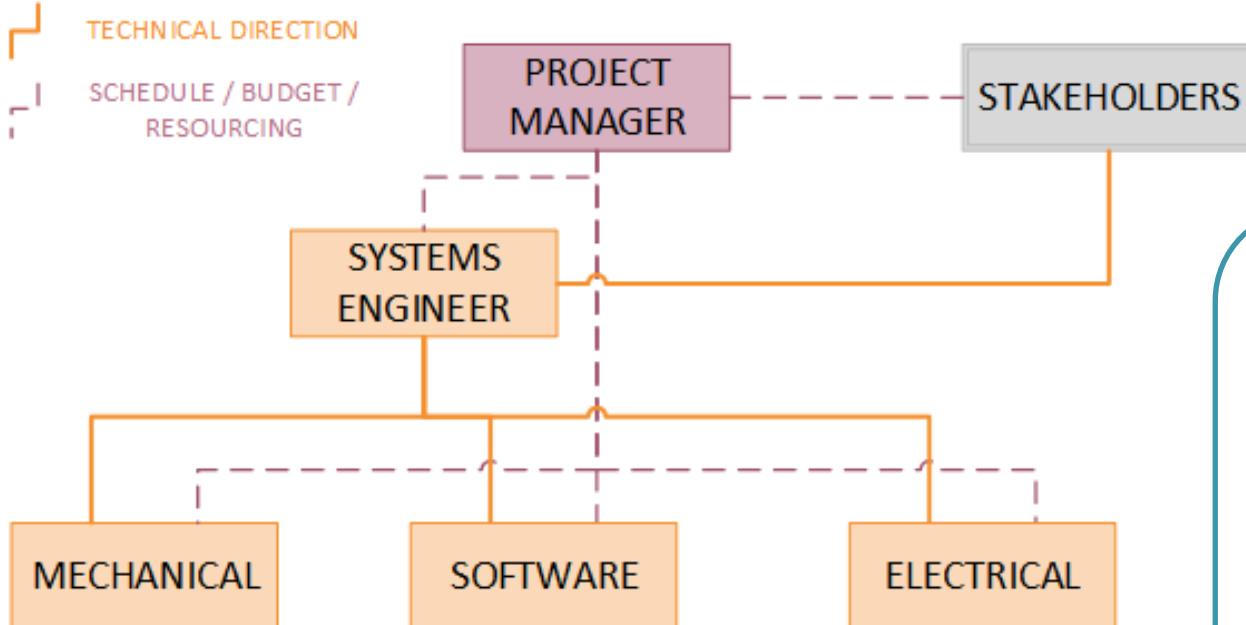
Baby Mop



Das Boot



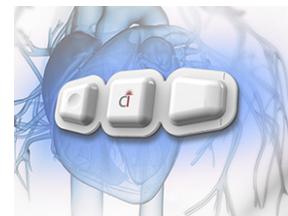
Lead Systems Engineering



To Maximize Value:
The SE has overall ownership of the **traceability**, the **system design**, and serves as **technical lead** for the project



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Excuses from Med. Industry

*It costs too
much*

Oh, we'll
provide the
requirements

*Can't the
PM be the
technical
lead*

*This project
isn't big
enough to
need a SE*

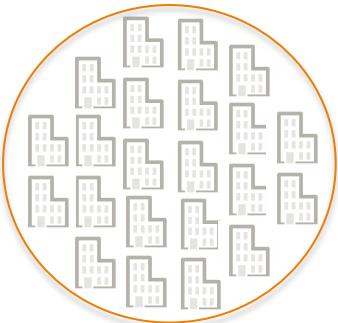
*Shouldn't the
engineers do
their own
traceability*

Syncroness' Potential Customers Say
They Don't Need a Systems Engineer

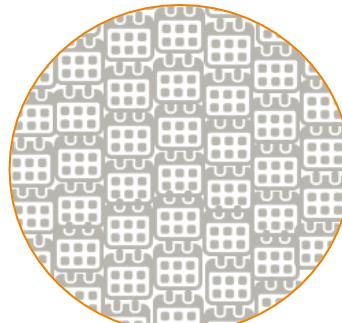
INTERVIEWS: Why doesn't (most of) the medical device industry think a Systems Engineer is valuable?



7 senior
medical
R&D-ers



22 different
companies



115 years
experience

Questions:

- What is it?
- Who does it?
- Is it valuable?

Interview Findings

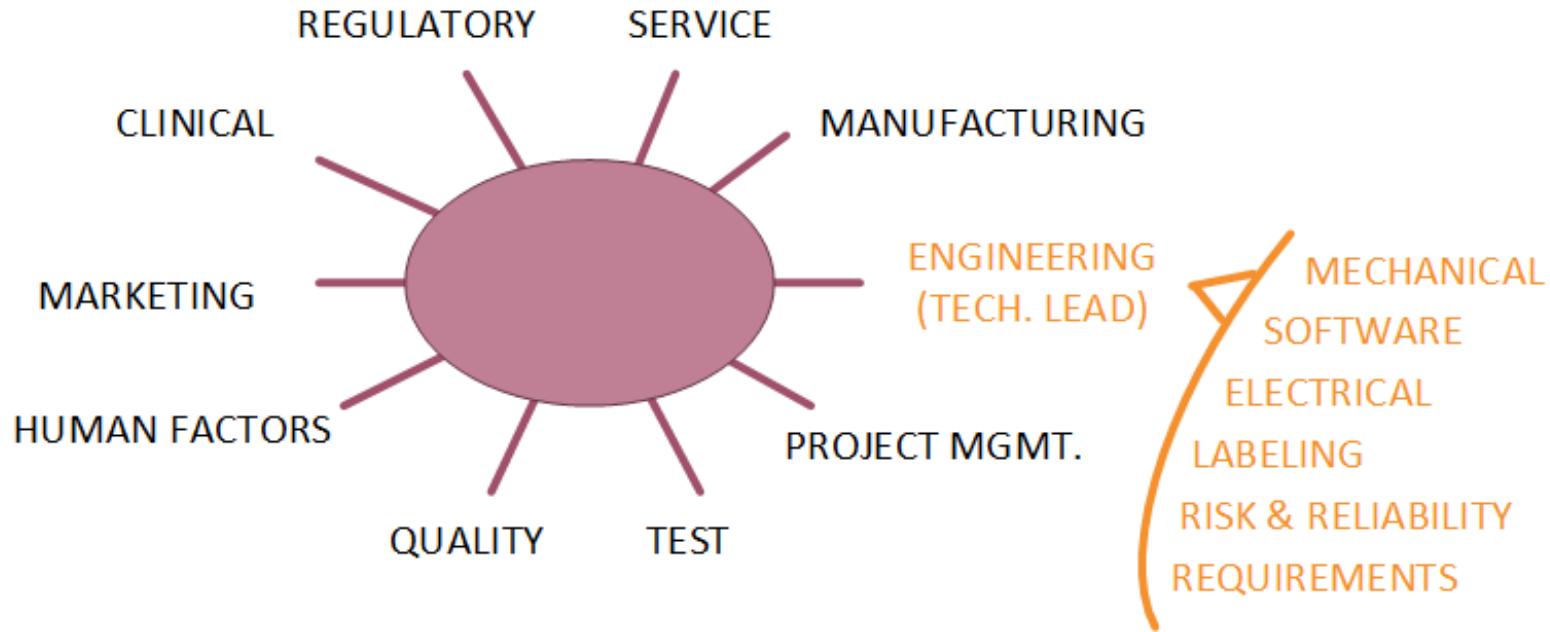
Negative impressions from:

- Limited Implementations of SE
- 'Disjointed' SE

Positive impressions from:

- Past experience with a talented (and empowered) SE

Typical Med. Device Team



Who's Doing the SE

Systems Engineering

- Requirements elicitation
- Requirements management
- Technical leadership
- Architecture
- System-level decision making
- Integration planning / testing
- Verification / test planning
- Risk management
- Validation test / planning
- Regulatory flow-down
- Reliability
- Design Transfer Liaison
- Technical quality-control

Project Manager or
Engineer Delegate

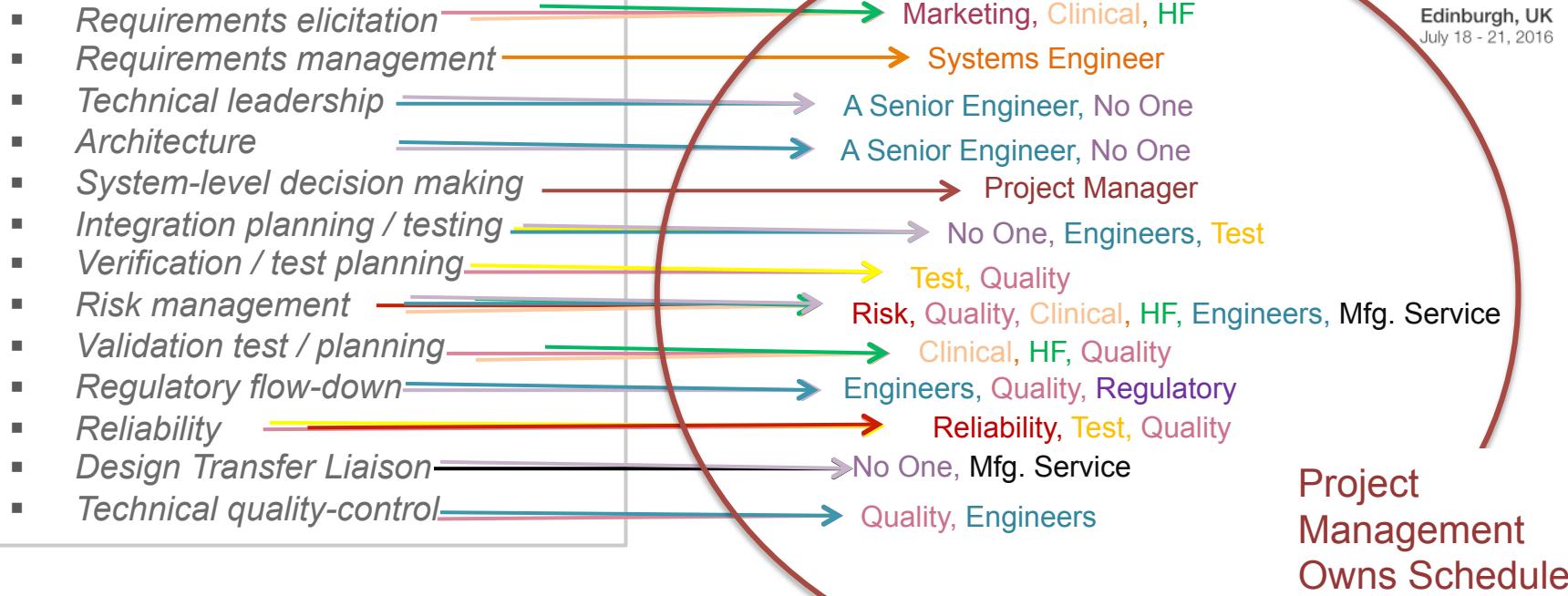
Quality, Well,
Sometimes the Engineers

No One

Who's Doing the SE



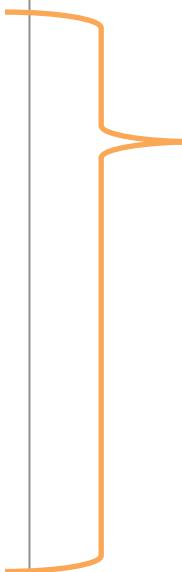
Systems Engineering



Who's Doing the SE

Systems Engineering

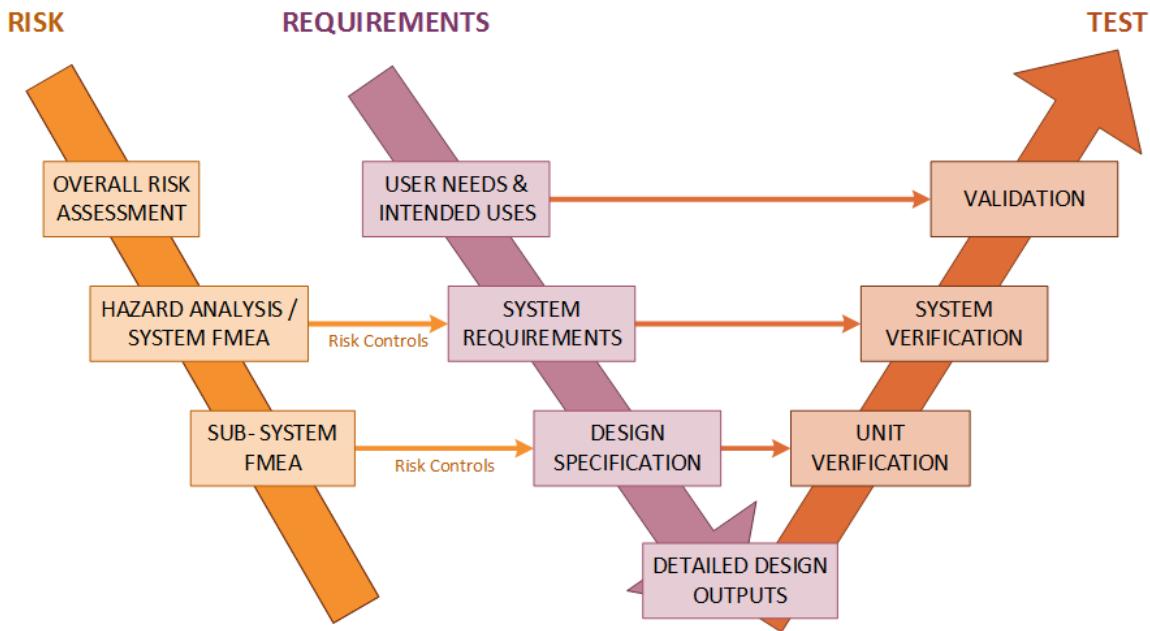
1. Requirements elicitation
2. Requirements management
3. Technical leadership
4. Architecture
5. System-level decision making
6. Integration test / planning
7. Risk management
8. Verification test / planning
9. Validation test / planning
10. Regulatory flow-down
11. Reliability
12. Design Transfer Liaison
13. Technical quality-control



Owned by a Lead Systems Engineer

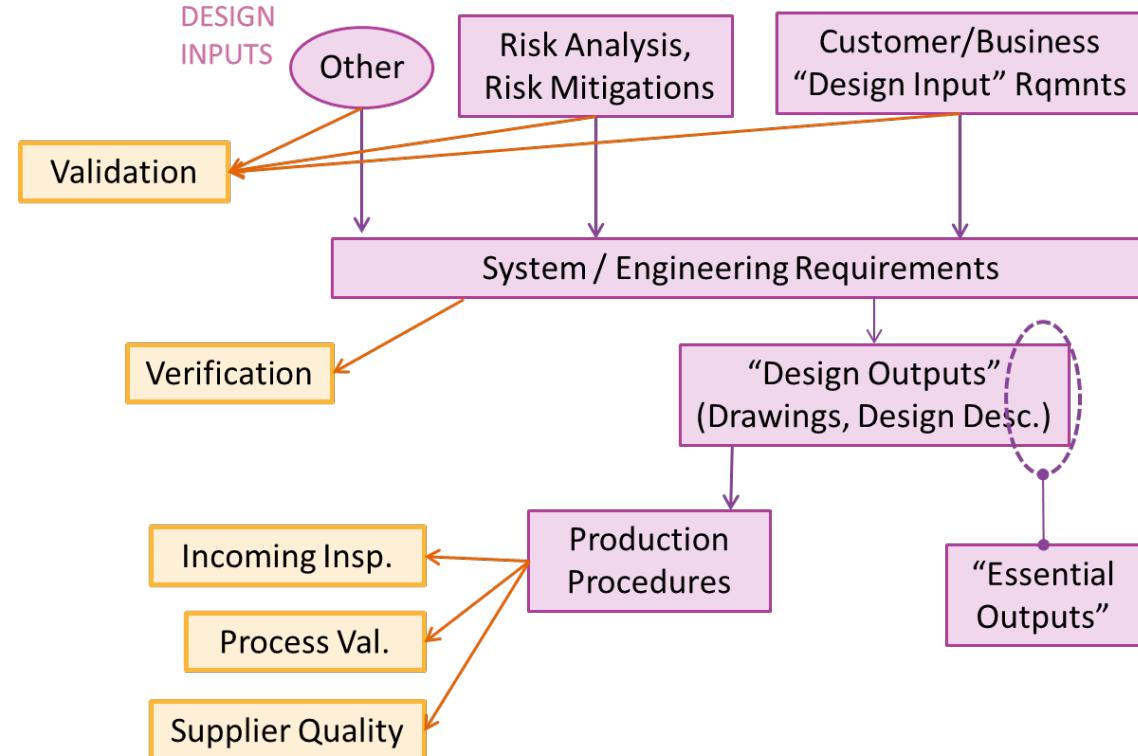
- With junior SEs to coordinate and get technical input from other functions
- With a project manager to coordinate resources, costs, schedule

Coherent Submissions



Put a Lead SE in charge of telling an overall design story. Make it easier for regulatory agencies to confirm your products are safe and effective.

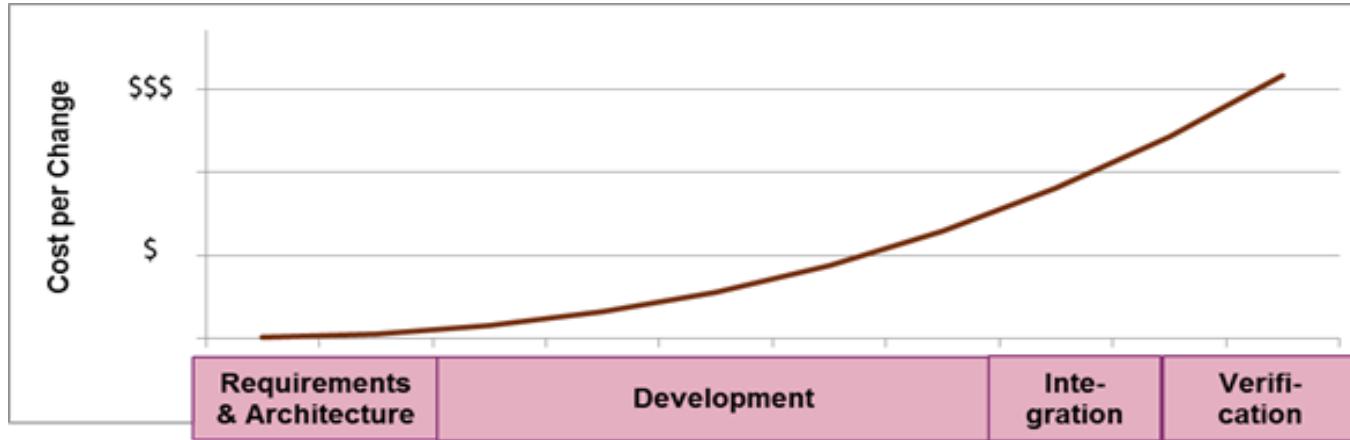
Consistently Focus Effort



Using a Lead SE can create a consistent 'Risk Based Approach'

- Minimize unneeded effort
- Reduce duplication
- Safer, more focused products, and a more cohesive story

Find Change Faster, Save \$



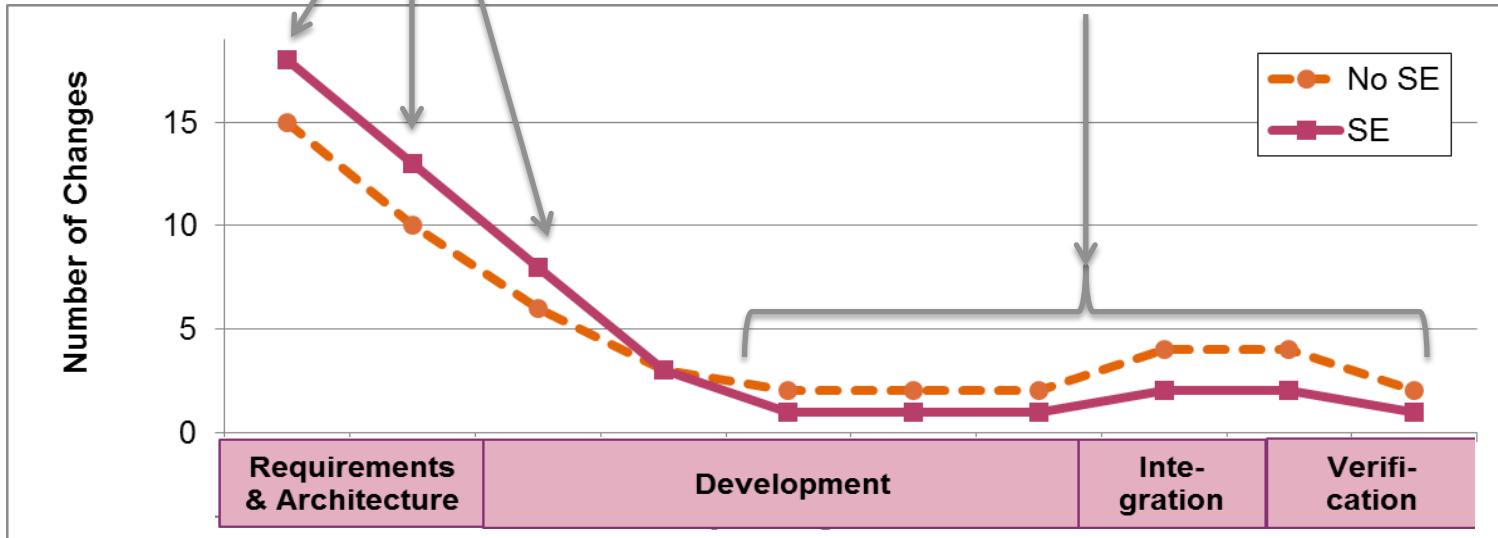
Goal: find and address changes/ issues as early as possible

- Cost of change increases exponentially as R&D continues
- Changes/Issues are inevitable, it's when you find them that matter

Find Change Faster, Save \$

- 1) Assume there are 50 inevitable changes/issues.
- 2) Having an SE helps you find a few more early in the project

(Which means less later on)

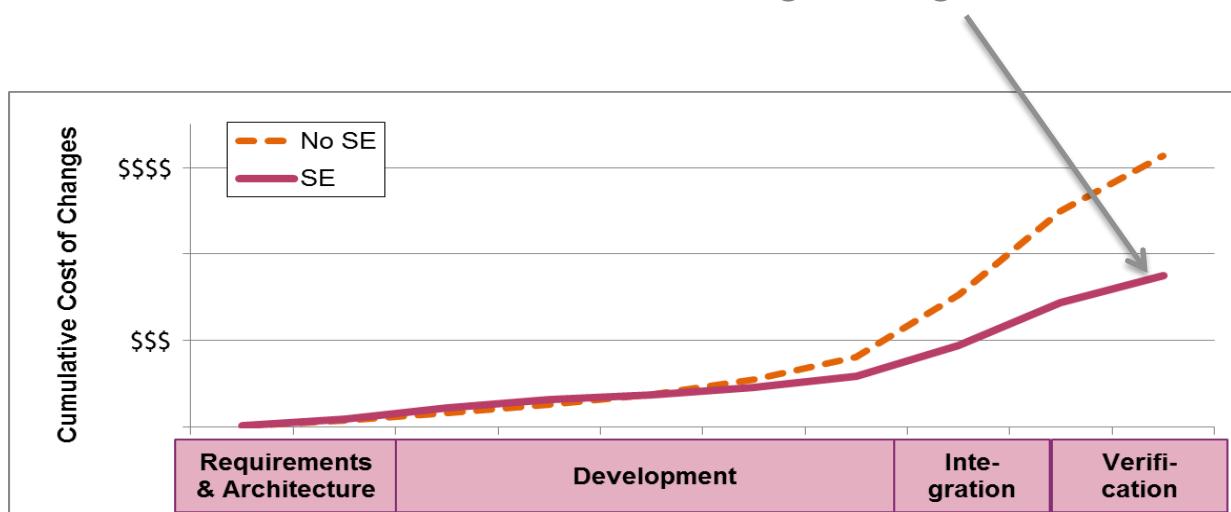


Find Change Faster, Save \$



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Finding changes a little earlier leads to big savings



- SE clarifies / finds requirements up front
- Capitalize by keeping a Lead SE involved to identify and address changes earlier

Sys Thinkers = Tech. Leads



“Big Picture” thinker



Agile mental ability – Can change perspectives



Inquisitive, thoughtful, values other perspectives

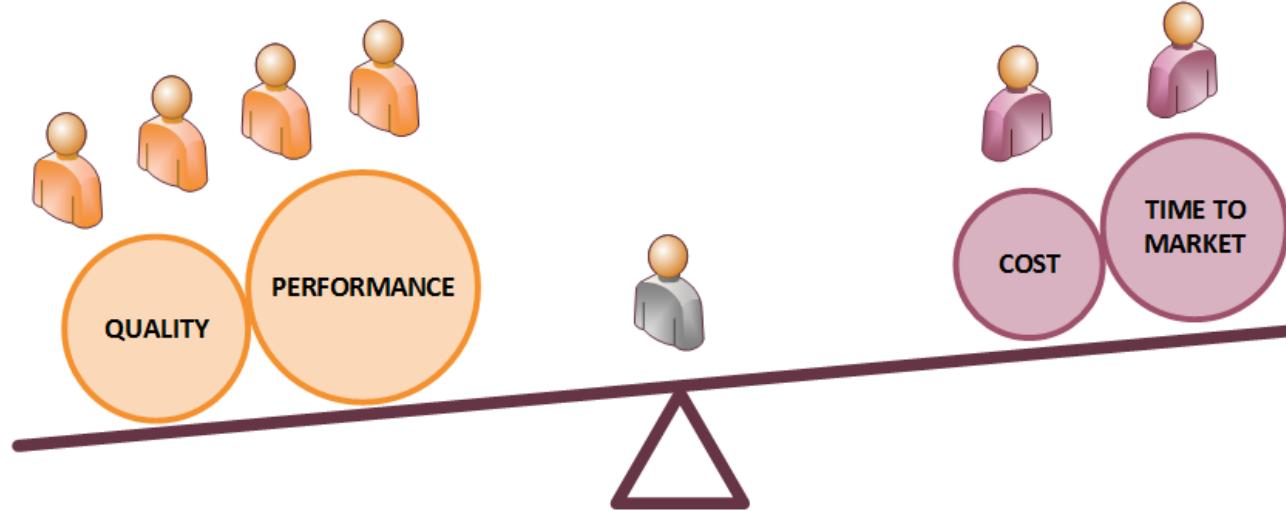


Makes decisions (ONLY) when appropriate



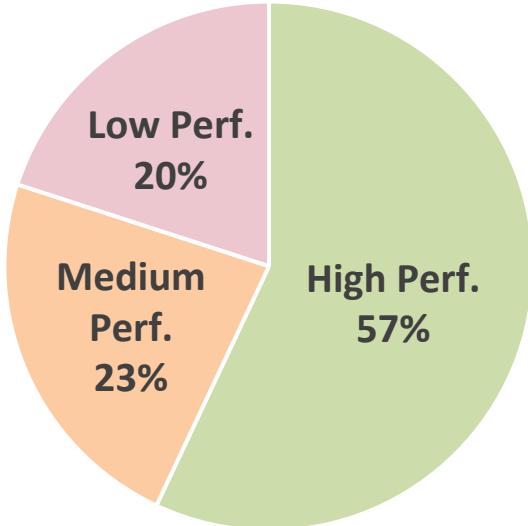
Identifies and trades risks - Surfaces and tests assumptions

Maintain Project Balance



- Let Project Management focus on cost targets and time to market
- Let a Lead Systems Engineer be neutral and evenly weigh both sides

Research Shows

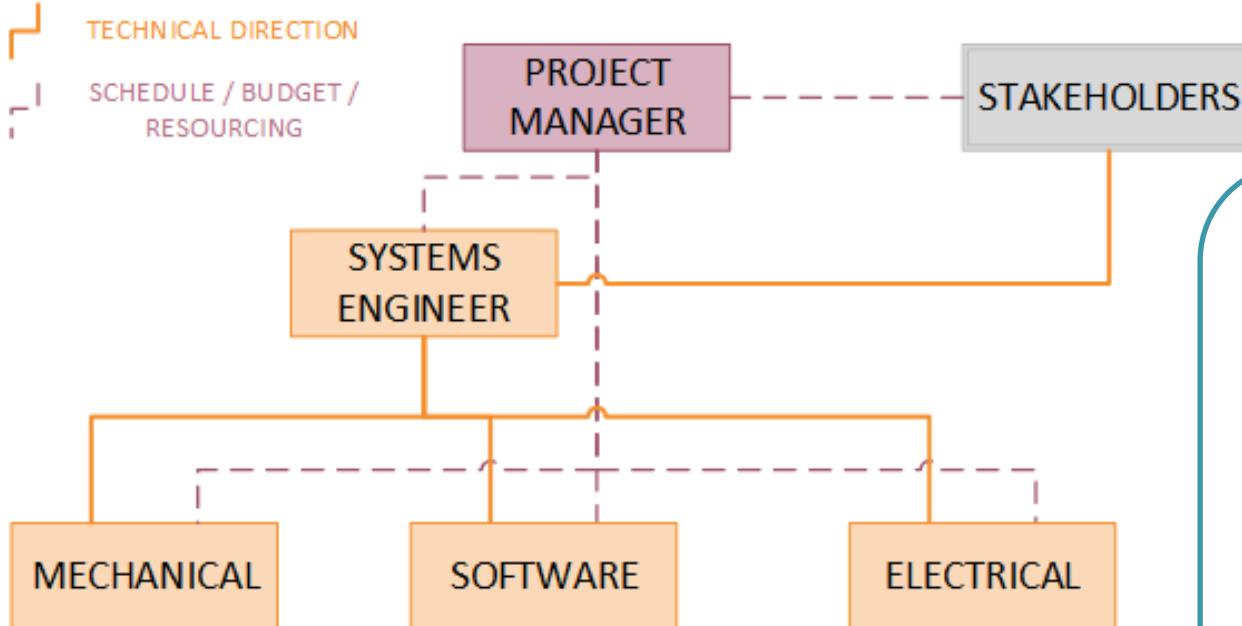


Project Performance with
High SE Capability Scores²

HOW YOU ADD SE MATTERS

- Research shows that SE practices benefit projects, on average.^{1,2}
- But, results are variable

Lead Systems Engineering



To Maximize Value:
The SE has overall ownership of the **traceability**, the **system design**, and serves as **technical lead** for the project

Improve your Medical Device Development with a Lead Systems Engineer

*They improve
project success*

*They create stronger
submissions*

*They focus
effort where it
matters*

*They help
find changes
faster which
saves money*

*They make
good
tech. leads*

*They balance
the scales so
cost & time to
market matter
as much as
quality and
functionality*



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