

Agile for System Development

Foundations, Good Ideas and Conversation Starters

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Agile Quality Systems, LLC

- 23 years medical device software & system development
- Author/owner/user of SOPs & Work Instructions for software and systems development
- ASQ Certified Quality Auditor, focusing on Design Controls, Risk Management, Complaint Handling
- 14 years Agile practitioner, Trainer, Agile Transformation Coach, Certified Scrum Master, Certified SAFe Program Consultant
- Lead author of AAMI TIR45 “Guidance on the use of AGILE practices in the development of medical device software” - Lead instructor for AAMI course on TIR45
- Adjunct Instructor for Design Control courses in St. Cloud State’s Master of Technology Quality program
- Consultant to large & small medical device organizations

Agile is Not Just for Software

- Scrum is used in many product-development contexts
- Agile Scaling concepts and frameworks address big system development
 - And integration of software teams using Agile with other development teams that may / may not be
- Scaled Agile Framework (SAFe)
 - Version 4.0 puts more emphasis on development of systems, aligning with Systems Engineering principles
 - For “large-scale, multidisciplinary software and cyber-physical systems”

Software development is not just Software Engineering

- Embedded software connects with products/ subsystems created by other engineering disciplines
- Big “software-only” systems need discipline of Systems Engineering
- “The Systems Engineering Engine”
 - NASA Systems Engineering Handbook provides a model of activities for developing big systems

Agile + Systems Engineering

- Agile (SAFe + Scrum + XP + Kanban + ...)

+

- Systems Engineering concepts

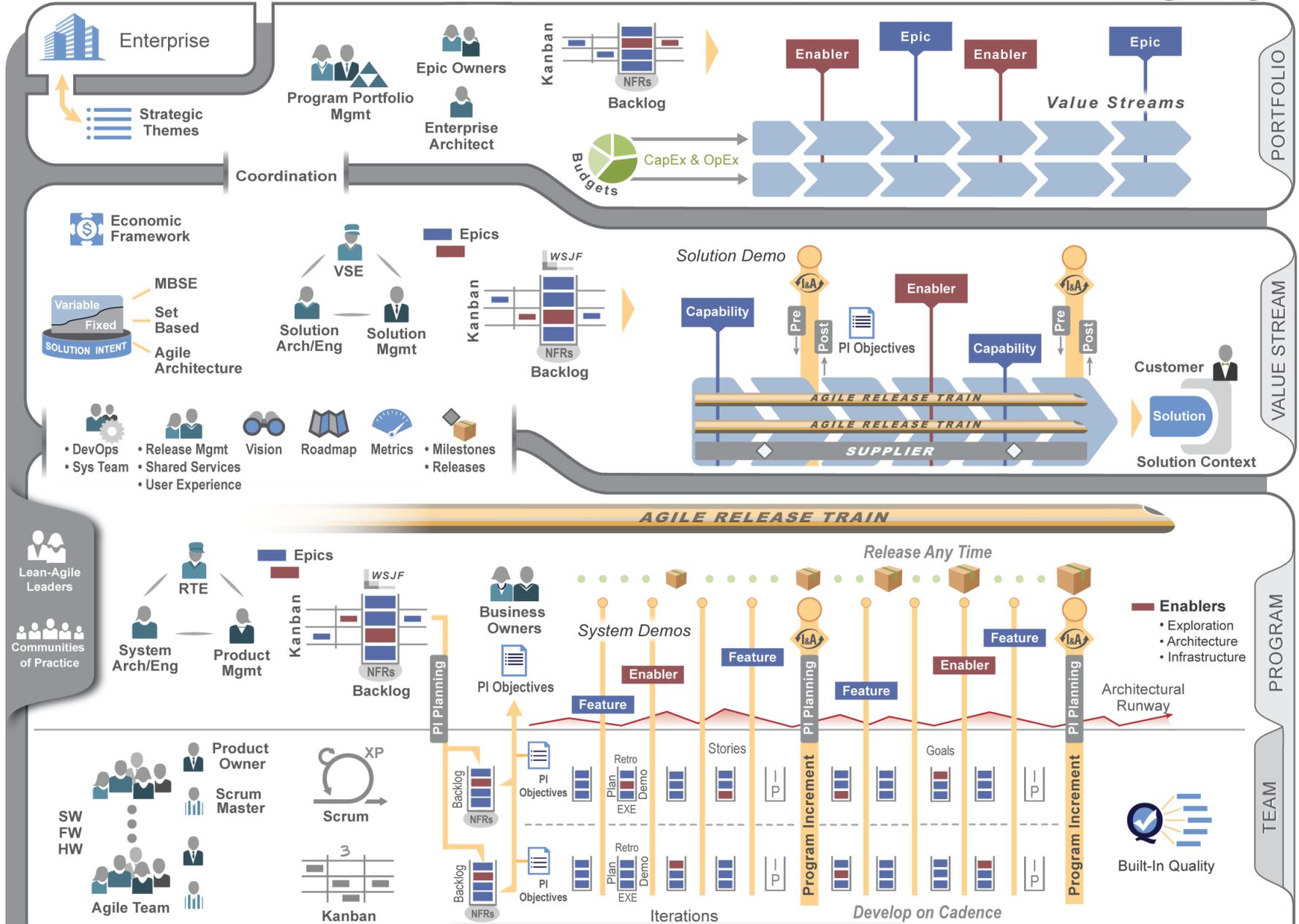
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- A really good thing

SAFe® content from Scaled Agile Inc

- The “Big Picture”
 - <http://scaledagileframework.com>
- “SAFe 4.0 in 8 Pictures”
 - <http://scaledagileframework.com/videos-and-presentations/>

SAFe® 4.0 for Lean Software and Systems Engineering



NASA SE Handbook

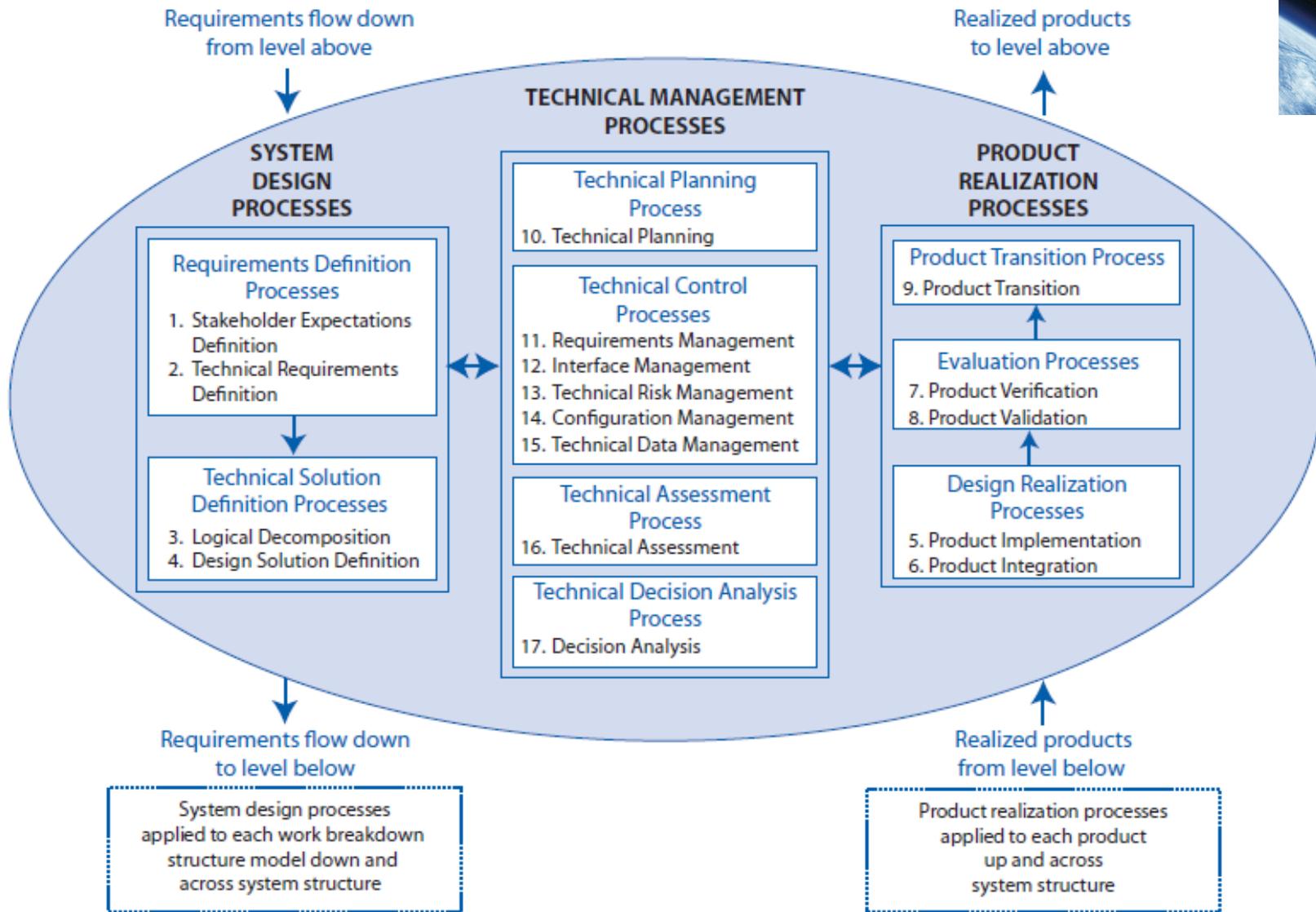
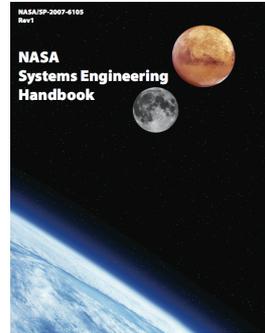
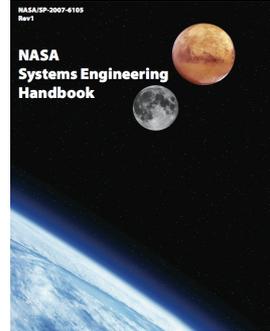


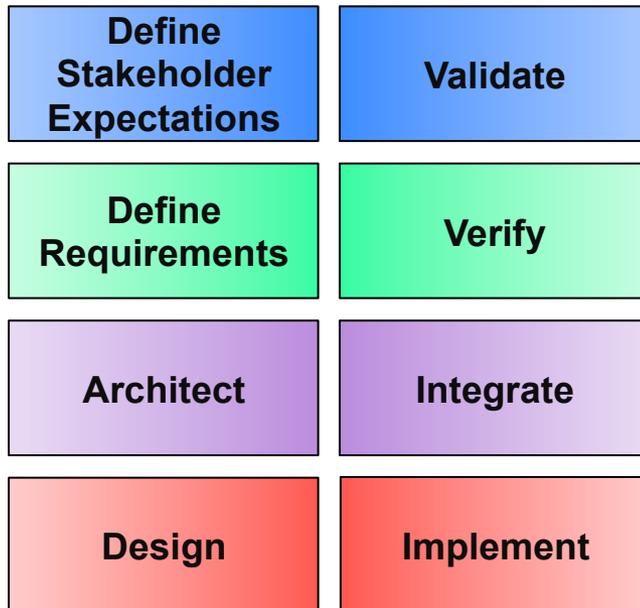
Figure 2.1-1 The systems engineering engine

The Systems Engineering Engine



System Development Processes

System Design Product Realization



Technical Management Processes

Technical Planning
Requirements Management
Interface Management
Risk Management
Configuration Management
Data Management

Adapted from: NASA Systems Engineering Handbook, NASA/SP-2007-6105

The Systems Engineering Engine

System

A statement of needs, desires, capabilities, and wants that are not expressed as a requirement (not expressed as a "shall" statement)...(see notes)

FDA: "User Needs & Intended Use"

Proof that the product accomplishes the intended purpose. Validation may be determined by a combination of test, analysis, and demonstration.

Expectations can be stated in either qualitative (nonmeasurable) or quantitative (measurable) terms. Requirements are always stated in quantitative terms.

The agreed-upon need, desire, want, capability...expressed as a "shall" statement...(see notes)

Physical Arch = The next-level subsystems/components
Functional Arch = Features, Functions, Organization of the requirements
Operational Arch = Allocate requirements to the next-level subsystems

Decisions about the solution to be implemented, which become requirements for the next-level subsystems/components. Example: Interface definition/specification.

Define Stakeholder Expectations

Validate

Define Requirements

Verify

Architect

Integrate

Design

Implement

Proof of compliance with specifications. Verification may be determined by test, analysis, demonstration, or inspection.

Integration = Build, assemble, connect, gather, etc. Includes the Verification that it integrated correctly
Integration Test = Tests that demonstrate the design has been satisfied by the integration of the subsystems that implement the design.

Design & Build the next-level
Buy
Re-Use

Systems Live Within A Context

**Users,
Stakeholders**

System

**Define
Stakeholder
Expectations**

Validate

**Define
Requirements**

Verify

Architect

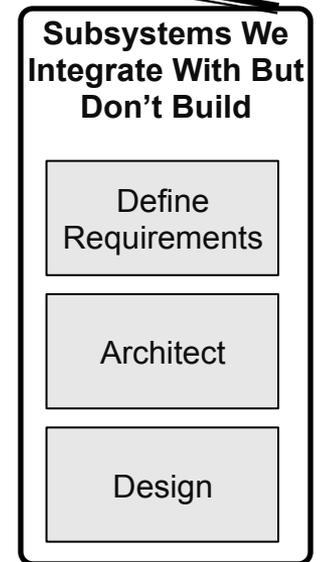
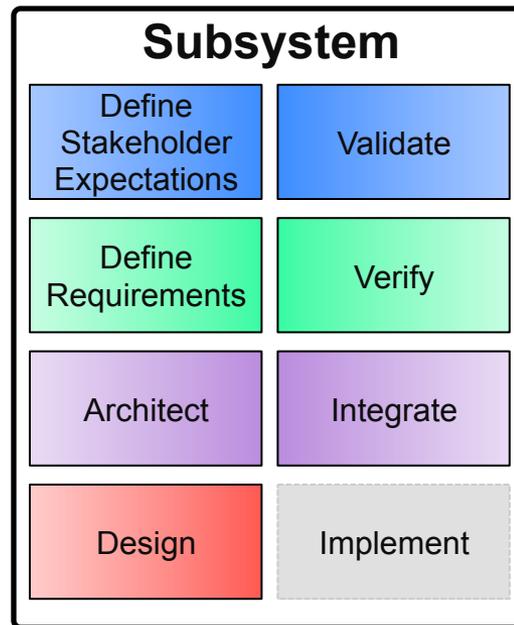
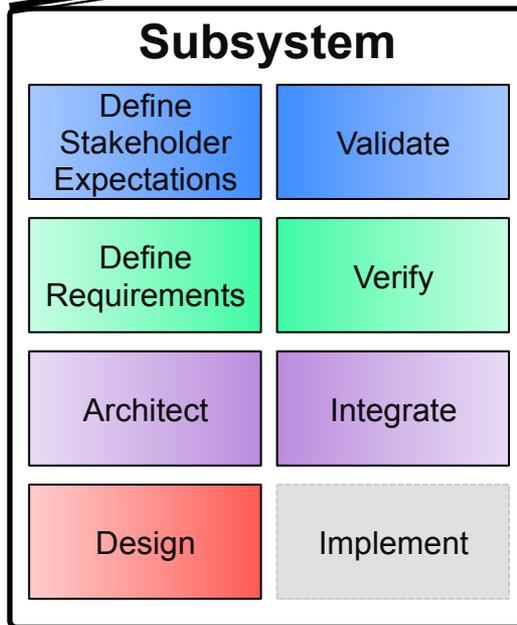
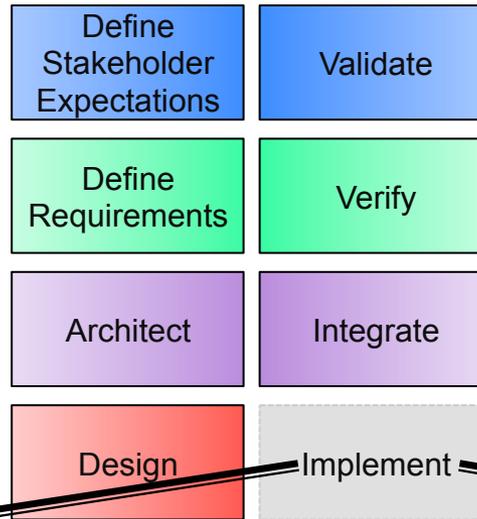
Integrate

Design

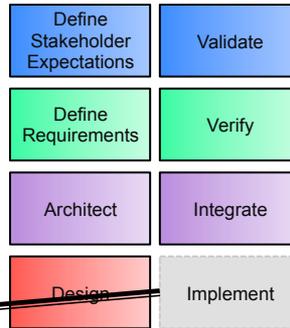
Implement

**Other
Systems**

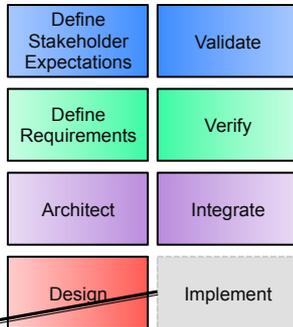
System



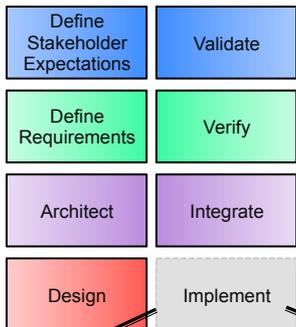
System



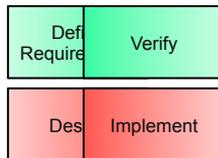
Subsystem



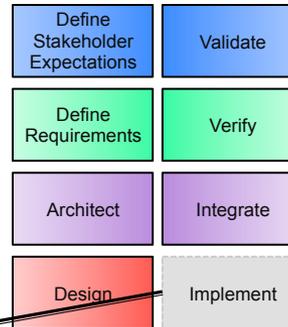
Subsystem



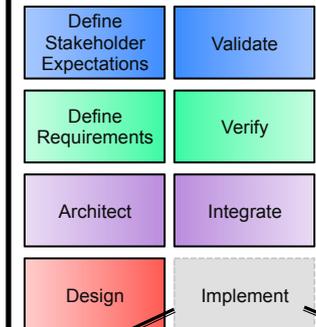
Components We Build



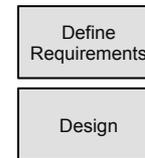
Subsystem



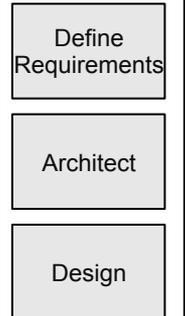
Subsystem



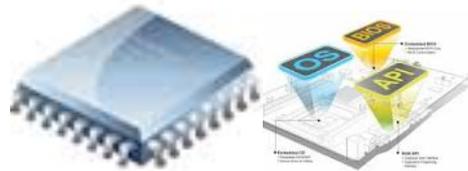
Components We Buy / Re-Use



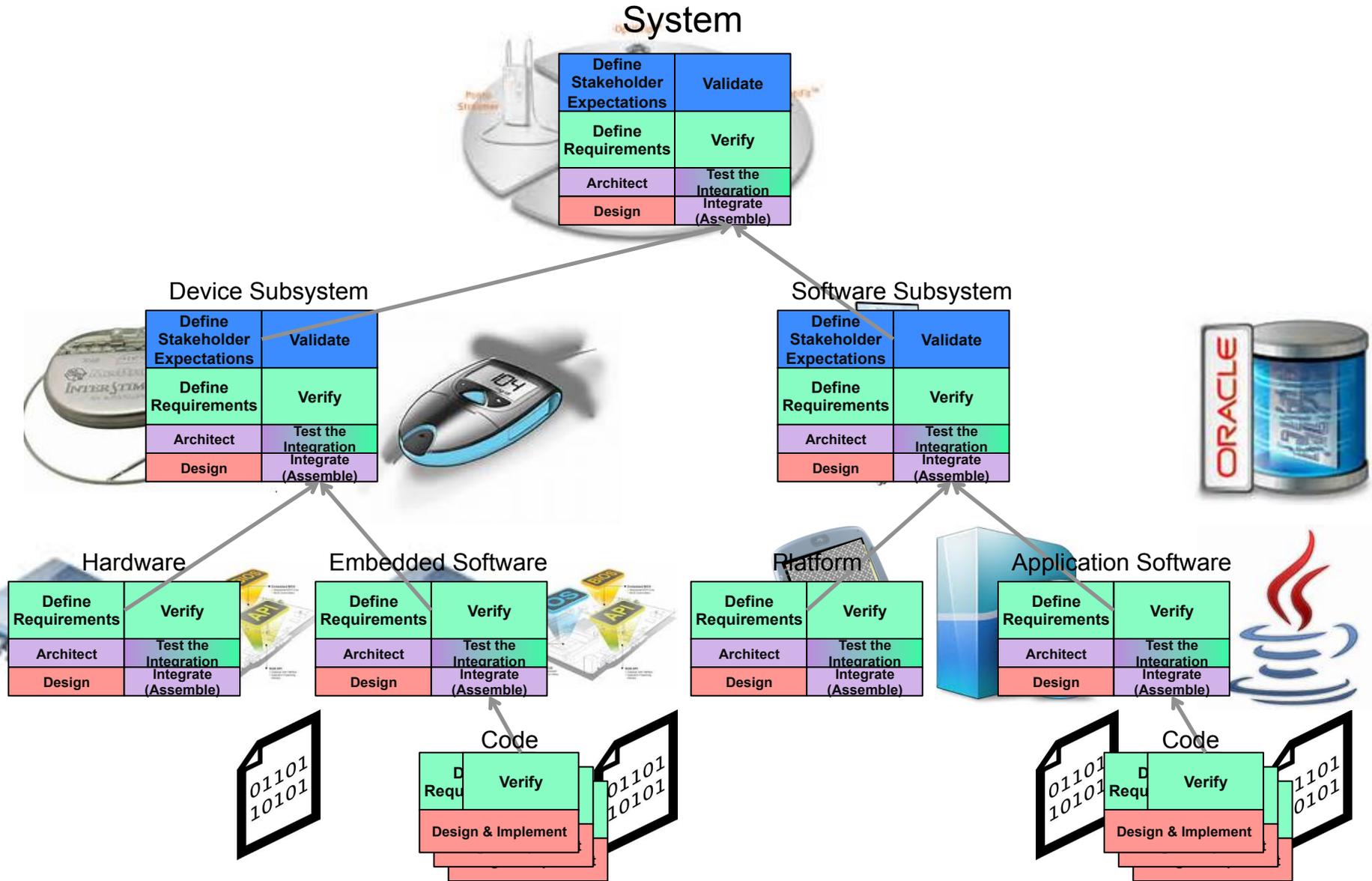
Subsystems We Integrate With But Don't Build



What is the System?



What is the System? And What are the Activities & Deliverables?



The System Development Activities and Deliverables are Determined by the System Architecture

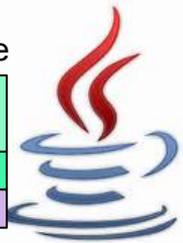
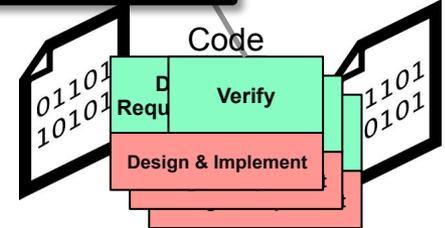
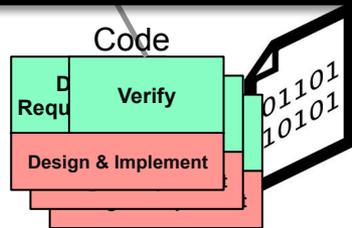
System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate

- Determined by the Architecture – what is built
 - Physical (products in a catalog, components on a BOM)
 - Functional (features, capabilities)
- Determined by the Requirements – what is defined
 - How are the requirements/specifications organized?
 - What are they specifying?
- Determined by the Tests – what is verified
 - What are the tests verifying?
 - Where are tests executed?

Hardware

Define Requirements	Verify
Architect	Test the Integration Integrate
Design	

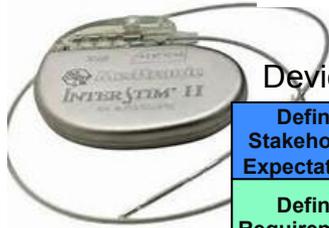


What is Your System?



System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



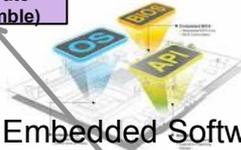
Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Hardware

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Embedded Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



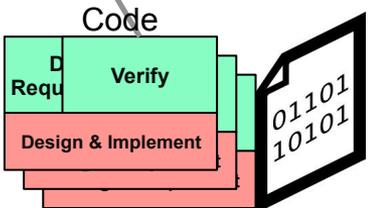
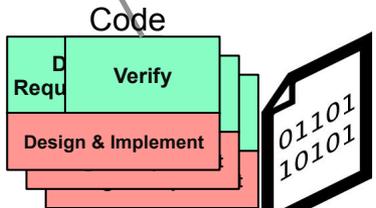
Platform

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Application Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



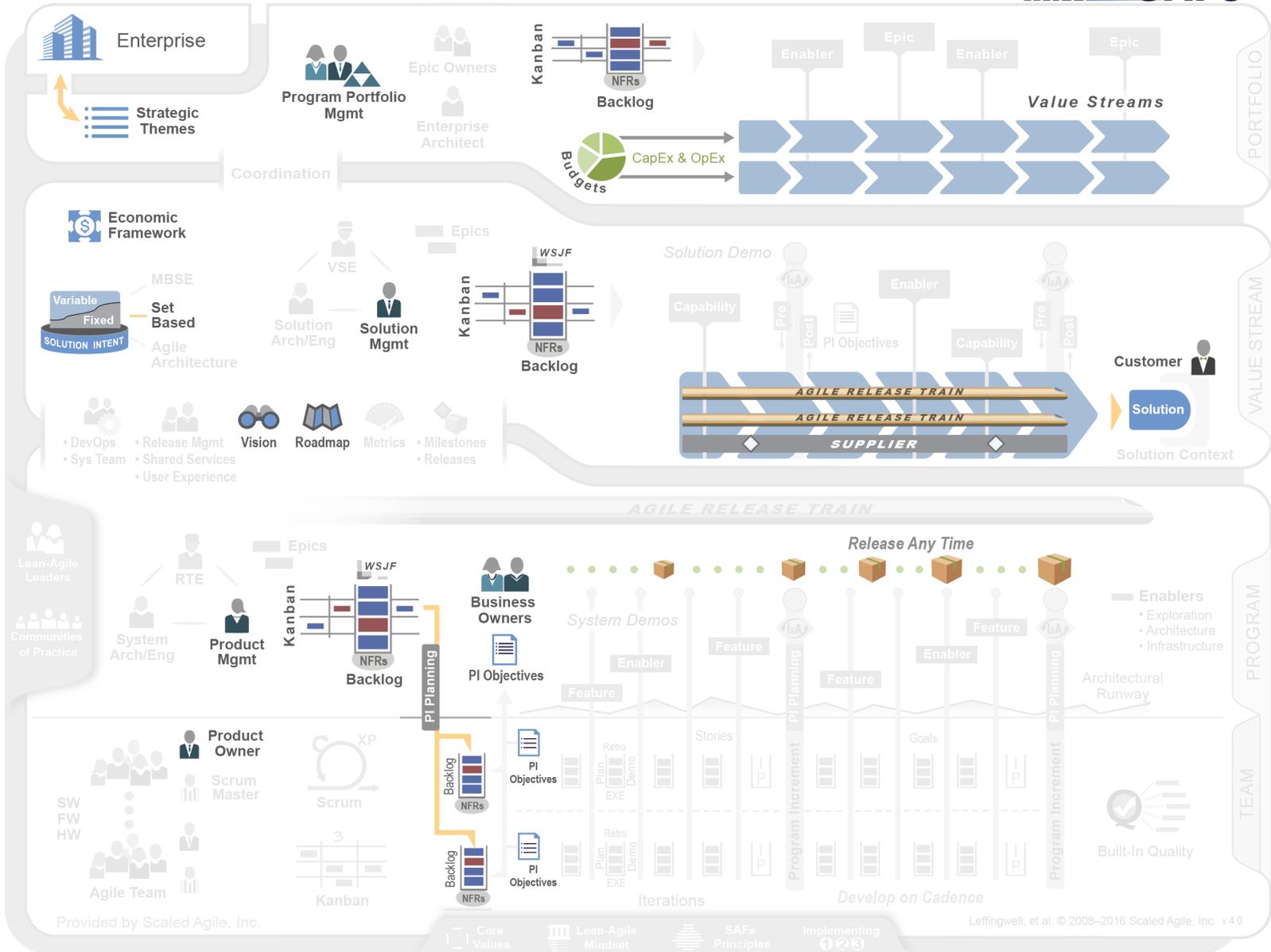
Overview of SAFe 4.0

- “SAFe 4.0 in 8 Pictures”
 - <http://scaledagileframework.com/videos-and-presentations/>

Applying SAFe to the Development of a System

- What is the System?
- What is the Value Stream(s)?
- What is the ART(s)?

SAFe® 4.0 for Lean Software and Systems Engineering

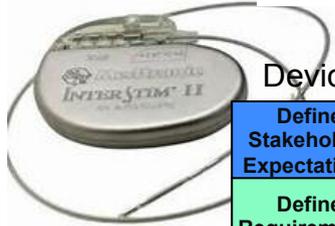


What is Your System?



System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



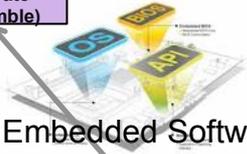
Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Hardware

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Embedded Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Platform

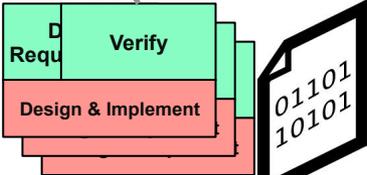
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



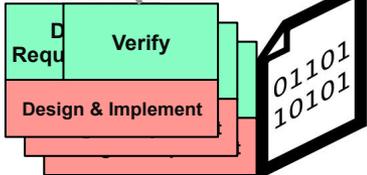
Application Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

Code



Code



What is Your System?

Value Stream
One ART?



System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Subsystem = ART?

Subsystem = ART?



Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	



Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	



Application Software

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	



Hardware

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

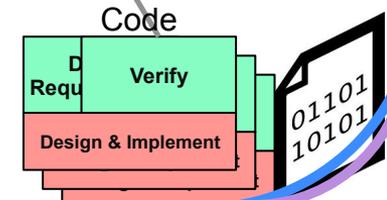
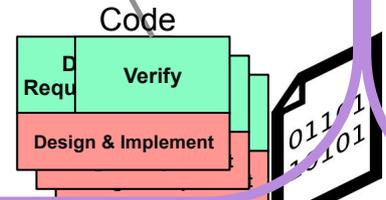
Embedded Software

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	



Platform

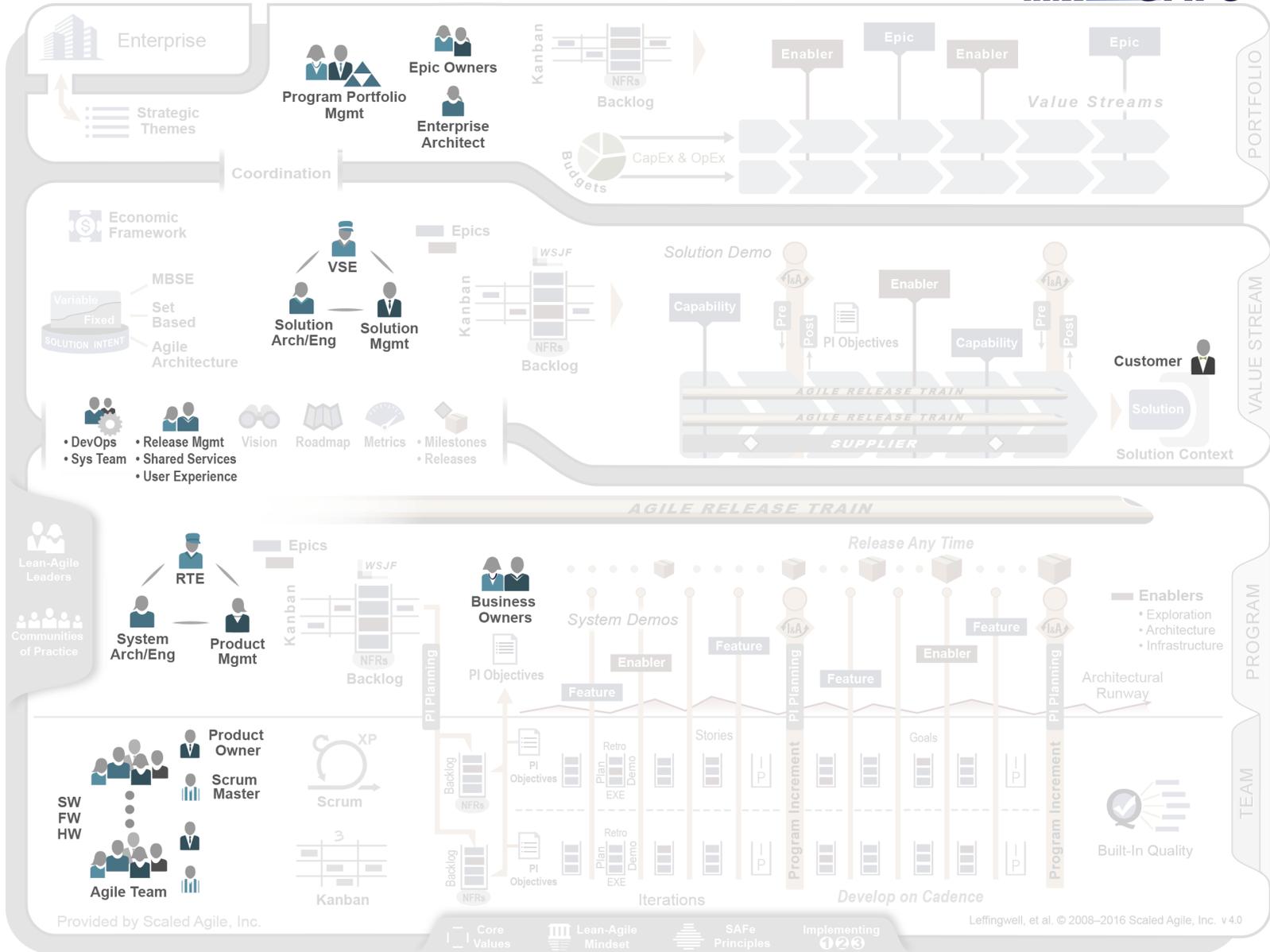
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	



Applying SAFe to the Development of a System

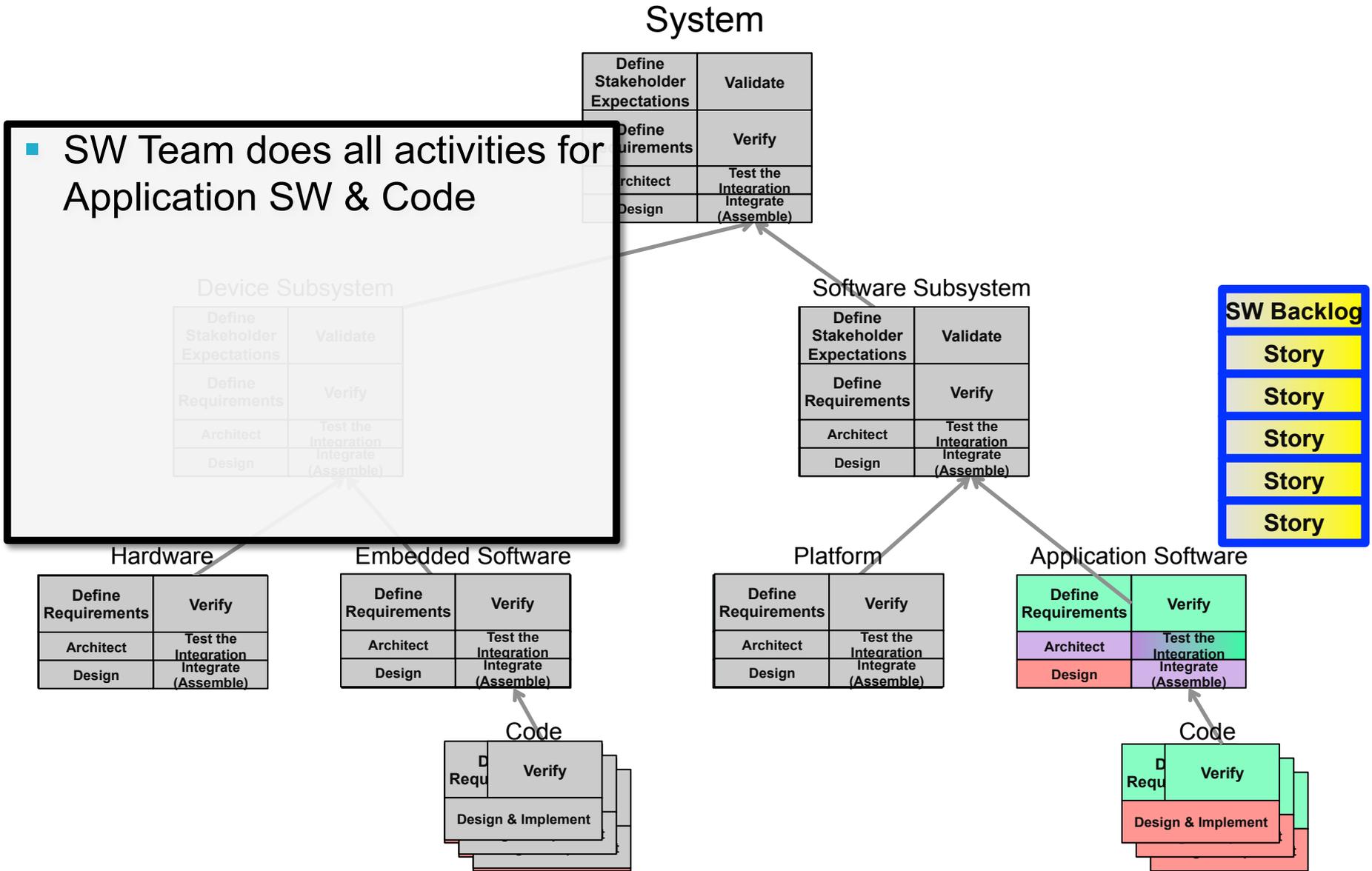
- What are the Teams?
 - What do they deliver?
 - What activities do they perform?
- What activities provide input to the teams?
 - And who does them?

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Application Software Team

- SW Team does all activities for Application SW & Code



Application Software Team

- SW Team does all activities for Application SW & Code
- Does team also do...?
 - Integration & Integration testing with Platform?
 - Arch & Design (at SW Subsys level)
 - Software Subsystem Definition and Verification?
 - Software Subsystem Stakeholder Expectations & Validation?

System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

SW Backlog
Story

Hardware

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Embedded Software

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

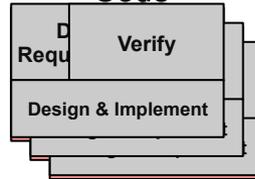
Platform

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

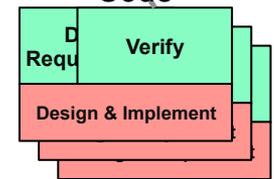
Application Software

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Code

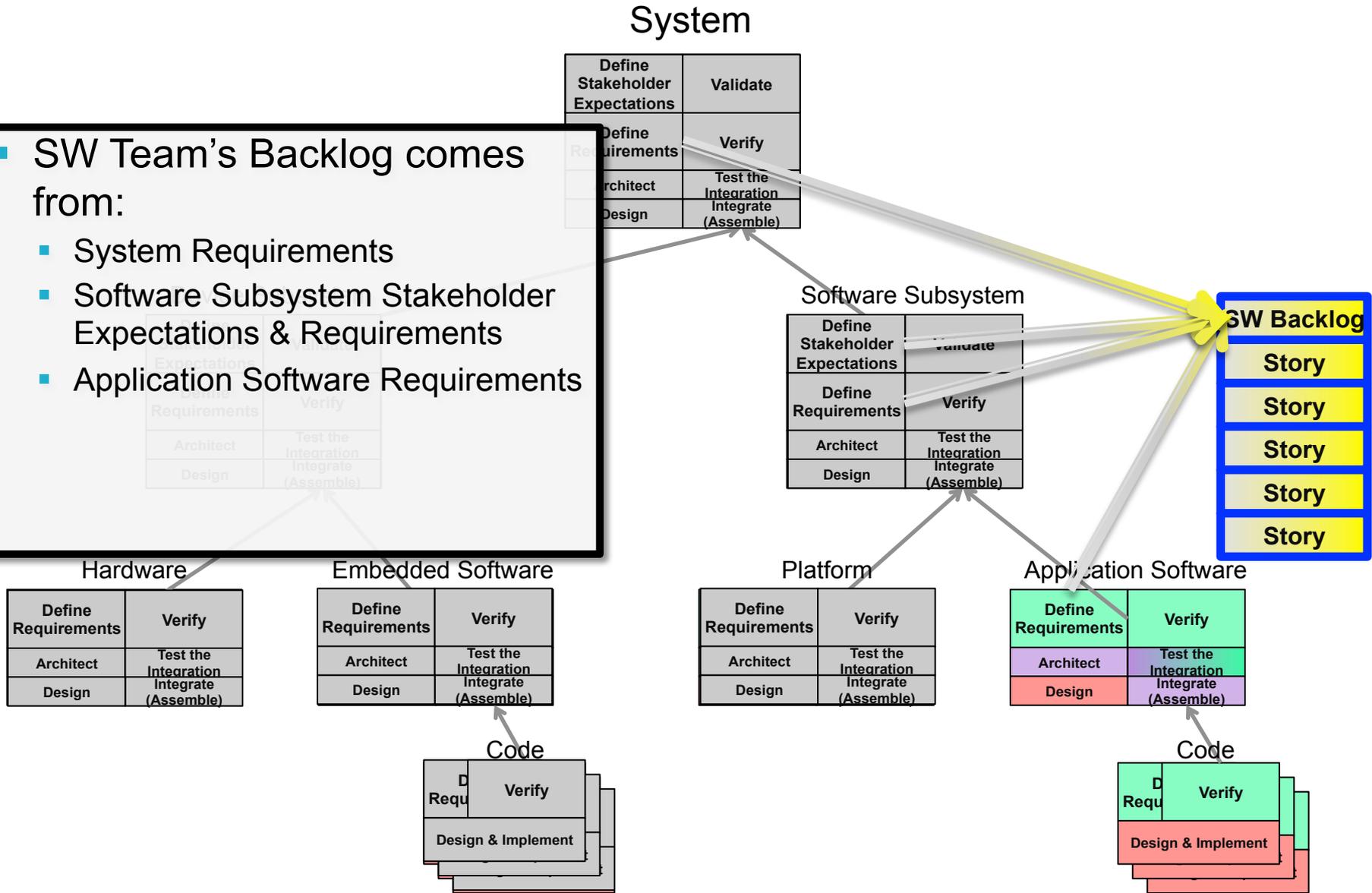


Code



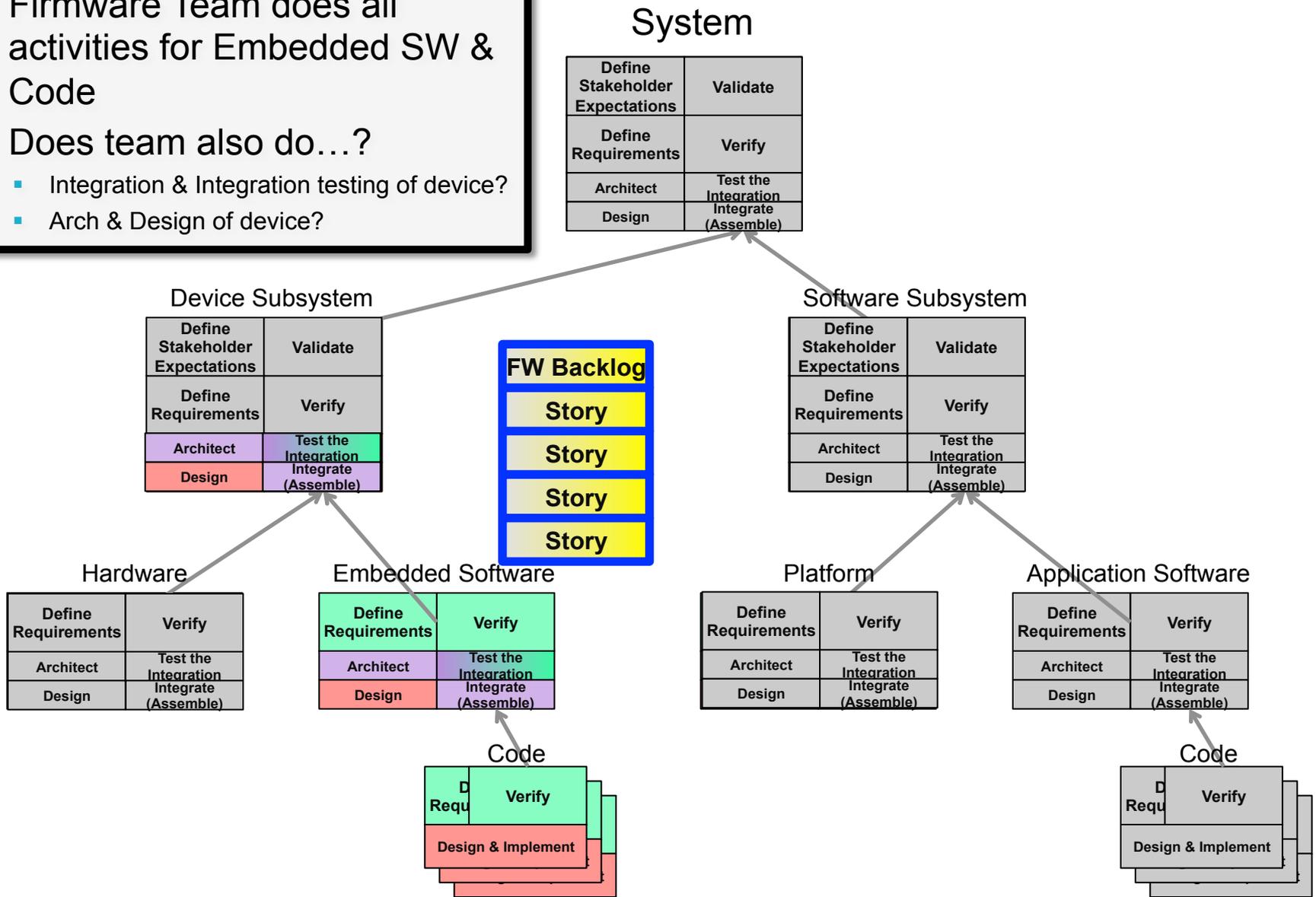
Application Software Team

- SW Team's Backlog comes from:
 - System Requirements
 - Software Subsystem Stakeholder Expectations & Requirements
 - Application Software Requirements



Embedded Software Team

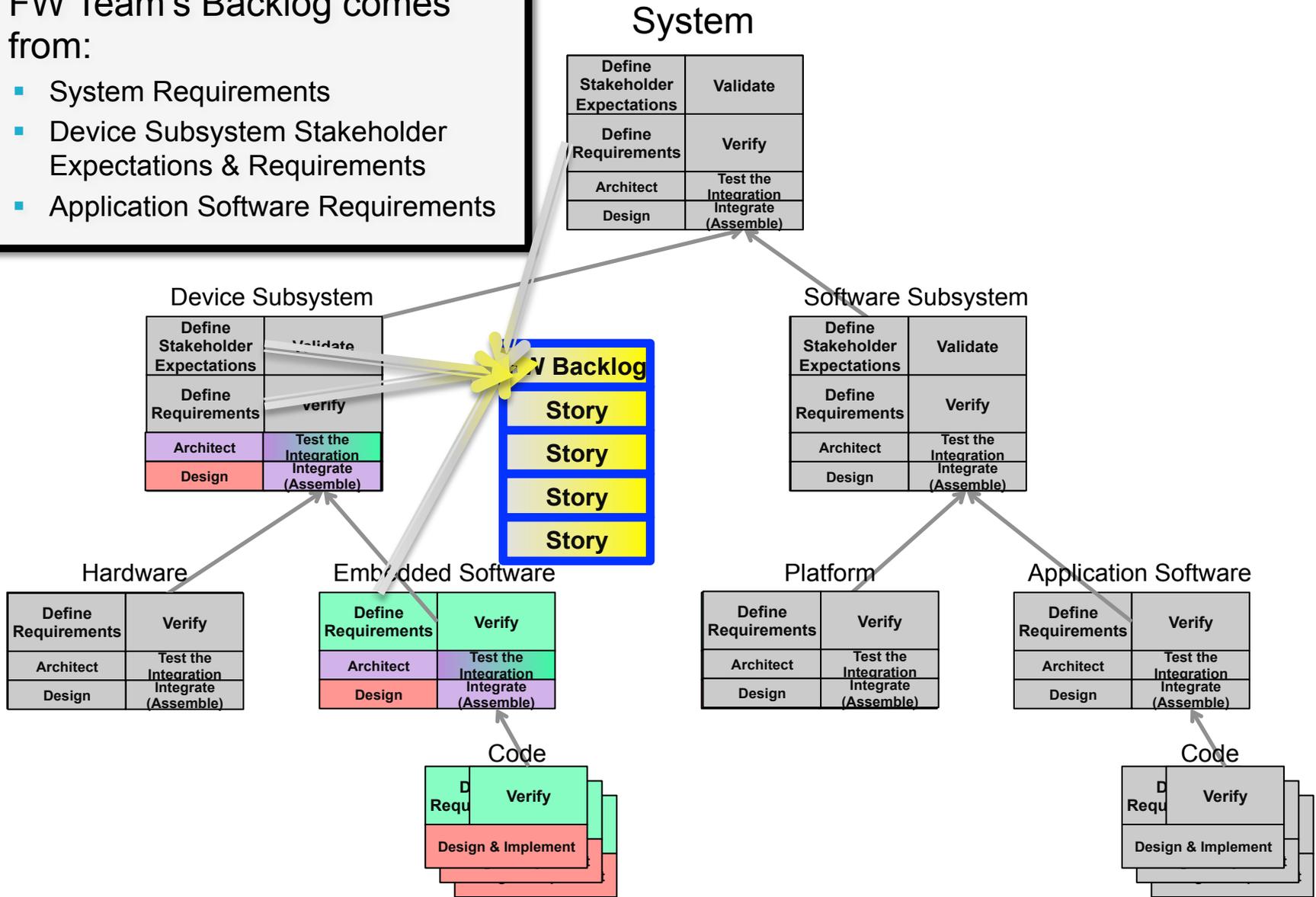
- Firmware Team does all activities for Embedded SW & Code
- Does team also do...?
 - Integration & Integration testing of device?
 - Arch & Design of device?



Embedded Software Team

FW Team's Backlog comes from:

- System Requirements
- Device Subsystem Stakeholder Expectations & Requirements
- Application Software Requirements



Hardware Team

- Hardware Activities
- Does Hardware Team do:
 - Integration & Integration testing of device?
 - Arch & Design of device?
 - Along with Firmware Team?

System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

- HW Backlog
- Story
- Story

Hardware

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Embedded Software

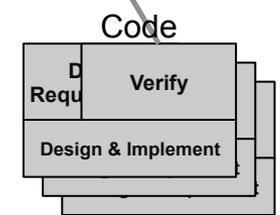
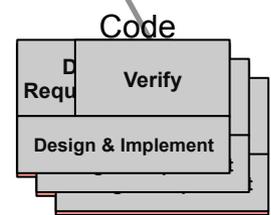
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Platform

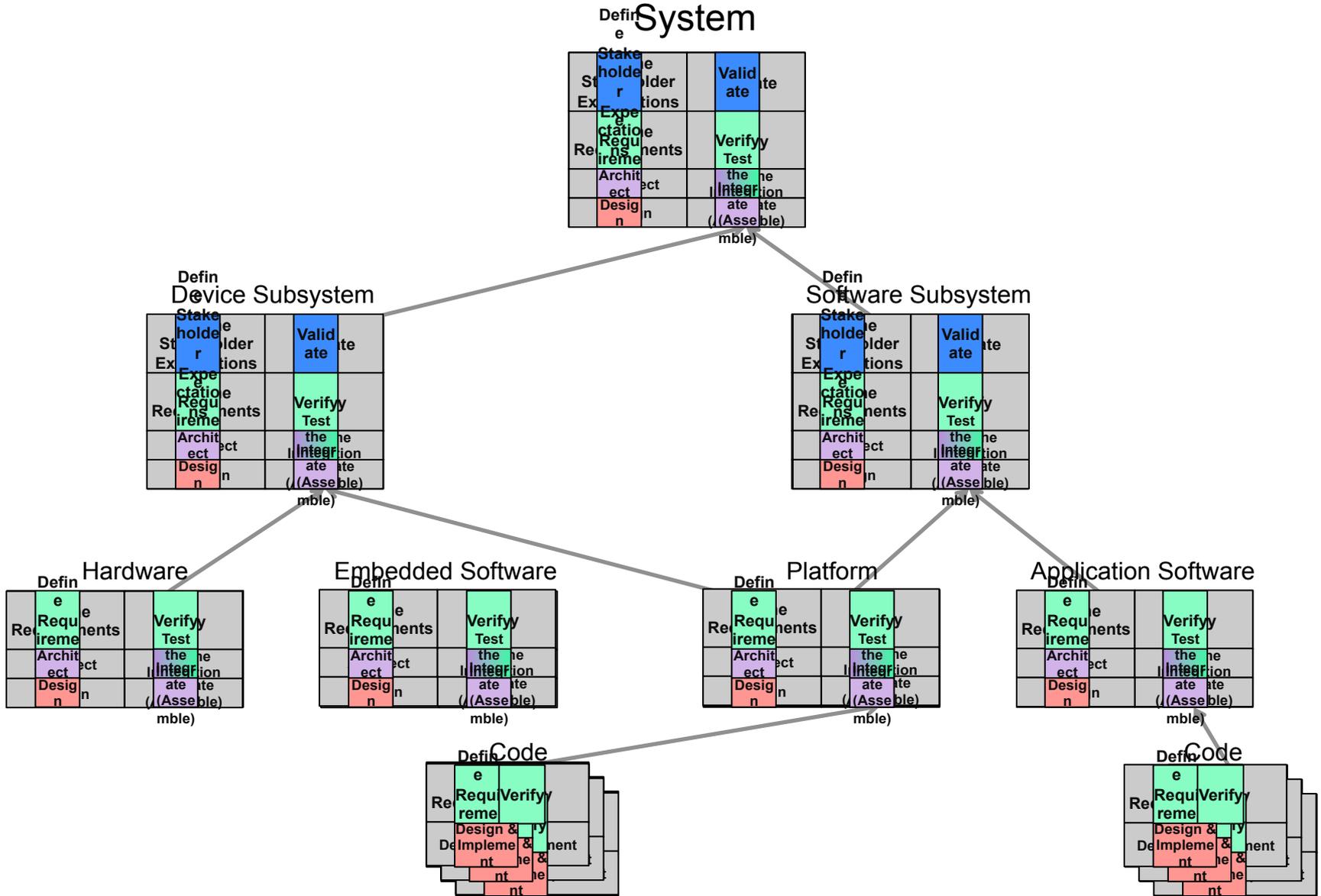
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Application Software

Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	



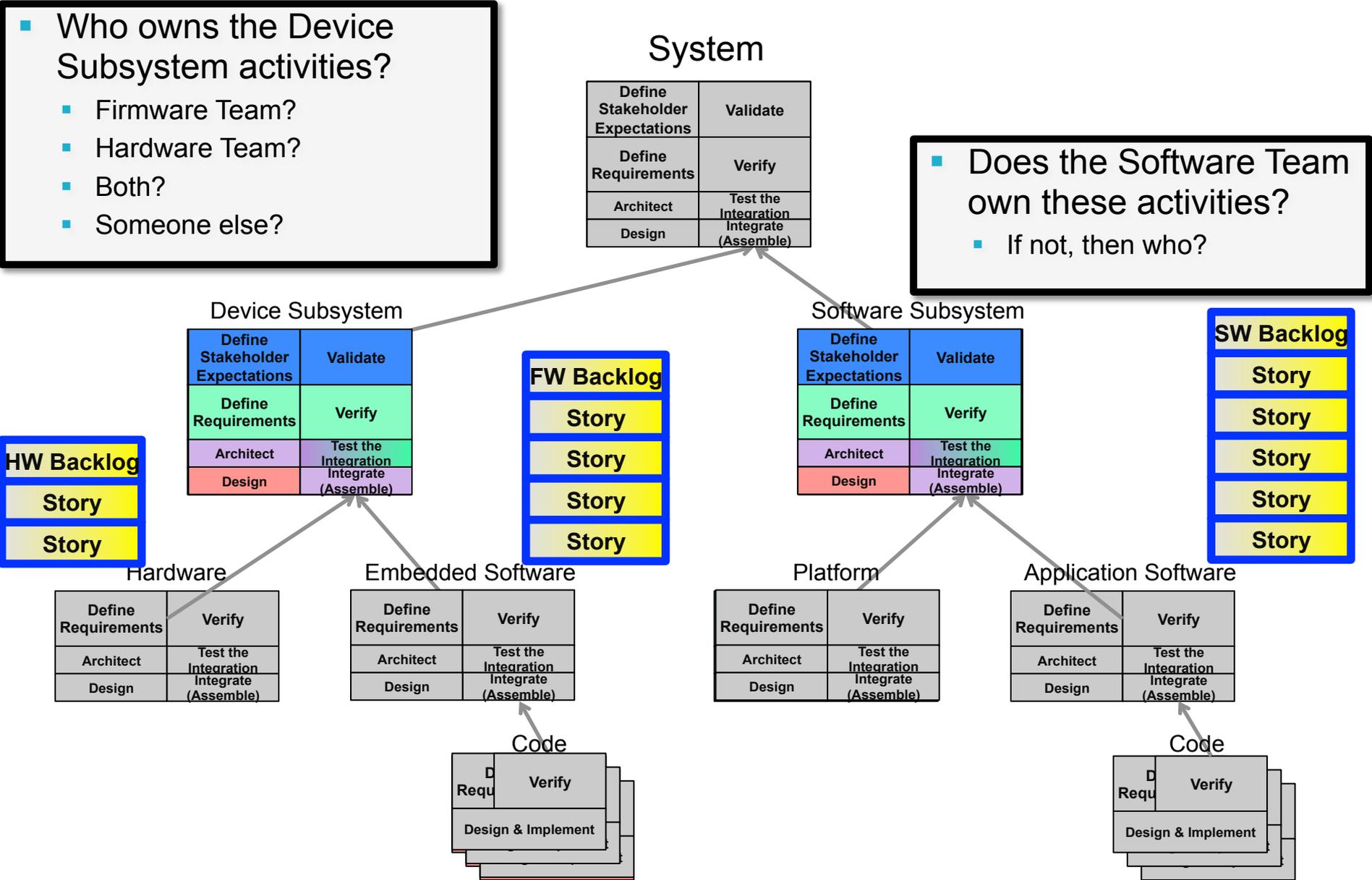
Cross-Functional Feature Team



Subsystem Activities – What team/role?

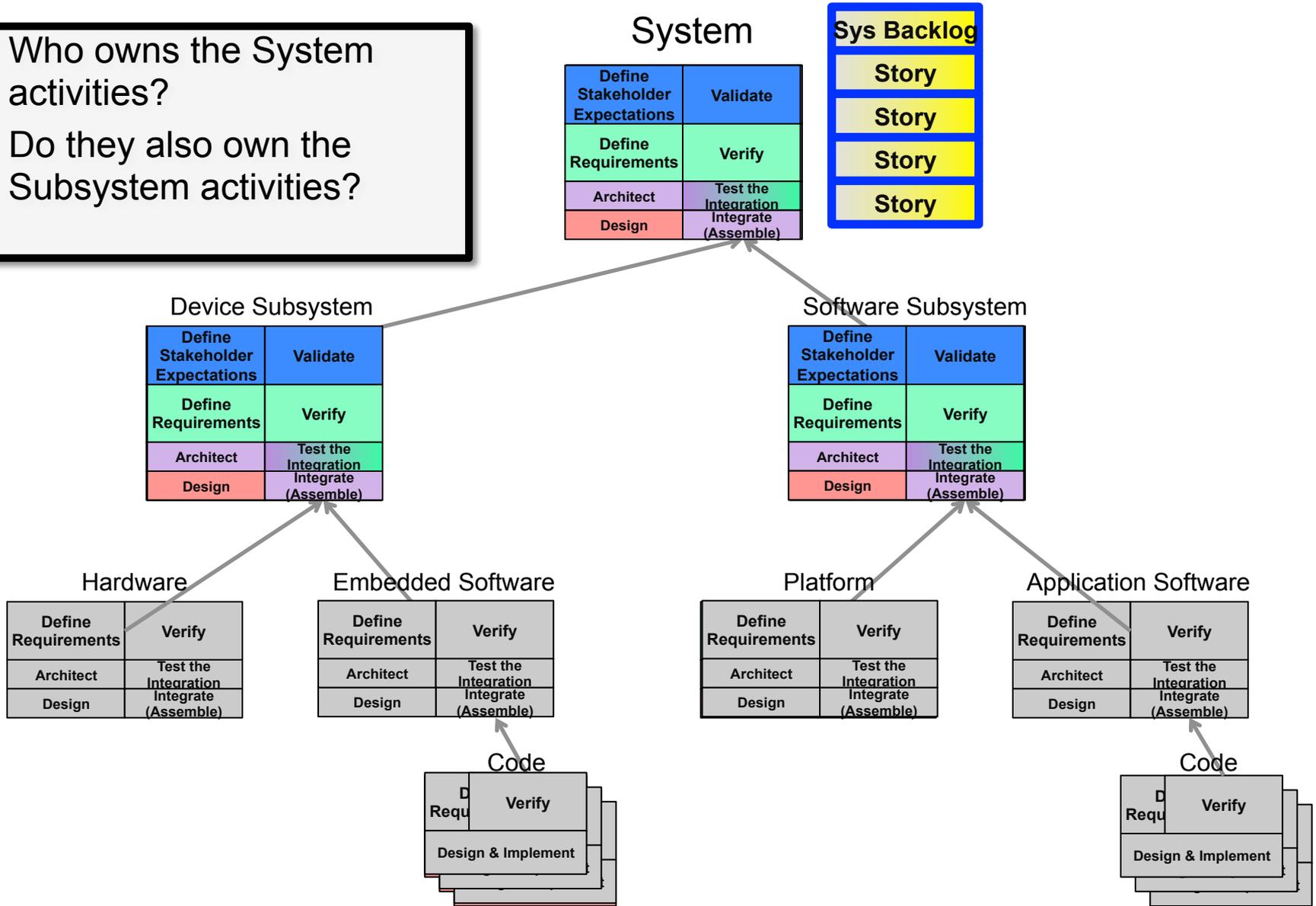
- Who owns the Device Subsystem activities?
 - Firmware Team?
 - Hardware Team?
 - Both?
 - Someone else?

- Does the Software Team own these activities?
 - If not, then who?

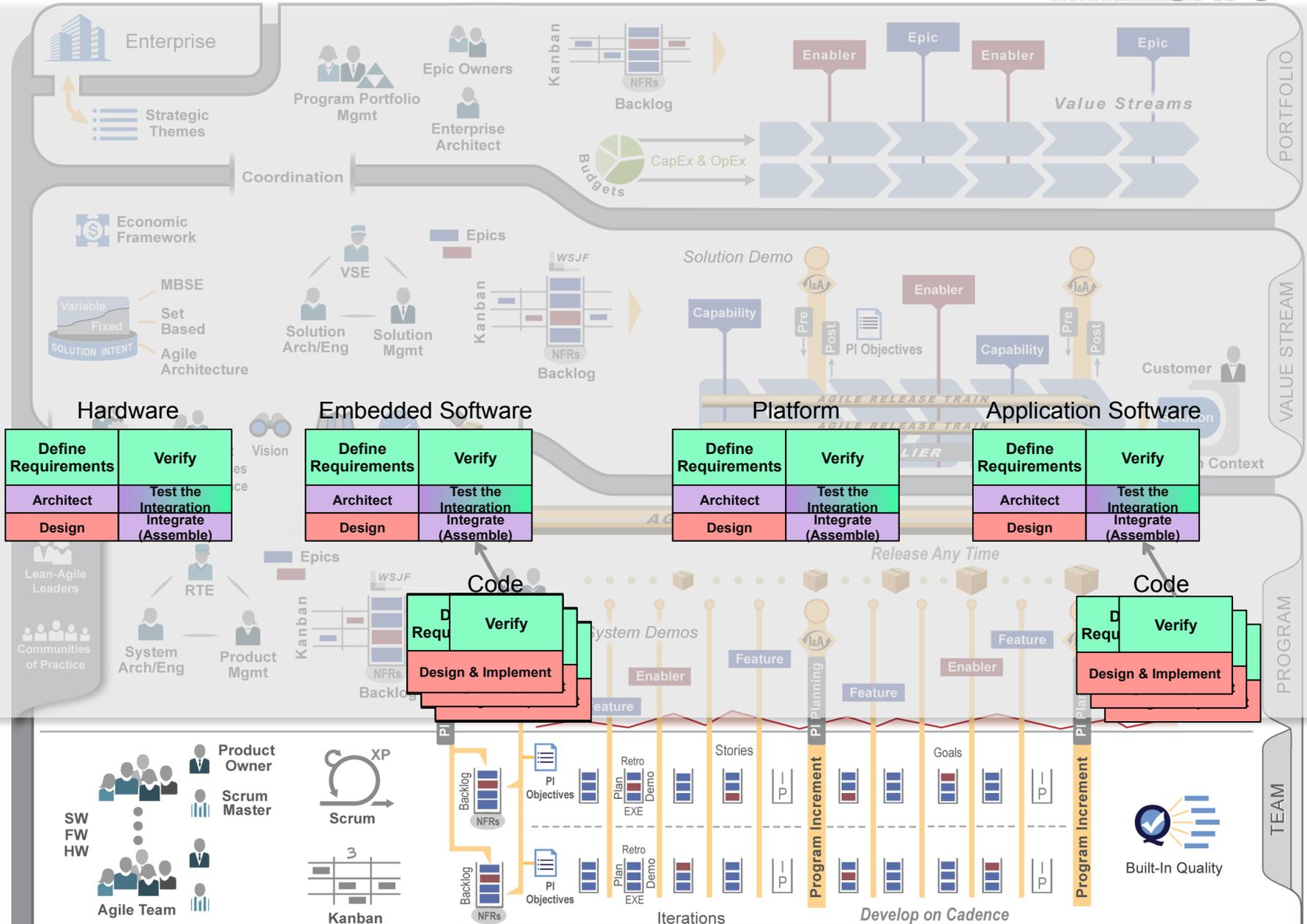


System Activities – What Team/Role

- Who owns the System activities?
- Do they also own the Subsystem activities?

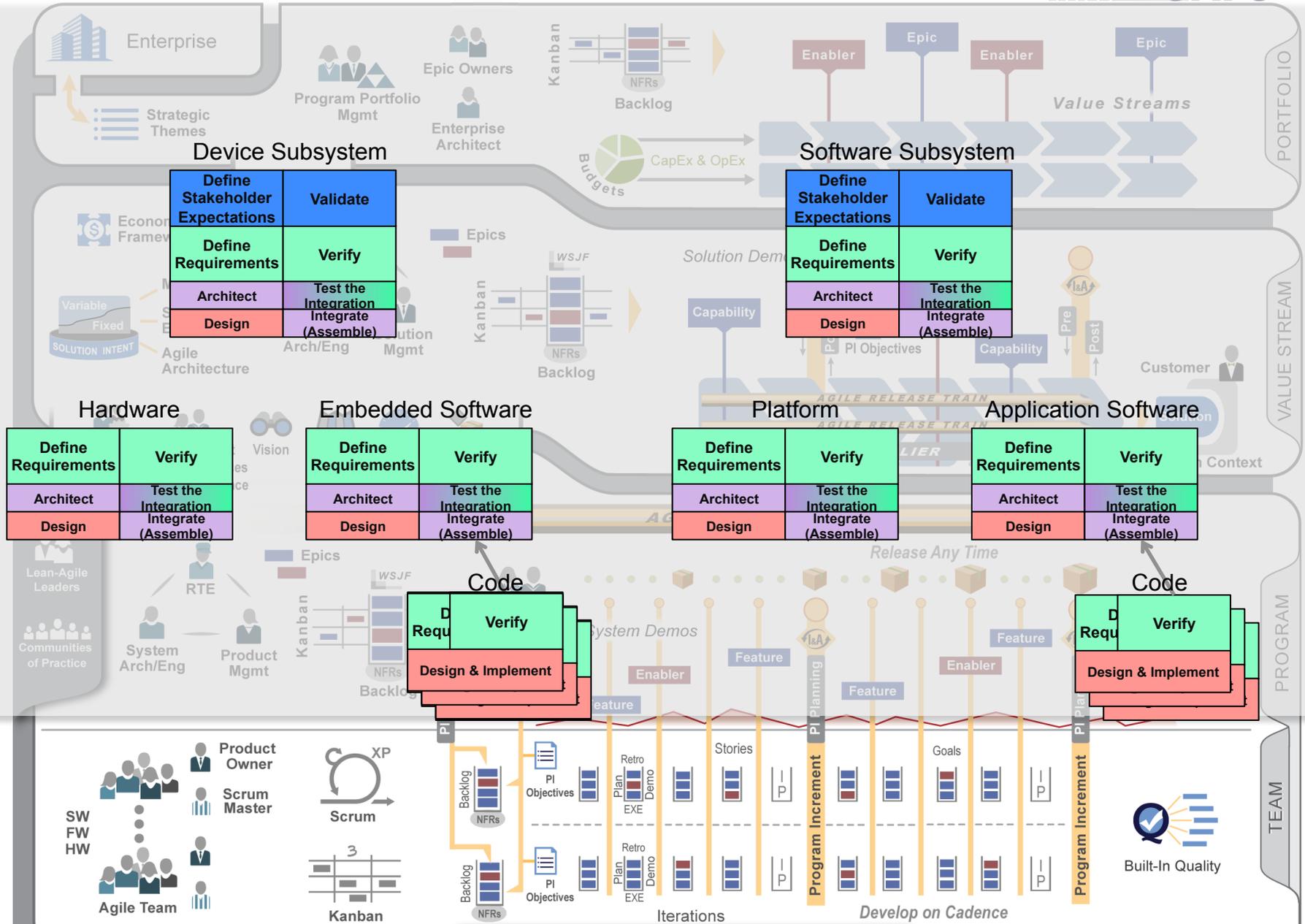


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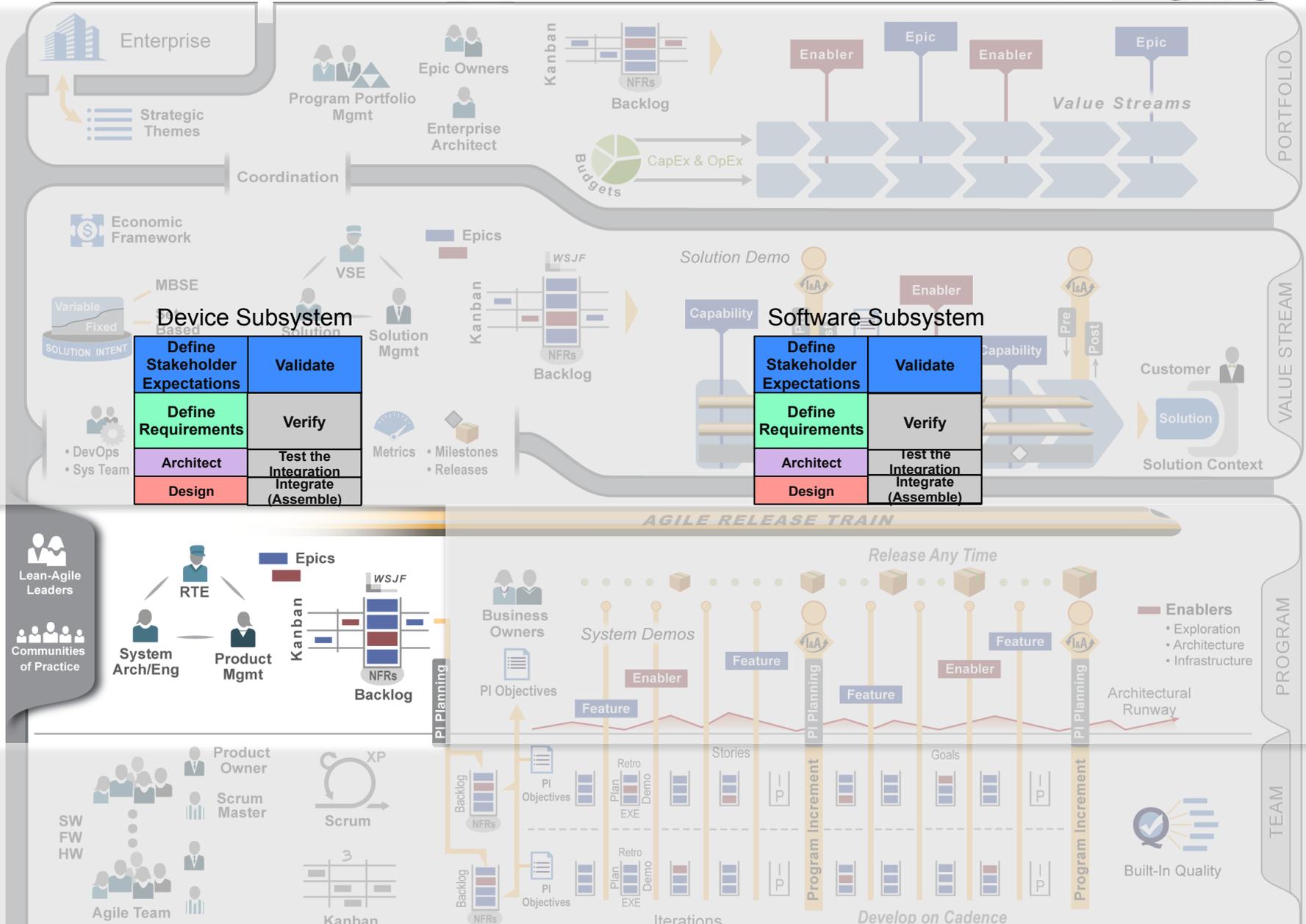


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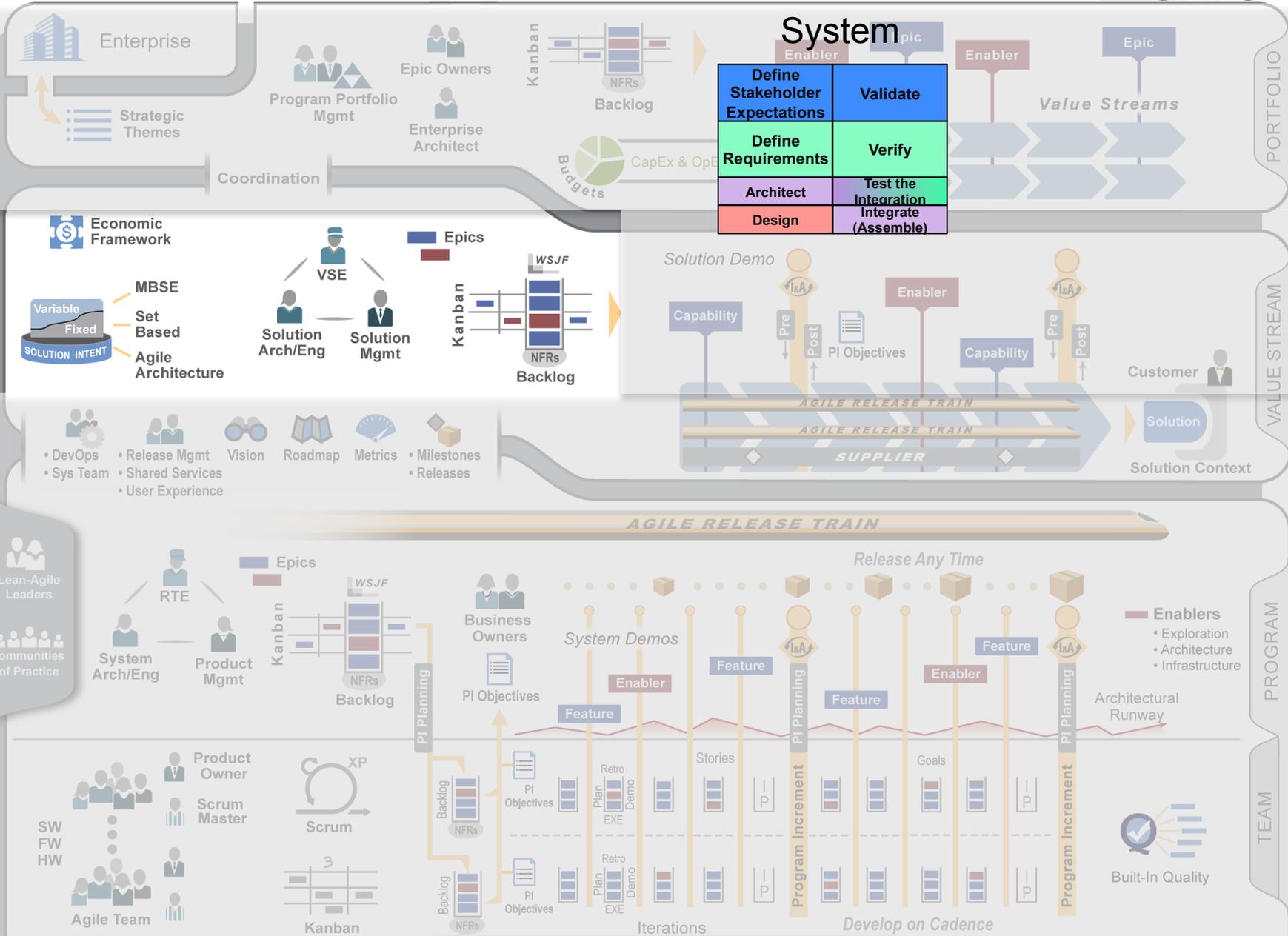
Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration Integrate (Assemble)
Design	

SAFe® 4.0 for Lean Software and Systems Engineering



Guidelines for Team Structure

- Team size
 - 3-9 (the Scrum rule) - “The 2 Pizza Rule”
- What is their Product?
 - What do they deliver? What do they demo?
- Who is their Product Owner? Stakeholders?
 - To whom do they deliver? Who is invited to the demo?
- What Activities must they perform? Are they capable?
 - Expertise & experience. Specialists and Generalists. Access to visitors/helpers when needed.
- Development Teams are a System
 - Define the boundaries, manage the interfaces

Agile for System Development

- Foundations, Good Ideas and Conversation Starters
- Did this enlighten you on some Foundational topics (SAFe, Systems Engineering Models)?
- Did this spark some Good Ideas?
- If you weren't here for the Conversation, well, these slides might not ...

Contact Information

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