Achieving Regulatory and Industry Standards Compliance with the Scaled Agile Framework®

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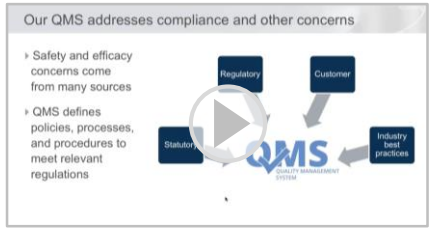
Agenda

- Regulatory requirements meet Agile development
- Meeting regulatory requirements with Lean-Agile development
  - Build the solution and compliance incrementally
  - Organize for value and compliance
  - Build quality and compliance in
  - Apply continuous verification and validation
- Summary

View a companion video of this presentation at https://youtu.be/-7rVOWTHZEw



Regulatory requirements meet Agile development

Traditional development challenges regulatory assessment

- Often results in late verification, validation, and opportunities for compliance assessment
- Can create a large bow wave of testing and compliance activity resulting in missed deadlines and windows for schedule compliance activities
- Despite best efforts, compliance with large batches and late feedback slows flow and results in worse outcomes and lower quality
- No way to leverage compliance knowledge to improve flow

Regulatory and compliance meet Agile

Regulatory and compliance

- Quality, safety, security, efficacy
- Specifications
- Verification and validation
- Objective evidence
- Inspections, audits, sign-off
- Quality management systems
- Metrics – defects, requirements coverage, code coverage, traceability

Agile Manifesto

Working software over comprehensive documentation

Customer collaboration over contract negotiation

Responding to change over following a plan

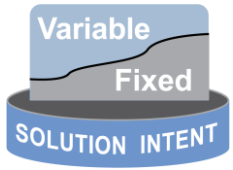
Welcome changing requirements….

CENELEC FDA ISO 13485 FEDERAL AVIATION ADMINISTRATION ISO 26262 MISRA bsi. ANSI American National Standards Institute AUTOMOTIVE SPICE®

Verification, validation, and compliance

Verification is the confirmation through objective evidence that the *specified requirements* have been fulfilled. Verification demonstrates that the design and implementation correctly and completely embody the requirements.

We built the solution right.



Validation is the confirmation via objective evidence that the system performs its intended function. The intended functions and how well the system performs those functions are determined by the customer.

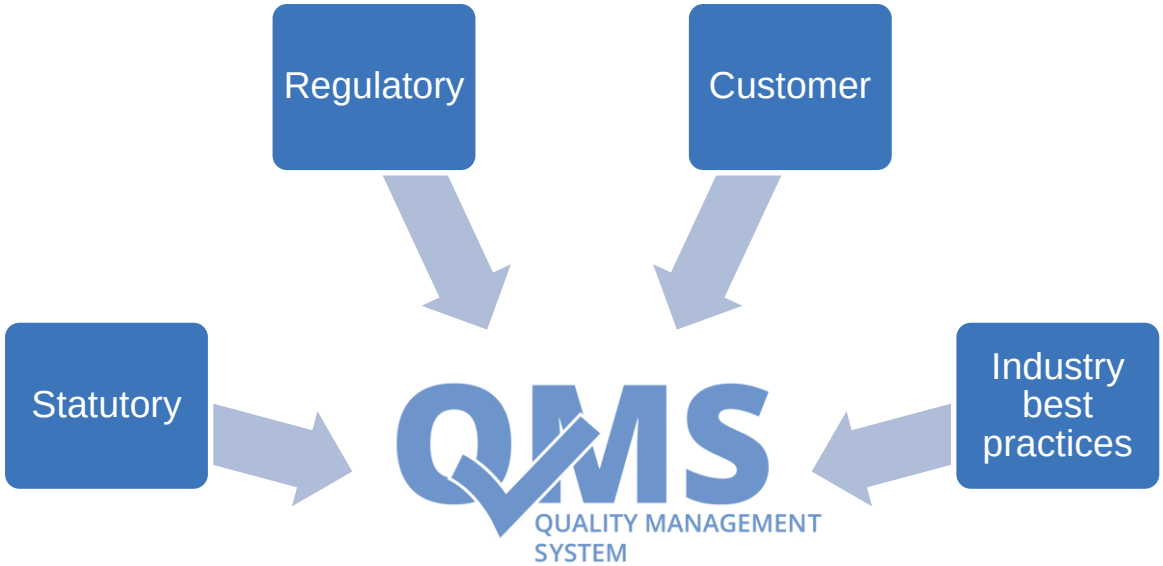
We built the right solution.

Compliance is an organization's adherence to relevant laws, specifications and guidelines. Compliance typically requires documented, objective evidence of solution V&V through tests, inspections, analysis, or demonstrations.

And we have evidence that we have done so.

Our QMS addresses compliance and other concerns

- Safety and efficacy concerns come from many sources
- QMS defines policies, processes, and procedures to meet relevant regulations



Two types of compliance requirements

On the Solution

Ensure product complies

"Sensitive information must be encrypted during transmission over networks that are easily accessed by malicious individuals"
– PCI Credit Card Standards

"Stopping from 20 miles per hour in a distance […] that is not greater than the distance specified in the table in paragraph (d) …"
– CFR Title 49 393.52 (automotive)

On the Quality Management System

Ensure process complies

"A documented software requirements specification (SRS) provides a baseline for both validation and verification." -- US FDA 21 CFR 820

"The purpose of the Quality Assurance Process is to provide independent and objective assurance that work products and processes comply with predefined provisions and plans and that non-conformances are resolved and further prevented" -- ISO 15504, ASPICE

However, Waterfall legacy has embedded itself in our QMS

Waterfall development creates many problems

- Under-estimated dependencies
- Massive growth in complexity
- Late delivery
- Little visibility into process
- Early commitment to specification that was insufficient
- Phase gates aren't helping reduce risk
- No way to improve systematically
- Late discovery of issues

"Any notion that we are mandated to apply a single-pass, waterfall model to software development is an industry myth, one which has likely been perpetuated by our own waterfall past ("we have always done it this way") and our existing quality management system, and not because "the regulations make us do it." *-- Dean Leffingwell*

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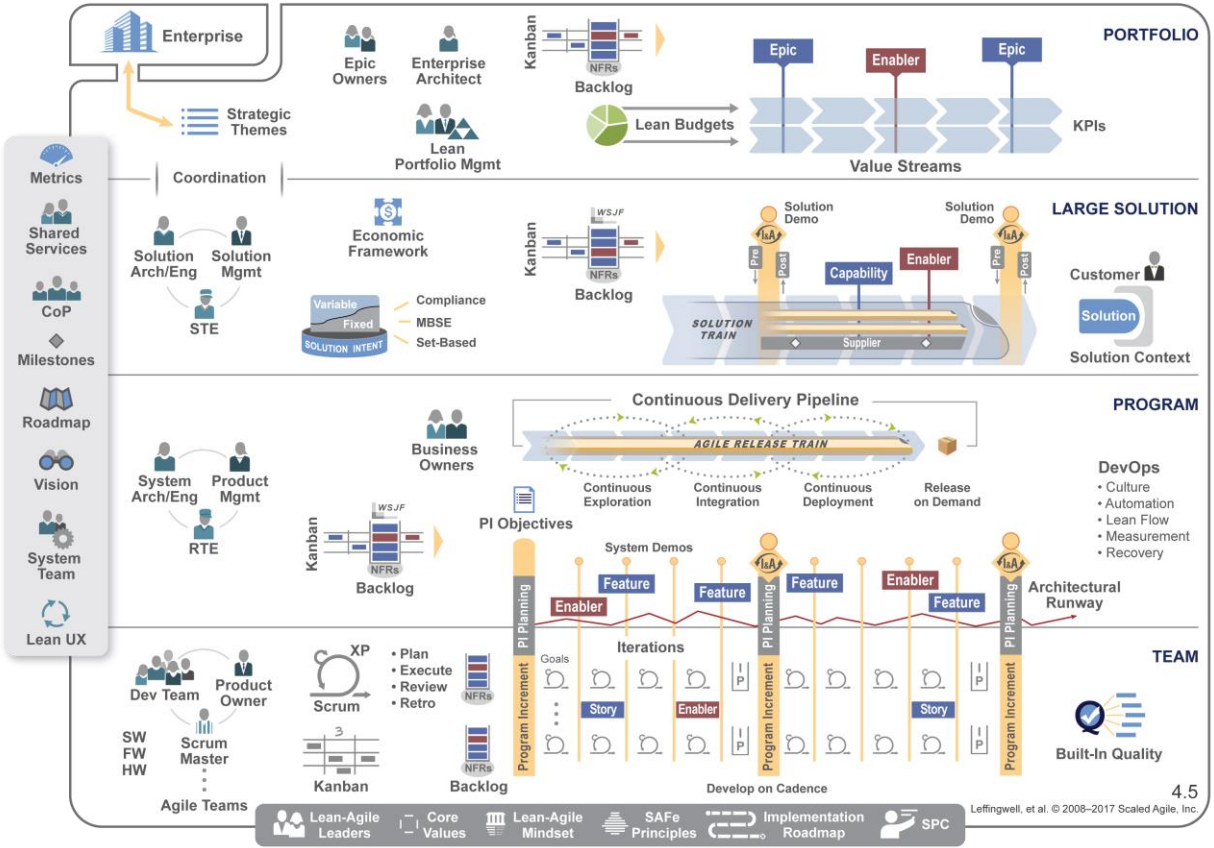
The Big Picture view



SAFe addresses both types of compliance requirements

Product is specified, designed, built and tested in accordance with regulations

bsi.
FEDERAL AVIATION ADMINISTRATION
CENELEC
ISO 13485
AUTOMOTIVE SPICE®
MISRA
FDA
ISO 26262

LEAN QMS
QUALITY MANAGEMENT SYSTEM

Variable
Fixed
SOLUTION INTENT
NFRs

Solution

Objective Evidence

Sign-off
Approval
Certification
Validation

Processes and procedures are performed in accordance with policy based on regulations

Build the solution and compliance incrementally

Organize for value and compliance

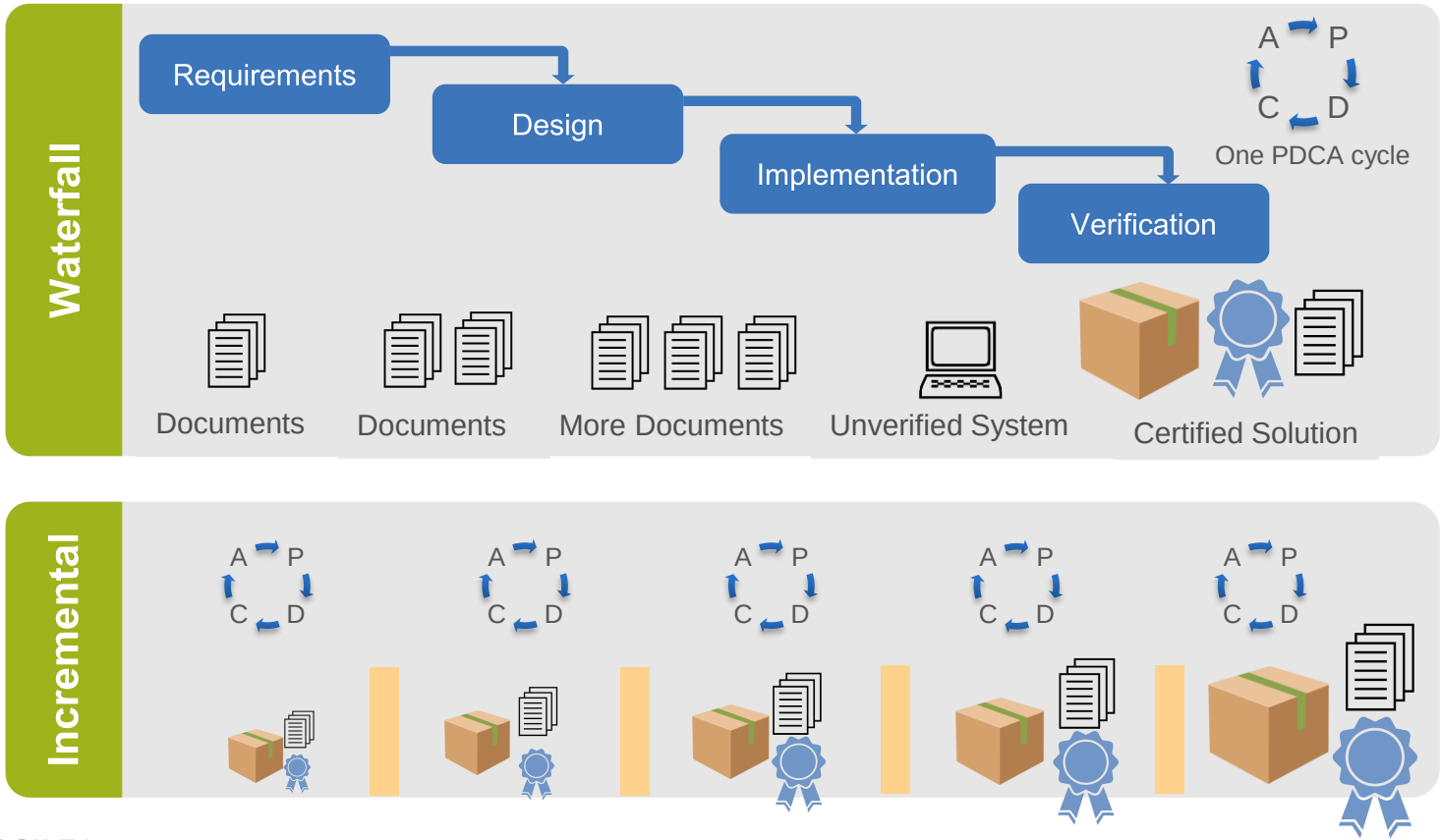
Build quality and compliance in

Apply continuous verification and validation

Meeting regulatory requirements with Lean-Agile development

Build the solution and compliance incrementally

Specify, build, and comply incrementally



Iterate within the product lifecycle

Conceive

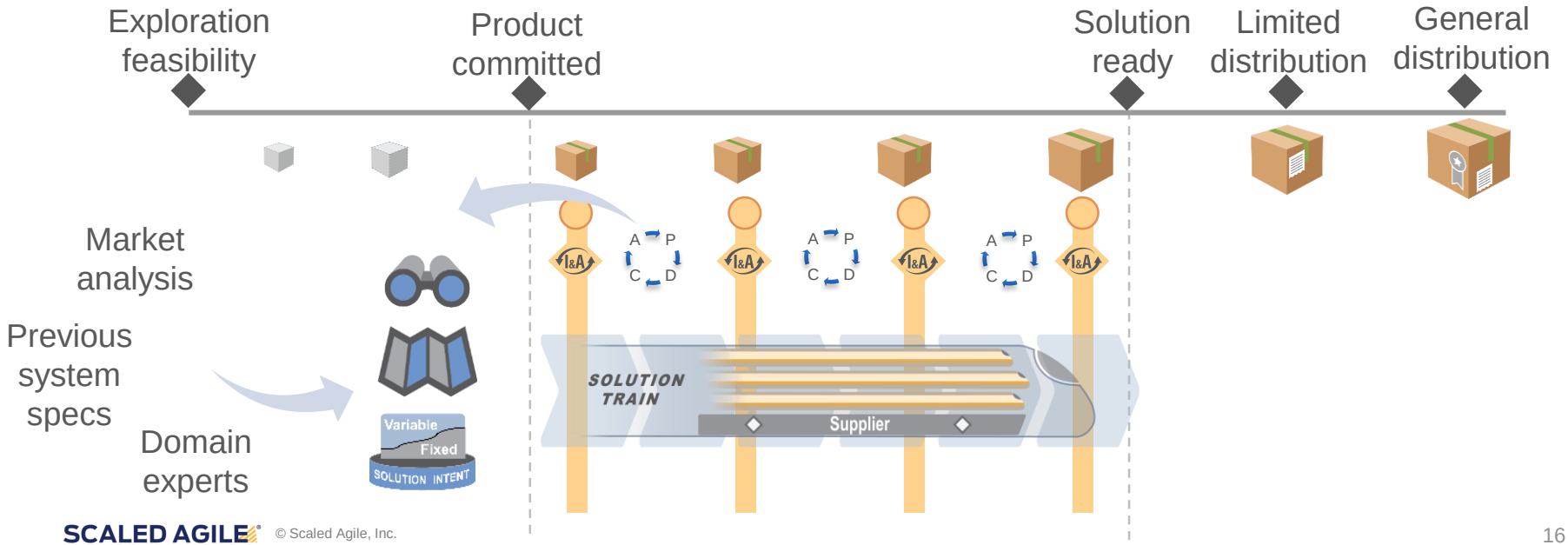
- Refine business need
- Postulate solution
- Create roadmap to realize

Build

- Use cadence to execute and adapt based on learning
- Continually refine solution, intent, and roadmap
- Regularly align teams and integrate solution

Verify and Validate

- Converge on optimal solution
- End users confirm decisions
- Validate in operational environment

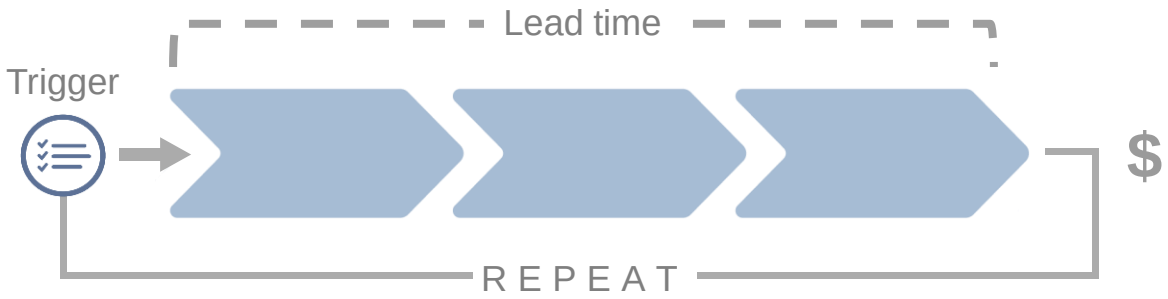


Provide objective evidence at every increment

Organize for value and compliance

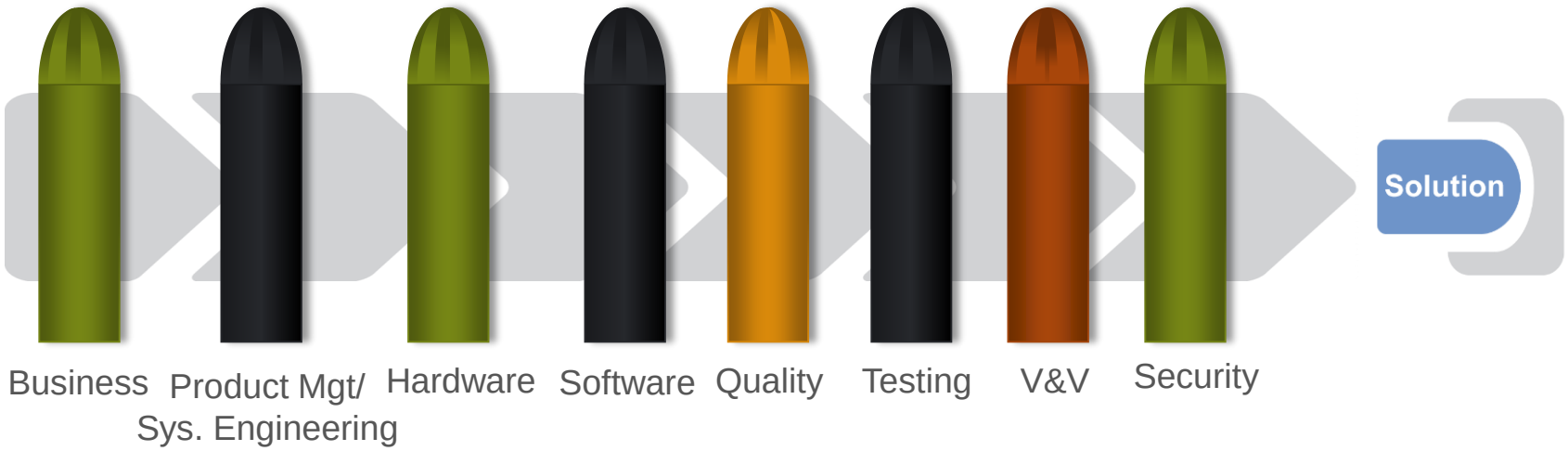
Take a systems view: understand the full Value Stream

A fundamental thinking construct in Lean

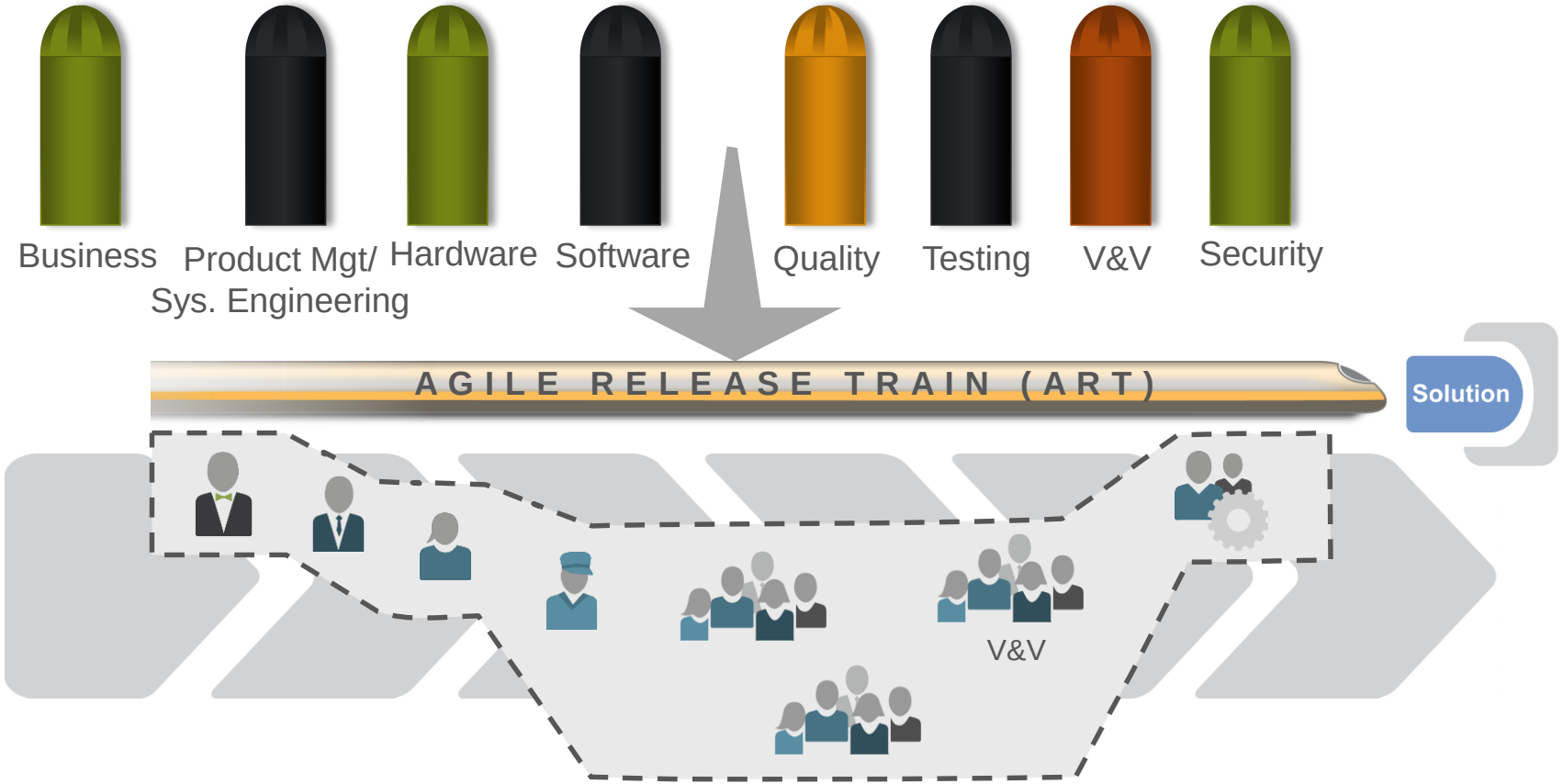


- Each Value Stream is the sequence of steps used to deliver value to the Customer
- It includes the whole sequence, from concept or customer order to delivery of value and/or receipt of cash
- It contains the people who do the work, as well as the flow of information and materials

Value streams cut across organizational silos

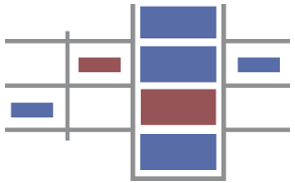


Cross-functional Agile Release Trains deliver value

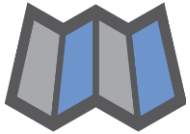


Integrate regulatory, customer, and compliance concerns

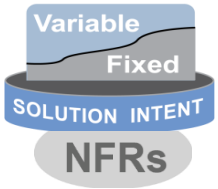
Kanban and Backlog
Align and focus on work priorities



Roadmap
Know solution's future plan



Solution Intent
Shared understanding of system's goals, specifications, and constraints



PI System Demo
Frequent feedback on fully-integrated system

PI Planning
Synchronizes on near term plan

Inspect & Adapt
Continuously improve together

Build quality and compliance in

Build quality practices into process as part of flow

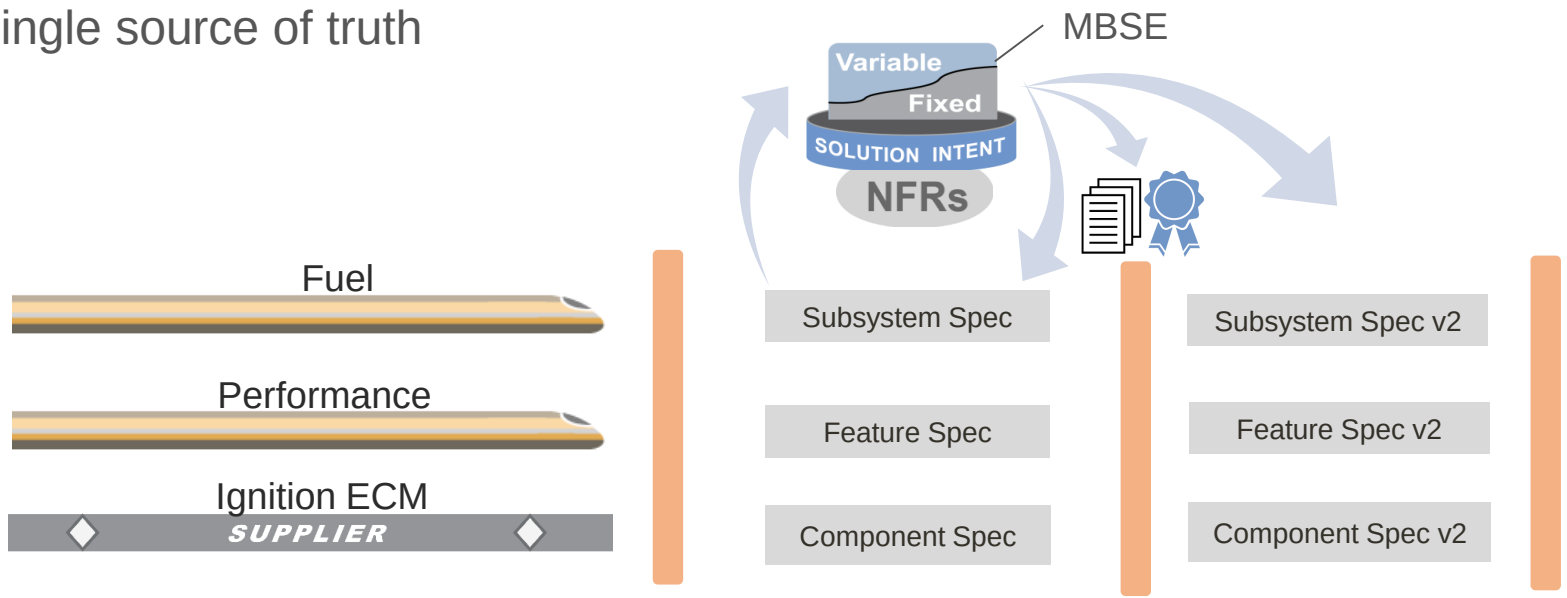
"Processes and procedures are performed in accordance with policy based on regulations"

LEAN QMS QUALITY MANAGEMENT SYSTEM

- Continuous integration
- Test-First
- Refactoring
- Pair-work
- Collective ownership
- Exploratory early iterations
- Model Based Systems Engineering (MBSE)
- Set-Based Design
- Frequent integration
- Design verification
- Reviews, audits, sign-offs
- V&V, IV&V
- Quality assurance activity
- Regulatory oversight
- Coverage, completeness

MBSE facilitates emergent specifications

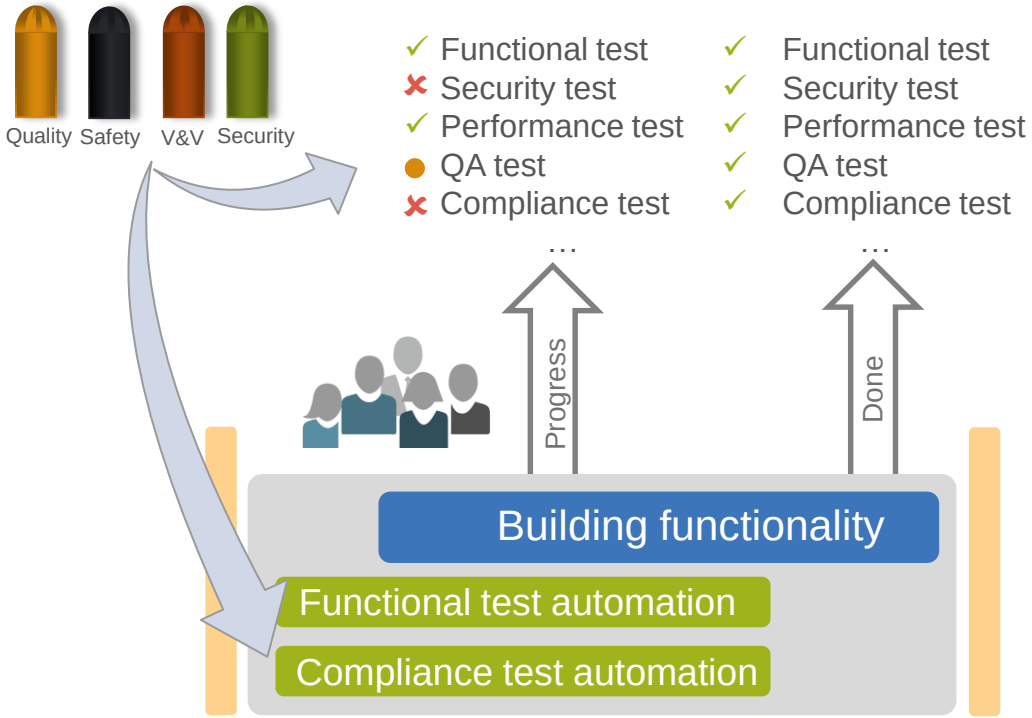
- Evolve specifications each increment
- Ensure alignment across all solution builders
- Generate specifications and compliance documents from models to ensure single source of truth



Accelerate feedback through automated compliance testing

Give teams automated scripts instead of checklists

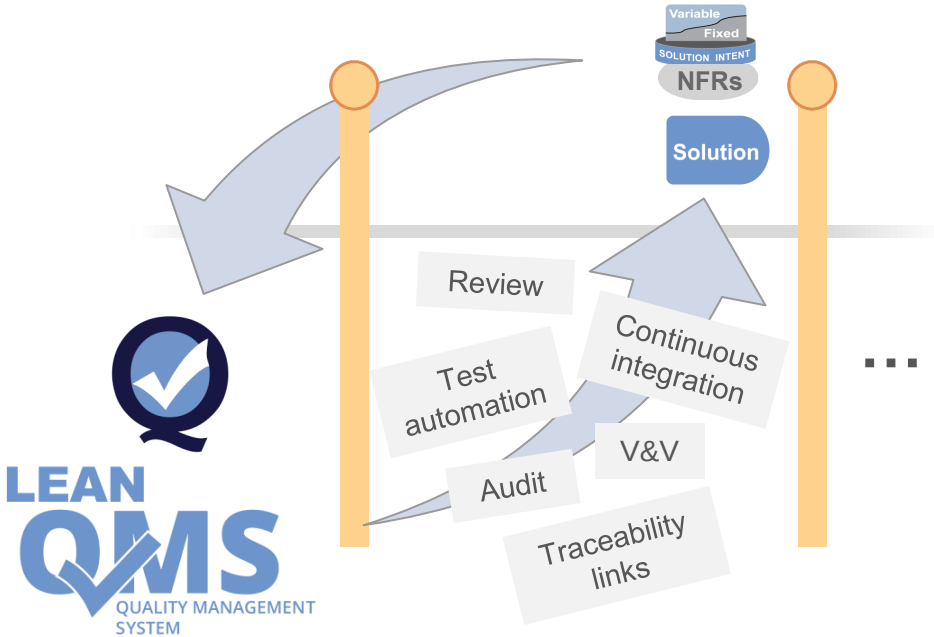
- Automate tests in the same iteration as the functionality
- Include tests for safety, security, performance, quality, etc.
- Invest in automated testing infrastructure to improve flow
- Actively maintain test data under version control



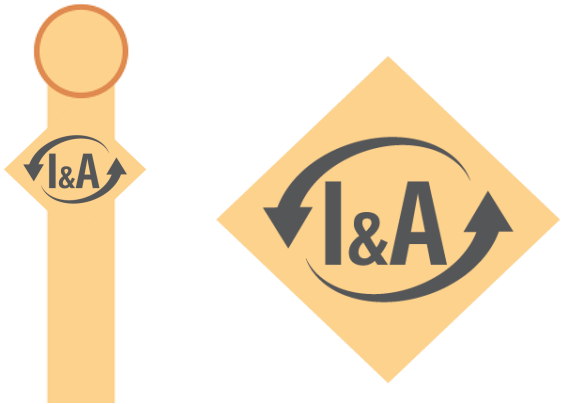
Continually reduce risk for meeting compliance objectives

Reduce last sign-off activity from a large, extended event to a quick, boring, non-event.

- Break compliance activities into smaller batches
- Regular cadence make compliance predictable
- Get visibility, transparency into assessment sooner
- Fast feedback continuously improves practices



Include compliance concerns in continuous improvement



Solution Demo

- Asses results of current compliance work and automated tests
- Demonstrate compliance status by assessing or generating latest information and documents

Quantitative Measurement

- Show trends towards meeting compliance solution and dev system
- % code coverage, % requirements coverage, peer reviews status
- % compliance concerns covered in automated tests

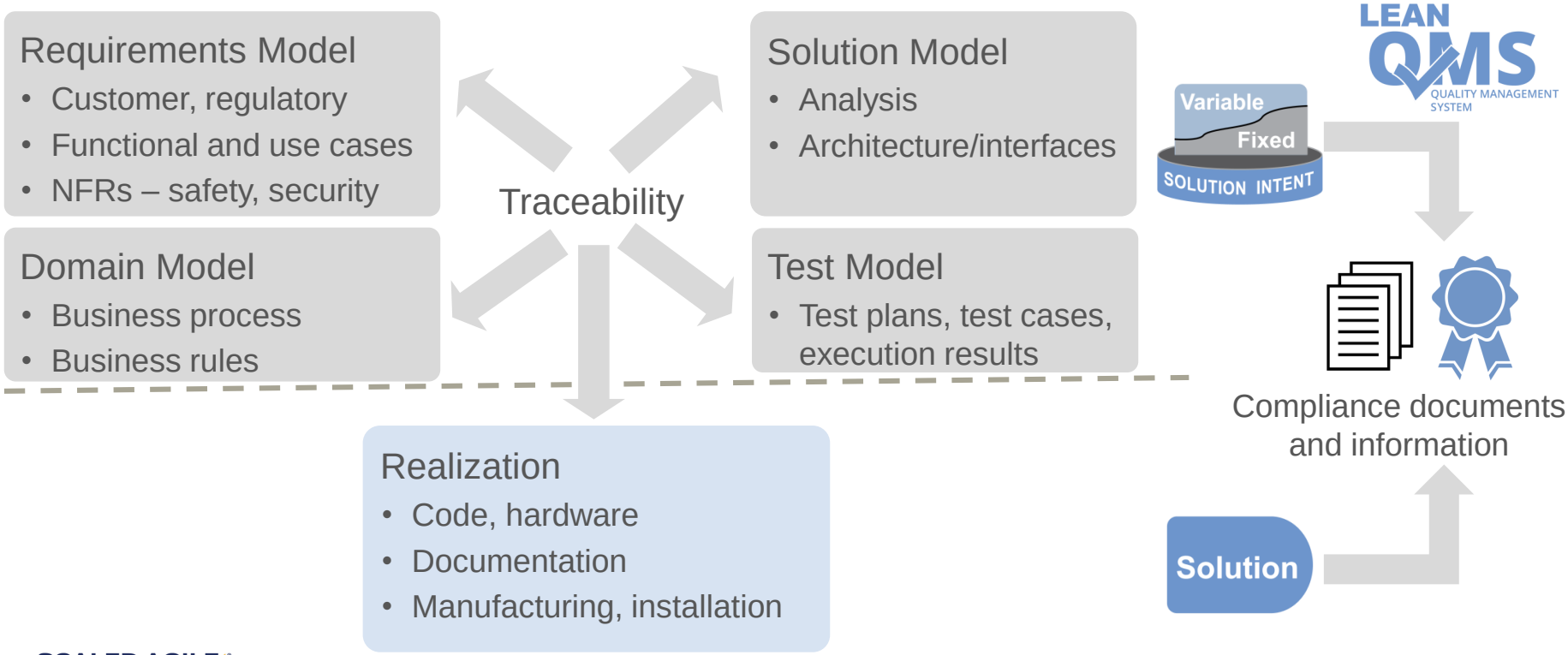
Retrospective and Problem Solving Workshop

- Are we sufficiently addressing compliance goals?
- Are policies or procedures inhibiting development?
- If so, can we find alternatives to meeting compliance goals

Apply continuous verification and validation

Solution Intent captures requirements and compliance info

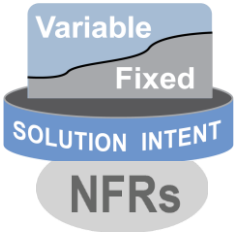
Trace regulation to place it's implemented and tests that demonstrate it



SAFe requirements model supports continuous verification

Backlog items

Solution specification and constraints



Enable functionality

Enabler

- Exploration
- Architecture
- Infrastructure
- Evaluate & feedback

Build functionality

Feature *realized by* Story (*)

Feature *tested by*:
- Feature acceptance test

Story *tested by*:
- Story acceptance test
- Unit test

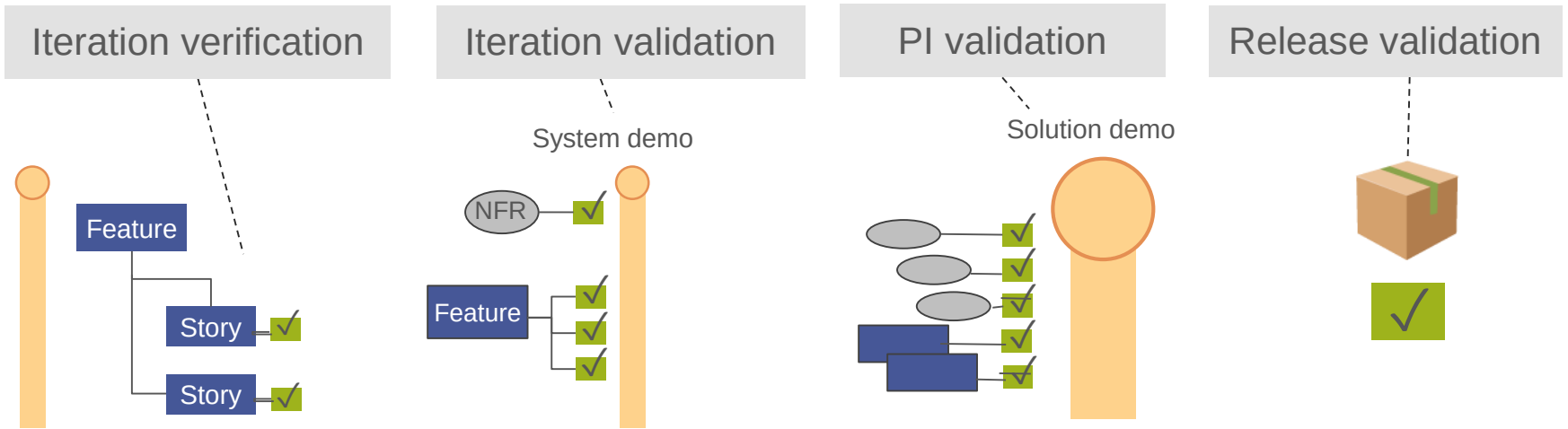
Constrains functionality

Nonfunctional Requirement *tested by*:
- System qualities test

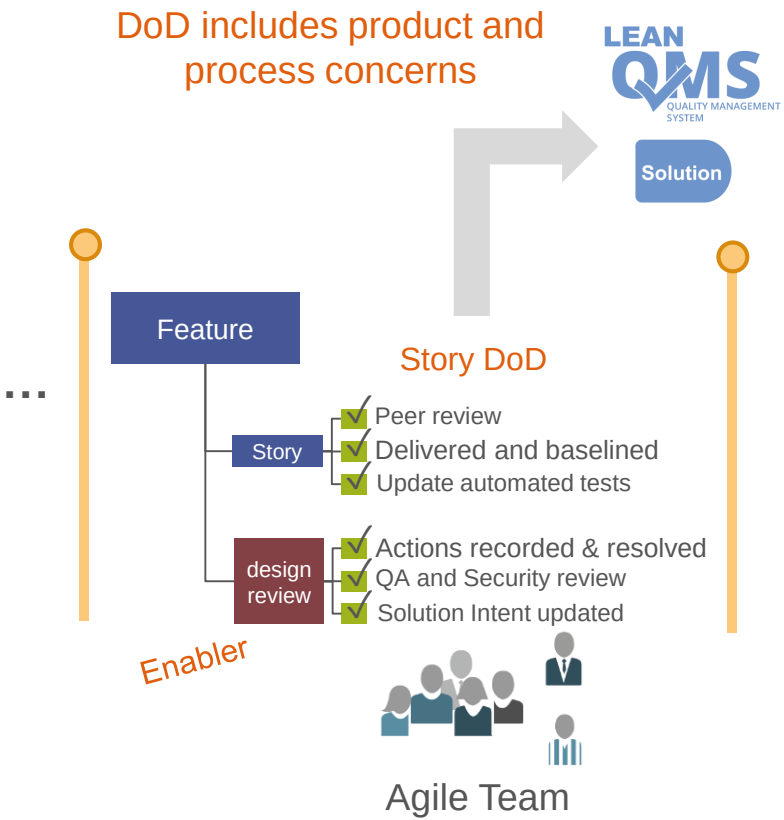
Strive for automation

Make V&V activities part of regular flow

- System demos include validation status towards compliance
- Include compliance concerns in Definition of Done (DoD)
- Development continuously verifies



Iteration verification

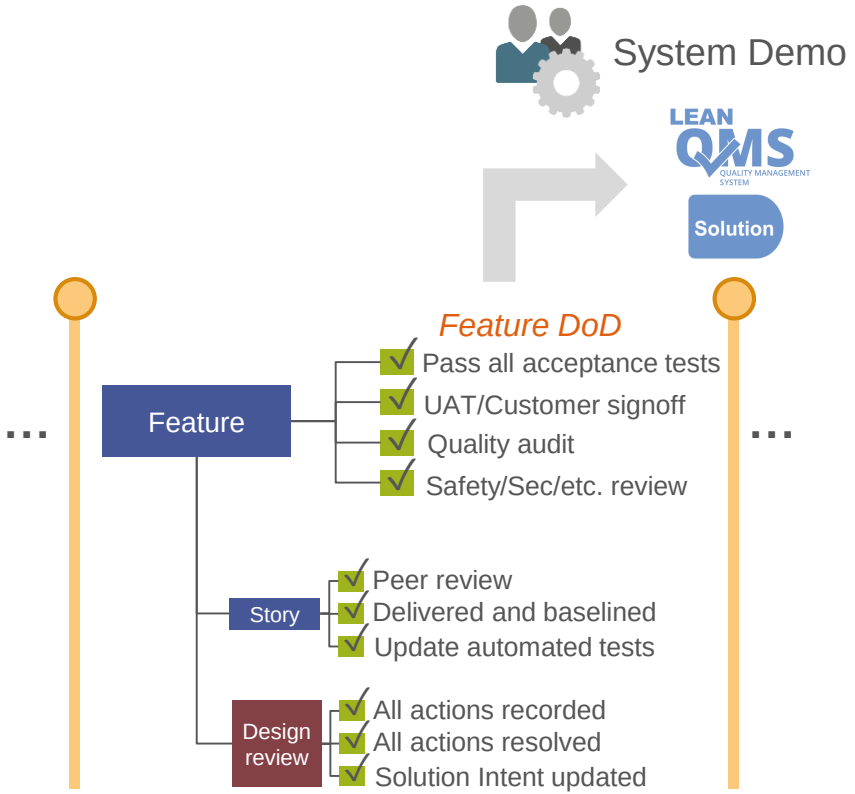


Continuous V&V for Team's work

- Peer review all engineering artifacts
- Deliver all artifacts to the common repository
- Reflect any discoveries or decisions in Solution Intent
- Test Solution with story acceptance tests (ideally automated)
- Ensure sufficient automation and/or compliance representatives to not bottleneck teams

Primarily development team responsibilities

Iteration validation

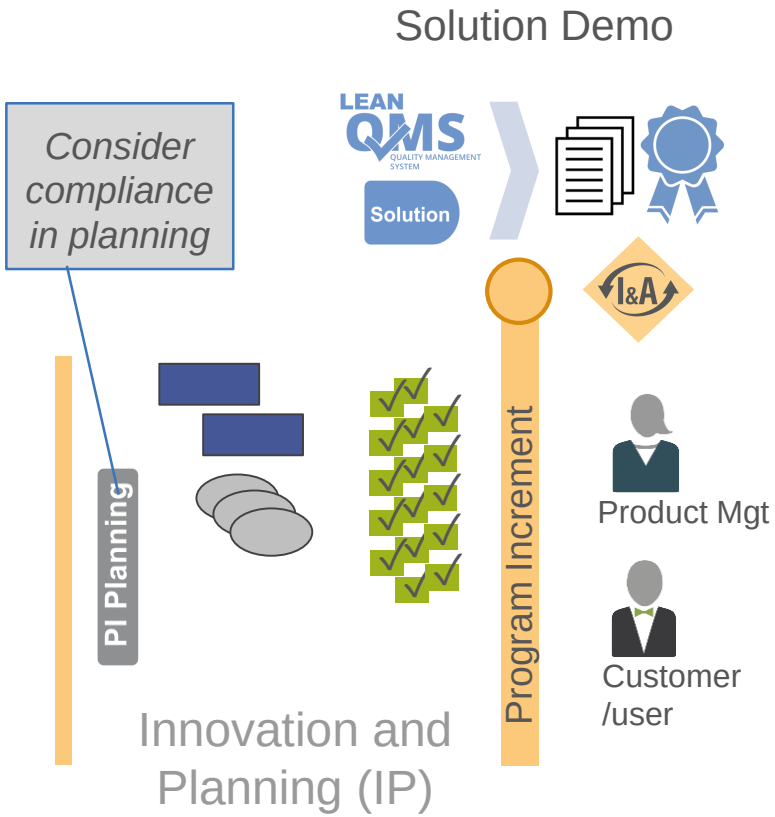


Evaluate full system increment

- Regression test all functional stories, NFRs, and feature acceptance tests
- Tested on end-to-end test environment
- User/Product Owner validation
- Update V&V tests
- Generate compliance docs and check progress towards acceptance

Development teams, system team and program shared V&V responsibilities

PI validation



Evaluate full PI system increment

- Regression test all functional stories and feature acceptance tests
- User, PO, and PM validation
- NFR tests
- Assess progress of compliance information and documentation

Program-based V&V responsibilities
(May require handoff to independent V&V)

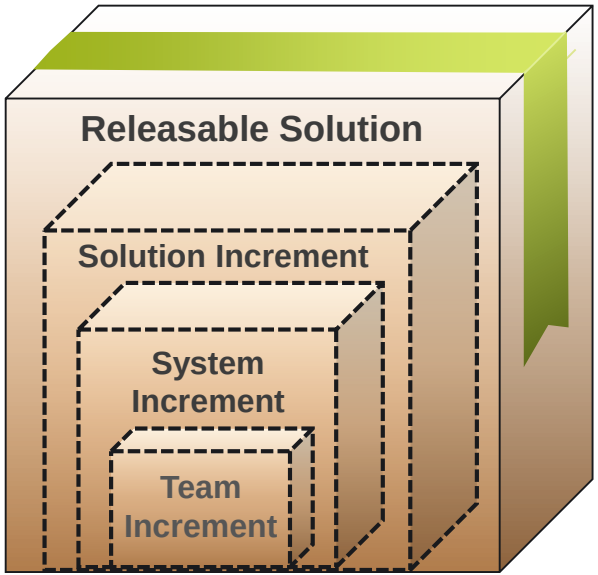
Release validation

Fitness for purpose

- Final validation
- Qualification including installation and operation
- User acceptance testing

Supporting documentation

- Installation, user, and other
- Compliance evidence



Summary

Summary

Build compliance into the system with SAFe

- Traditional QMS locks in waterfall development, and all its challenges – large batches, late feedback, slows flow
- SAFe provides lean-agile mechanisms to achieve compliance
- Results in a leaner, more efficient development which produces better outcomes, higher quality

Here’s how…

- Build the solution and compliance incrementally
- Organize for value and compliance
- Build quality and compliance in
- Apply continuous verification and validation