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# **Proceeding Operation of the Unprecedented Process**

Mandate: **Ready Agile Systems**

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

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

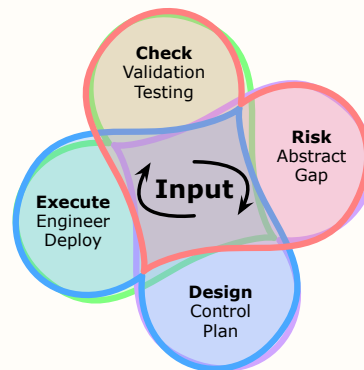
Value: **Efficiency, Improvement, Elastic Scope,  
Quality Validation and Robustness**

# Eliminate Exceptions Tracing Minimum Objective Plan

Input Drives (**Operational Objective**)



Feeds Design/Check Cycle (**Process Development**)



Directs Execute/Risk Cycle (**Production Success**)

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# Repeating Patterns

**Improvement combined with objective is success**

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

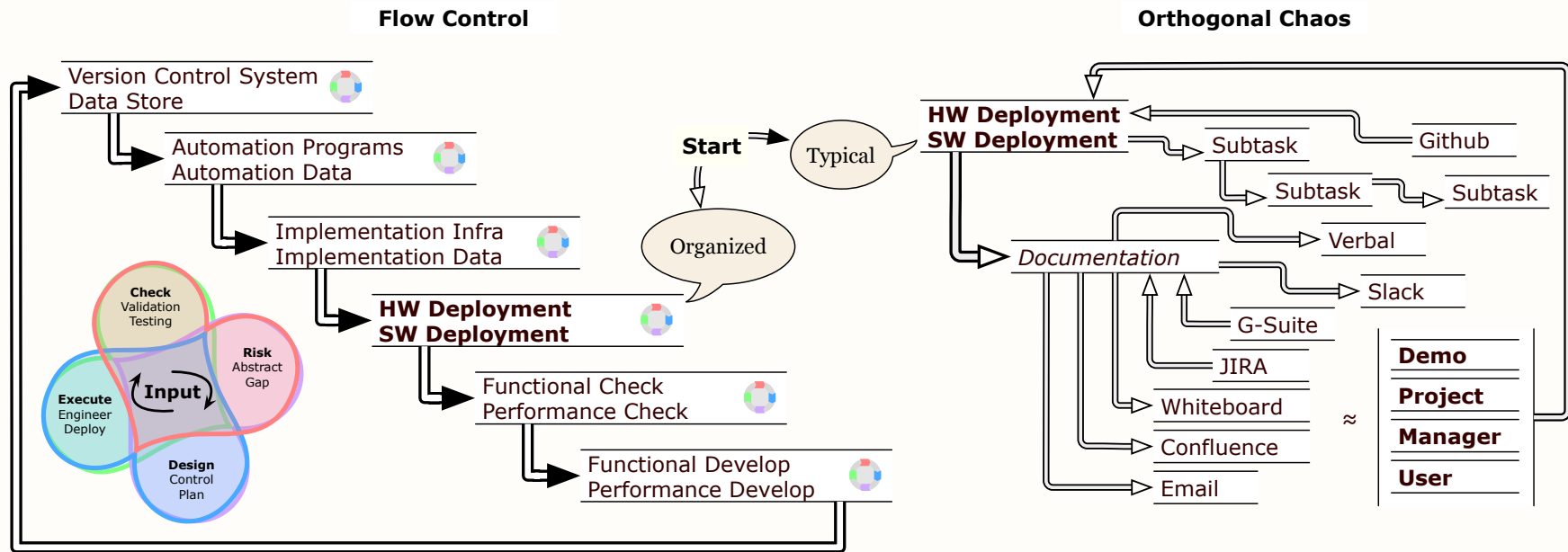
**Theory of Constraints** Unconstrained systems have unlimited performance

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

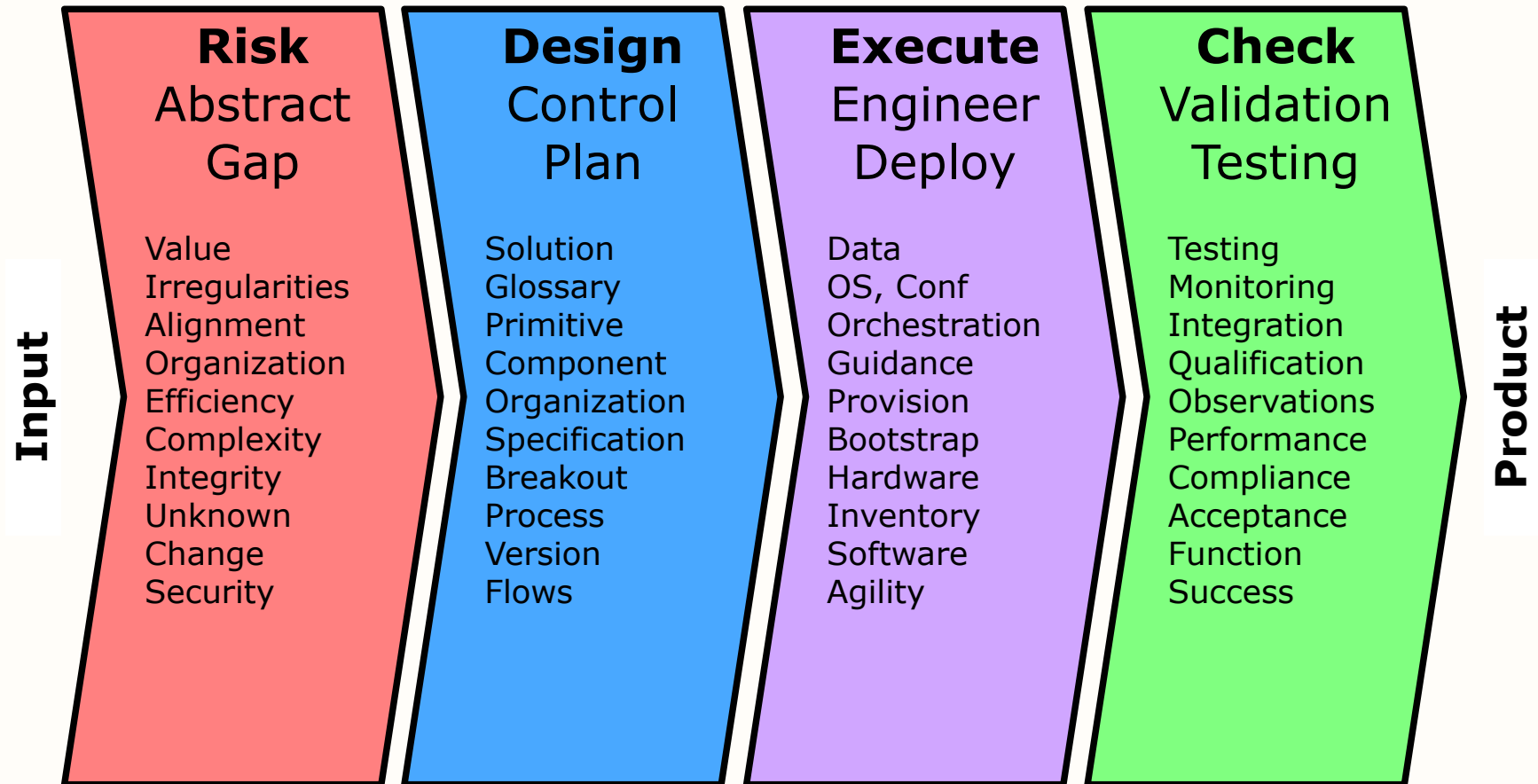
**Gold's Law** Nothing goes as planned because the outcome takes precedence over the process

## Flows, Configuration, Performance, Checks

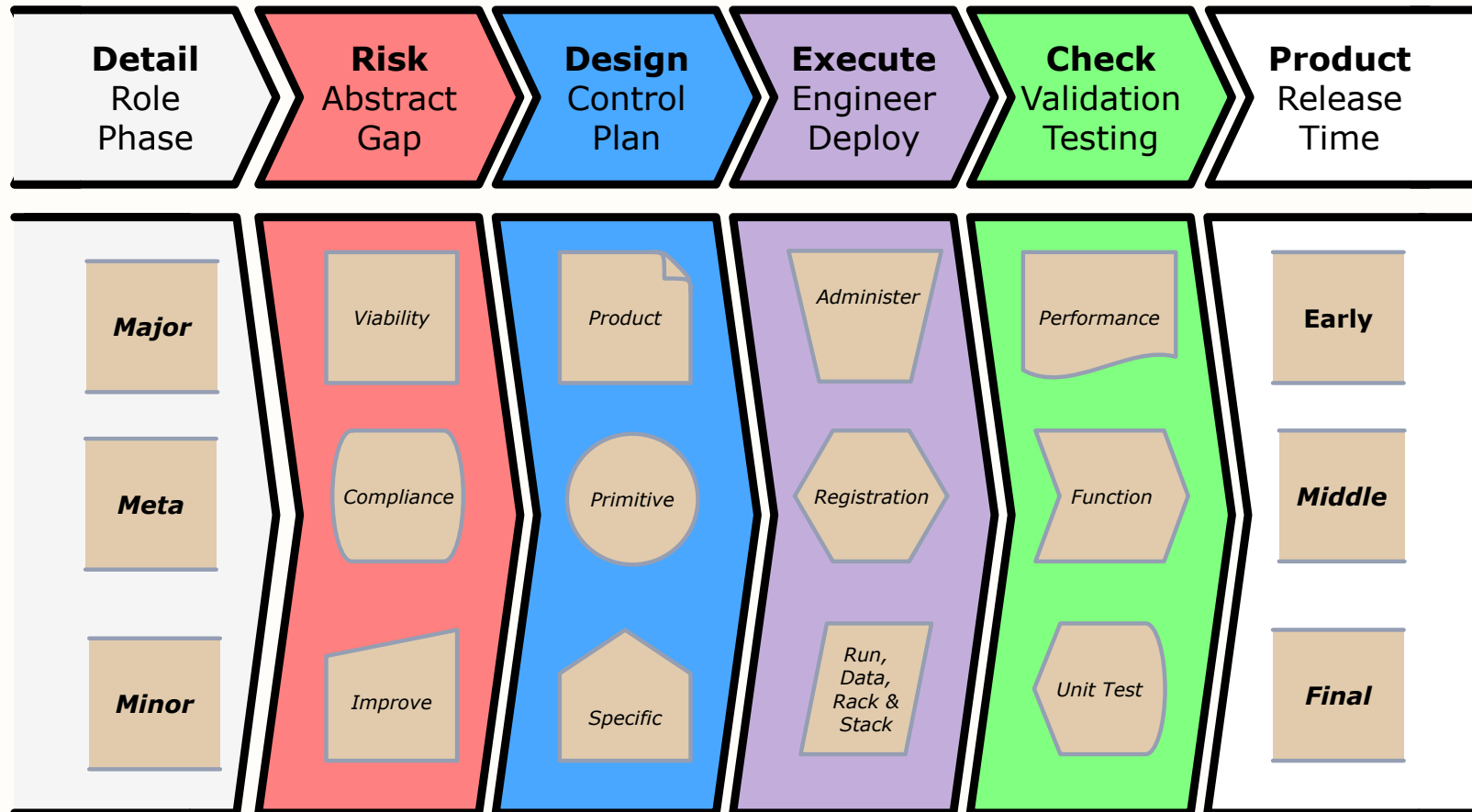
## Flows, Configuration, Performance, Checks



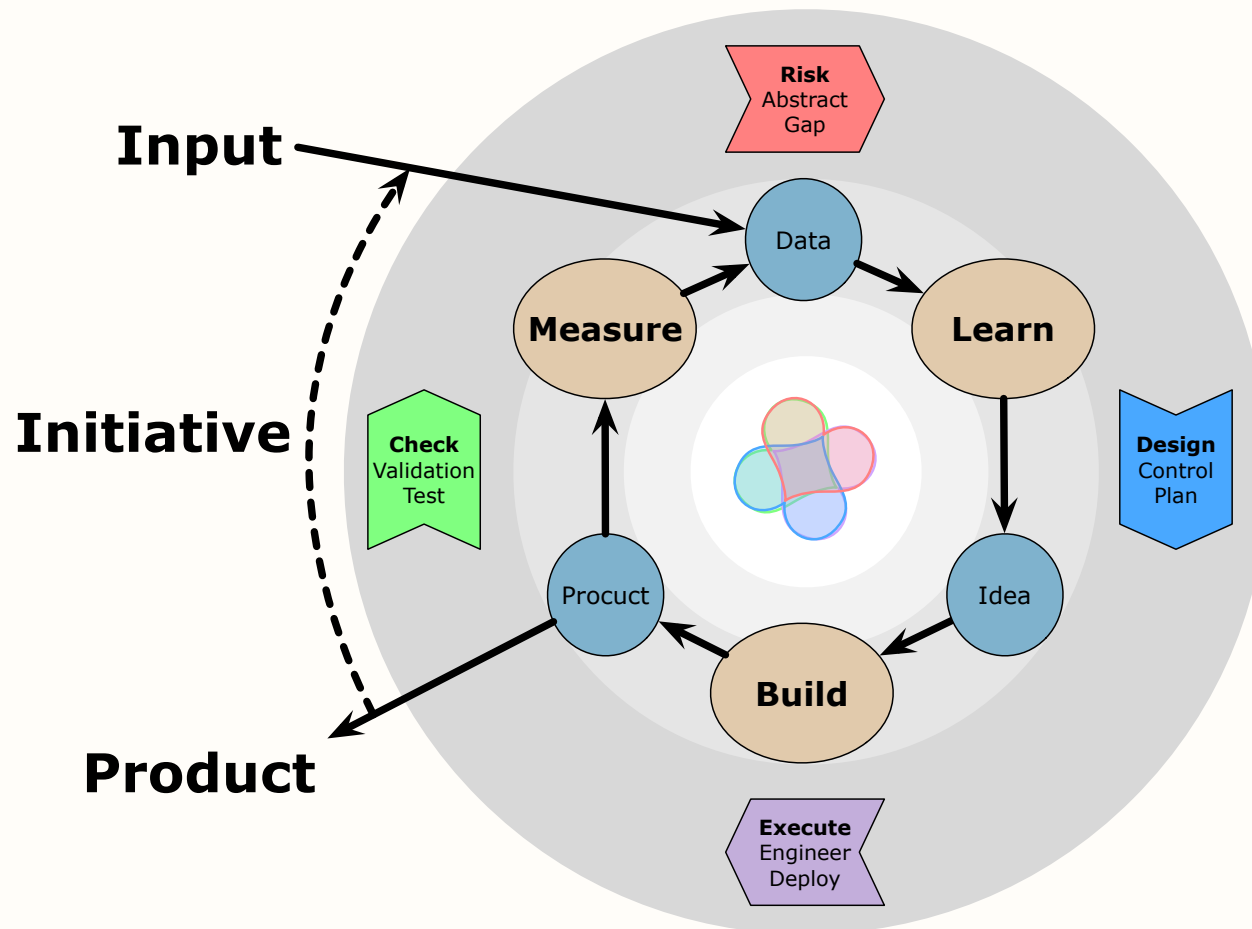
# Four Phase Process System



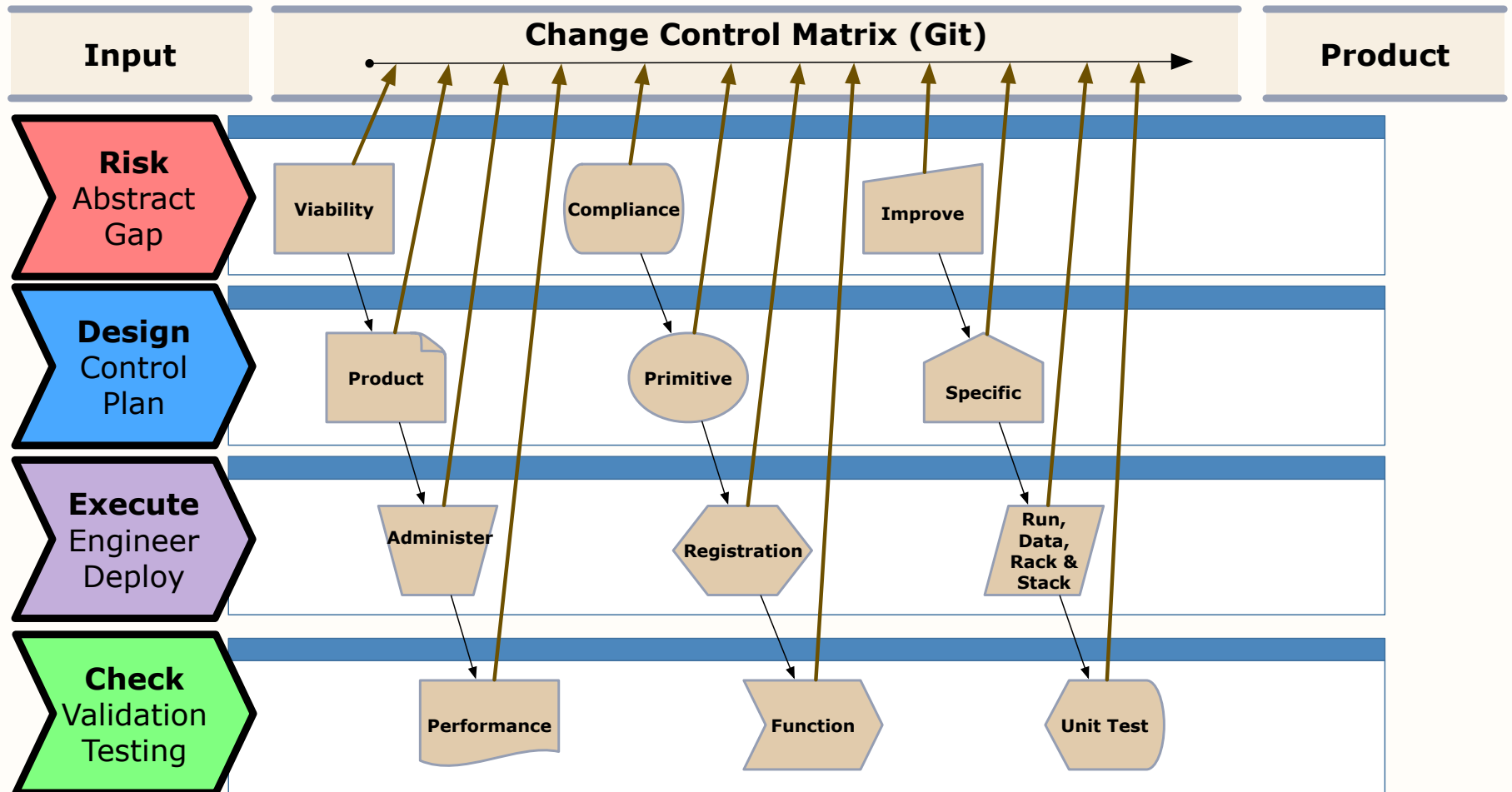
# Continuous Railroad



# Feedback Loop

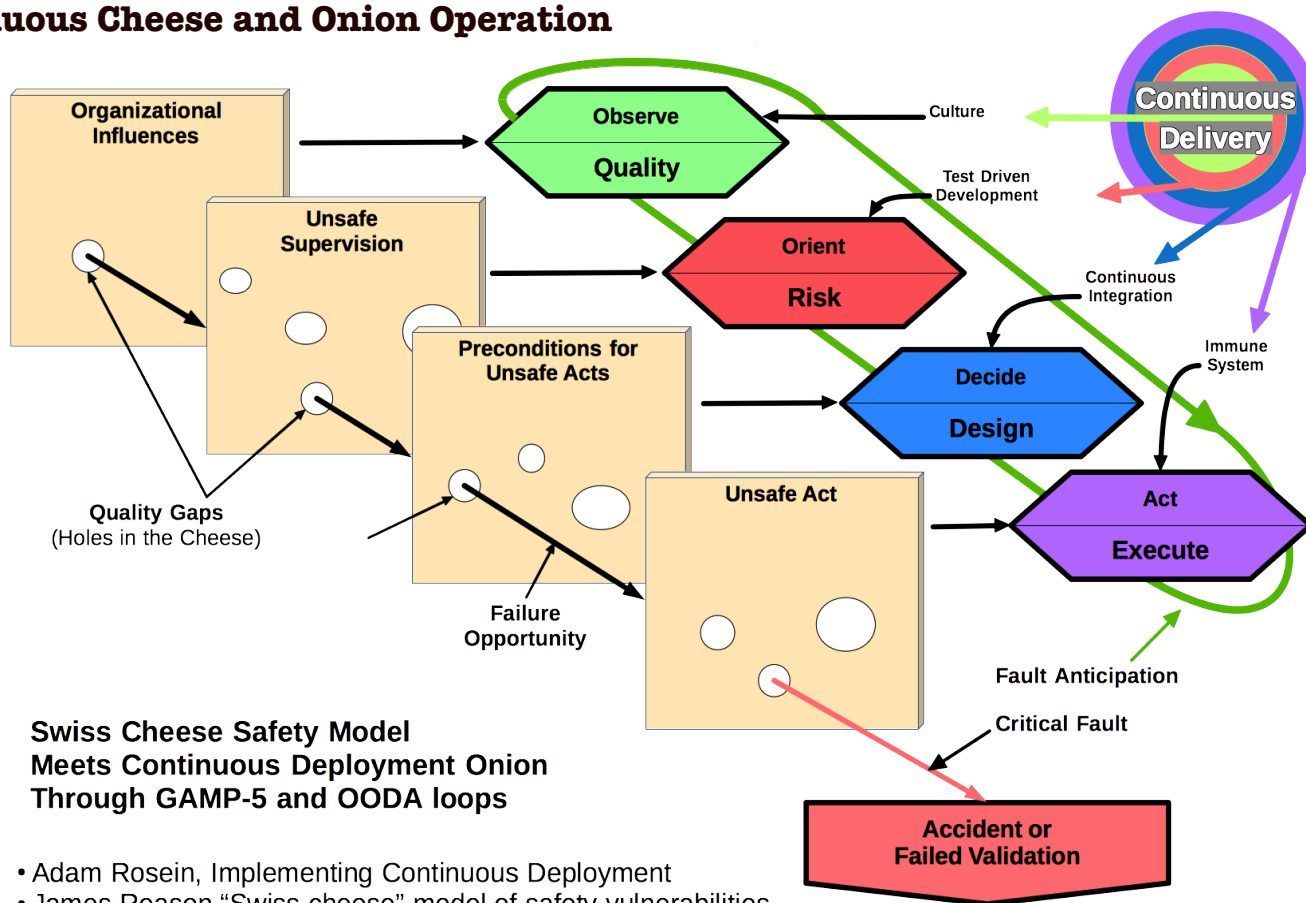


# Simultaneous Swim-lanes





## Continuous Cheese and Onion Operation



- 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

## The Unprecedented Process