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A Systems Engineering Approach To An Integrated Design Controls and Risk Management Framework in Medical Device Development.

Agenda

- What Is Design Controls (DC) & Risk Management (RM)?
- Why is it important?
- Integrated DC & RM Framework
- Risk Based Framework Outcomes
  - Requirement Criticality Assessment
  - Product Specification Criticality Assessment
- How Integration Helps?
- Considerations For Implementing The Framework
- Takeaways
- Q&A

What is Design Controls (DC) and Risk Management ?

Design Controls

"A set of quality practices and procedures implemented by the manufacturer to ensure that the product meets the user needs, intended uses and product requirements"

+

Risk Management

"Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk"

→

Robust & Safe Design

Why is it important?

01 Drive Robust Design Selection based on User Safety

- More opportunities to mitigate risk through "Inherent Safety by Design"
- Effective verification strategies based on criticality of requirement
- Understand critical areas of interest early in design.

02 Make Design Process More Efficient

- Reduce reconciliation effort during Design Reviews
- Enable better alignment b/w Design,Risk and Manufacturing
- Lesser design deficiency surprises during Design Transfer

03 Reduce Product Recalls

- Robust Design means lesser failures in the field
- Product Recalls are cost/image intensive to company
  - Increase in 11% for product recalls b/w 2022 and 2023 [1]

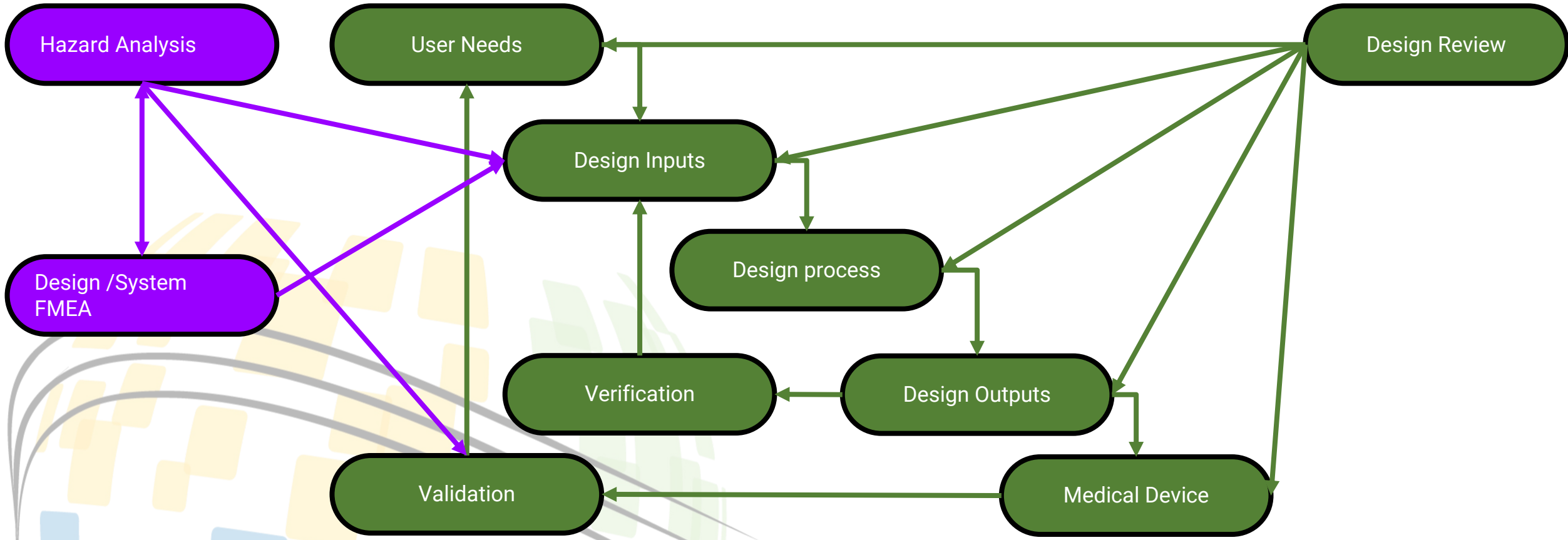
04 Successful Regulatory Audits

- Integrated system indicates successful quality systems application & improves audit success rate

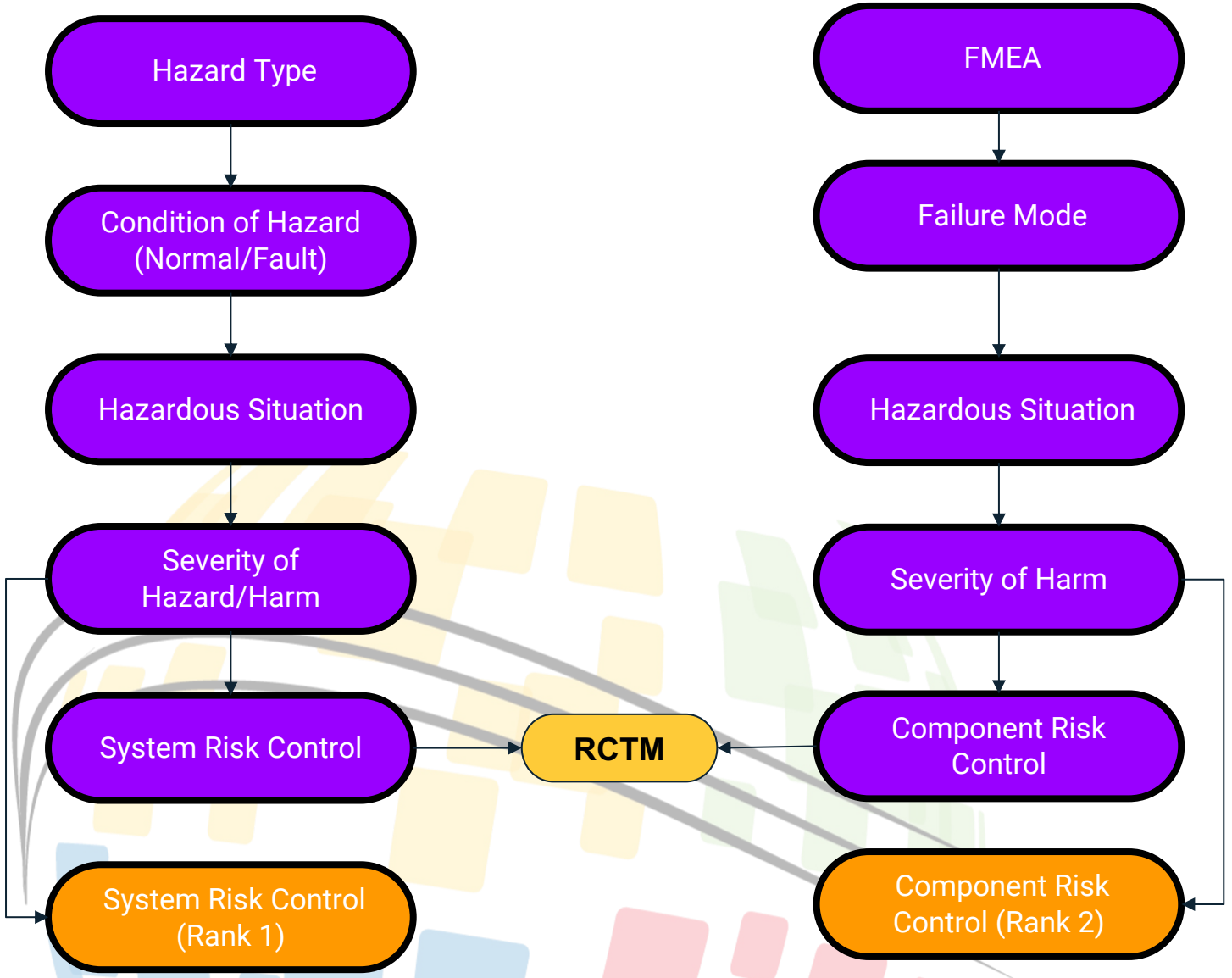
05 Reduce Pressure on Post Market Engineering

- Fewer design changes required during initial product release and helps focus more on product innovation than remediation

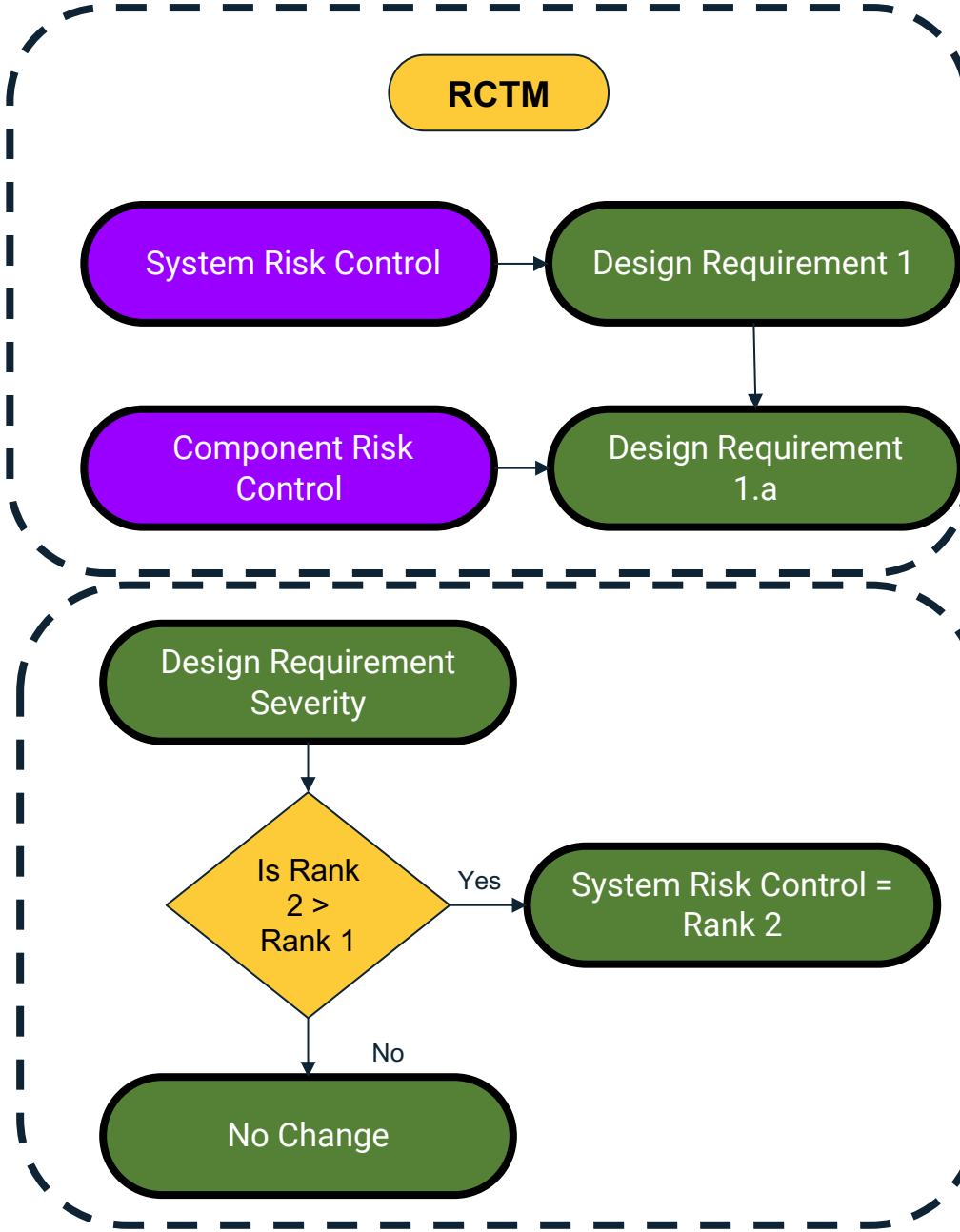
Integrated DC and RM FrameWork - FDA WaterFall Design Process



Risk Based FrameWork - Requirement Criticality Assessment



*RCTM - Risk Control Trace Matrix



Risk Based FrameWork - Requirement Criticality Estimation Matrix - System Level

***SOTA - State Of The Art**

	Requirement Criticality
Severity 5	**Critical**
Severity 4 & 3	**Essential**
Severity 2 and 1	**Design Detail**

Note: At System level we may not have full picture on the relevant verification methods or SOTA, so system level criticality is only a function of severity

Note: System criticality inherits the highest risk/severity from sub-system because that is the weakest link in the chain.

Note: System Criticality assessment helps to provide areas for focus during overall system integration

Critical	**Requirement serves as a Risk Control and compromise of requirement has direct impact to Form, Fit, Function and compromises the safety of the product. Requirement should drive sub system assessment to see if severity can be mitigated/eliminated. Criticality verified during system integration and system verification phases.**
Essential	**Requirement may serve as a Risk Control and compromise of requirement may impact Form,Fit or Function that could result in a safety issue. Criticality verified during system validation**
Design Detail	**Requirement is not required to serve as a Risk Control and compromise of requirement has negligible impact to product and safety. Criticality verification on an as-need basis.**

Risk Based FrameWork - Requirement Criticality Estimation Matrix - Sub System and Lower

***SOTA - State Of The Art**

	If requirement is new to design and not previously verified and has Limited/No history for SOTA* (NUD Feature)	If requirement has evidence of previously being verified and has some history for SOTA*
Severity 5	**Critical**	**Critical**
Severity 4	**Critical**	**Essential**
Severity 2 and 3	**Essential**	**Essential**
Severity 1	**Essential**	**Design Detail**

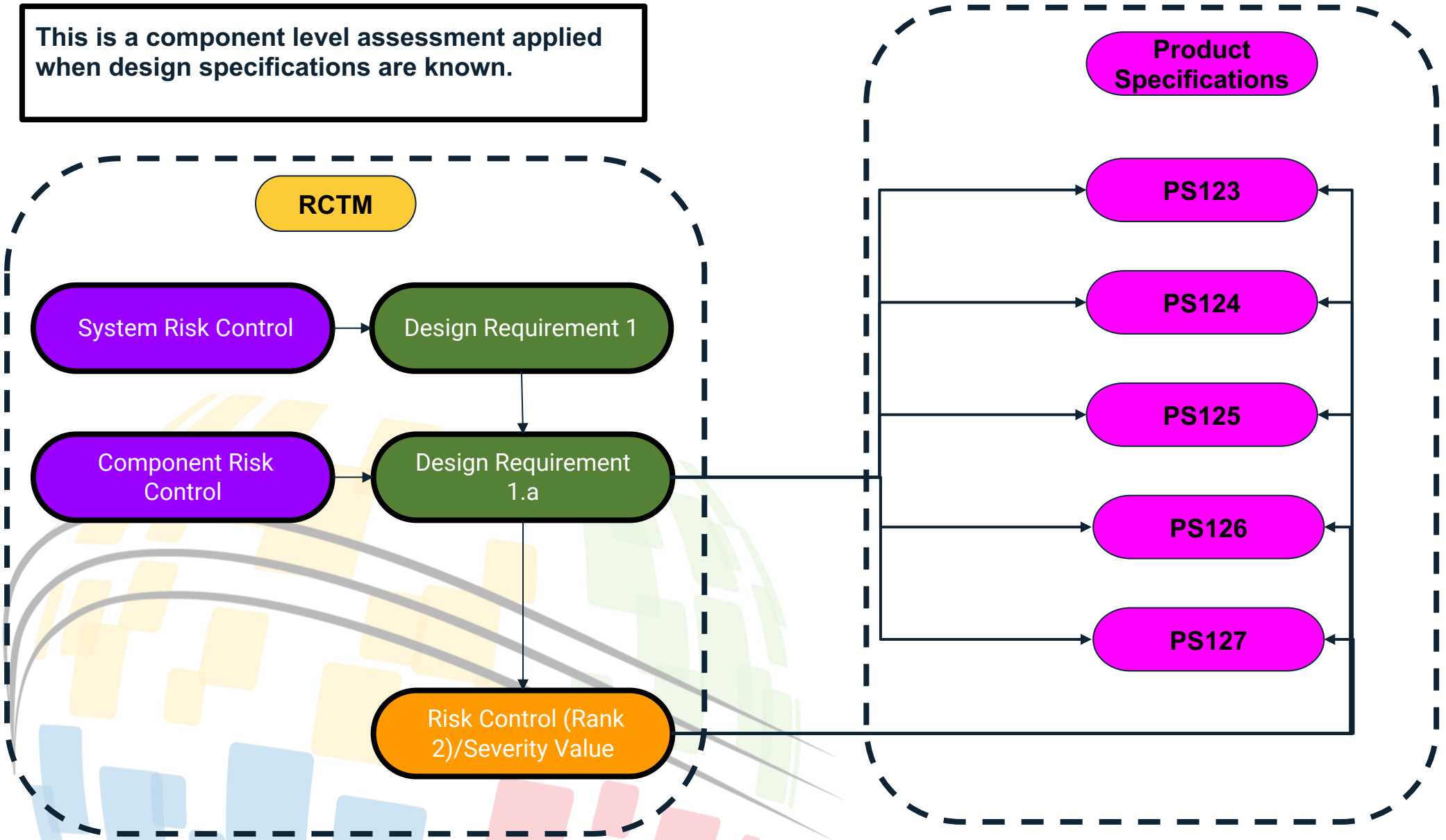
Note: System Requirement criticality may differ from sub-system criticality.

Note: System Requirement criticality will evolve. Idea is to drive an approach to ensure sub-systems are as safe as possible.

Critical	**Requirement serves as a Risk Control and compromise of requirement has direct impact to Form, Fit, Function and compromises the safety of the product.**
Essential	**Requirement may serve as a Risk Control and compromise of requirement may impact Form,Fit or Function that could result in a safety issue. Requirement may need additional testing to demonstrative effectiveness.**
Design Detail	**Requirement is not required to serve as a Risk Control and compromise of requirement has negligible impact to product and safety. Examples include device aesthetic appearances.**

Risk Based FrameWork - Product Specification Criticality Assessment

This is a component level assessment applied when design specifications are known.



Risk Based FrameWork - Product Specification Criticality Estimation Matrix

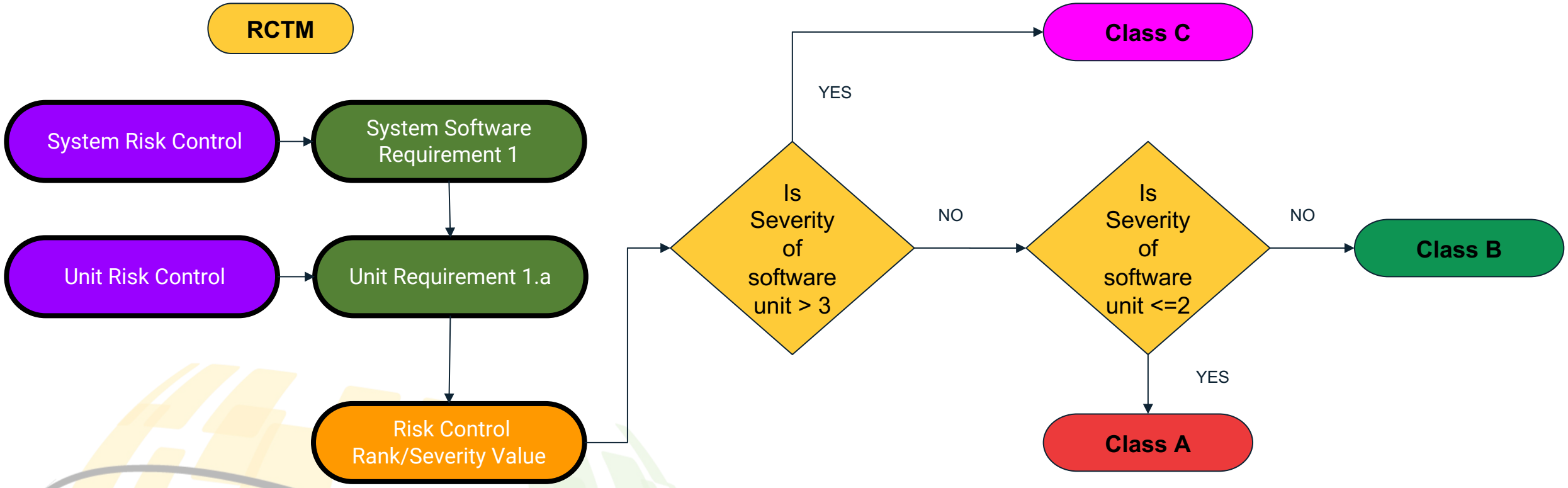
	If Product Specification requires establishment of new process/inspection and has demonstrated only system reliability	If Product Specification can be realized through an already established process and has demonstrated both system and component level reliability
Severity 5	**Critical**	**Critical**
Severity 4	**Critical**	**Essential**
Severity 2 and 3	**Essential**	**Design Detail**
Severity 1	**Design Detail**	**Design Detail**

Note: This estimation generally occurs during Design Transfer Phase

Note: At times requirement criticality can be different from specification criticality.

Critical	**Product specification when compromised has an immediate direct impact to form, fit, function and the safety of the product.**
Essential	**Product specification when compromised may result in impact to form, fit, function of the product and/or delayed safety impact**
Design Detail	**Product specification when compromised usually does not impact form, fit, function or safety. Usually these are cost to business and/or minor user inconvinience**

Risk Based FrameWork - Software System



A severity based assessment to software helps to focus on key areas during software development.

How Integration Helps?

01	**Robust Design Selection**	• System and sub system are reviewed as a function of safety and thereby drive more opportunities to drive “safety by design”
02	**Efficient Design Process**	• Risk Control Trace always connects Design requirements and associated risk. • Consistent use of risk an input through design and manufacturing
03	**More Reliable Product**	• Requirements are classified based on risk. • Engineers have visibility early on which areas to focus before starting testing and verification
04	Requirements Software Tool	• Method can be integrated within a requirements management system.

Considerations For Implementing The Framework

01

Forming stages of Integration takes time and money. Plan accordingly.

02

Training is critical to success. All stakeholders should be familiar with basic structure of system

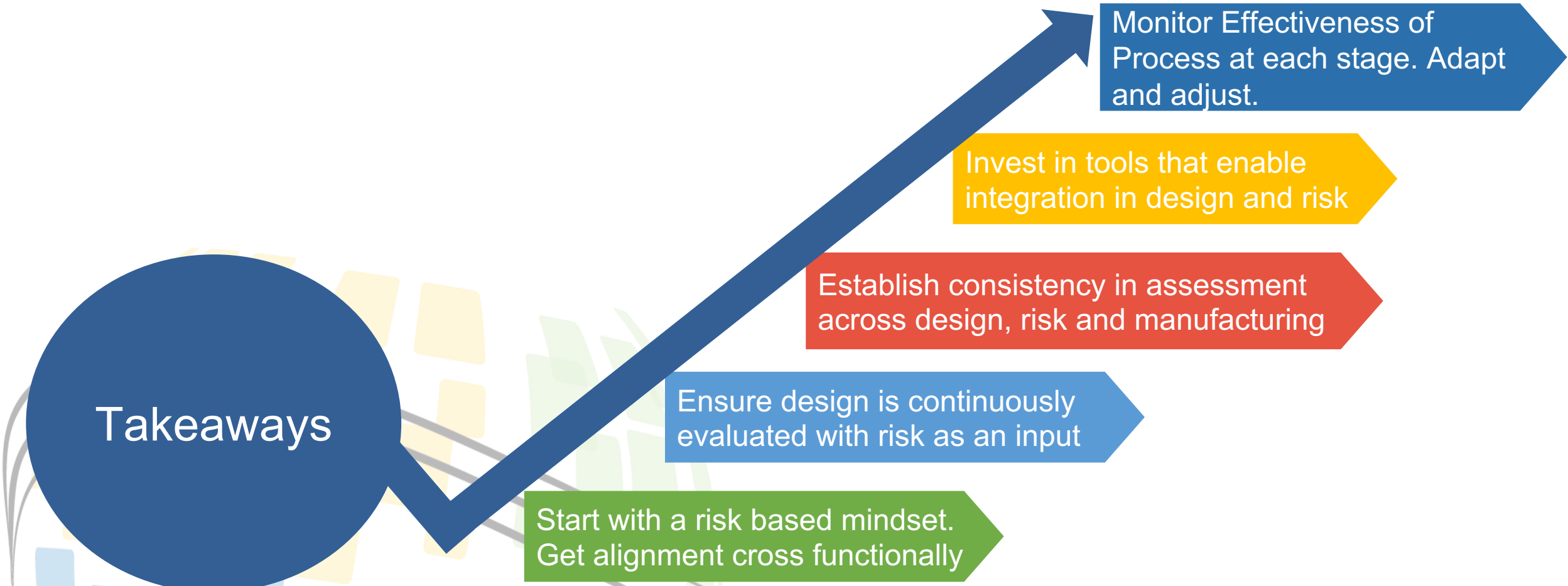
03

The system is not intended to replace Design Reviews. Phase Reviews are essential

04

Understand your products and scale integration accordingly. Start small but aim big

Takeaways


Monitor Effectiveness of Process at each stage. Adapt and adjust.
Invest in tools that enable integration in design and risk
Establish consistency in assessment across design, risk and manufacturing
Ensure design is continuously evaluated with risk as an input
Start with a risk based mindset. Get alignment cross functionally