
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**

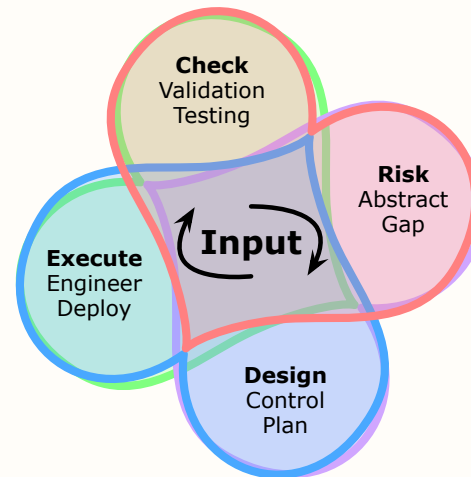
Value: **Efficiency, Improvement, Elastic Scope,
Quality Validation and Robustness, Expectedness**

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

Computer Science Oxymoron (Alan Kay)

ABC Option Testing (Risk Adverse)

Empirical Plan (Multi-perspective)
Last/Loudest Reconciliation (Average Consensus)
Confrontation Consequences (Unaligned Vectors)
Iteration of Integration (Ample Future)

Scientific Method (with Cheese and Onion)

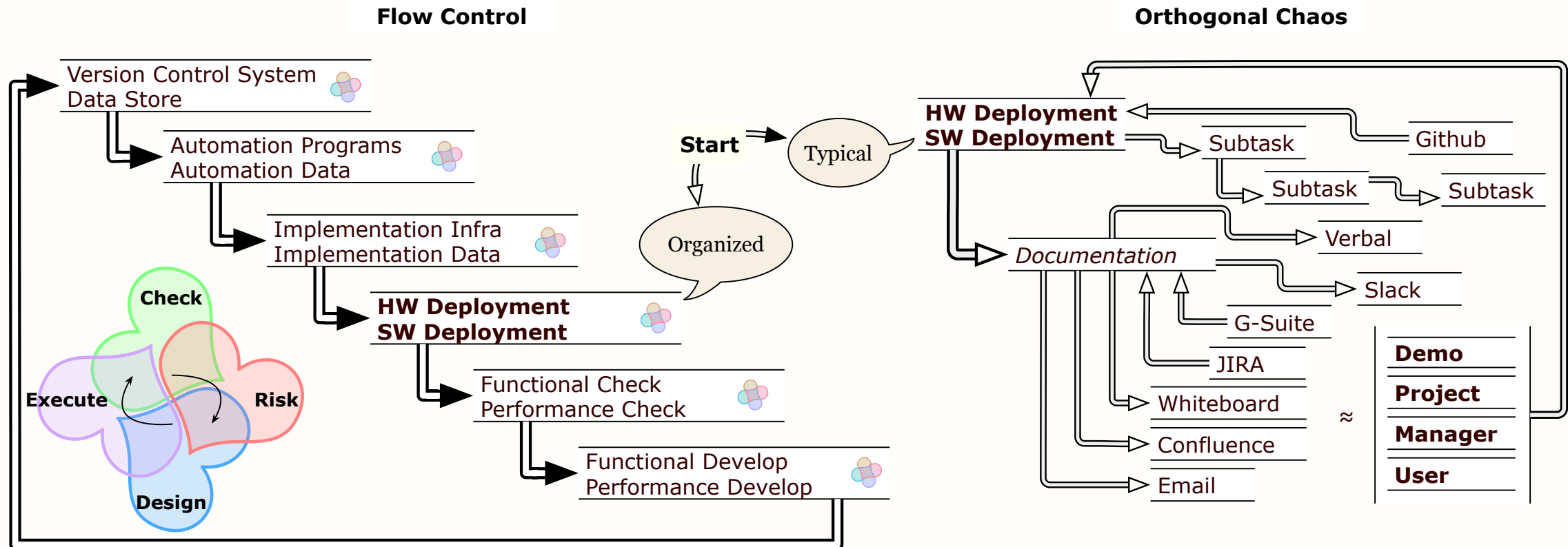
- 1) Observe (Input)
- 2) Assert (Plan)
- 3) Hypothesis (Execute)
- 4) Predict (Check)
- 5) Tabulate (Risk)
- 6) Iterate (Product)

Engineering (Risk Plan)

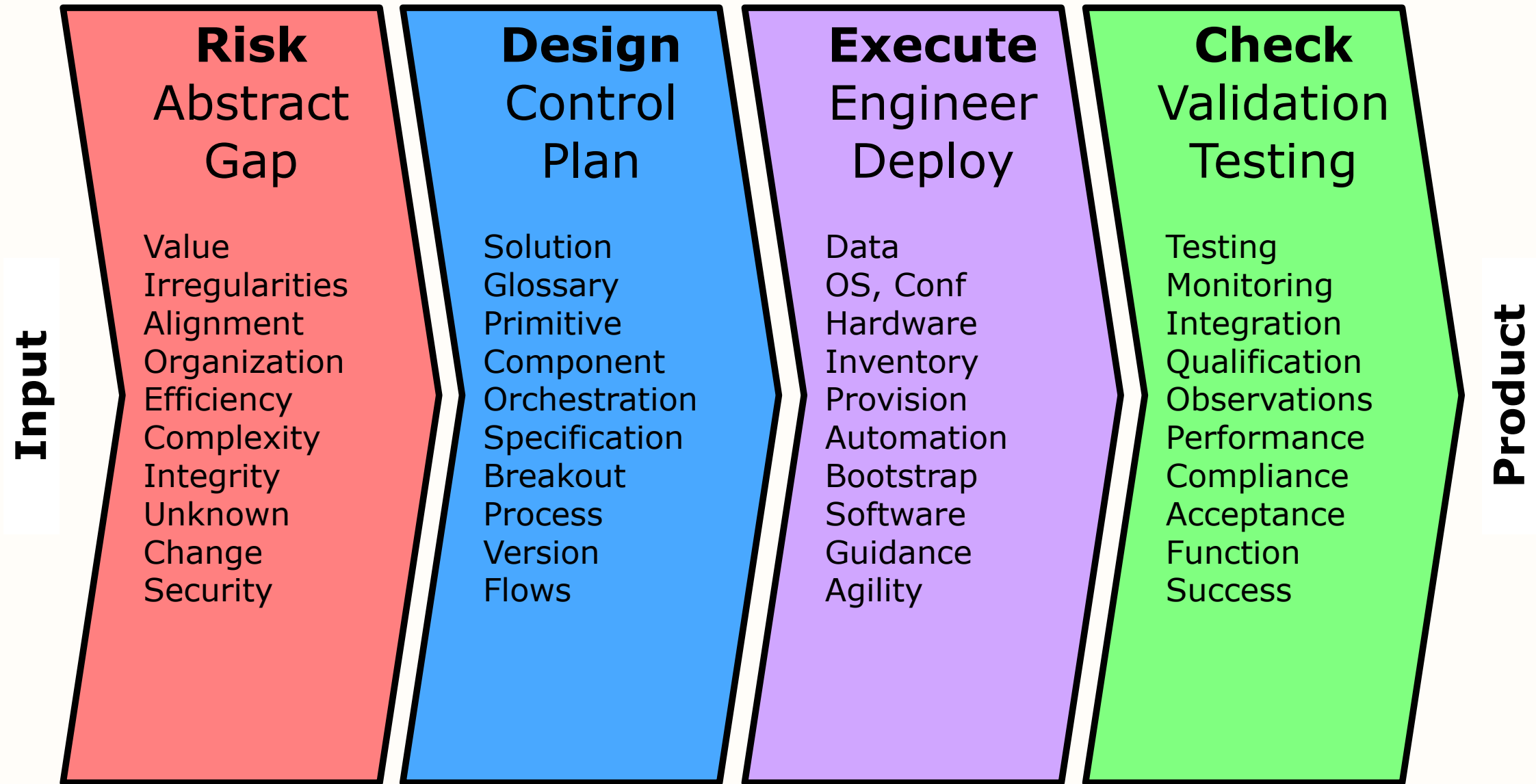
Operational Control (Objective)
Tools Alignment (Development)
MVP Purpose built (Operation)

Bootstrap Deploy Iteration

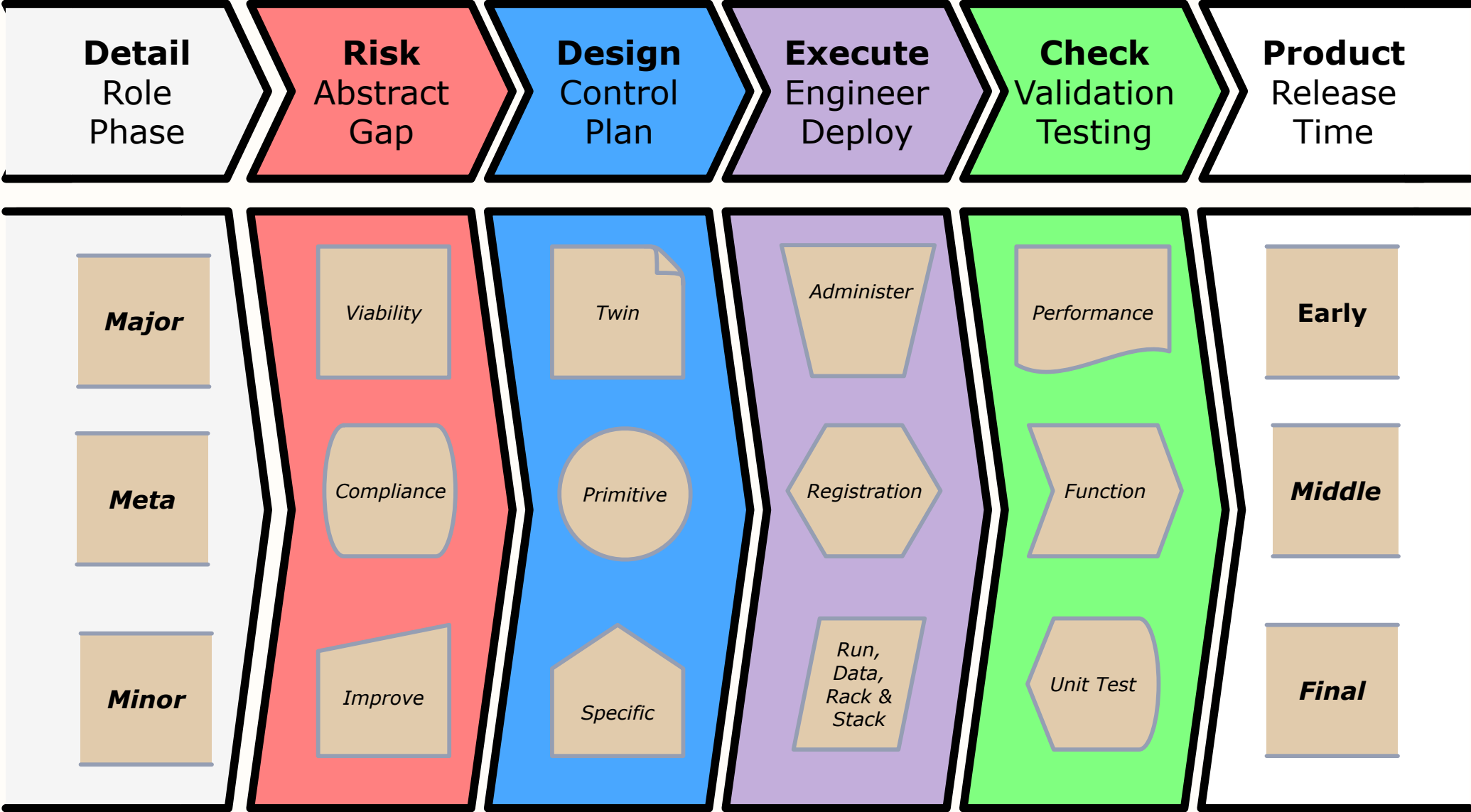
Flows, Configuration, Performance, Checks



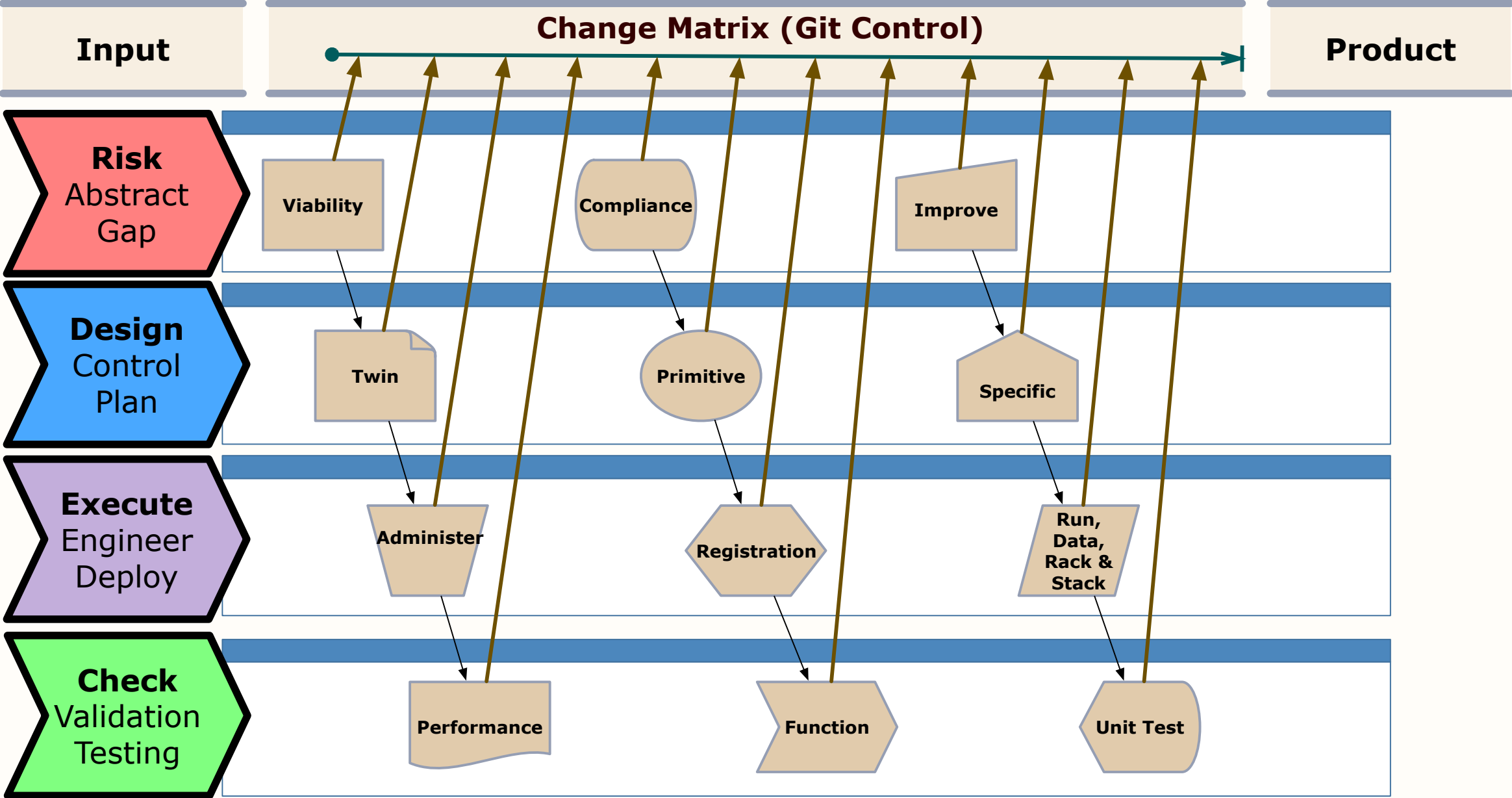
Four Phase Process System



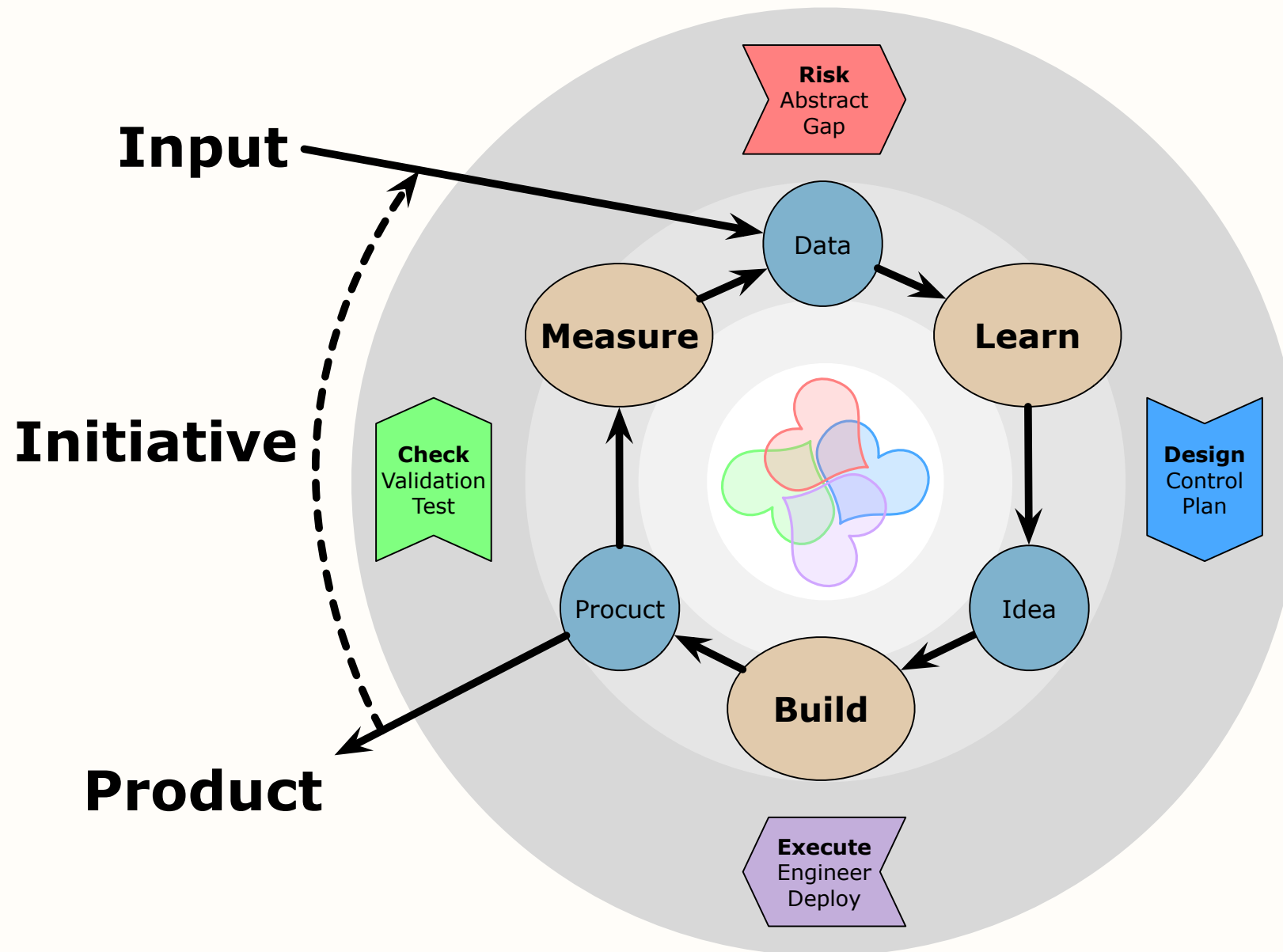
Continuous Delivery



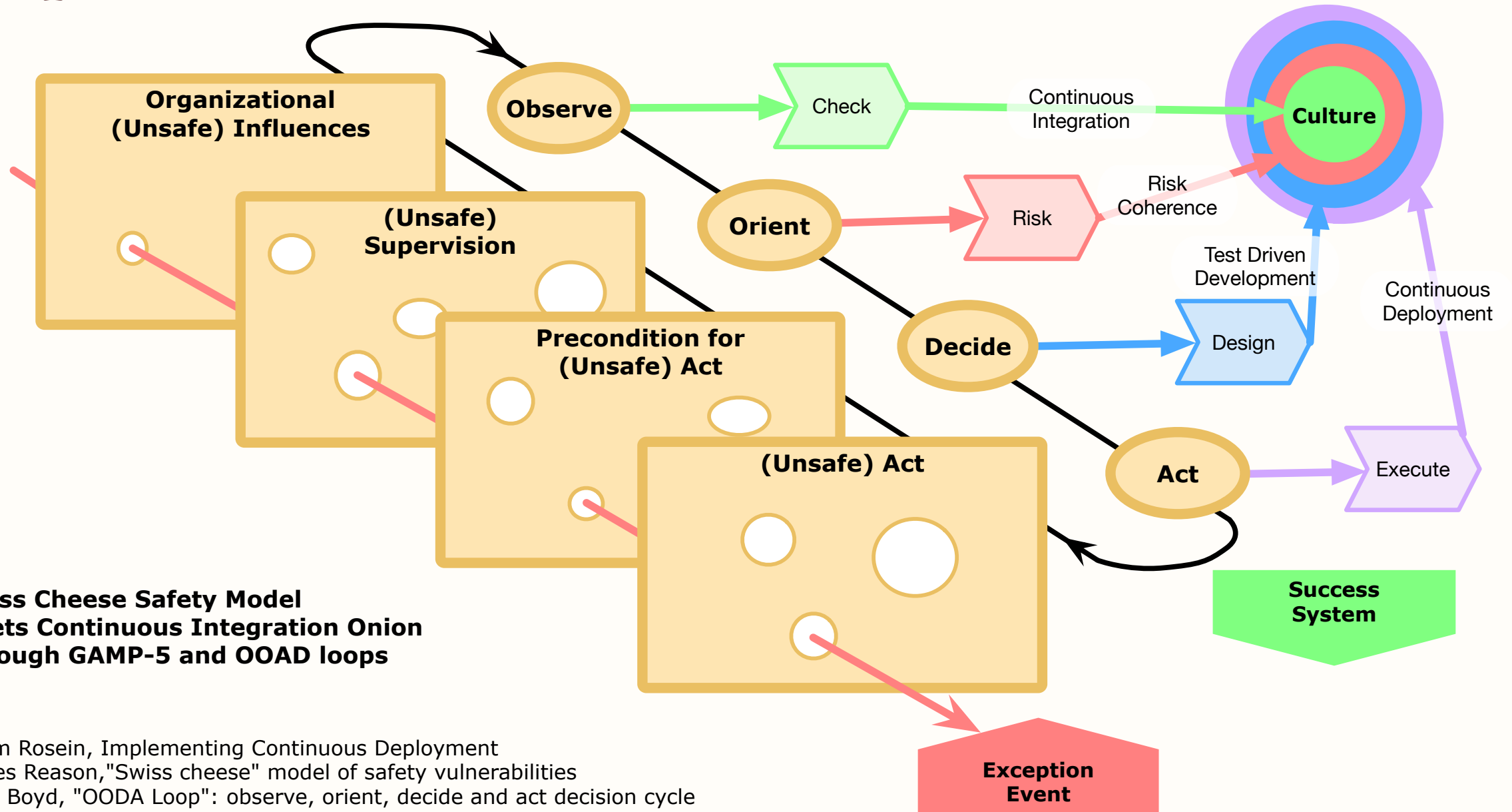
Objective Improvement



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