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

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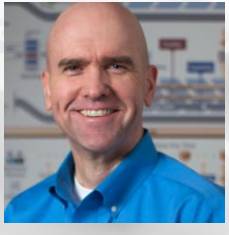

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SCALED AGILE®

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

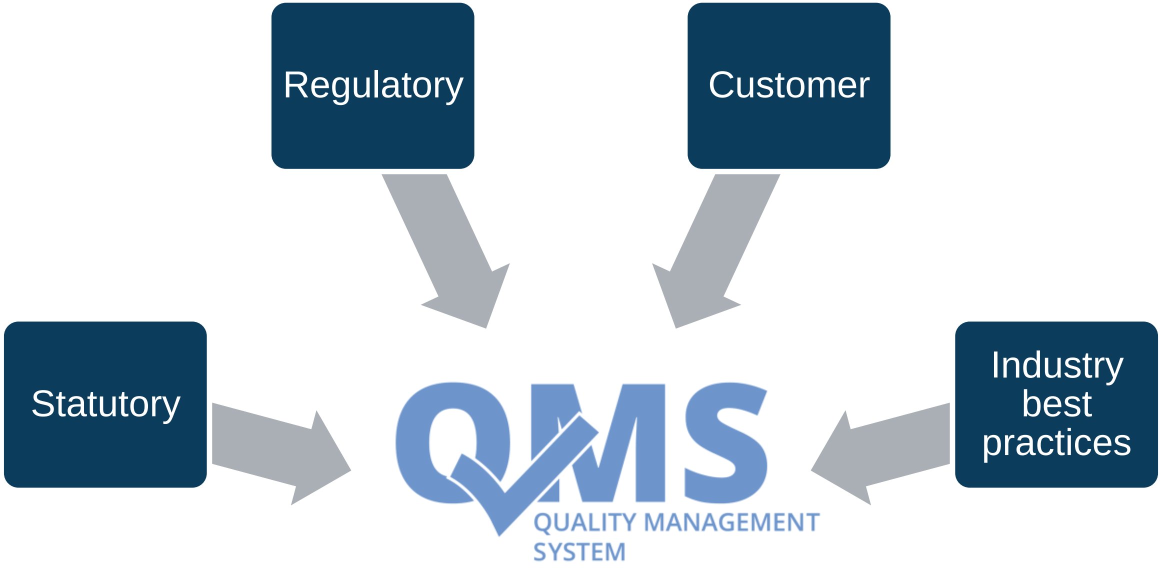
Responding to change over following a plan

Welcome changing requirements….

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

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)

Solution

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

QMS
QUALITY MANAGEMENT SYSTEM

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

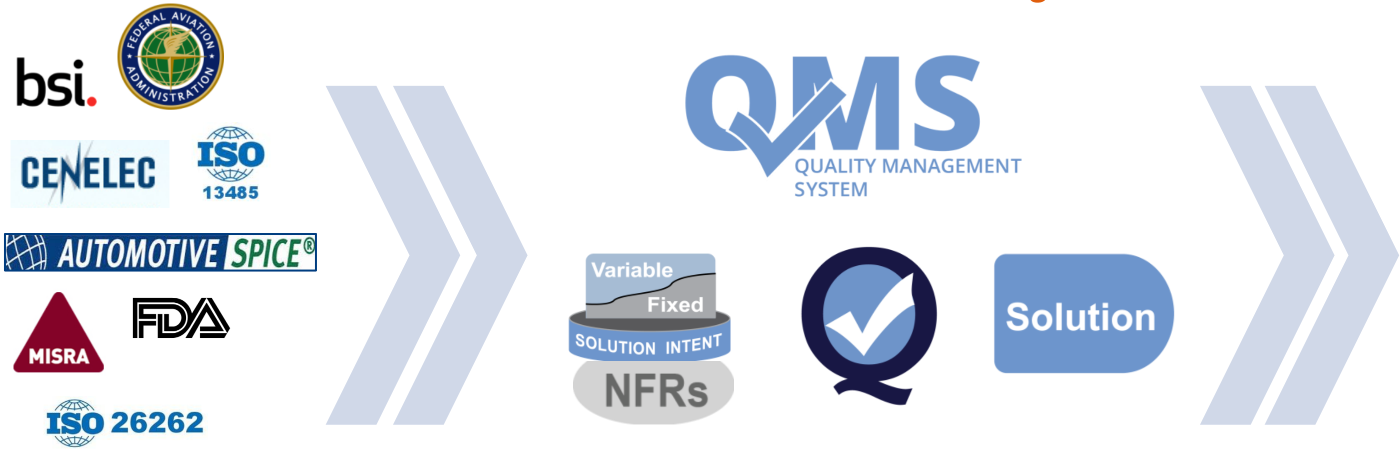
Knowledge for people building
the world's most important systems

SAFe® is a freely revealed knowledge base of integrated, proven patterns for enterprise Lean-Agile development.

www.scaledagileframework.com

SAFe addresses both types of compliance requirements

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



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

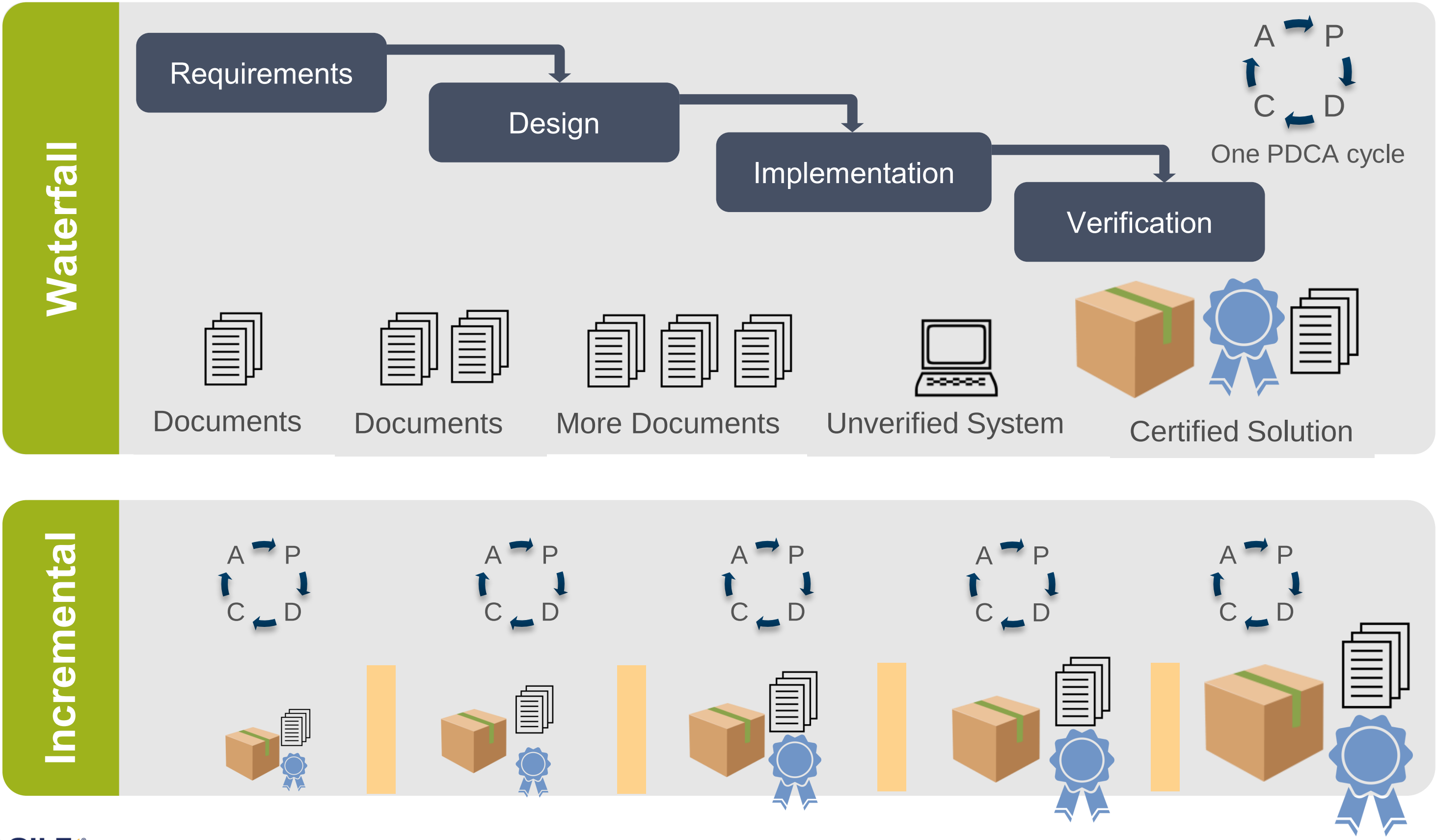
Build quality and compliance in

Apply continuous verification and validation

Meeting regulatory requirements with Lean-Agile development

Build the solution and compliance incrementally

Specify, build, and comply incrementally

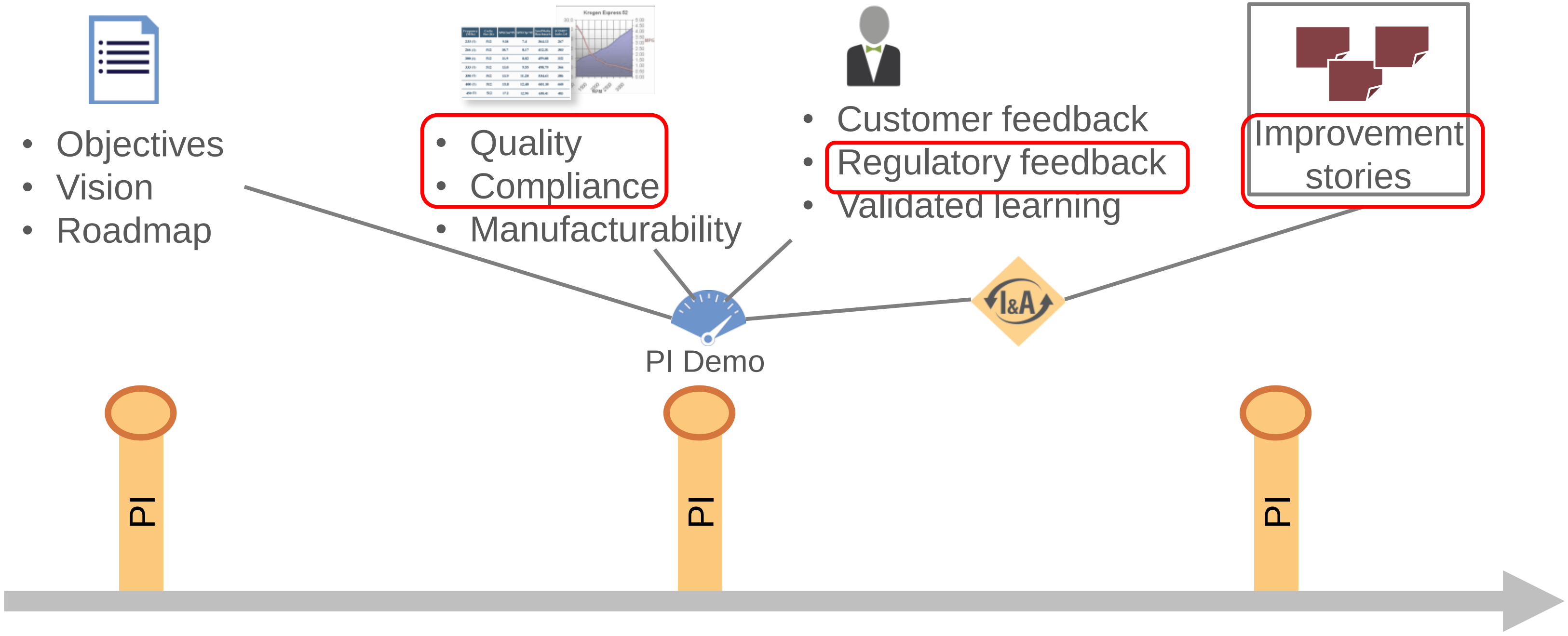


Provide objective evidence at every increment

Solution progress

Delivery progress

Relentless improvement



- Objectives
- Vision
- Roadmap

- Quality
- Compliance
- Manufacturability

- Customer feedback
- Regulatory feedback
- Validated learning

Improvement stories

PI Demo

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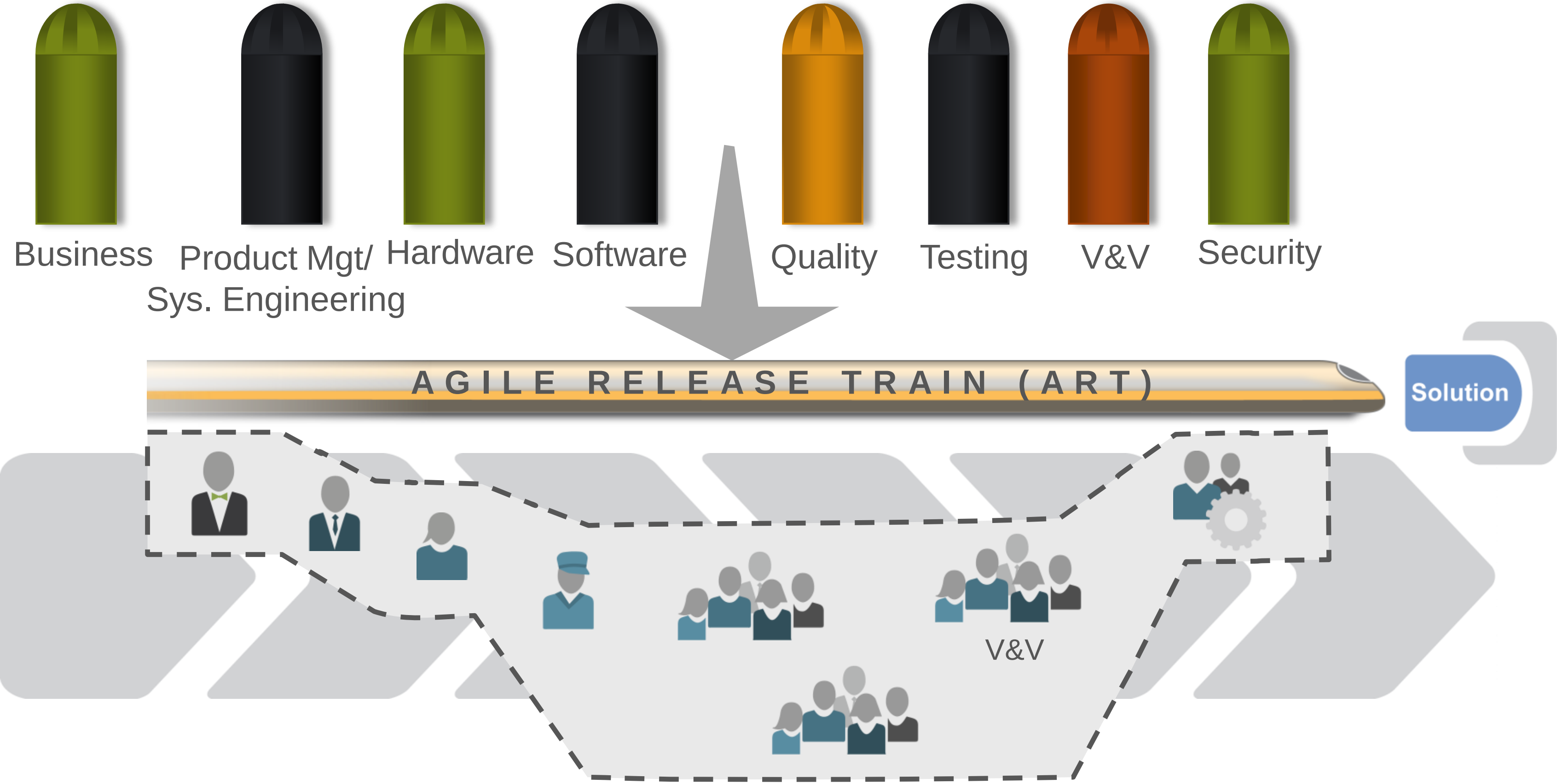
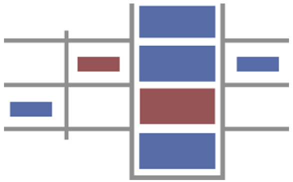
Organize for value and compliance

Cross-functional Agile Release Trains deliver value

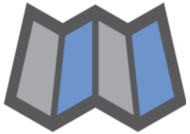


Integrate regulatory, customer, and compliance concerns

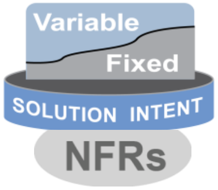
Kanban and Backlog
Align and focus on work priorities



Roadmap
Know solution's future plan



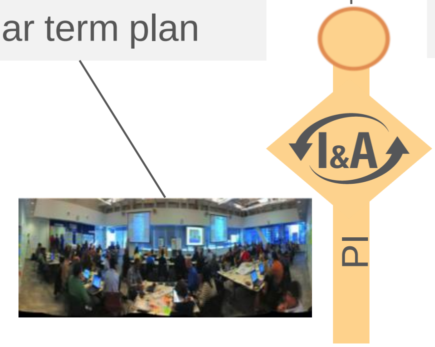
Solution Intent
Shared understanding of system's goals, specifications, and constraints



PI 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”

QMS
QUALITY MANAGEMENT SYSTEM

- Continuous integration
- Test-First
- Refactoring
- Pair-work
- Collective ownership

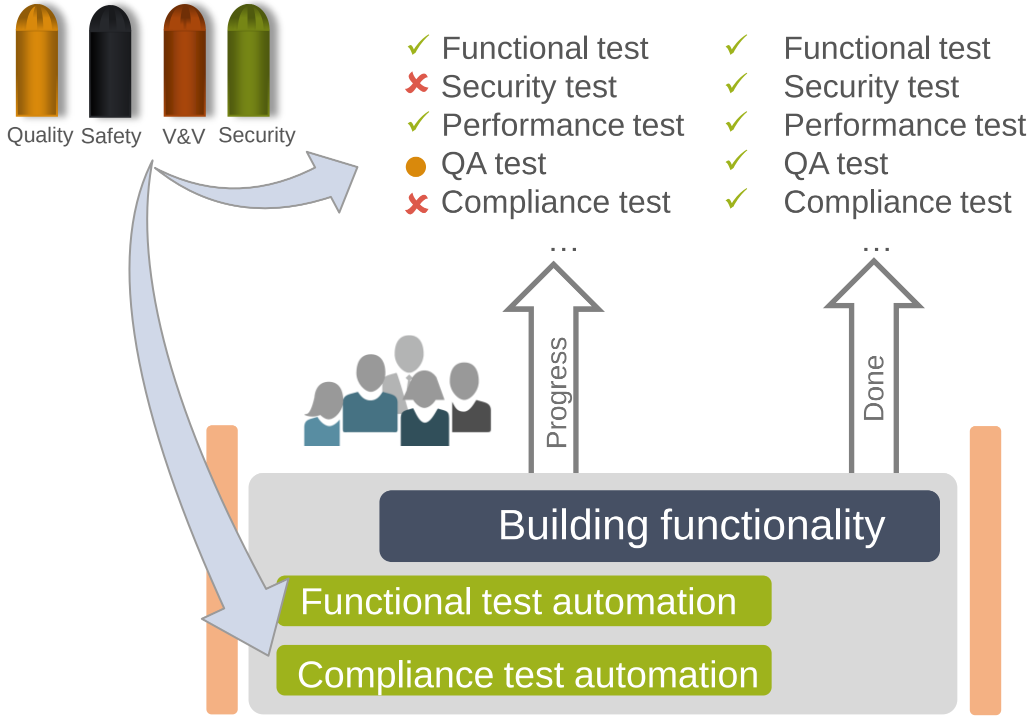
- Exploratory early iterations
- Model Based Systems Engineering (MBSE)
- Set-Based Design
- Frequent integration
- Design verification

- Reviews, audits, sign-offs
- V&V, IV&V
- Quality assurance activity
- Regulatory oversight
- Coverage, completeness

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



Quality Safety V&V Security

✓ Functional test
✗ Security test
✓ Performance test
● QA test
✗ Compliance test
…

✓ Functional test
✓ Security test
✓ Performance test
✓ QA test
✓ Compliance test
…

Progress

Done

Building functionality

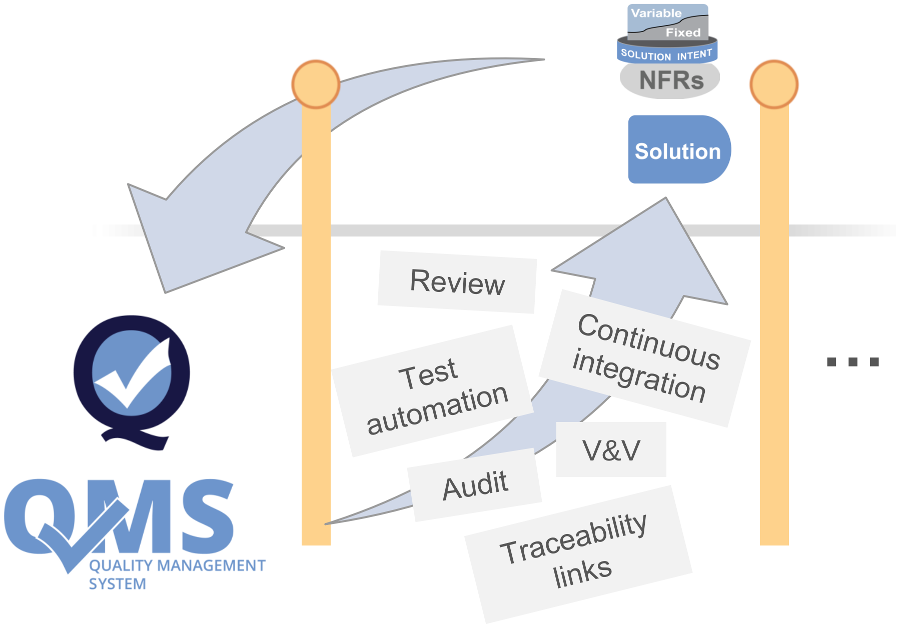
Functional test automation

Compliance test automation

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

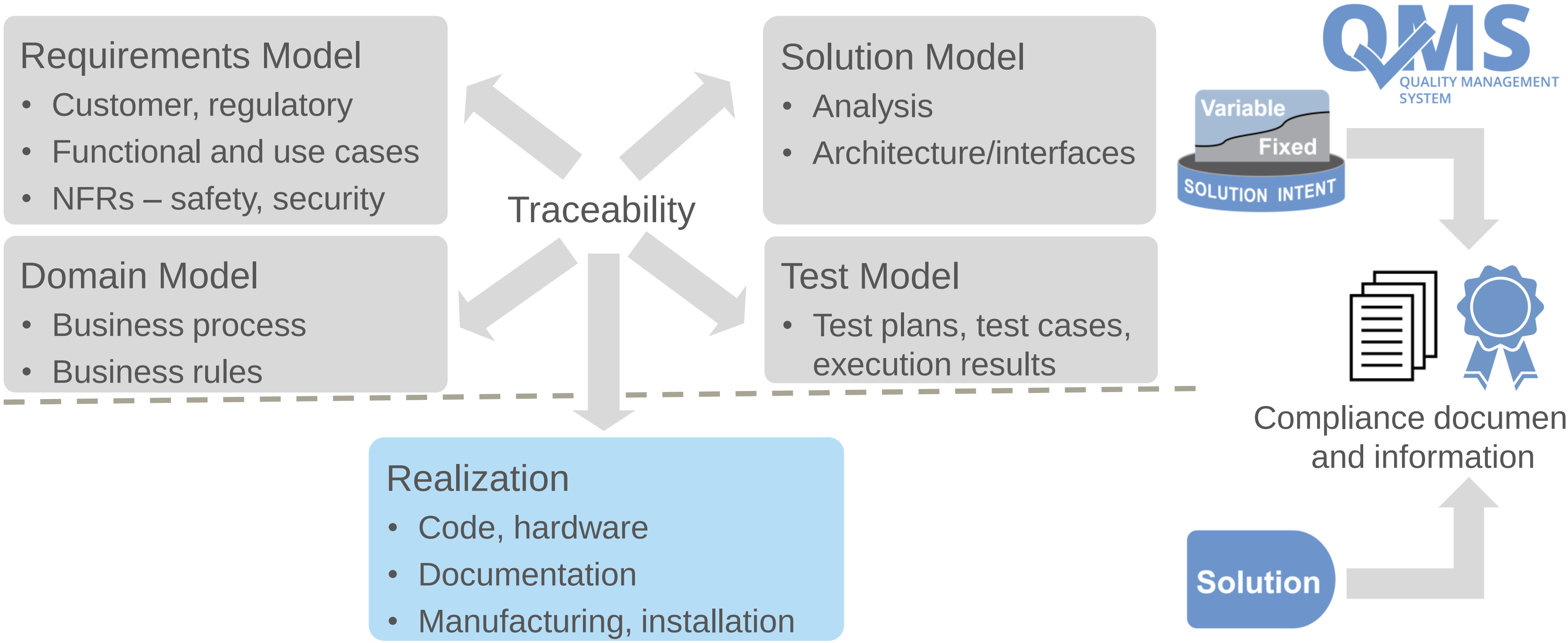
Retrospective and Problem Solving Workshop

- 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



Requirements Model

- Customer, regulatory
- Functional and use cases
- NFRs – safety, security

Domain Model

- Business process
- Business rules

Traceability

Solution Model

- Analysis
- Architecture/interfaces

Test Model

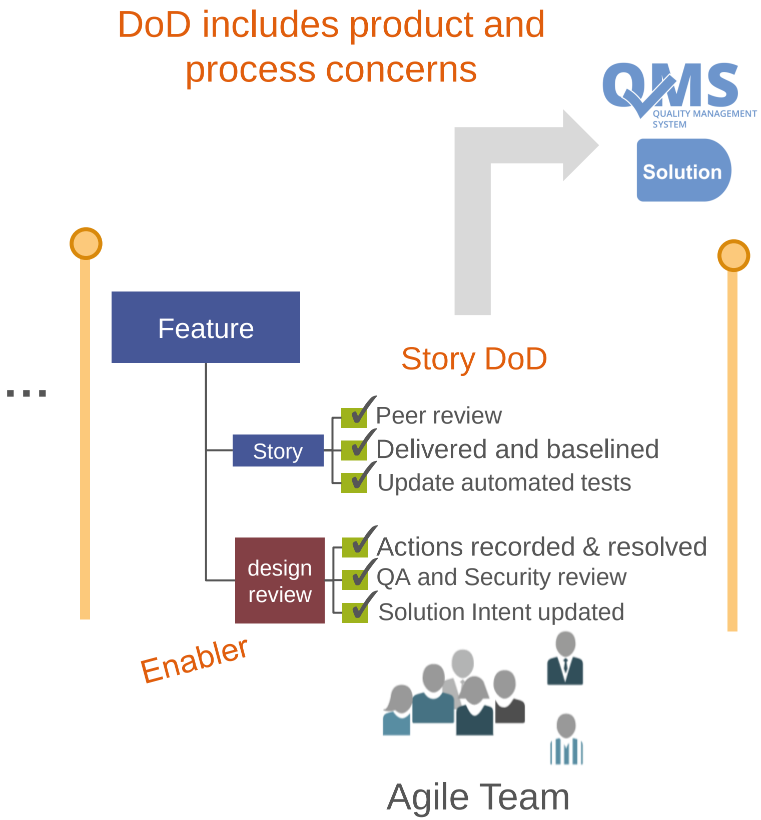
- Test plans, test cases, execution results

Realization

- Code, hardware
- Documentation
- Manufacturing, installation

Compliance documents and information

Iteration verification

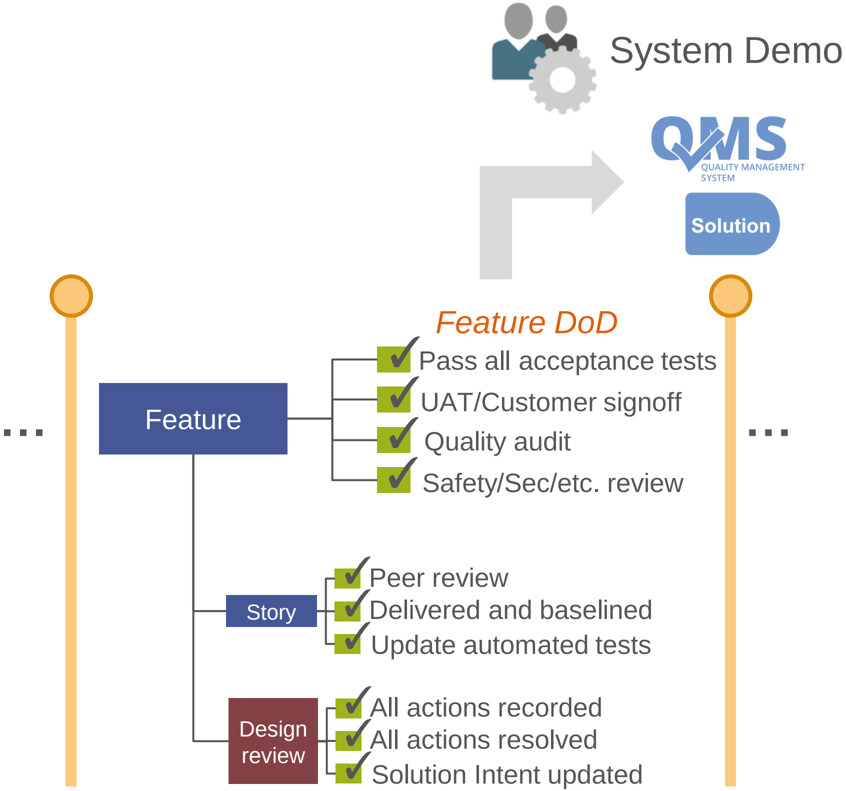

DoD includes product and process concerns
QMS
QUALITY MANAGEMENT SYSTEM
Solution
…
Feature
Story DoD
Story
✓ Peer review
✓ Delivered and baselined
✓ Update automated tests
design review
✓ Actions recorded & resolved
✓ QA and Security review
✓ Solution Intent updated
Enabler
Agile Team

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

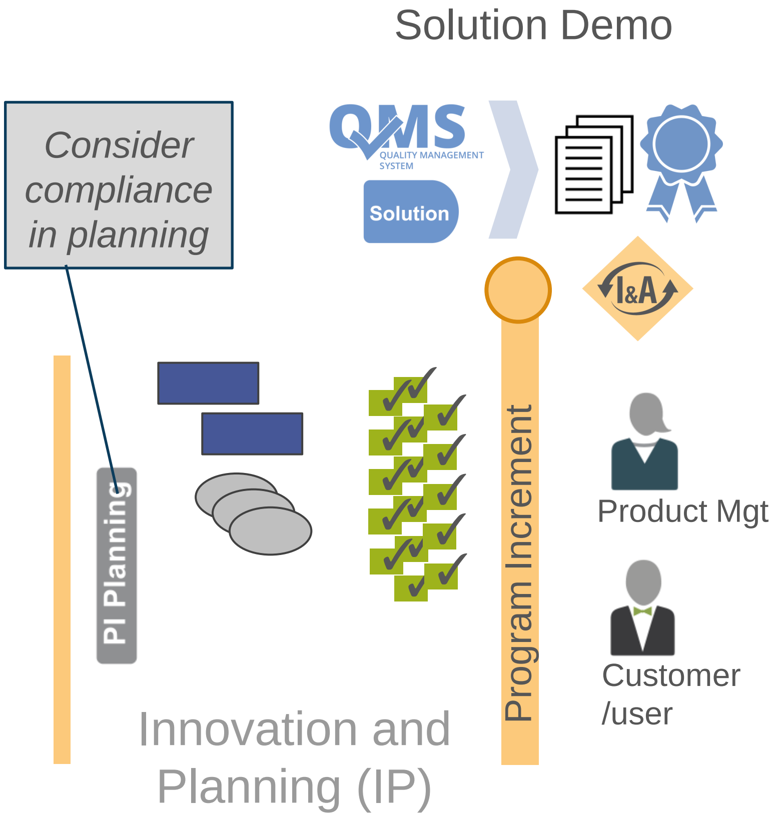


Evaluate full system increment

- 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


Solution Demo
Consider compliance in planning
QMS
QUALITY MANAGEMENT SYSTEM
Solution
I&A
PI Planning
Program Increment
Product Mgt
Customer /user
Innovation and Planning (IP)

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)

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

Questions?