



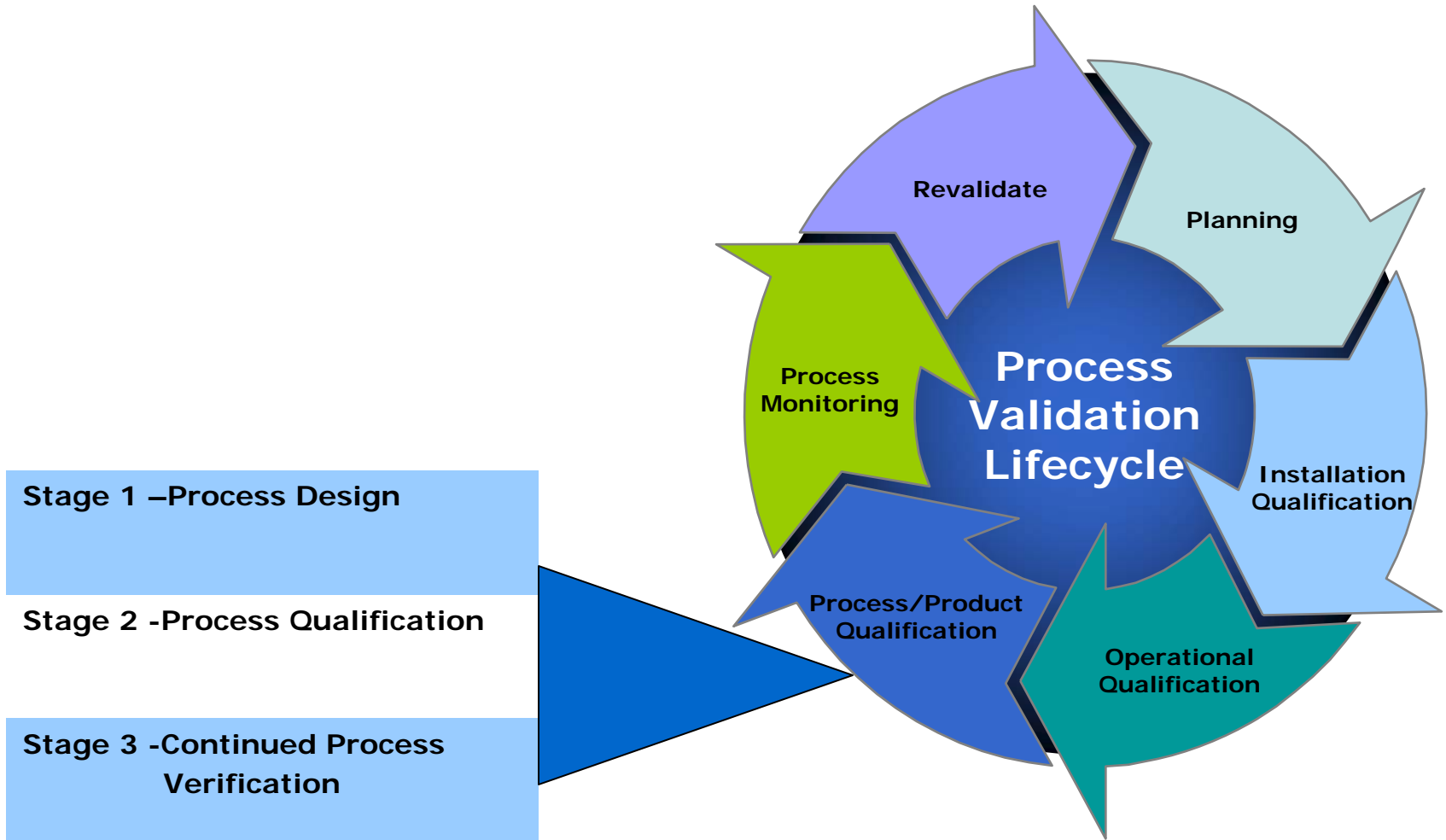
Building and Tailoring a Lean Six Sigma Approach for Validation Processes

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Definition Changes

- 1987: *Process validation* is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics
- 2008: *Process validation* is defined as the collection and evaluation of data, from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering quality products.

Key Difference



2008 Definitions

- **Stage 1 - Process Design**

The commercial process is defined during this stage based on knowledge gained through development and scale-up activities

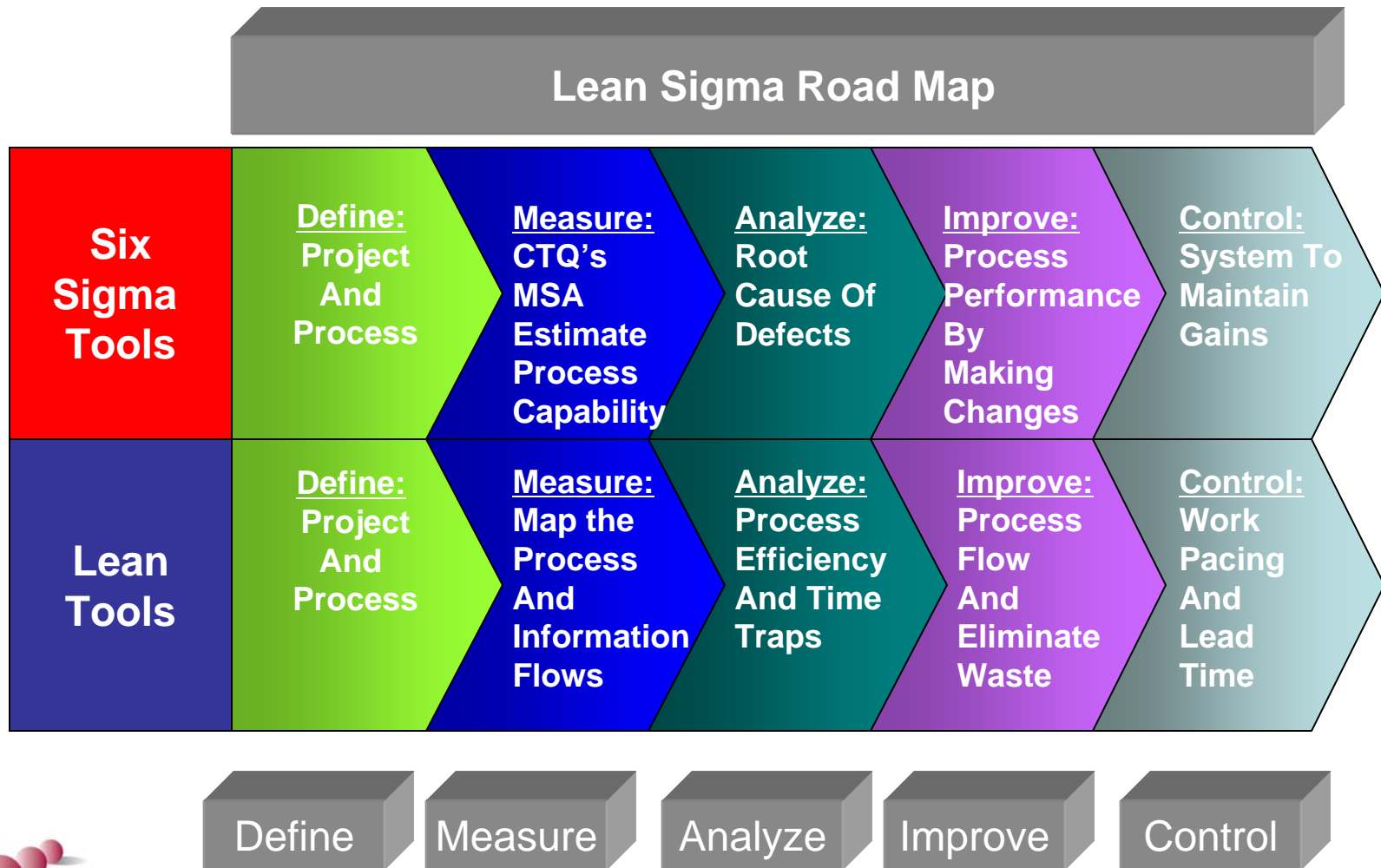
- **Stage 2 - Process Qualification:**

During this stage the process design is confirmed as being capable of reproducible commercial manufacturing

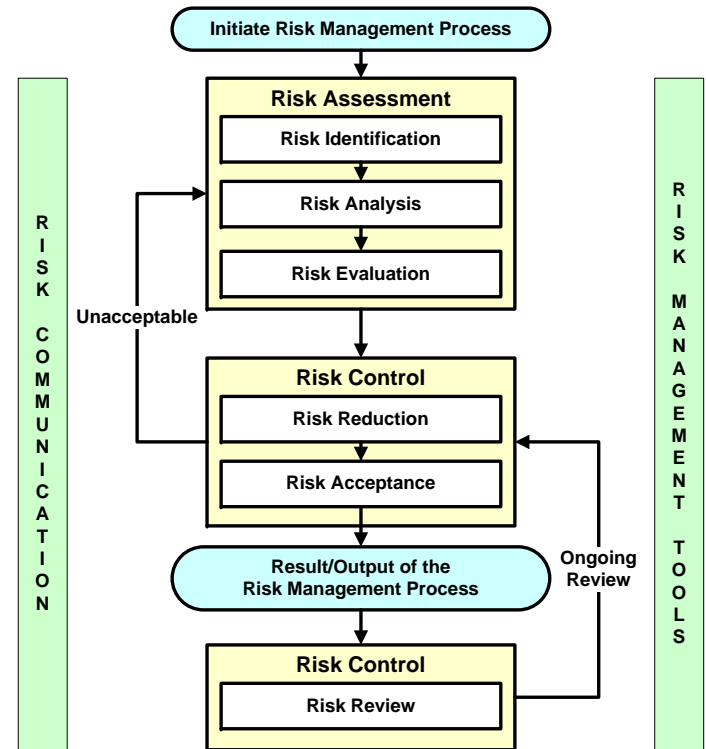
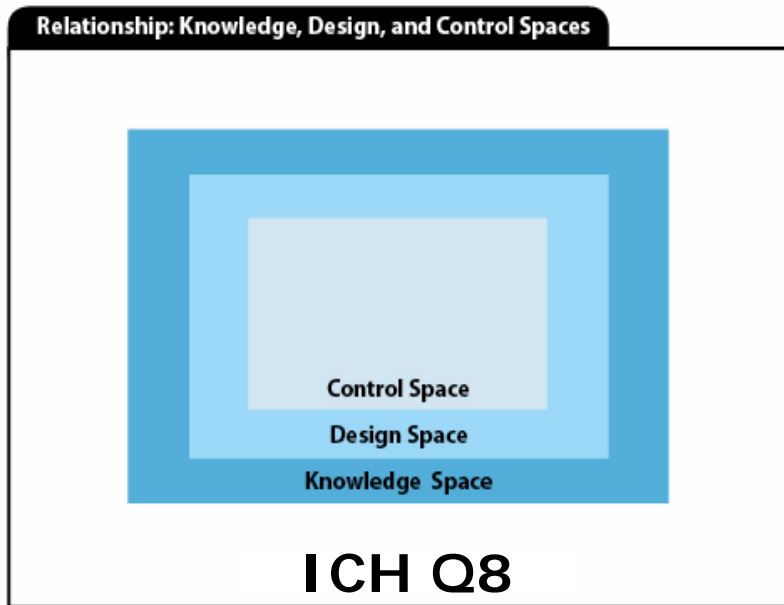
- **Stage 3 - Continued Process Verification:**

Ongoing assurance is gained during routine production that the process remains in a state of control

The Lean Six Sigma Roadmap



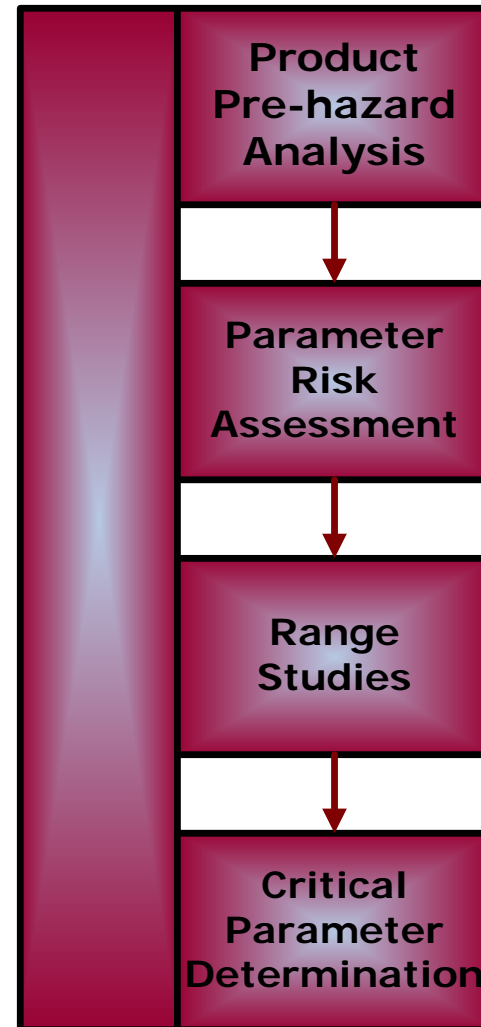
ICH Drivers for Process Design



Process Design Activities

Integrating risk management at the outset of process design focuses the process measurement tools on the critical success metrics

As you move from the knowledge space to the design space we move away from the edge of failure



Process Qualification Considerations

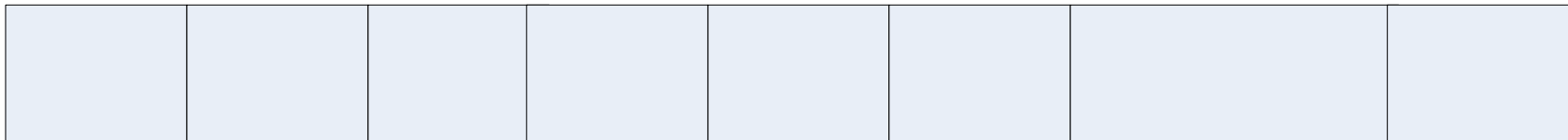
- If the process design was completed thoroughly:
 - Edge of failure was identified
 - Non-critical process variables were identified
 - MSA concluded measurement tools are capable
 - Control range has been determined
 - Solid understanding of how process variability affects product performance

PV Then and Now

1987 Process Validation Lifecycle



2009 Process Validation Lifecycle



Conclusion

- The framework of most operational Excellence programs align themselves well with the new PV guidance
- Extracting the tools and milestones from a structured investigation program will provide an objective framework for process development
- Risk Management tools, when properly applied represent an opportunity for continuous improvement and monitoring which can translate to business performance

Thank you for your attention!

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