Deliver Value Faster in Regulated Industries with SAFe and IBM Solutions

The Continuous Engineering Experts

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Compliance meets lean-agile

Regulatory/Compliance

ensure health and welfare

➡ Quality, safety, security, etc.

➡ Verification and validation

➡ Inspections, audits, sign-off

➡ Metrics – defects, req coverage, code coverage, etc.

➡ Agile metrics - % tests automated, # new tests, # refactors

Lean-agile

shortest sustainable lead-time

➡ Organize around value

➡ Apply cadence and synchronization

➡ Build quality in

➡ Deliver business value earlier and continuously

➡ Make work and progress visible

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Why the focus on principles?

A common disease that afflicts management the world over is the impression that "Our problems are different". They are different to be sure, but the principles that will help to improve quality of product and service are universal in nature.   —W. Edwards Deming

100 books

Principles
over
Practices

100 implementations

➡ A Lean-Agile transformation will deliver substantial benefits

➡ But it is a significant change and every implementation is different

➡ Leaders should understand why the practices work; it's part of "knowing what it is they must do"

➡ If a practice needs to change, understanding the principles will assure the change moves the enterprise in the right direction

Apply Lean-Agile Principles

#1-Take an economic view

#2-Apply systems thinking

#3-Assume variability; preserve options

#4-Build incrementally with fast, integrated learning cycles

#5-Base milestones on objective evaluation of working systems

#6-Visualize and limit WIP, reduce batch sizes, and manage queue lengths

#7-Apply cadence, synchronize with cross-domain planning

#8-Unlock the intrinsic motivation of knowledge workers

#9-Decentralize decision-making

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How Do Scrum and Agile Help Teams?

Fosters decentralized decisions

Better aligned to deliver value faster

Reduced WIP drives focus

Synchronized around common ceremonies

Smaller batches move through system faster

Regular cadence limits variability to single Sprint

Incremental development provides fast feedback

Product Owner

Product Backlog (Stories)

Sprint Backlog (Stories)

24 Hours

30-day Sprint

Potentially Shippable Software

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Sprint Planning

Sprint Review (Demo)

Sprint Retrospective

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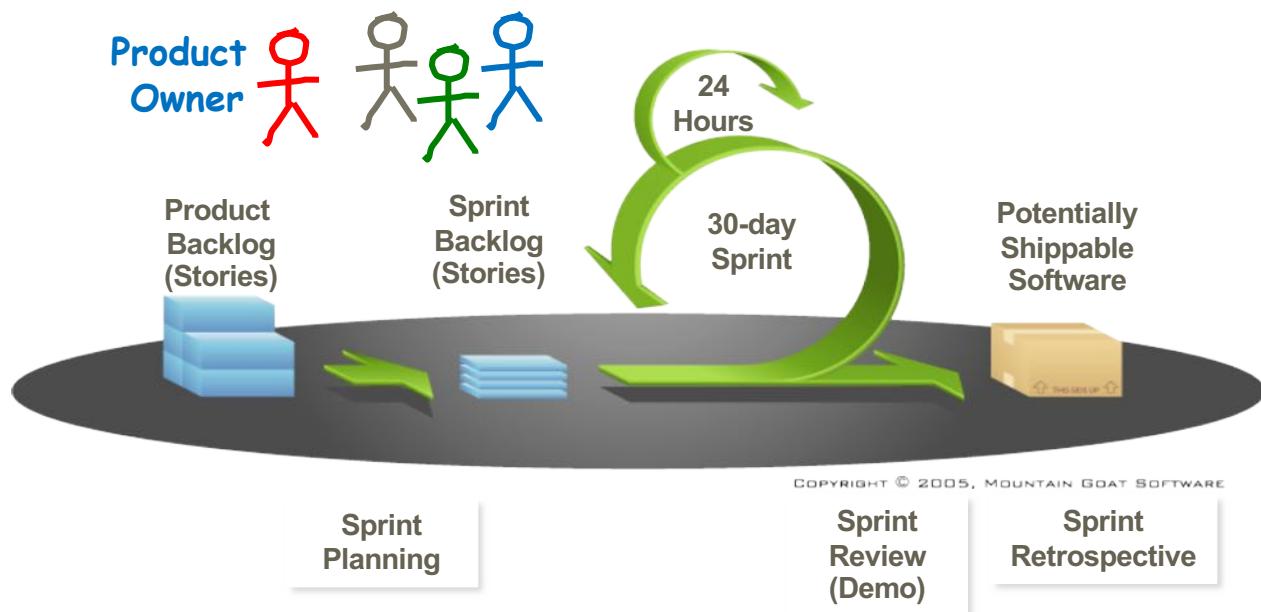
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Scaled Agile Framework (3-level)

SAFe® 4.0 for Lean Software and Systems Engineering
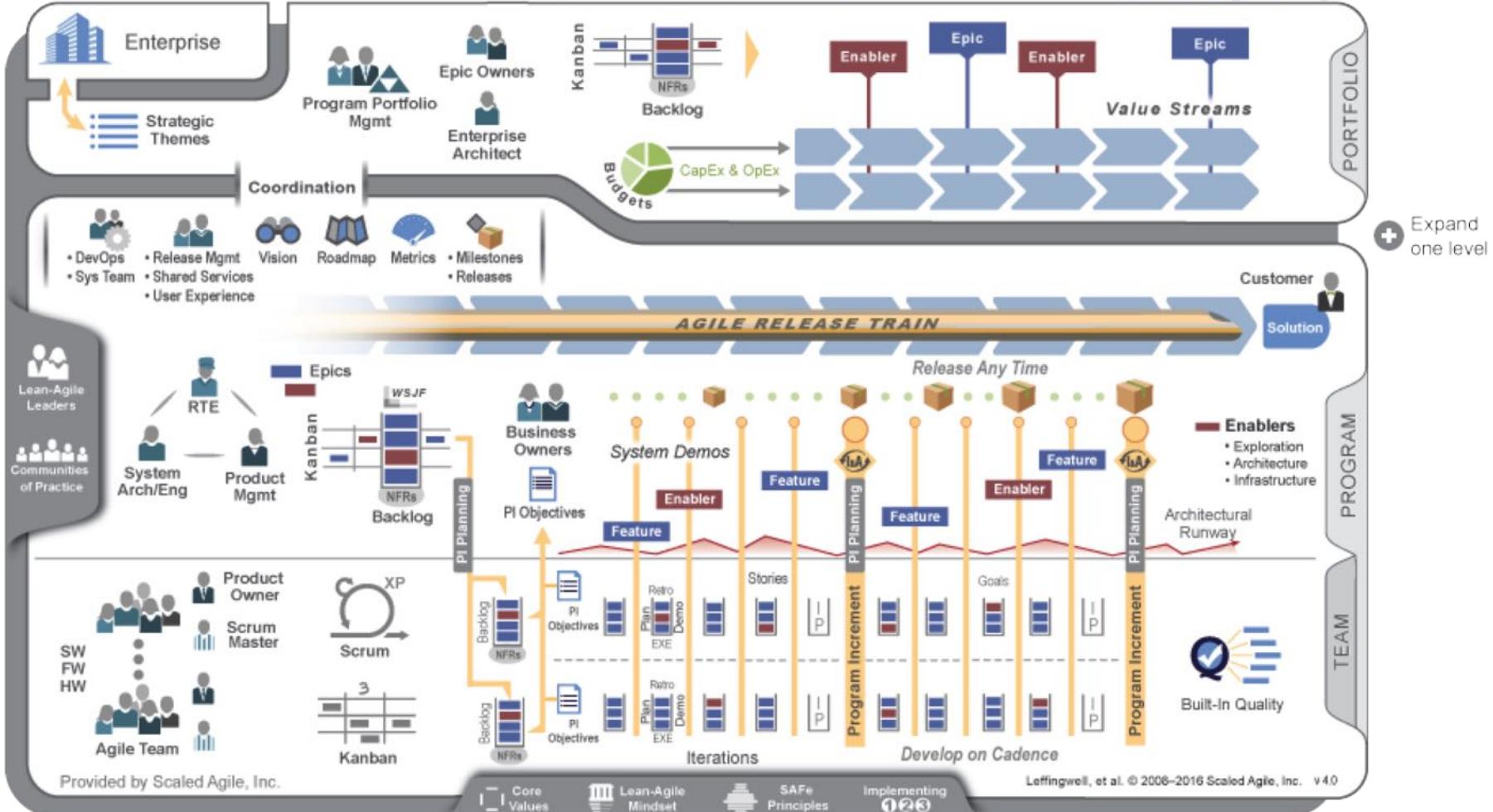
Scaled Agile Framework (4-level)

SAFe® 4.0 for Lean Software and Systems Engineering
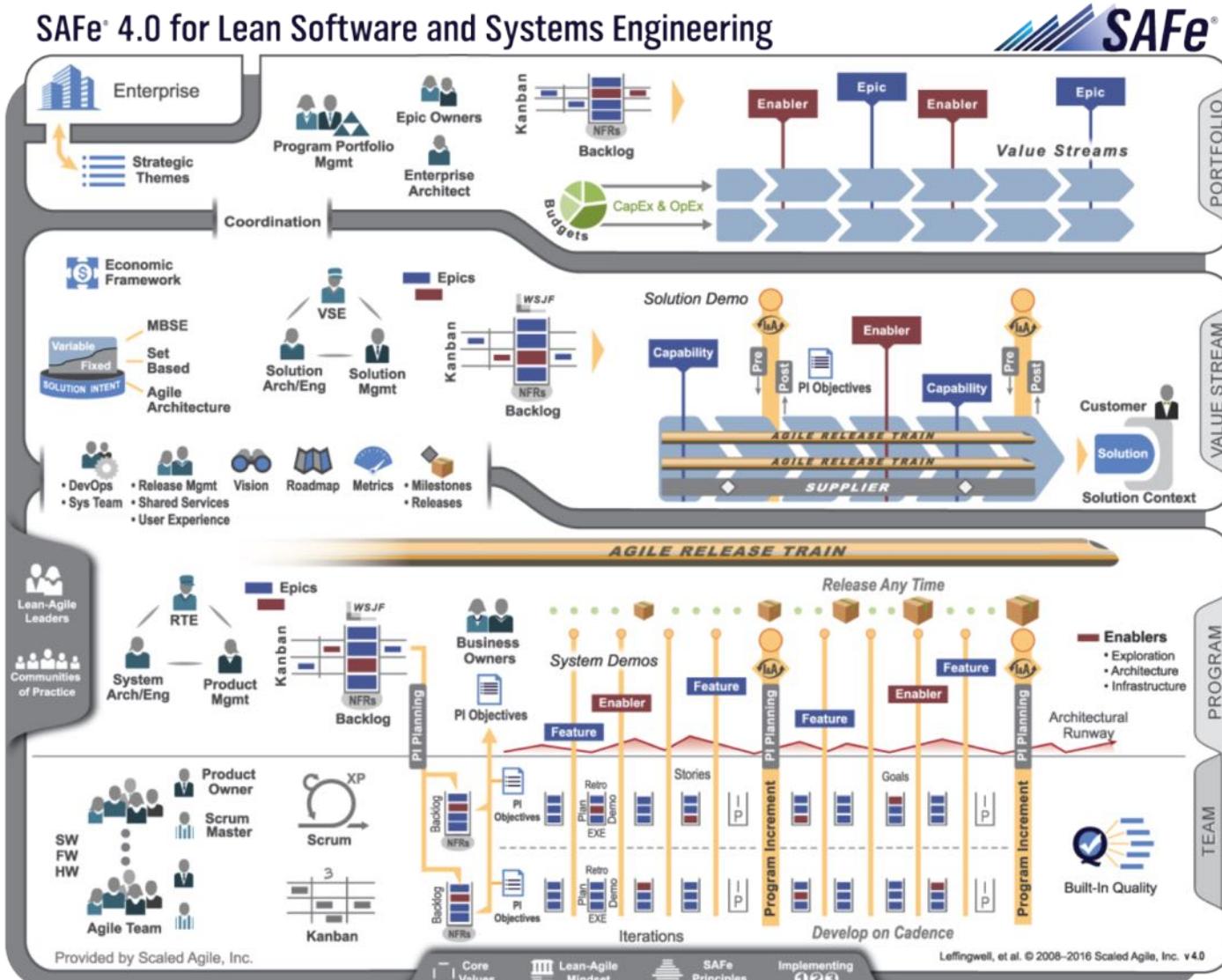
Adopt principles to support regulated industries

1) Take an economic view

2) Apply cadence and synchronization

3) Base milestones on objective evaluation of working systems

4) Build incrementally with fast, integrated learning cycles

5) Visualize and limit WIP

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1) Take an economic view

➡ Optimize around value delivery

➡ Deliver quickly by minimizing handoffs, delays, waiting, and eliminating waste

➡ Facilitate early and incremental verification and validation, reviews, sign-off, etc.

"There is nothing so useless as doing efficiently that which should not be done at all."
—Peter F. Drucker

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Ensure EVERYONE is on the value stream

➡ Goal is reduced waste – waiting, delays, hand offs, batch sizes, WIP

➡ SAFe identifies stakeholders, customer, suppliers

➡ But, also includes anyone who reviews, approves, signs-off

  ▪ QA, safety, customer, regulatory, legal, procurement, etc.

• Shared Services

Quality   Safety   Legal   Regulatory

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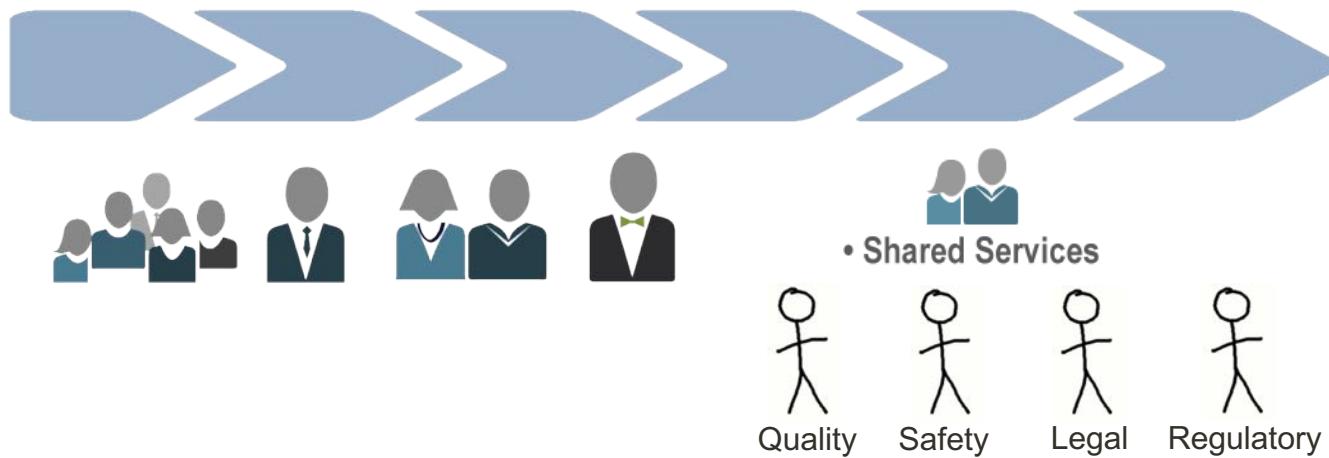
Defining Verification, Validation, and Compliance

Validation ensures a solution fulfills its intended purpose. In many industries, that purpose is to meet the intended user's operational needs. In others, validation also represents procedures were properly followed for solution building, installation, and operation.

"you built the right solution"

Verification ensures a solution meets a set of specifications, regulations or other conditions imposed at the start of development. In development, verification exercises all or part of a solution, or some proxy for the solution (model, simulation), to ensure the results meet tolerances. In post-development, verification repeats tests to ensure the final product meets those conditions.

"you built the solution right"

Both verification and validation may require documented, objective evidence through tests, inspections, analysis, or demonstrations necessary to support compliance and certification.

2) Apply cadence and synchronization

➡ Align and focus on short term vision

➡ Make unpredictable events predictable

➡ Reduce delay and batch size for compliance activities

➡ Deliver value sooner; perform quality activities continually, not at end

"Cadence and synchronization limit the accumulation of variance"
*—Don Reinertsen*

IV&V Test

Quality Review

Customer Sign-off

Compliance Test

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Achieve verification with Solution Intent

➡ Relate Solution Intent knowledge to demonstrate compliance

➡ Where required, generate documents from related model data

➡ Establish Solution Intent structure early, populate over time

Requirements Model
- Use Case
- NFRs – safety, security
- Customer, regulatory

Solution Model
- Analysis
- Architecture/interfaces
- Domain (ecad, mcad, sw)

Variable
Fixed
SOLUTION INTENT

Domain Model
- Business process
- Business rules

Traceability

V&V Model
- Reviews/signatures
- Test plans, cases, exec

Realization
- Code + build/deploy
- Docs (user, man, install, …)
- Manufacturing specs (TDP)

Solution

Compliance docs

Align requirements, construction, and test

➡ Align everyone on what to produce this PI

➡ Synchronize fixed solution intent with test plans and compliance artifacts

- What Features are part of this PI?

- When is a Feature ready to be tested, reviewed, etc.?
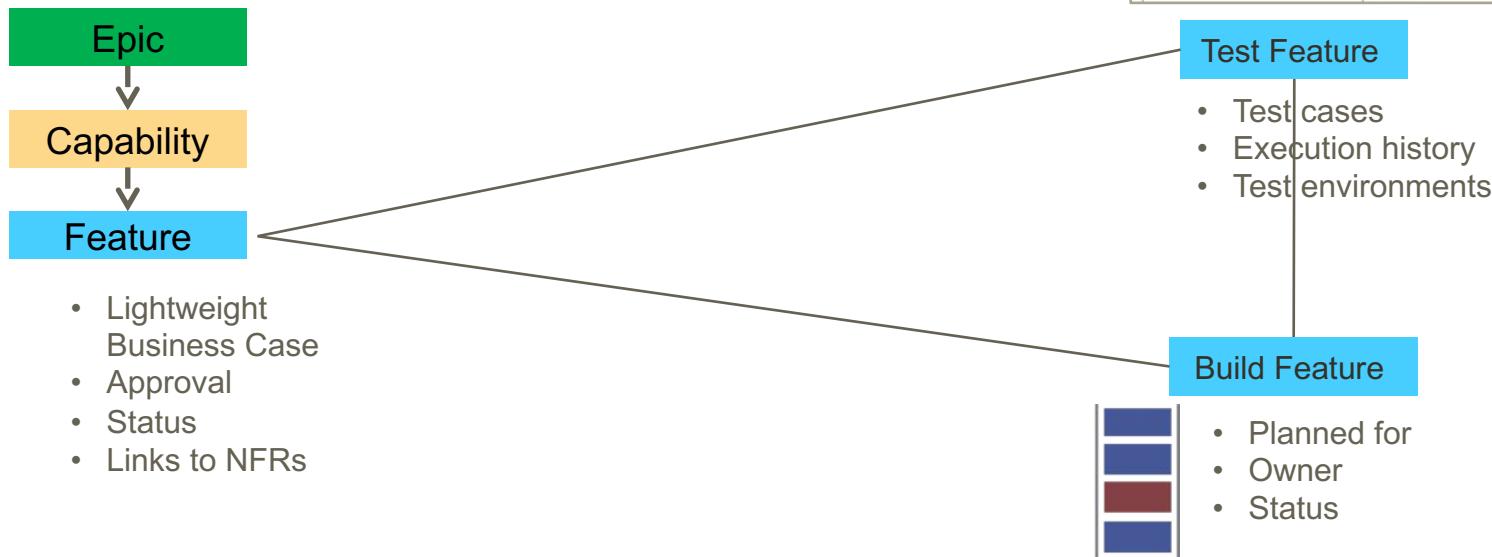
Reconcile with changing requirements

Actions
- Reconcile Removed Items
- Reconcile Deleted Items
- Reconcile Updated Items

Requirements changed since the last reconciliation

Show All ▾ Items per page

☐ Summary

☐ 1011: Requirement1

Epic

↓

Capability

↓

Feature

- Lightweight Business Case
- Approval
- Status
- Links to NFRs

Test Feature

- Test cases
- Execution history
- Test environments

Build Feature

- Planned for
- Owner
- Status

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Define scalable Definition of Done (DoD)

➡ Testing and compliance are continuous, part of process

Story (within Sprint)	Feature (within Increment)	Increment/Release
• Acceptance passed (auto) • DBT tests passed (auto) • Standards met (SW, HW) • Peer reviews (SW, HW) • Accepted by PO	• Deployed to V&V/QA for end-end system testing • QA/Customer/etc. review • Included in build/deploy process • Documentation updated • Accepted by Prod Mgr	• Deployed to IV&V testing • Customer signoff • Assess compliance status via report generation (RPE)

➡ Enforce DoD with process actions

Ensure unit test pass before delivering code

Ensure reviewer viewed all changes

Cannot deliver code until peer review

Only Quality role can set a Feature to done

Workspace must be caught up before delivery

Cannot change work item state after delivery to test

E-Sig required for sign-off

Cannot accept Story until all issues from review are resolved
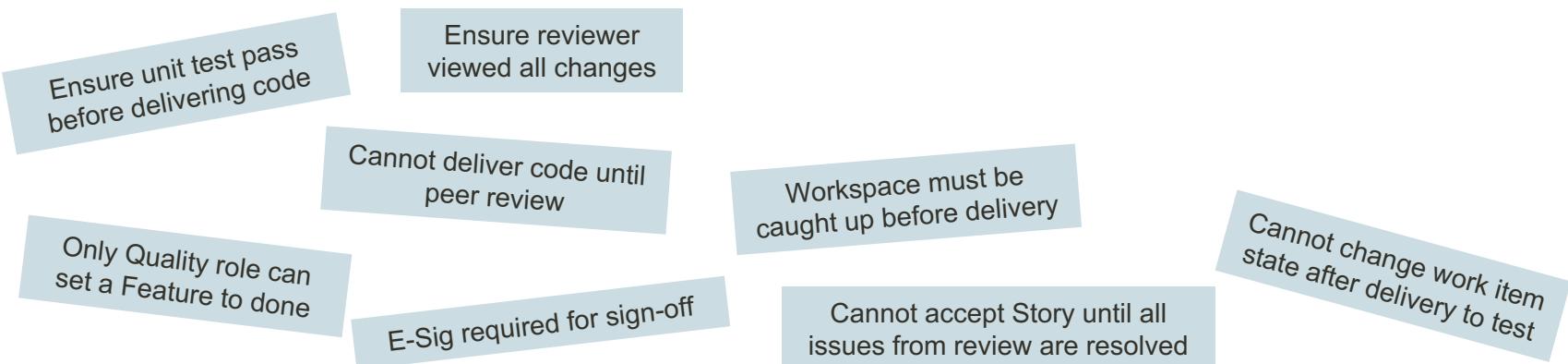
Continuous review and approval process

➡ Reviews are part of the process (Definition of Done)

➡ Strive for lean process – attack delay, waste, WIP

➡ RTC (6.x) supports review

- Peer review

code review

approval

- Quality review, approval
- Customer signoff

'32: Flow Rate'

- Baseline
- Submit compliance docs
- Regulatory sign off

- IV&V (BDT from previous)
- Generate compliance docs for status

Story   Story   Feature   Feature   Feature   Feature

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Agile Testing Quadrants
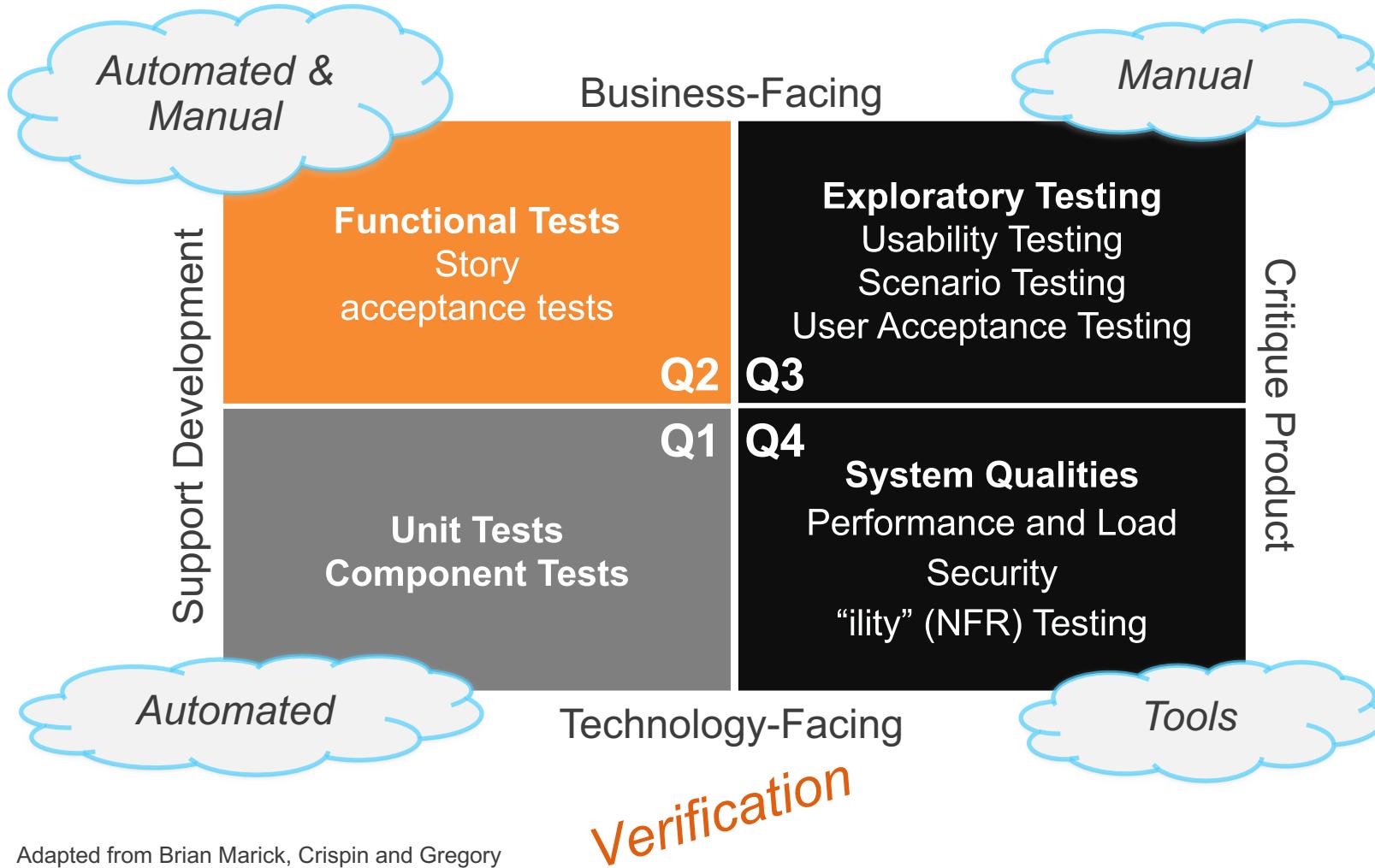
Adapted from Brian Marick, Crispin and Gregory

Apply continuous verification and validation each PI

➡ Test solution in as full a context as feasible each increment

➡ Evaluate progress of solution *and* progress towards compliance

➡ Without continuous V&V, quality and certification are uncertain

Verification (internal)

- NFRs
- Req coverage
- Code coverage
- Dev milestones achieved

To-date generated compliance docs

Validation (external)

- Functional tests, UAT
- Automated/manual
- NFR tests for compliance

To-date generated compliance docs

Program Increment

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3) Base milestones on objective evaluation of working systems

➡ Emergent design w/ refactoring for continuous improvement and removing technical debt

➡ Frequent integration provides small work, fast feedback

➡ Test-driven – otherwise, quality is speculative

  ▪ Automated, run frequently, in real env, for all artifacts

➡ Pair work, frequent peer review

"Stop depending on inspections"
-- Edwards Deming

Create testing environments early

➡ Strive for early, end-to-end systems integration

➡ Grow early production approximation(s) based on economics

➡ Bring in manufacturing early; use true production facility

➡ <u>Frequent tests == more test environments</u>

Dev Kit   SIL/Sim   Rev 1 HW   HIL   Sys Int   Mule
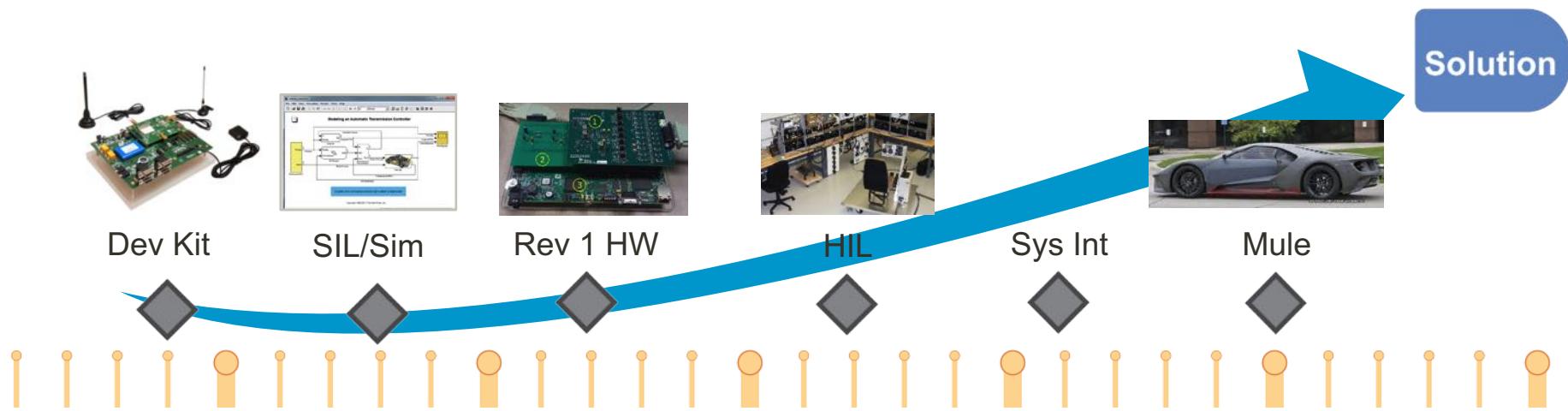
4) Build incrementally with fast, integrated learning cycles

➡ Exploration is continuous, not all up front

➡ Faster feedback on req and des decisions

➡ Everyone contributes to learning, not "leads"

➡ Specifications complete at end; evolve with learning
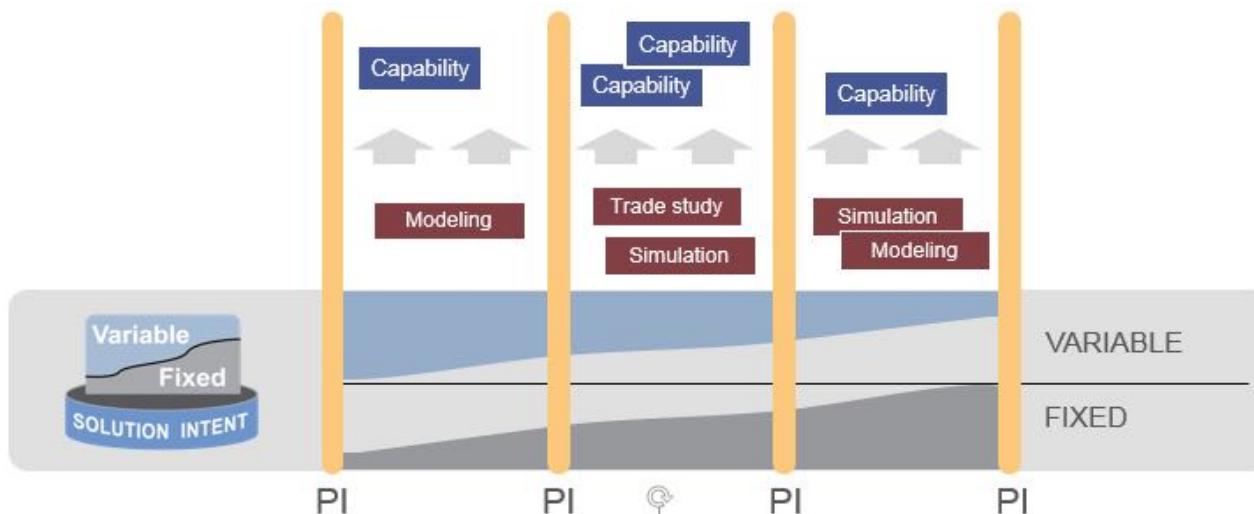
"The more detailed we made our plans, the longer our cycle times became"
—Don Reinertsen,

"The best architectures, requirements, and designs emerge"
-- Agile Manifesto

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5) Visualize and limit WIP

➡ Quality and compliance are continuous processes

  ▪ Visualize progress towards completion

  ▪ Generate compliance reports (don't bolt on at end)

➡ Encourages quality behavior and (eventually) culture

➡ Increase trust with business, customer, regulatory

"All is visible. All is known."
— From SAFe Core Values

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Measure progress at each System Demo

➡ Towards release, improved process, and compliance

Epic Progress
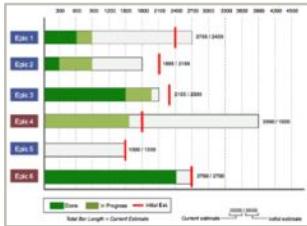
Progress towards release

Epic Burnup
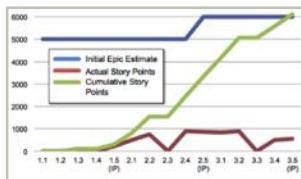
PI Predictability

### Defects
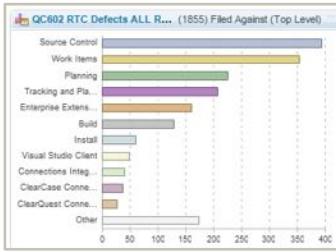
Team's Feature DoD
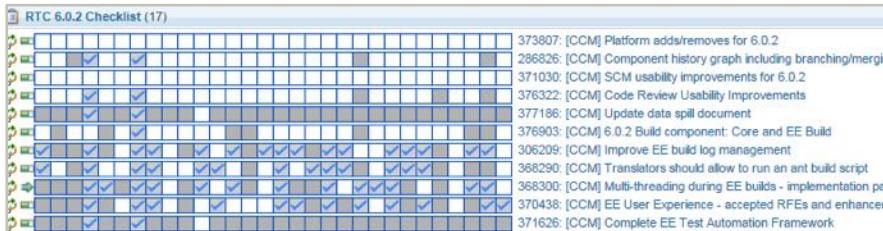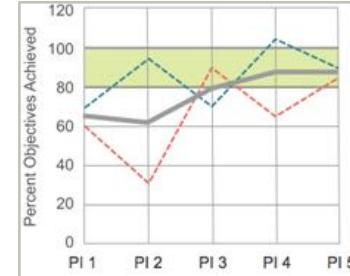
## Progress following process (WIP constraints)

Cumulative Flow
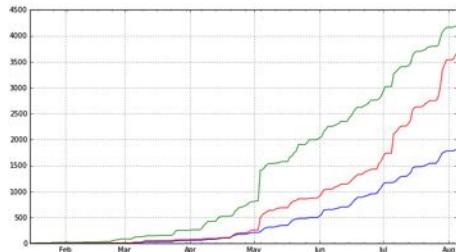
Kanban Board
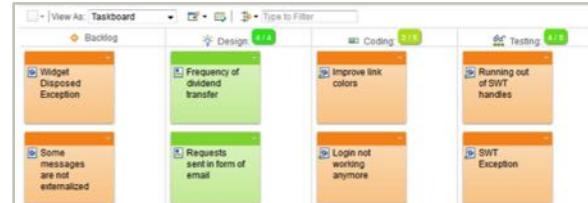
Measure progress towards compliance

➡ Architect CE products with the end in mind – compliance

➡ Define and enforce overall schema (dashboard w/ anti-queries)

➡ Ensure signatures where necessary

➡ Automate – coverage, quality, etc.

### Existing Defects

Defect Fix Rate
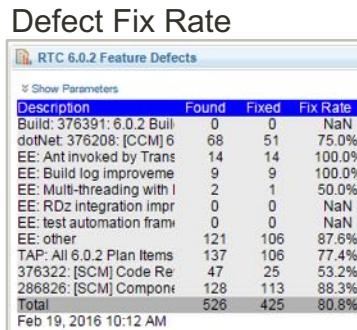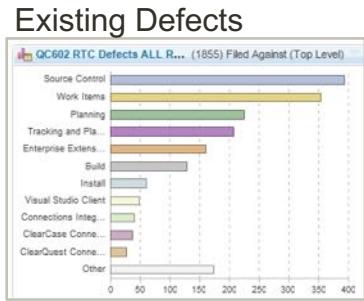
### Requirements Coverage

System Requirement	System Requirement	Software Requirement	Software Requirement	Test Case ID	Test Case
178	Donor Dividend Allocation	188	Donation by Amount	13	Donation amount limit
		319	Dividend allocation by percent	18	Dividend Allocation by
				19	Allocate Dividends to
		74	Frequency of dividend transfer	1	Verify dividend transfe
181	Organizations can apply	238	Requests sent in form of hard	4	Process hard copy re

Compliance Documents

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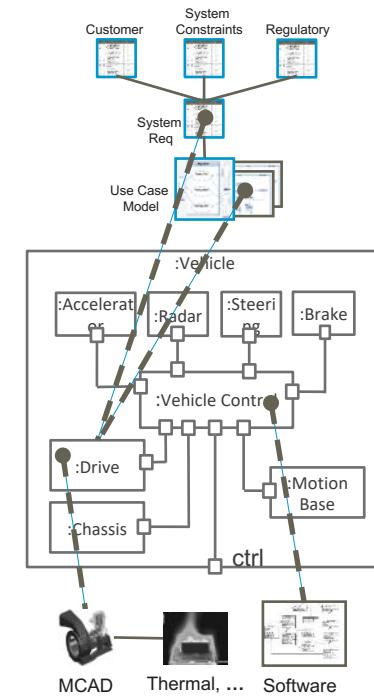
Summary - SAFe 4.0

Work management
Emergent planning
V&V
Visualization
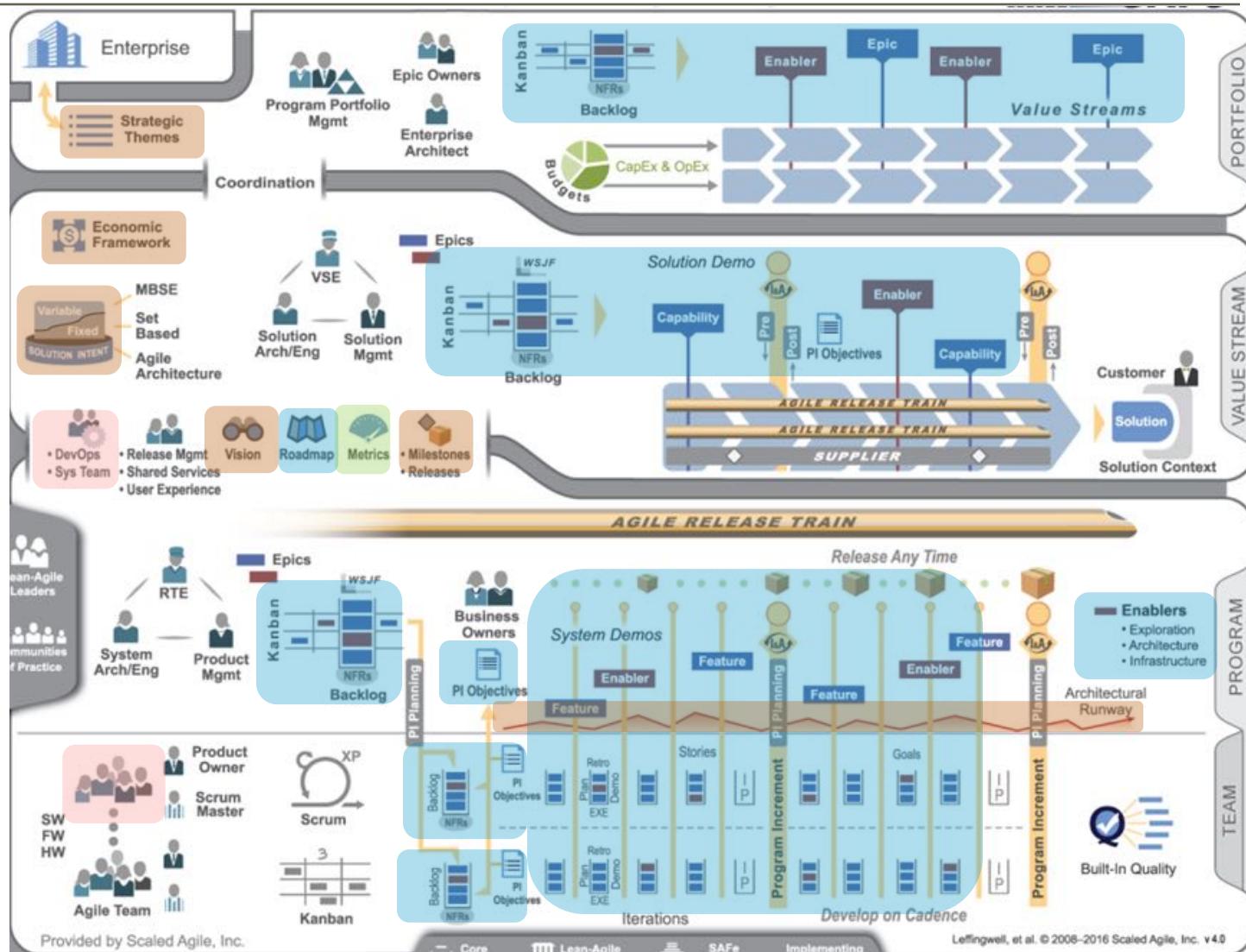
Adopt SAFe

Ready

Plan

Prepare Leaders

Courses	Days	Who Teaches
Leading SAFe (SA Certificate)	2	SPC
SAFe for Teams (SP Certificate)	2	SPC
SAFe Scrum Master (Certification / Orientation)	3 / ½	SPC
SAFe Product Owner (Certification / Orientation)	2 / ½	SPC
Implementing SAFe (SPC Certification)	4	SPCT

Train Everyone

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Adopt SAFe

AGILE RELEASE TRAIN

☑ **Launch ARTs**

➡ **Run initial 1-2 PI Planning and I&A sessions**

➡ **Mentor executives and leadership**

➡ **Remove roadblocks to learning and adoption**

➡ **Plan your expanded adoption**

➡ **Integrate Agile ALM & PLM tools to support your teams**

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