Be Lean and Be Safe:
Applying Agile to Design Medical Devices

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Introductions

Ram Nanjun

Lean/Agile Coach

GE Healthcare

- 25 years of software development experience in a variety of roles
- Experience with different methodologies (Waterfall, Iterative, Agile)
- Joined GE August 2013 - creating a culture of continuous improvement
- Rolled out Scaled Agile Framework® since 2011 to 50+ programs across Nokia and GE Healthcare

Ianne Howards Koritzinsky

Design Controls Manager

GE Healthcare

- 26 years of experience in Systems, Software Engineering and Quality in GE Healthcare
- 9 years mentoring programs across all GEHC businesses to apply Design Controls and SDLC
- Guided hundreds of engineers and QA to adopt Agile practices in compliance with Design Controls and SDLC since 2012

Agenda & Introductions

- ✓ Pulse Point
- ✓ Phases of Scaled Agile Framework® (SAFe®)
- ✓ Recipe for Compliance in SAFe®
- ✓ Simulation
- ✓ Conclusion

Pulse Point

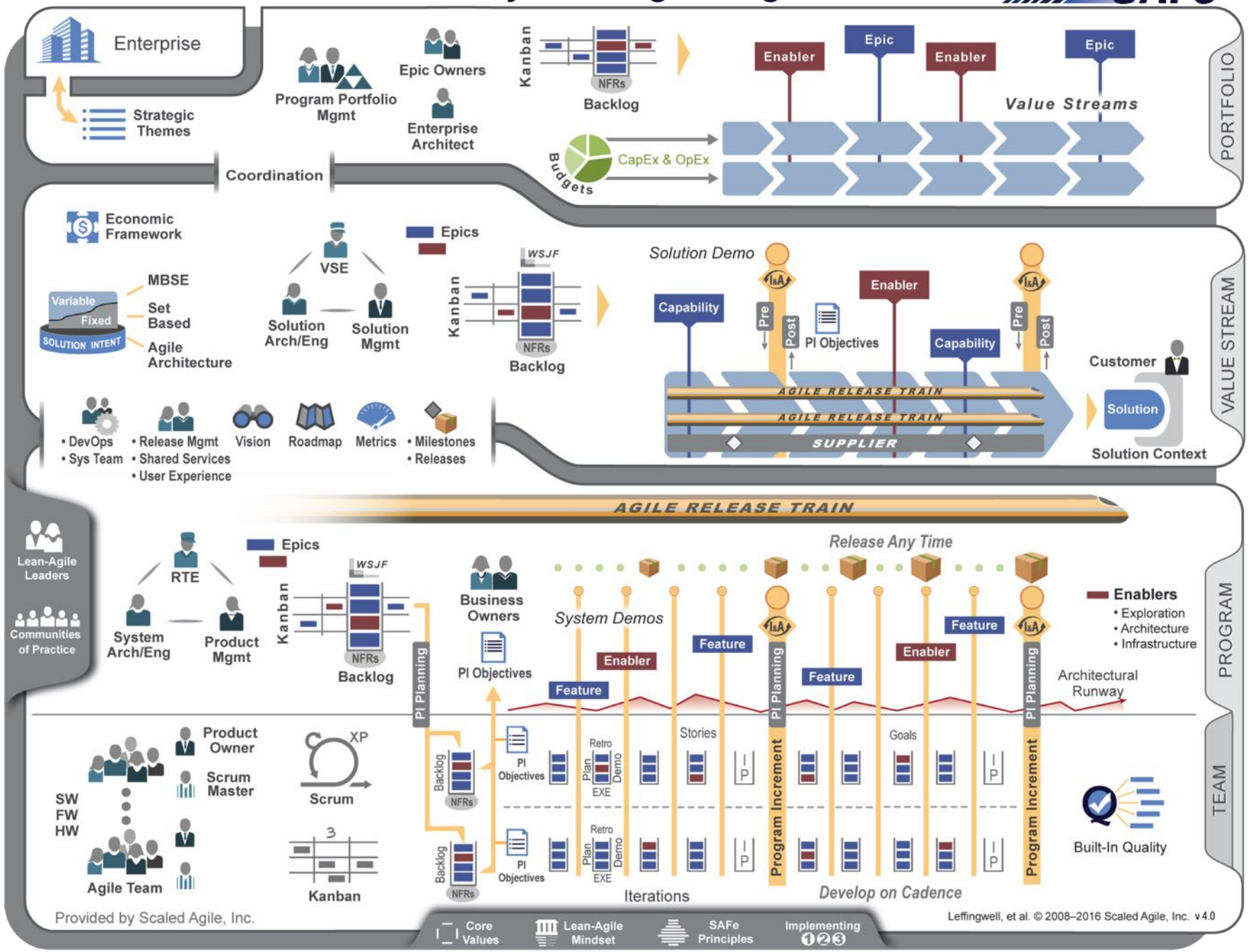
Are you a beginner, intermediate, or expert for:

Agile?

Developing medical devices?

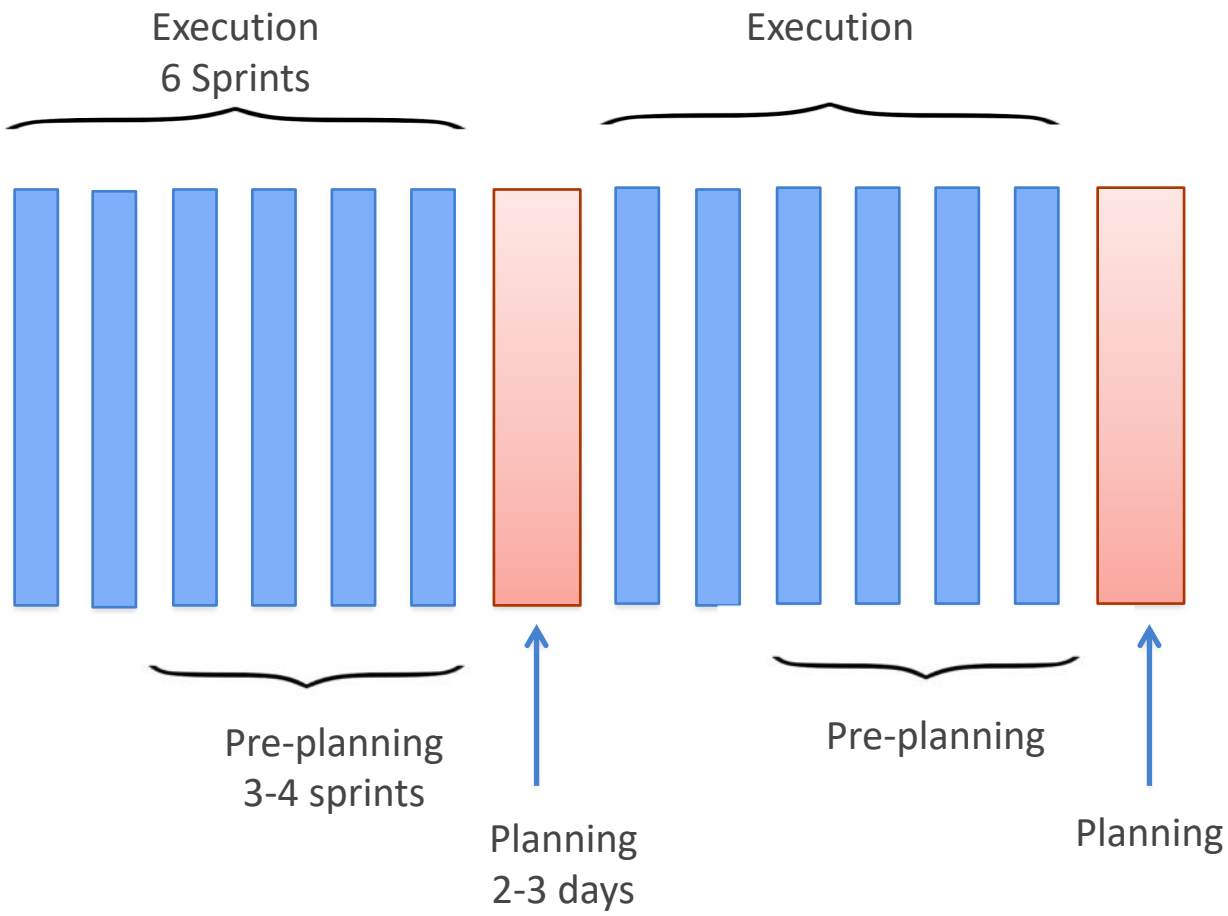
Agile Framework

SAFe® 4.0 for Lean Software and Systems Engineering



3 Key Phases in SAFe®

Pre-Planning, Planning, Execution



What is the recipe for compliance in SAFe ®?

Recipe for Quality + Agile

You will need to establish

- Quality tasks to deliver incrementally
- Objective evidence of compliance

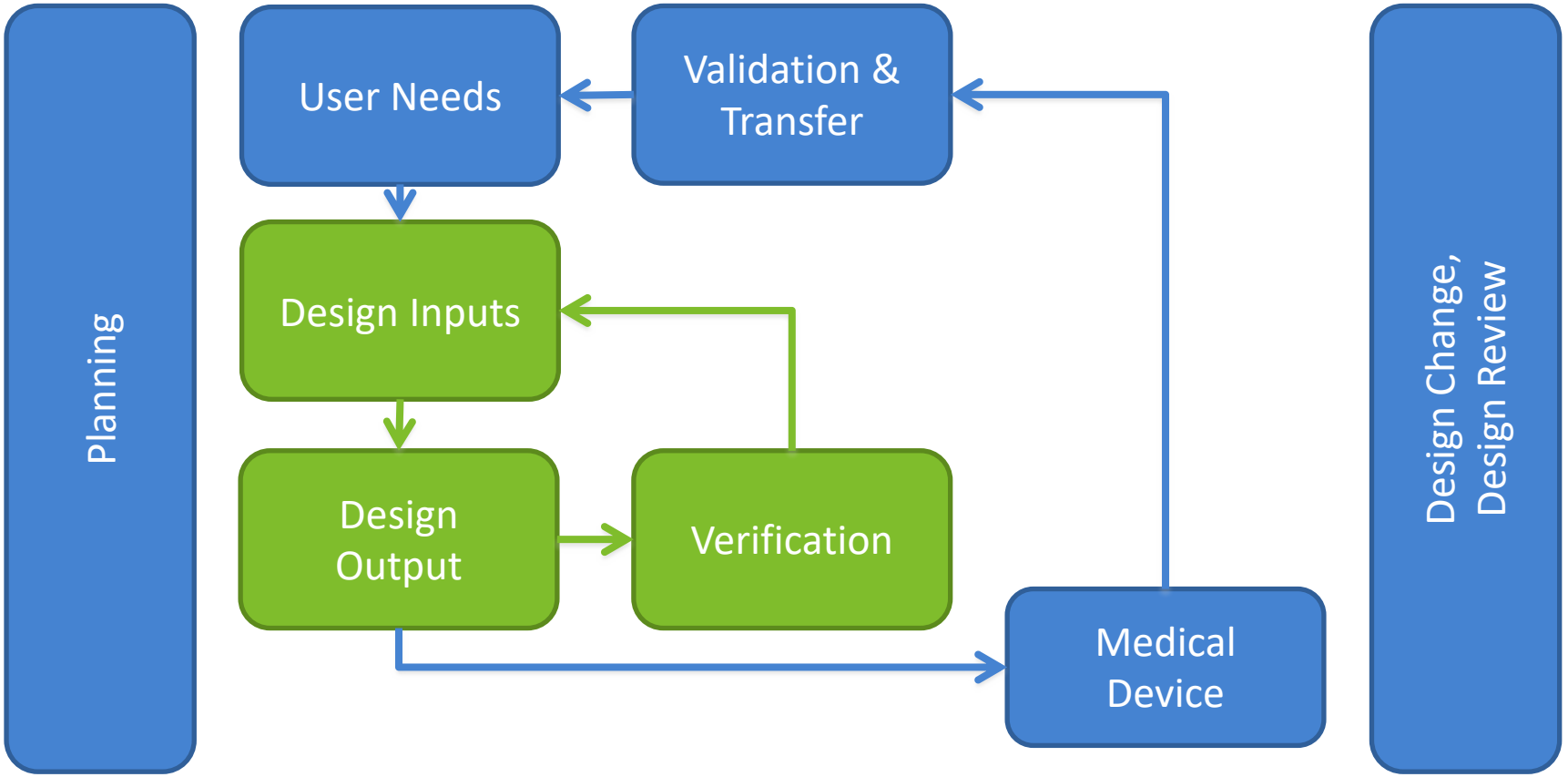
Key Steps:

- Include quality deliverables into DoR & DoD
- Preplanning: Do quality work necessary to meet DoR
- Planning: Account for quality work & estimates
- Execution: Complete quality deliverables within sprints

Team owns incremental development of quality

Establish Quality Tasks & Objective Evidence

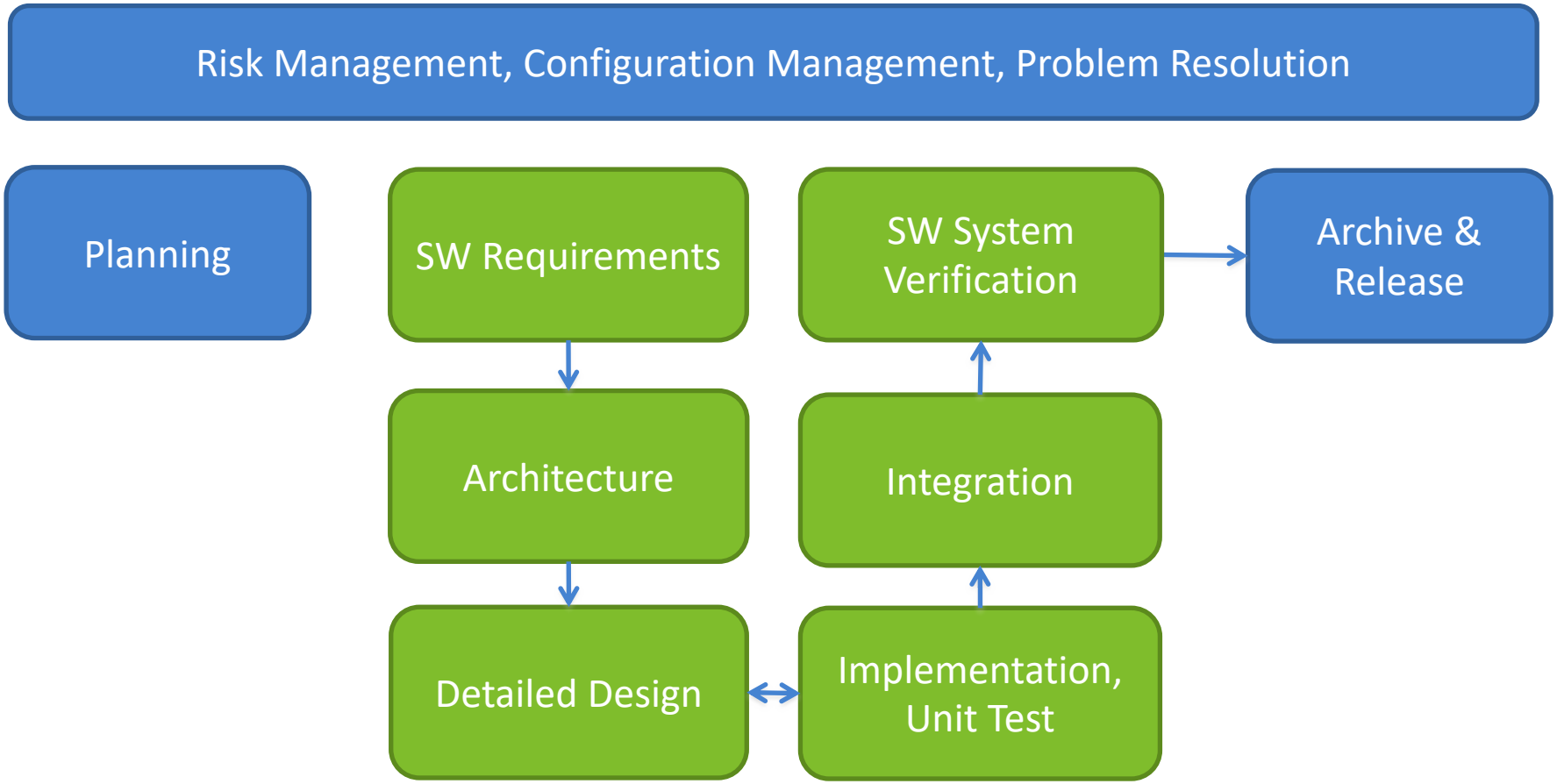
Quality Tasks for Design Controls



- The FDA Quality System Regulation (QSR) 21CFR part 820 [4]
- ISO 13485 Medical devices — Quality Management Systems [1]

ISO 62304: Software Development Lifecycle

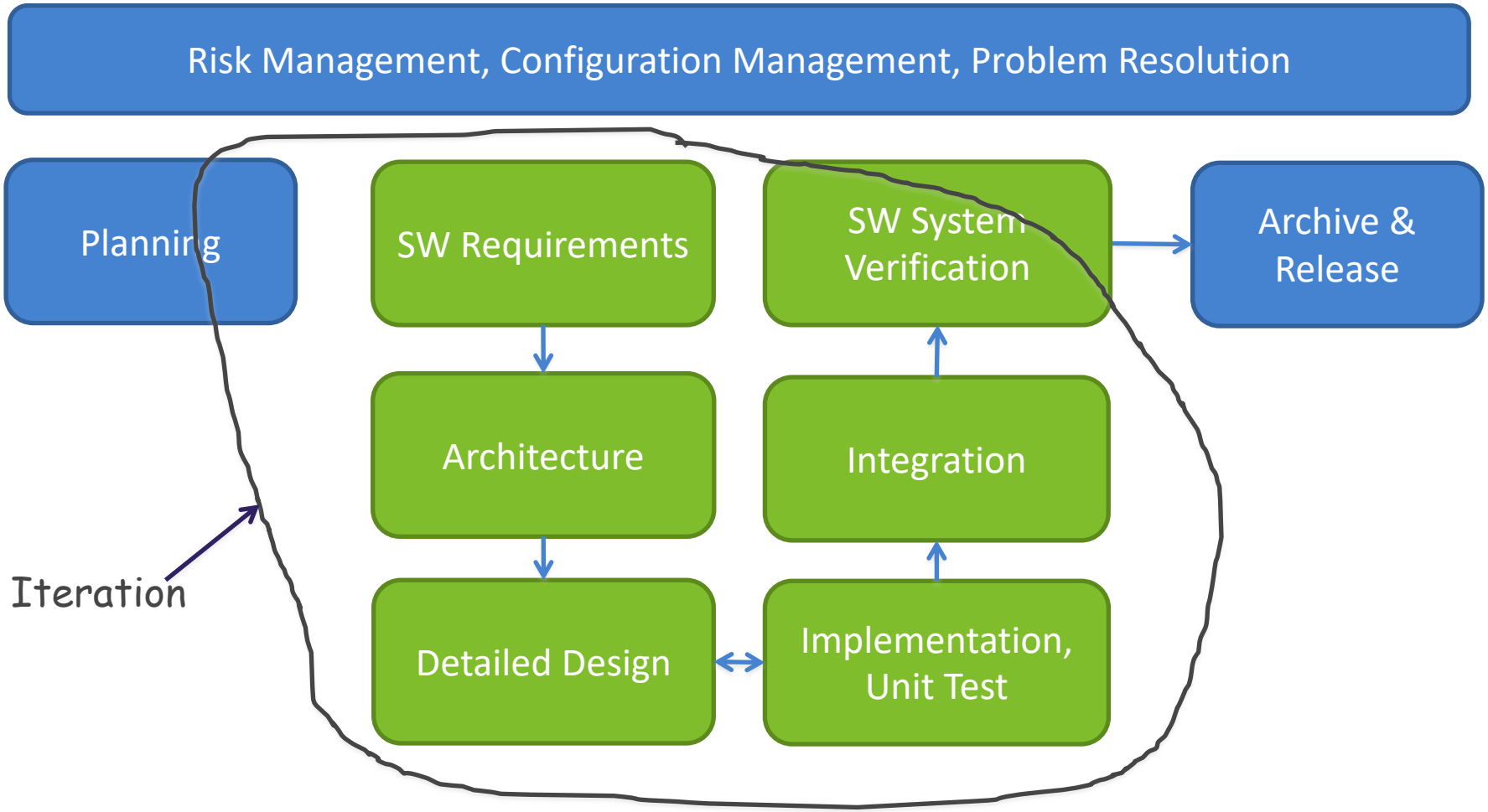
[2], [3]



Ensures safety through process controls For Software Development

Iterative Thinking

[2] [3]



Include Quality deliverables in DoR & DoD

What could you include in….

[3],[6]

Definition of Ready (DoR)

- Architectural runway
- Potential hazards identified
- System requirements draft
- Concept design

Definition of Done (DoD)

- Detailed Design documented
- Mitigations verified and traced
- Requirements reviewed & documented
- Code in config mgmt
- Verification results

Reasons to include Quality deliverables in DoR/DoD

- Ensure the completed stories incorporate **safety**
- Provide **objective evidence**
- Avoid technical **debt**
- Sustainable **velocity** that includes quality

Don’t start a story that isn’t ready….
Don’t accept a story before it is done

Do necessary quality work during pre-planning

Pre-Planning

4-6 weeks before next PI planning session

To understand content of PI

Preliminary Design Inputs	Initial Architecture	Preliminary Plans	Hazards & preliminary causes
Product Owners	Architects	Sys/SW Engineers	Sys/SW Engineers

Account for Quality Work in planning

Planning

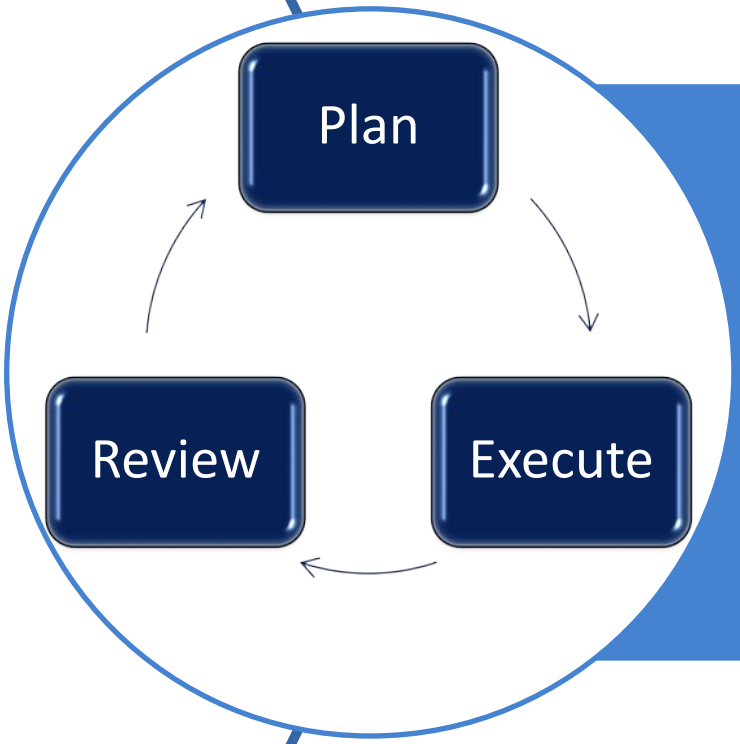
2 days before starting next increment

Establish backlog, commit resources using

Systems Engineers	SW Engineers	Product Owners	Team
Design Plans Verification Plans	SW Development Plans Configuration management plan	Post Market Feedback Residual Anomalies Design Inputs	Definition of Ready Definition of Done

Complete quality deliverables within sprints

Execution



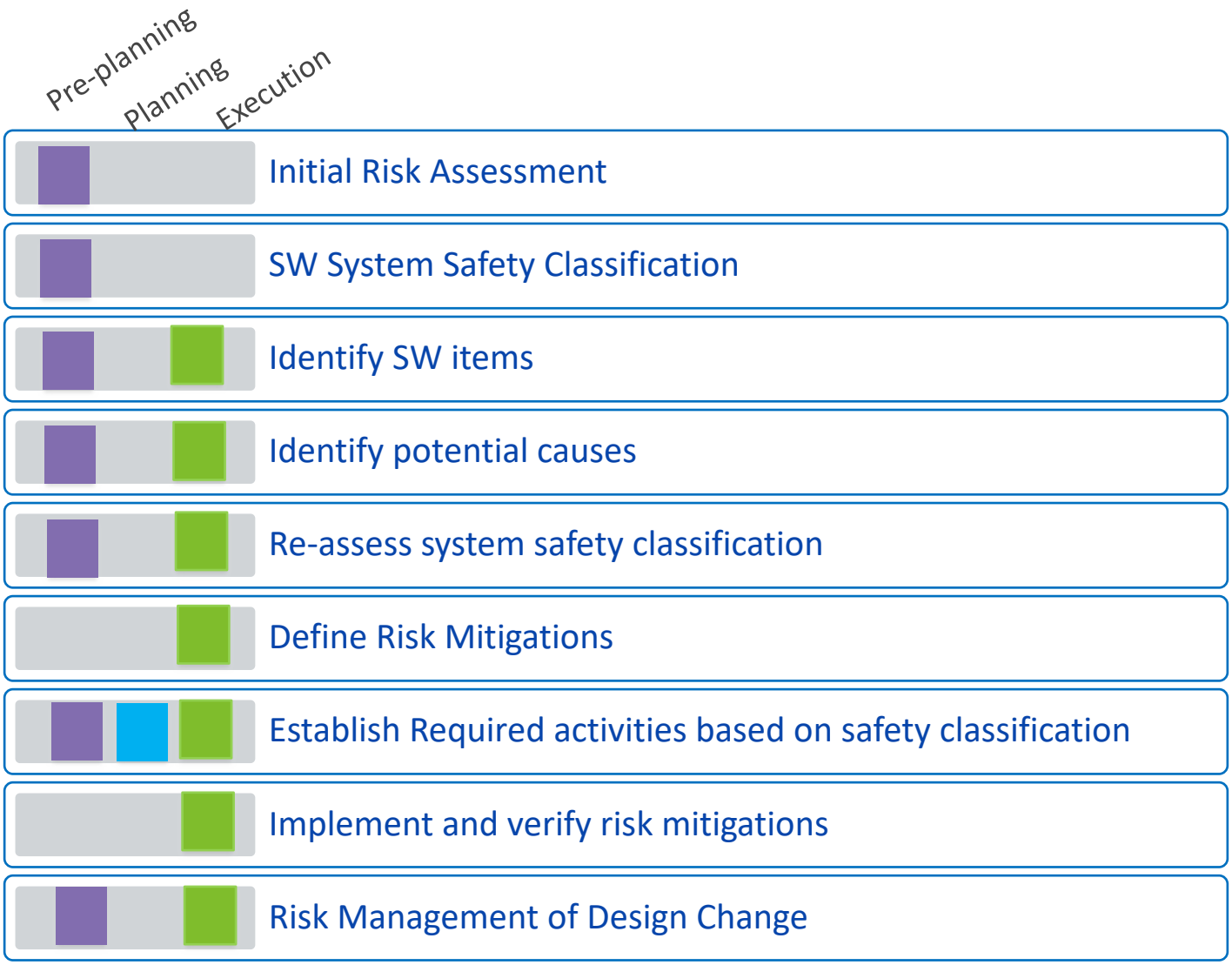
Sprint Level Quality Deliverables

- Risk Management: Causes ID & Mitigated
- Requirements documented & traced
- Detailed Design
- Working Code under configuration mgmt
- Automated tests & results
- Verification results

Team implements stories from plan to deliver quality

Aligning Risk Management Tasks to Agile

[2],[7]



Final Verification

[1].[2].[3],[4],[5],[8]

May be shortened by

- Applying rigorous change control
- Meeting DoD continuously
- Avoiding technical debt
- Automating testing

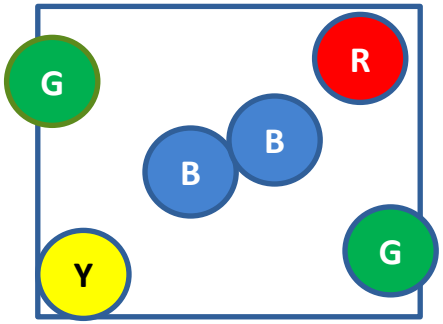
Concerns

- Complexity of product
- Maturity of team

Leverage incremental verification for leaner final verification

Simulation

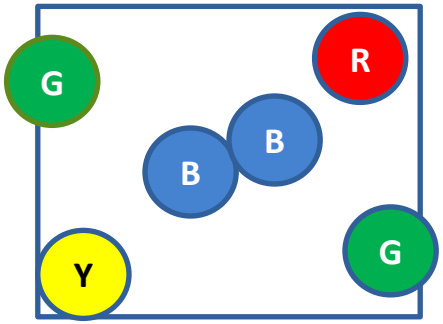
Exercise : Dot Game



Rules

- Form teams of 5-6 people at each table
- Each table is a scrum team
- Scrum team makes post-it notes with dots placed according to the design spec
- Each person on scrum team has to put on a dot

Exercise : Process



Step 1 - SAFe Release Planning (3 mins)
OBJECTIVE : Estimate how many post-its can be completed in a release of 5 Sprints. Capture on a sheet of paper for each team.

Step 2 – Planning and Execution (5 mins)
Sprint Planning (2 mins)
Execution (3 mins)

Step 3 – Demo and Review (5 mins)

Step 4 – Retrospective (10 mins)

Summary

- Establish quality tasks to deliver incrementally
- Establish objective evidence of compliance
- Include quality deliverables in DoR & DoD
- Prepare quality deliverables as needed during pre-planning
- Account for quality work & estimates when planning
- Complete quality deliverables when executing sprints

Ensure team owns incremental development of quality

Bibliography

[1] ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*

[2] EN 62304:2006+A1:2015, Medical device software — Software life-cycle processes

[3] AAMI TIR45:2012, Technical Information Report. Guidance on the use of AGILE practices in the development of medical device software

[4] Quality System Regulation, 21 CFR 820 (the QSR)

[5] *General principles of software validation; Final guidance for industry and FDA staff*, 2002

[6] Scaled Agile Framework. http://www.scaledagileframework.com

[7] ANSI/AAMI/IEC Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software

[8] FDA Center for Devices and Radiological Health. Design Control Guidance for Medical Device Manufacturers. March 1997.

