Proceeding Operation of the Unprecedented Process

Mandate: **Ready Agile Systems**

Ordinance: **Deploy, Twin, Control, Scale, Change (Details, Systems, Duplication, Maintenance)**

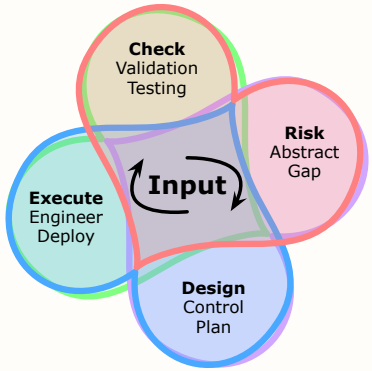
Solution: **Input Risk Coherence, Requirement Based Assurance, Narrative Control, Exception Prevention, Automation and Anticipation**

Value: **Efficiency, Improvement, Elastic Scope, Quality Validation and Robustness, Expectedness**

Eliminate Exceptions Success System (Tracing Minimum Objective Plan)

Input Drives (**Objective**)

Design/Check (**Development**)



Execute/Risk (**Operation**)

Repeating Patterns of Input Cycles

Improved Objective is Success

Successive Inputs Promotes Ongoing Return
Due to Ongoing Improvements Limitations

Little's Law Overall improvement is the limit of process development value

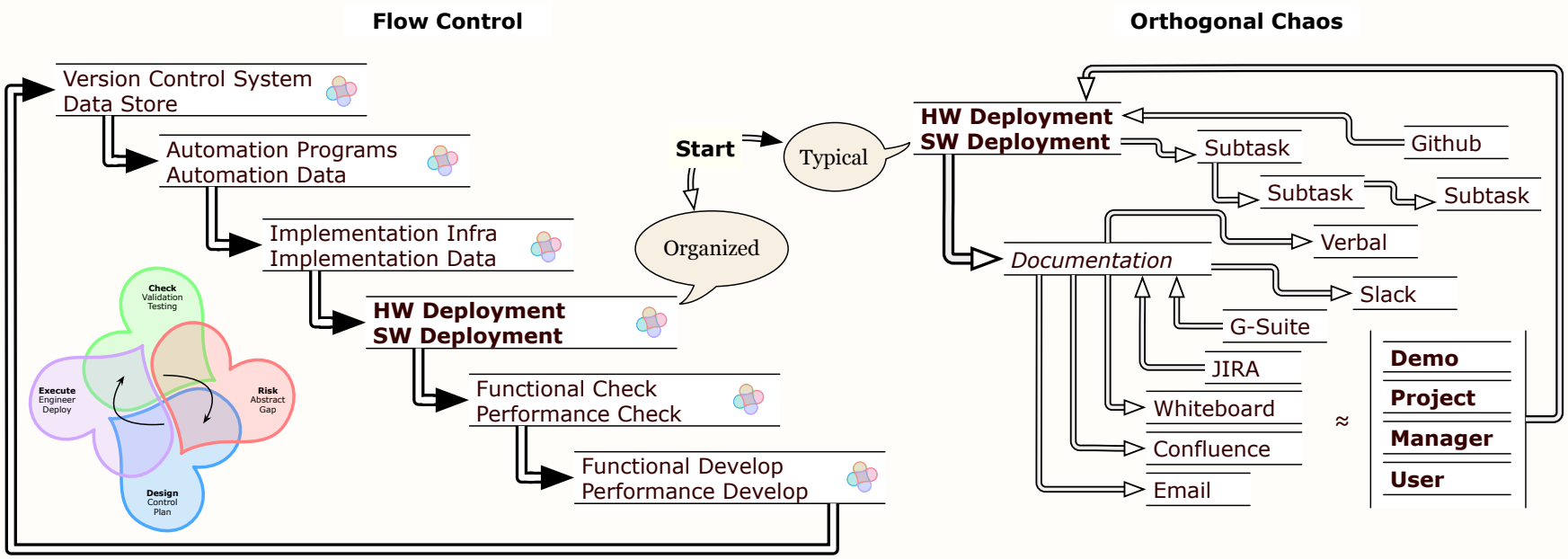
Theory of Constraints Unconstrained systems have unlimited performance

Conway's Law Organization designs are copies of the the systems within the organization

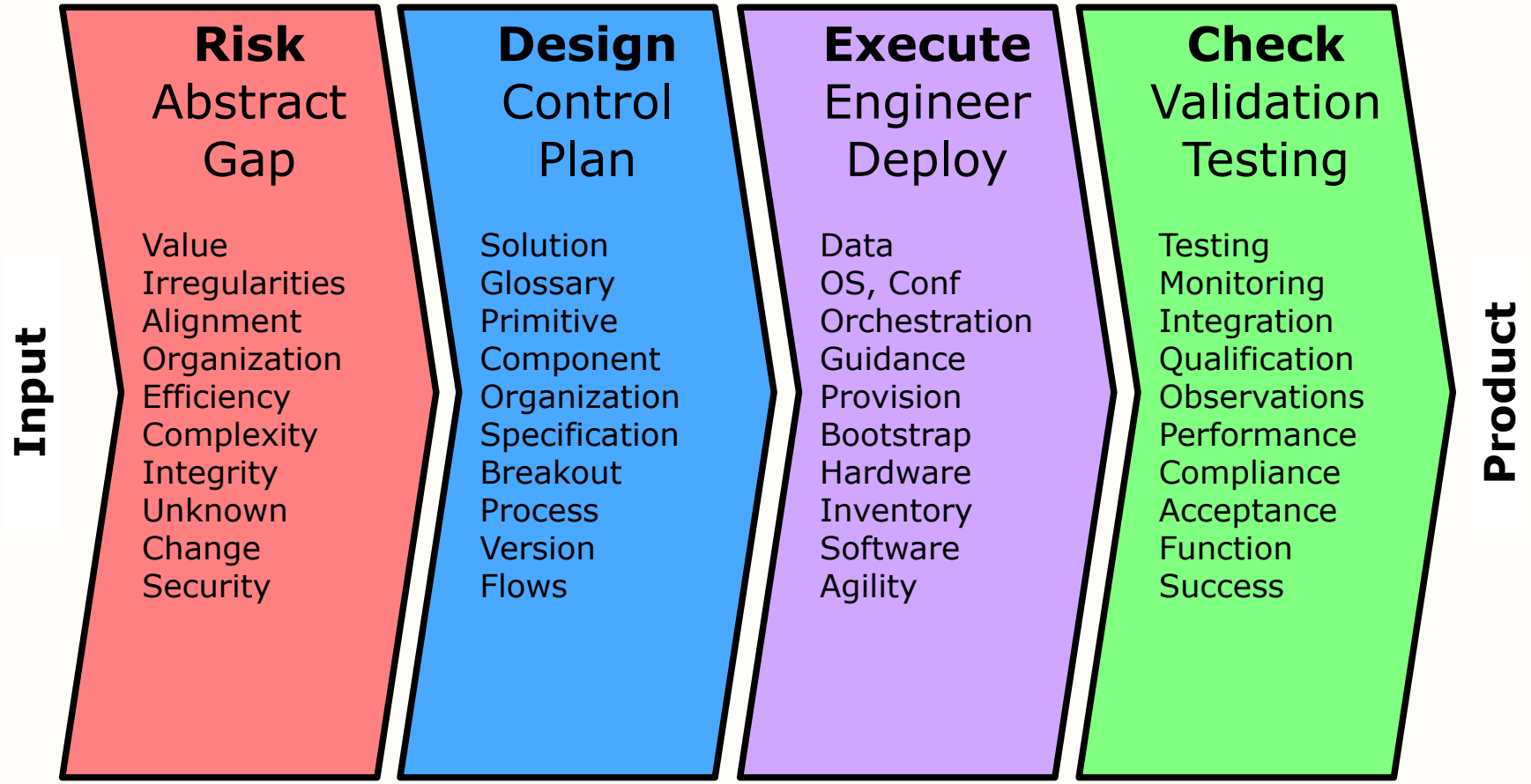
Gold's Law Nothing goes as planned because the outcome takes precedence over the process

Bootstrap Deploy Integration

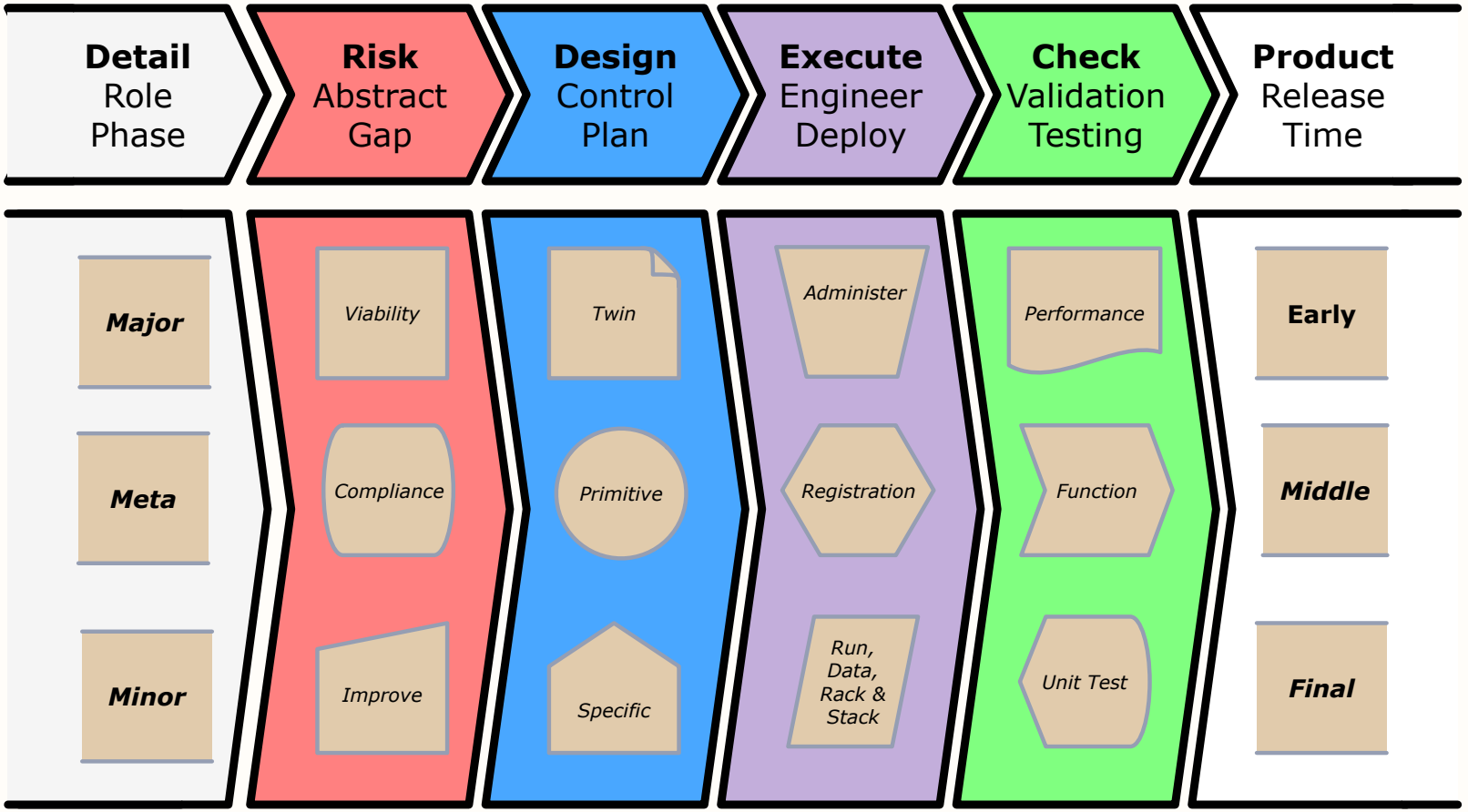
Flows, Configuration, Performance, Checks



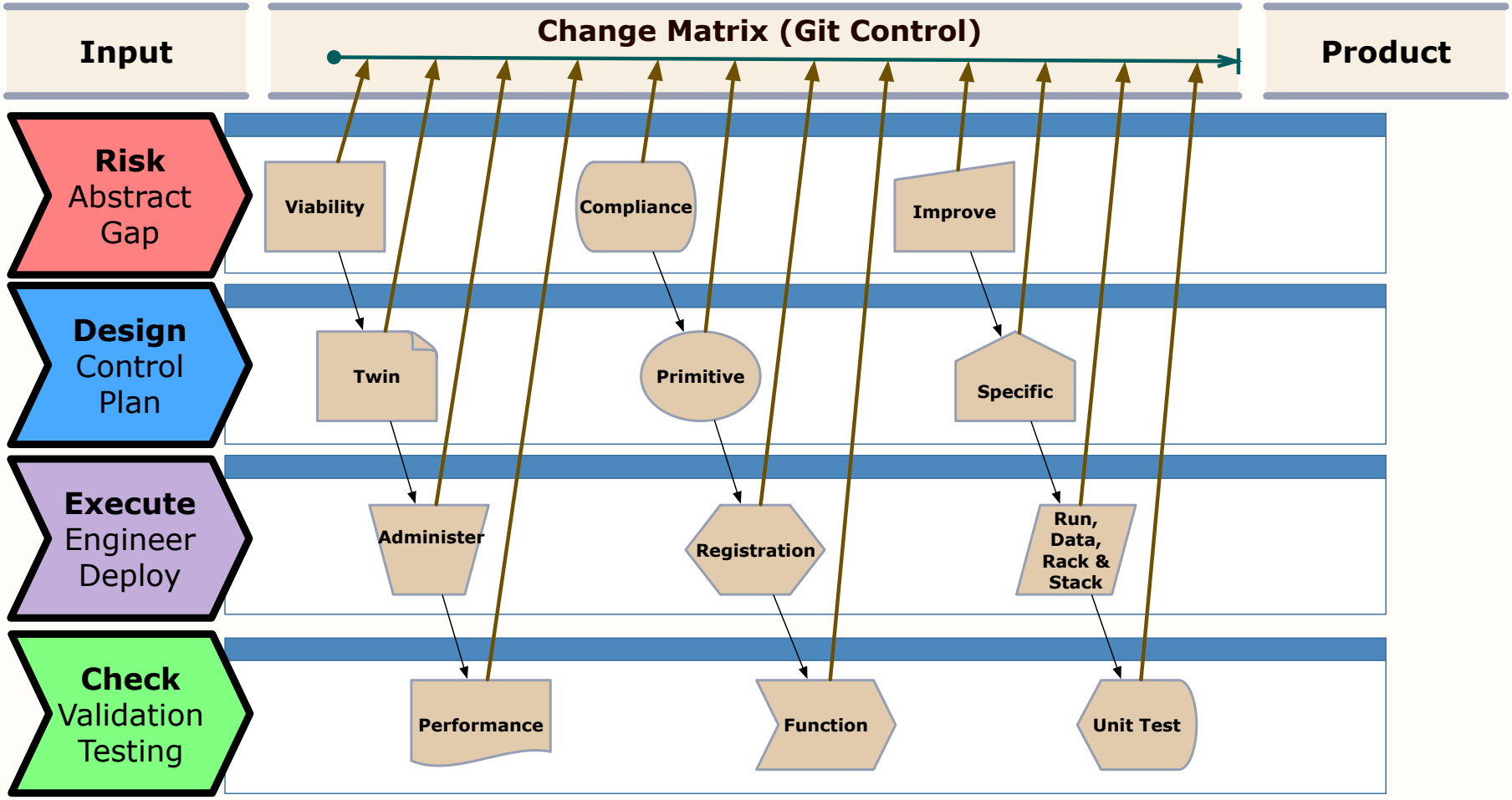
Four Phase Process System



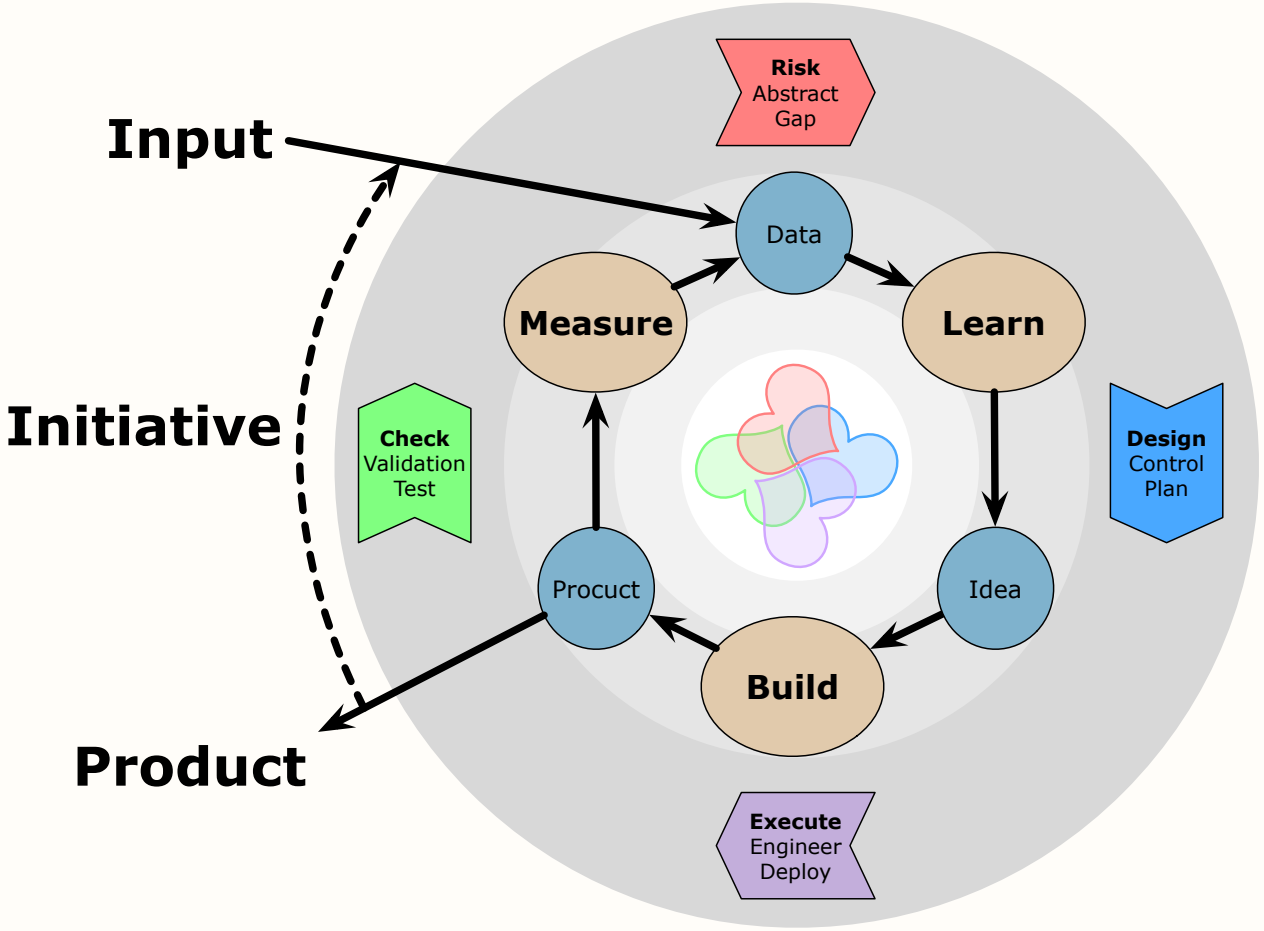
Continuous Delivery



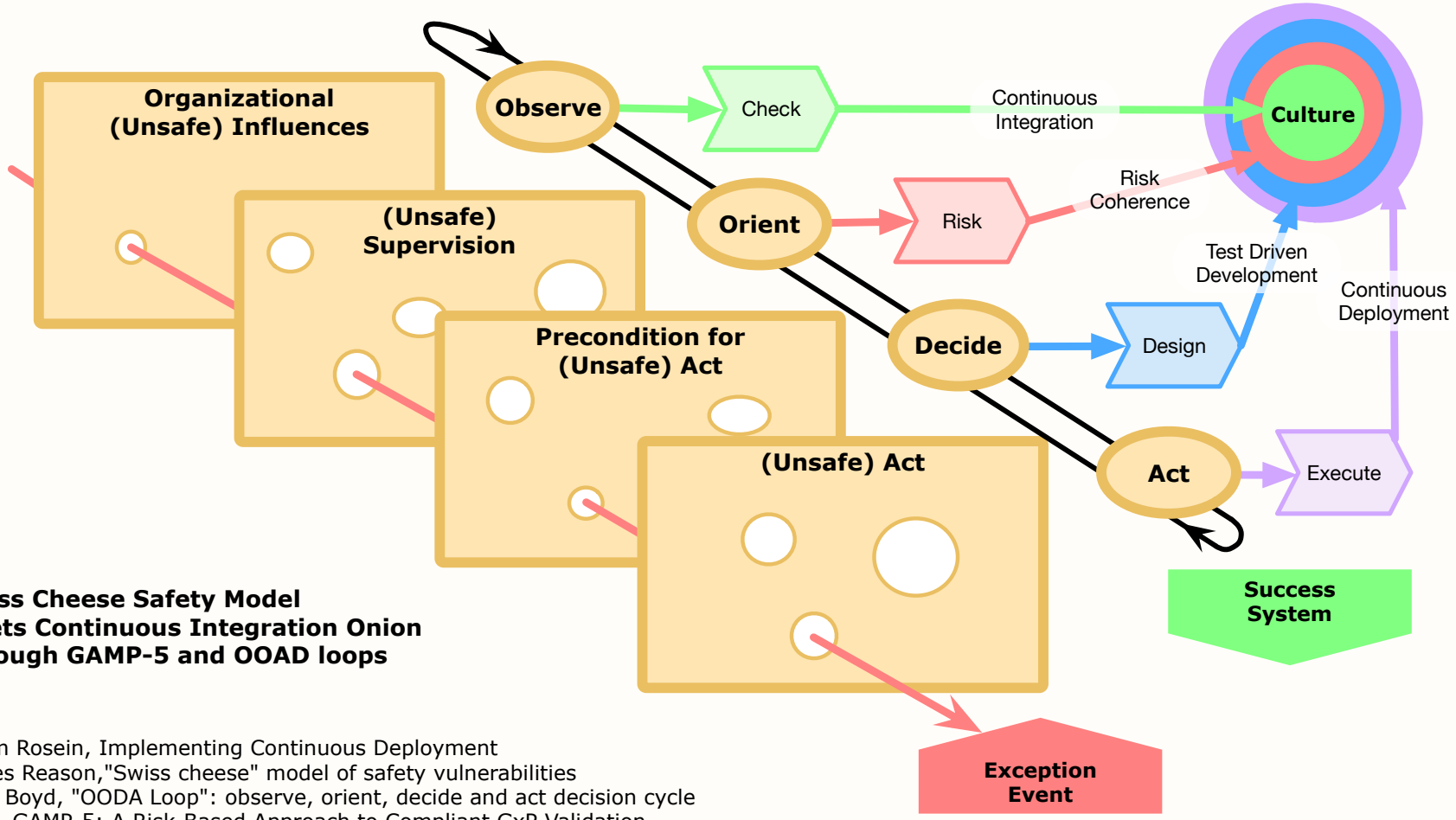
Objective Improvement



Improvement Loop



Unprecedented Cheese and Onions



Swiss Cheese Safety Model
Meets Continuous Integration Onion
Through GAMP-5 and OOAD loops

Adam Rosein, Implementing Continuous Deployment
James Reason,"Swiss cheese" model of safety vulnerabilities
John Boyd, "OODA Loop": observe, orient, decide and act decision cycle
ISPE, GAMP-5: A Risk-Based Approach to Compliant GxP Validation